Contents Of Appendices

Title X - Population Research And Voluntary Family Planning Programs Appendix-1

PHPS Part 59 ..... Appendix 2

Title X Funded Family Planning Program Requirements. ..... Appendix 3

2014QFP. ..... Appendix 3A

2017 QFP.. ..... Appendix 3B

IDPH Review Tool ... . Appendix 4

Chart Audit .. .. Appendix 5

IDPH Clinical Review Tool . ..... Appendix 6

Provider Review. ..... Appendix 7

Agency Administrative On-Site Review. ..... Appendix 8

IDPH DA Medical Directors. ..... Appendix 9

Medical Advisory Committee Members .. .. Appendix 10

Location Of MH Services . ..... Appendix 11

IAC FP ... . Appendix 12

IAC ARNP ... . Appendix 13

Iowa Code Nursing ... . Appendix 14

Iowa Code Dispensing .. .. Appendix 15

Rule N-7 18 022 Family Planning Program.. ..... Appendix 16

DHS Family Planning Program ..... Appendix 17

IAC PAs. ..... Appendix 18

IAC Child Abuse ..... Appendix 19

IAC Mandatory Reporting Training Required ..... Appendix 20

IAC Reporting Procedure ..... Appendix 21

IAC Chapter 709 Sexual Abuse Rev 10-11. ..... Appendix 22

DHS Guide For Mandatory Reporters. ..... Appendix 23

Sexual Exploitation Of A Minor Section 728.12 ..... Appendix 24

Minor-Consent-Iowa-April-2015 ..... Appendix 25

Incest Section 726.2 ..... Appendix 26

Mandatory Reporting Juvenile Justice Section 232.69 ..... Appendix 27

Well Woman Visit - ACOG ..... Appendix 28

ACOG Routine Pelvic Exam 5-09 New. ..... Appendix 29

ASCCP Updated Guidelines - 3.21.13. ..... Appendix 30

ASCCP Algorithms - Updated Consensus Guidelines For Managing Abnormal Cervical Cancer Screening Tests And Cancer Precursors ..... Appendix 31

ACOG Abnormal Pap Smear in Adolescents 6-09 New ..... Appendix 32

Comparison Of PAP Guidelines Appendix 33

US MEC Criteria ..... Appendix 34

Update To CDC US MEC ..... Appendix 34A

CDC STD-Treatment Guidelines-2010 ..... Appendix 35

Fees For Medical Records ..... Appendix 36

Job Aids and Checklists ..... Appendix 37

Contraceptive Counseling Checklist ..... Appendix 38

US SPR . ..... Appendix 39

Home Visitation Services . ..... Appendix 40

Male Health_2014_V2 .. .. Appendix 41

Checklist For Required Annual Trainings And Certifications For Title X ..... Appendix 42

ACOG DMPA ..... Appendix 43

Draft Title X Implementation Template Appendix44

Title-X-Program-Policy-Notice-Integrating-With-Primary-Care-Providers Appendix45

Affordable Care Act Section1557 Communications Requirements (002) ..... Appendix 46

Fiscal Review Tool ..... Appendix 47

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [1] participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976;
$115,000,000 for the fiscal year ending September 30, 1977;
$136,400,000 for the fiscal year ending September 30, 1978;
$200,000,000 for the fiscal year ending September 30, 1979;
$230,000,000 for the fiscal year ending September 30, 1980;
$264,500,000 for the fiscal year ending September 30, 1981;
$126,510,000 for the fiscal year ending September 30, 1982;
$139,200,000 for the fiscal year ending September 30, 1983;
$150,030,000 for the fiscal year ending September 30, 1984; and
$158,400,000 for the fiscal year ending September 30, 1985.

---

[1] So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be “family”.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004 [300a-2]

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a)Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b)Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c)A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in

accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008 [1] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[1] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Sec.
59.1 To what programs do these regulations apply?
59.2 Definitions.
59.3 Who is eligible to apply for a family planning services grant?
59.4 How does one apply for a family planning services grant?
59.5 What requirements must be met by a family planning project?
59.6 What procedures apply to assure the suitability of informational and educational material?
59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?
59.8 How is a grant awarded?
59.9 For what purposes may grant funds be used?
59.10 What other HHS regulations apply to grants under this subpart?
59.11 Confidentiality.
59.12 Additional conditions.

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

59.201 Applicability.
59.202 Definitions.
59.203 Eligibility.
59.204 Application for a grant.
59.205 Project requirements.
59.206 Evaluation and grant award.
59.207 Payments.
59.208 Use of project funds.
59.209 Civil rights.
59.210 Inventions or discoveries.
59.211 Publications and copyright.
59.212 Grantee accountability.
59.213 [Reserved]
59.214 Additional conditions.
59.215 Applicability of 45 CFR part 74.

Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). ''Low-income family'' also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and

may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by §59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral

[1] Section 205 of Pub. L. 94–63 states: ''Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.''

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of nonfederal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and

Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a–1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a–1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act.

(b) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) *Nonprofit* private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Training* means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided,* That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a–1, and 300a–4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

[1] Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation impelmenting such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the

approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or

assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.
59a.1 Programs to which these regulations apply.
59a.2 Definitions.
59a.3 Who is eligible for a grant?
59a.4 How are grant applications evaluated?
59a.5 Awards.
59a.6 How may funds or materials be used?
59a.7 Other HHS regulations that apply.

Subpart B—Establishment of Regional Medical Libraries

59a.11 Programs to which these regulations apply.
59a.12 Definitions.
59a.13 Who is eligible for a grant?
59a.14 How to apply.
59a.15 Awards.
59a.16 What other conditions apply?
59a.17 Other HHS regulations that apply.

SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b–2, 286b–5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b–5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to ''grant(s)'' shall include ''cooperative agreements(s).''

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other than a medical library, whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

Program Requirements for Title X Funded Family Planning Projects

Version 1.0 April 2014

Table of Contents

Acronyms 3

Commonly Used References 3

Introduction 5

Overview of Program Requirements 6

1. Applicability 6

2. Definitions 6

3. Eligibility 8

4. Application 8

5. Criteria for Funding 9

6. Notice of Award 10

7. Use of Grant Funds 10

8. Project Management and Administration 10

8.1 Voluntary Participation 10

8.2 Prohibition of Abortion 11

8.3 Structure and Management 11

8.4 Charges, Billing, and Collections 12

8.5 Project Personnel 13

8.6 Staff Training and Project Technical Assistance 14

8.7 Planning and Evaluation 14

9. Project Services and Clients 15

10. Confidentiality 17

11. Community Participation, Education, and Project Promotion 17

12. Information and Education Materials Approval 17

13. Additional Administrative Requirements 18

13.1 Facilities and Accessibility of Services 18

13.2 Emergency Management 19

13.3 Standards of Conduct 19

13.4 Human Subjects Clearance (Research) 19

13.5 Financial and Reporting Requirements 20

14. Additional Conditions 20

15. Closeout 20

16. Other Applicable HHS Regulations and Statutes 20

Links

Title X Statute http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Title X Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Appropriations Language/Legislative Mandates http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/legislative-mandates/

Sterilization of Persons in Federally Assisted Family Planning Projects Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Department of Health and Human Services Regions http://www.hhs.gov/opa/regional-contacts/

ACRONYMS

The following is a list of acronyms and abbreviations used throughout this document.

ACRONYM/ ABBREVIATION	
CFR	Code of Federal Regulations
FDA	U.S. Food and Drug Administration
FPL	Federal Poverty Level
HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
I&E	Information and Education
NOA	Notice of Award
OASH	Office of the Assistant Secretary for Health
OGM	Office of Grants Management
OMB	Office of Management and Budget
OPA	Office of Population Affairs
OSHA	Occupational Safety and Health Administration
PHS	U.S. Public Health Service
STD	Sexually Transmitted Disease

COMMONLY USED REFERENCES

As a Federal grant program, requirements for the Title X Family Planning Program are established by Federal law and regulations. For ease of reference, the law and regulations most cited in this document are listed below. Other applicable regulations and laws are cited throughout the document.

Law	Title X Public Law (“Family Planning Services and Population Research Act of 1970”)	Public Law 91-572
Law	Title X Statute (“Title X of the Public Health Service Act”)	42 U.S.C.300, *et seq.*
Regulation	Sterilization Regulations (“Sterilization of persons in Federally Assisted Family Planning Projects”)	42 CFR part 50, subpart B
Regulation	Title X Regulations (“Project Grants for Family Planning Services”) (	42 CFR part 59, subpart A
Regulation	HHS Grants Administration Regulations	45 CFR parts 74

	("Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations" (part 74) and "Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments" (part 92))	and 92
Regulation	"Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations"	2 CFR 215 (OMB Circular A-110)
OMB Circular	"Grants and Cooperative Agreements with State and Local Governments"	OMB Circular A-102

INTRODUCTION

To assist individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572). The law amended the Public Health Service (PHS) Act to add Title X, "Population Research and Voluntary Family Planning Programs." Section 1001 of the PHS Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."

The Title X Family Planning Program is the only Federal program dedicated solely to the provision of family planning and related preventive health services. The program is designed to provide contraceptive supplies and information to all who want and need them, with priority given to persons from low-income families. All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis. Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing, and referral; and pregnancy diagnosis and counseling. By law, Title X funds may not be used in programs where abortion is a method of family planning.

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). OASH is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth in 42 CFR 59.7(a). Final award decisions are made by the Regional Health Administrator for the applicable Public Health Service Region in consultation with the Deputy Assistant Secretary for Population Affairs and the Assistant Secretary for Health or their designees. The HHS Regional Offices monitor program performance of Title X grantees in each respective region.

The Title X Family Planning Guidelines consist of two parts, 1) *Program Requirements for Title X Funded Family Planning Projects* (hereafter referred to as *Title X Program Requirements*) and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*.

These documents have been developed to assist current and prospective grantees in understanding and implementing the family planning services grants program authorized by Title

X of the PHS Act (42 U.S.C. 300 *et seq.*). These documents also form the basis for monitoring projects under the Title X program.

OVERVIEW OF PROGRAM REQUIREMENTS

This document is organized into 16 sections that describe the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations (42 CFR part 59, subpart A), and in other applicable Federal statutes, regulations, and policies. Links to the Title X statute and implementing regulations, other statutory provisions that are applicable to the Title X program, regulations related to sterilization, and additional resources to maximize the quality of services offered by Title X projects are provided on page 2 of this document.

The concise explanation of general program requirements that follows can be used to help prepare a grant application or monitor funded programs for compliance with Title X requirements. In addition, prospective applicants and grantees should consult all of the resources and references identified in this document for more complete information and to ensure that the project application and program operations comply with these and other Federal requirements.

Additional documents, including the annual *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (Title X Funding Opportunity Announcement), other Funding Opportunity Announcements for OPA priority areas, and relevant language in Federal appropriations laws, contain the most current information about Title X program requirements and are generally updated annually. The Title X Funding Opportunity Announcement includes the most recent list of program priorities and key issues, and identifies geographic areas where there will be a grant competition for the applicable fiscal year. Subject to the availability of funds, the funding announcement is published annually and posted on the HHS Grants.gov Website Portal. The *Program Requirements for Title X Funded Family Planning Projects* is posted on the OPA website (http://www.hhs.gov/opa). In general, the requirements that apply to the direct recipients of Title X funds also apply to sub-recipients and contractors (HHS Grants Policy Statement, 2007).

1. APPLICABILITY

As stated above, the requirements set forth in this document apply to the award of grants under section 1001 of the PHS Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children (42 CFR 59.1).

2. DEFINITIONS

Terms used throughout this document include:

TERM	DEFINITION
The Act or Law	Title X of the Public Health Service Act, as amended
Family	A social unit composed of one person, or two or more persons living together, as a household
Low-income family	A family whose total annual income does not exceed 100% of the most recent Federal Poverty Guidelines; also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources
Grantee	The entity that receives Federal financial assistance via a grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding
Nonprofit	Any private agency, institution, or organization for which no part of the entity's net earnings benefit, or may lawfully benefit, any private stakeholder or individual.
Project	Activities described in the grant application and any incorporated documents supported under the approved budget. The "scope of the project" as defined in the funded application consists of activities that the total approved grant-related project budget supports.
Secretary	The Secretary of Health and Human Services and any other officer or employee of the U.S. Department of Health and Human Services to whom the authority involved has been delegated.
Service Site	The clinics or other locations where services are provided by the grantee or sub-recipient.
Sub-recipients	Those entities that provide family planning services with Title X funds

	under a written agreement with a grantee. May also be referred to as delegates or contract agencies.
State	Includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau.

3. ELIGIBILITY

Any public or nonprofit private entity located in a state (which includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant (42 CFR 59.2, 42 CFR 59.3).

Even where states apply for a family planning services grant, local and regional entities may also apply directly to the Secretary for a family planning services grant. Faith-based organizations and American Indian/Alaska Native/Native American organizations are eligible to apply for Title X family planning services grants. Private nonprofit entities must provide proof of nonprofit status during the application process.

Although State agencies are eligible for funding, the Title X statute specifically protects the right of local and regional entities to apply directly to the Secretary for a family planning services grant (Section 1001(b), PHS Act).

4. APPLICATION

The Office of Population Affairs publishes, at a minimum, an annual announcement of the availability of Title X family planning services grant funds that sets forth specific application requirements and evaluation criteria. Applications must be submitted to OASH, Office of Grants Management (OGM) on the forms required by HHS, in the manner required, and approved by an individual authorized to act for the applicant. The application process is conducted through an electronic grants system.

If an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential sub-

recipients that have previously provided or propose to provide family planning services to the area to be served by the applicant (42 CFR 59.5 (a)(10)(i)).

Unless otherwise instructed, applicants should respond to the standard instructions contained in the grant application package as well as any HHS supplemental instructions.

Successful applications must include:

- a narrative description of the project and the manner in which the applicant intends to conduct the project and comply with all requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification of the amount of grant funds requested (42 CFR 59.4(c)(2)) and which is consistent with the terms of Section 1006(a) of the Act, as implemented by regulation (42 CFR 59.7(b));
- a description of the standards and qualifications the project will use for all personnel and facilities; and
- other pertinent information as may be required by the Secretary (42 CFR 59.4(c)(4)).

Title X grant funds cannot constitute 100% of a project's estimated costs; therefore, applicants must clearly specify all other sources of funding that will be used to support the Title X project (42 CFR 59.7(c)).

5. CRITERIA FOR FUNDING

Within the limits of funds available for these purposes, grants are awarded for the establishment and operation of projects that will best promote the purposes of Section 1001 of Title X of the PHS Act. The application must address all seven points contained in section 59.7(a) of the regulations. These are the criteria HHS uses to determine which family planning projects to fund and in what amount.

In making funding decisions, HHS takes into account:

- the number of patients, and, in particular, the number of low-income patients to be served;
- the extent to which family planning services are needed locally;
- the relative need of the applicant;
- the capacity of the applicant to make rapid and effective use of the Federal assistance;
- the adequacy of the applicant's facilities and staff;
- the relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and
- the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations.

Funding of applications that propose to rely on other entities to provide services will take into

consideration the extent to which the applicant indicates it will be inclusive in considering all entities that are eligible to receive Federal funds to best serve individuals in need throughout the anticipated service areas.

6. NOTICE OF AWARD

The Notice of Award (NOA) is the document that informs the grantee of the duration of HHS support for the project without requiring it to recompete for funds (42 CFR 59.8 (a)). This period of funding is called the "project period." The project is generally funded in increments known as "budget periods." Each budget period is typically 12 months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.
Decisions regarding whether and at what level to continue awards are based on factors such as the adequacy of the grantee's programmatic progress, management practices, compliance with the terms and conditions of the previous award, program priorities, and the availability of appropriations. In all cases, subsequent budget periods, also known as non-completing continuation awards, require a determination by HHS that continued funding is in the best interest of the government.

The U.S. government is not obligated to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application (42 CFR 59.8(c)).

Grantees must provide the awarding agency with timely and unrestricted access to examine all records, books, papers, and documents related to the award (45 CFR 74.53 and 92.42). Records must be maintained generally for 3 years from submission of the final federal financial report (45 CFR 74.53)

7. USE OF GRANT FUNDS

All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. The Notice of Award (NOA) provides other stipulations regarding the use of funds. Funds must be used in accordance with the Title X family planning services projects regulations, the terms and conditions of the award, and the HHS grants administration regulations set out at 45 CFR parts 74 and 92.

8. PROJECT MANAGEMENT AND ADMINISTRATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered.

8.1 Voluntary Participation

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)).

A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

8.2 Prohibition of Abortion

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Grantees and sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning. Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled *Provision of Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41281, and the final rule entitled *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41270.

Grantees are also responsible for monitoring sub-recipients' compliance with this section.

8.3 Structure and Management

Family planning services under a Title X grant may be offered by grantees directly and/or by sub-recipient agencies operating under the umbrella of a grantee. However, the grantee is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by sub-recipients. Where required services are provided by referral, the grantee is expected to have written agreements for the provision of services and reimbursement of costs as appropriate.

8.3.1 The grantee must have a written agreement with each sub-recipient and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Title X Program Requirements, as well as other applicable requirements (45 CFR parts 74 and 92).

8.3.2 If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by the grantee must be maintained by the sub-recipient (45 CFR parts 74 and 92).

8.3.3 The grantee must ensure that all services purchased for project participants will be authorized by the project director or his designee on the project staff (42 CFR 59.5(b)(7)).

8.3.4 The grantee must ensure that services provided through a contract or other similar arrangement are paid for under agreements that include a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary (42 CFR 59.5(b)(9)).

8.3.5 Sub-recipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5 (a)(10)).

8.3.6 The grantee and each sub-recipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures must be maintained as required (45 CFR parts 74.20 and 92.20).

8.4 Charges, Billing, and Collections

The grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the projects. Clients must not be denied project services or be subjected to any variation in quality of services because of inability to pay.

Projects should not have a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services

8.4.1 Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).

Within the parameters set out by the Title X statute and regulations, Title X grantees have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.

8.4.2 A schedule of discounts, based on ability to pay, is required for individuals with family

incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).

8.4.3 Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).

8.4.4 For persons from families whose income exceeds 250% of the FPL, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).

8.4.5 Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2).

8.4.6 Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts must be made to obtain third party payment without the application of any discounts(42 CFR 59.5(a)(9)).

Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

8.4.7 Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or sub-recipient agency is required (42 CFR 59.5(a)(9)]

8.4.8 Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

8.4.9 Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.

8.5 Project Personnel

Title X grantees must have approved personnel policies and procedures.

8.5.1 Grantees and sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies should include,

but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

8.5.2 Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).

8.5.3 Projects must be administered by a qualified project director. Change in Status, including Absence, of Principal Investigator/Project Director and Other Key Personnel requires pre-approval by the Office of Grants Management. For more information, see HHS Grants Policy Statement, 2007 Section II-54.

8.5.4 Projects must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6).

8.5.5 Appropriate salary limits will apply as required by law.

8.6 Staff Training and Project Technical Assistance

Title X grantees are responsible for the training of all project staff. Technical assistance may be provided by OPA or the Regional Office.

8.6.1 Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).

8.6.2 The project's training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking

8.6.3 The project's training plan should provide for routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

8.7 Planning and Evaluation

Grantees must ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)). In order to adequately plan and evaluate program activities, grantees should develop written goals and objectives for the project period that are specific, measurable, achievable, realistic, time-framed, and which are consistent with Title X Program Requirements. The program plan should be based on a needs assessment. Grantee project plans must include an evaluation component that identifies indicators by which the program measures the

achievement of its objectives. For more information on quality improvement, see *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.*

9. PROJECT SERVICES AND CLIENTS

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects must provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services.

9.1 Priority for project services is to persons from low- income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).

9.2 Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).

9.3 Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).

9.4 Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

9.5 Projects must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8).

9.6 All grantees should assure services provided within their projects operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.

9.7 All projects must provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of

this care.

9.8 All projects must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. (42 CFR 59.5(a)(1)).

9.9 Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

9.10 Projects must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5)).

9.11 Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- prenatal care and delivery;
- infant care, foster care, or adoption; and
- pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).

9.12 Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

"Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

10. CONFIDENTIALITY

Every project must have safeguards to ensure client confidentiality. Information obtained by the project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).

11. COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Title X grantees are expected to provide for community participation and education and to promote the activities of the project.

11.1 Title X grantees and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).

11.2 Projects must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)). The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

11.3 Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial (42 CFR 59.5 (b)(3).

12. INFORMATION AND EDUCATION MATERIALS APPROVAL

Every project is responsible for reviewing and approving informational and educational materials. The Information and Education (I&E) Advisory Committee may serve the community participation function if it meets the requirements, or a separate group may be identified .

12.1 Title X grantees and sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials developed or made available under the project prior to their distribution (Section 1006

(d)(2), PHS Act; 42 CFR 59.6(a)).

12.2 The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2)).

12.3 Each Title X grantee must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6(b)(1)). This Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

12.4 The grantee may delegate I&E functions for the review and approval of materials to sub-recipient agencies; however, the oversight of the I&E review process rests with the grantee.

12.5 The Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the I&E materials rests with the Advisory Committee.

12.6 The I&E Advisory Committee(s) must:

- consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- consider the standards of the population or community to be served with respect to such materials;
- review the content of the material to assure that the information is factually correct;
- determine whether the material is suitable for the population or community to which it is to be made available; and
- establish a written record of its determinations (Section 1006(d), PHS Act; 42 CFR 59.6(b)).

13. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

13.1 Facilities and Accessibility of Services

Title X service sites should be geographically accessible for the population being served. Grantees should consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' abilities to access services.

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR part 84).

13.2 Emergency Management

All grantees, sub-recipients, and Title X clinics are required to have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities must meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes).

Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). Disaster plans and emergency exits are addressed under 29 CFR 1910, subpart E. The basic requirements of these regulations include, but are not limited to:

- Disaster plans (e.g. fire, bomb, terrorism, earthquake, etc.) have been developed and are available to staff.
- Staff can identify emergency evacuation routes.
- Staff has completed training and understand their role in an emergency or natural disaster.
- Exits are recognizable and free from barriers.

13.3 Standards of Conduct

Projects are required to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

13.4 Human Subjects Clearance (Research)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise their Regional Office in writing of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9).

13.5 Financial and Reporting Requirements

Audits of grantees and sub-recipients must be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133).

Grantees must comply with the financial and other reporting requirements set out in the HHS grants administration regulations (45 CFR parts 74 and 92), as applicable. In addition, grantees must have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS.

Grantees must demonstrate continued institutional, managerial, and financial capacity (including funds sufficient to pay the non-Federal share of the project cost) to ensure proper planning, management, and completion of the project as described in the award (42 CFR 59.7(a)).

Grantees must reconcile reports, ensuring that disbursements equal obligations and drawdowns. HHS is not liable should the recipient expenditures exceed the actual amount available for the grant.

14. ADDITIONAL CONDITIONS

With respect to any grant, HHS may impose additional conditions prior to or at the time of any award, when, in the judgment of HHS, these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds (42 CFR 59.12).

15. CLOSEOUT

Within 90 days of the end of grant support, grantees must submit:

- a final Federal Financial Report (FFR)
- a final progress report

Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal Government may recover amounts based on the results of an audit covering any part of the period of grant support (HHS Grants Policy Statement, II-90).

For a complete list of requirements, grantees should review the HHS Grants Policy Statement, available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf

16. OTHER APPLICABLE HHS REGULATIONS AND STATUTES

Attention is drawn to the following HHS Department-wide regulations that apply to grants under Title X. These include:

- 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements;
- 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure;
- 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board;
- 45 CFR Part 74: Uniform administrative requirements for awards and sub-awards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments, and Indian tribal governments;
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964;
- 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title;
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance;
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance;
- 45 CFR Part 92: Uniform administrative requirements for grants and cooperative agreements to State and local governments; and
- 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities.

In addition, the following statutory and regulatory provisions may be applicable to grants under Title X:

- The Patient Protection and Affordable Care Act (Public Law 111-148);
- The Trafficking Victims Protection Act of 2000, as amended (Public Law 106-386);
- Sex Trafficking of Children or by Force, Fraud, or Coercion (18 USC 1591);
- The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191); and
- Appropriations language that applies to the Title X program for the relevant fiscal year.

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 63 / No. 4

April 25, 2014

Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONTENTS

Introduction 1
Methods 3
Contraceptive Services 7
Pregnancy Testing and Counseling 13
Clients Who Want to Become Pregnant 14
Basic Infertility Services 15
Preconception Health Services 16
Sexually Transmitted Disease Services 18
Related Preventive Health Services 20
Summary of Recommendations for Providing Family Planning and Related Preventive Health Services 21
Conducting Quality Improvement 21
Conclusion 25
Appendix A 30
Appendix B 35
Appendix C 45
Appendix D 47
Appendix E 48
Appendix F 51

Disclosure of Relationship

CDC, our planners, content experts, and their spouses/partners wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested Citation: [Author names; first three, then et al., if more than six.] [Title]. MMWR 2014;63(No. RR-#):[inclusive page numbers].

Centers for Disease Control and Prevention

Thomas R. Frieden, MD, MPH, *Director*
Harold W. Jaffe, MD, MA, *Associate Director for Science*
Joanne Cono, MD, ScM, *Acting Director, Office of Science Quality*
Chesley L. Richards, MD, MPH, *Deputy Director for Public Health Scientific Services*
Michael F. Iademarco, MD, MPH, *Director, Center for Surveillance, Epidemiology, and Laboratory Services*

MMWR Editorial and Production Staff (Serials)

John S. Moran, MD, MPH, *Acting Editor-in-Chief*
Christine G. Casey, MD, *Editor*
Teresa F. Rutledge, *Managing Editor*
David C. Johnson, *Lead Technical Writer-Editor*
Jeffrey D. Sokolow, MA, *Project Editor*

Martha F. Boyd, *Lead Visual Information Specialist*
Maureen A. Leahy, Julia C. Martinroe,
Stephen R. Spriggs, Terraye M. Starr
Visual Information Specialists
Quang M. Doan, MBA, Phyllis H. King
Information Technology Specialists

MMWR Editorial Board

William L. Roper, MD, MPH, Chapel Hill, NC, Chairman
Matthew L. Boulton, MD, MPH, Ann Arbor, MI
Virginia A. Caine, MD, Indianapolis, IN
Barbara A. Ellis, PhD, MS, Atlanta, GA
Jonathan E. Fielding, MD, MPH, MBA, Los Angeles, CA
David W. Fleming, MD, Seattle, WA
William E. Halperin, MD, DrPH, MPH, Newark, NJ
King K. Holmes, MD, PhD, Seattle, WA
Timothy F. Jones, MD, Nashville, TN
Rima F. Khabbaz, MD, Atlanta, GA
Dennis G. Maki, MD, Madison, WI
Patricia Quinlisk, MD, MPH, Des Moines, IA
Patrick L. Remington, MD, MPH, Madison, WI
William Schaffner, MD, Nashville, TN

Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Prepared by
Loretta Gavin, PhD,[1] Susan Moskosky, MS,[2] Marion Carter, PhD,[1] Kathryn Curtis, PhD,[1] Evelyn Glass, MSPH,[2] Emily Godfrey, MD,[1] Arik Marcell, MD,[3] Nancy Mautone-Smith, MSW,[2] Karen Pazol, PhD,[1] Naomi Tepper, MD,[1] Lauren Zapata, PhD[1]
[1]*Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC*
[2]*Office of Population Affairs, US Department of Health and Human Services, Rockville, Maryland*
[3]*The Johns Hopkins University and the Male Training Center for Family Planning and Reproductive Health, Baltimore, Maryland*

Summary

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide quality family planning services, which include contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, and sexually transmitted disease services. The primary audience for this report is all current or potential providers of family planning services, including those working in service sites that are dedicated to family planning service delivery as well as private and public providers of more comprehensive primary care.

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. Nearly one half of all pregnancies are unintended, with more than 700,000 adolescents aged 15–19 years becoming pregnant each year and more than 300,000 giving birth. One of eight pregnancies in the United States results in preterm birth, and infant mortality rates remain high compared with those of other developed countries.

This report can assist primary care providers in offering family planning services that will help women, men, and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy. The report provides recommendations for how to help prevent and achieve pregnancy, emphasizes offering a full range of contraceptive methods for persons seeking to prevent pregnancy, highlights the special needs of adolescent clients, and encourages the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine and adopted by HHS.

Introduction

The United States continues to face challenges to improving the reproductive health of the U.S. population. Nearly half (49%) of all pregnancies are unintended (*1*). Although adolescent birth rates declined by more than 61% during 1991–2012, the United States has one of the highest adolescent pregnancy rates in the developed world, with >700,000 adolescents aged 15–19 years becoming pregnant each year and >300,000 giving birth (*2,3*). Approximately one of eight pregnancies in the United States results in a preterm birth, and infant mortality rates remain high compared with other developed countries (*3,4*). Moreover, all of these outcomes affect racial and ethnic minority populations disproportionately (*1–4*).

Corresponding preparers: Loretta Gavin, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Telephone: 770-488-6284; E-mail: lcg6@cdc.gov; Susan Moskosky, MS, Office of Population Affairs, US Department of Health and Human Services. Telephone: 240-453-2818; E-mail: susan.moskosky@hhs.gov.

Family planning services can help address these and other public health challenges by providing education, counseling, and medical services (*5*). Family planning services include the following:

- providing contraception to help women and men plan and space births, prevent unintended pregnancies, and reduce the number of abortions;
- offering pregnancy testing and counseling;
- helping clients who want to conceive;
- providing basic infertility services;
- providing preconception health services to improve infant and maternal outcomes and improve women's and men's health; and
- providing sexually transmitted disease (STD) screening and treatment services to prevent tubal infertility and improve the health of women, men, and infants.

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide family planning services by:

- defining a core set of family planning services for women and men,
- describing how to provide contraceptive and other clinical services, serve adolescents, and perform quality improvements, and
- encouraging the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine (IOM) and adopted by HHS (*6*).

The collaboration between CDC and OPA drew on the strengths of both agencies. CDC has a long-standing history of developing evidence-based recommendations for clinical care, and OPA's Title X Family Planning Program (*7*) has served as the national leader in direct family planning service delivery since the Title X program was established in 1970.

This report provides recommendations for providing care to clients of reproductive age who are in need of family planning services. These recommendations are intended for all current or potential providers of family planning services, including those funded by the Title X program.

Current Context of Family Planning Services

Women of reproductive age often report that their family planning provider is also their usual source of health care (*8*). As the U.S. health-care system evolves in response to increased efforts to expand health insurance coverage, contain costs, and emphasize preventive care (*9*), providers of family planning services will face new challenges and opportunities in care delivery. For example, they will have increased opportunities to serve new clients and to serve as gateways for their clients to other essential health-care services. In addition, primary care and other providers who provide a range of health-care services will be expected to integrate family planning services for all persons of reproductive age, including those whose primary reason for their health-care visit might not be family planning. Strengthened, multidirectional care coordination also will be needed to improve health outcomes. For example, this type of care coordination will be needed with clients referred to specialist care after initial screening at a family planning visit, as well as with specialists referring clients with family planning needs to family planning providers.

Defining Quality in Family Planning Service Delivery

The central premise underpinning these recommendations is that improving the quality of family planning services will lead to improved reproductive health outcomes (*10–12*). IOM defines health-care quality as the extent to which health-care services improve health outcomes in a manner that is consistent with current professional knowledge (*10,13*). According to IOM, quality health care has the following attributes:

- **Safety.** These recommendations integrate other CDC recommendations about which contraceptive methods can be provided safely to women with various medical conditions, and integrate CDC and U.S. Preventive Services Task Force (USPSTF) recommendations on STD, preconception, and related preventive health services.
- **Effectiveness.** These recommendations support offering a full range of Food and Drug Administration (FDA)–approved contraceptive methods as well as counseling that highlights the effectiveness of contraceptive methods overall and, in specific patient situations, draws attention to the effectiveness of specific clinical preventive health services and identifies clinical preventive health services for which the potential harms outweigh the benefits (i.e., USPSTF "D" recommendations).
- **Client-centered approach.** These recommendations encourage taking a client-centered approach by 1) highlighting that the client's primary purpose for visiting the service site must be respected, 2) noting the importance of confidential services and suggesting ways to provide them, 3) encouraging the availability of a broad range of contraceptive methods so that clients can make a selection based on their individual needs and preferences, and 4) reinforcing the need to deliver services in a culturally competent manner so as to meet the needs of all clients, including adolescents, those with limited English proficiency, those with disabilities, and those who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ). Organizational policies, governance structures, and individual attitudes and practices all contribute to the cultural competence of a health-care entity and its staff. Cultural competency within a health-care setting refers to attitudes, practices, and policies that enable professionals to work effectively in cross-cultural situations (*14–16*).
- **Timeliness.** These recommendations highlight the importance of ensuring that services are provided to clients in a timely manner.
- **Efficiency.** These recommendations identify a core set of services that providers can focus on delivering, as well as ways to maximize the use of resources.
- **Accessibility.** These recommendations address how to remove barriers to contraceptive use, use the family planning visit to provide access to a broader range of primary care and behavioral health services, use the primary care visit to

provide access to contraceptive and other family planning services, and strengthen links to other sources of care.

- **Equity.** These recommendations highlight the need for providers of family planning services to deliver high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities.
- **Value.** These recommendations highlight services (i.e., contraception and other clinical preventive services) that have been shown to be very cost-effective (*17–19*).

Methods

Recommendations Development Process

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health and OPA, in consultation with a wide range of experts and key stakeholders. More information about the processes used to conduct systematic reviews, the role of technical experts in reviewing the evidence, and the process of using the evidence to develop recommendations is provided (Appendix A). A multistage process was used to develop the recommendations that drew on established procedures for developing clinical guidelines (*20*,*21*). First, an Expert Work Group* was formed comprising family planning clinical providers, program administrators, and representatives from relevant federal agencies and professional medical associations to help define the scope of the recommendations. Next, literature about three priority topics (i.e., counseling and education, serving adolescents, and quality improvement) was reviewed by using the USPSTF methodology for conducting systematic reviews (*22*). The results were presented to three technical panels† comprising subject matter experts (one panel for each priority topic) who considered the quality of the evidence and made suggestions for what recommendations might be supported on the basis of the evidence. In a separate process, existing clinical recommendations on women's and men's preventive services were compiled from more than 35 federal and professional medical associations, and these results were presented to two technical panels of subject matter experts, one that addressed women's clinical services and one that addressed men's clinical services. The panels provided individual feedback about which clinical preventive services should be offered in a family planning setting and which clinical recommendations should receive the highest consideration.

CDC and OPA used the input from the subject matter experts to develop a set of core recommendations and asked the Expert Work Group to review them. The members of the Expert Work Group were more familiar with the family planning service delivery context than the members of the Technical Panel and thus could better comment on the feasibility and appropriateness of the recommendations, as well as the supporting evidence. The Expert Work Group considered the core recommendations by using the following criteria: 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences, (e.g., the likelihood that implementation of the recommendation will have a substantial effect on health outcomes might be considered more than the logistical challenges of implementing it) (*20*). In certain cases, when the evidence from the literature reviews was inconclusive or incomplete, recommendations were made on the basis of expert opinion. Finally, CDC and OPA staff considered the individual feedback from Expert Work Group members when finalizing the core recommendations and writing the recommendations document. A description of how the recommendations link to the evidence is provided together with the rationale for the inclusion of each recommendation in this report (Appendix B).

The evidence used to prepare these recommendations will appear in background papers that will be published separately. Resources that will help providers implement the recommendations will be provided through a web-based tool kit that will be available at http://www.hhs.gov/opa.

Audience for the Recommendations

The primary audience for this report is all providers or potential providers of family planning services to clients of reproductive age, including providers working in clinics that are dedicated to family planning service delivery, as well as private and public providers of more comprehensive primary care. Providers of dedicated family planning services might be less familiar with the specific recommendations for the delivery of preconception services. Providers of more comprehensive primary care might be less familiar with the delivery of contraceptive services, pregnancy testing and counseling, and services to help clients achieve pregnancy.

This report can be used by medical directors to write clinical protocols that describe how care should be provided. Job aids and other resources for use in service sites are being developed and will be made available when ready through OPA's website (http://www.hhs.gov/opa).

* A list of the members of the Expert Work Group appears on page 52.
† A list of the members of the technical panels appears on pages 52 and 53.

In this report, the term "provider" refers to any staff member who is involved in providing family planning services to a client. This includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff, and health educators. The term "service site" represents the numerous settings in which family planning services are delivered, which include freestanding service sites, community health centers, private medical facilities, and hospitals. A list of special terms used in this report is provided (Box 1).

The recommendations are designed to guide general clinical practice; however, health-care providers always should consider the individual clinical circumstances of each person seeking family planning services. Similarly, these recommendations might need to be adapted to meet the needs of particular populations, such as clients who are HIV-positive or who are substance users.

Organization of the Recommendations

This report is divided into nine sections. An initial section provides an overview of steps to assess the needs of a client and decide what family planning services to offer. Subsequent sections describe how to provide each of the following services: contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, STD services and related preventive health services. A final section on quality improvement describes actions that all providers of family planning services should consider to ensure that services are of high quality. More detailed information about selected topics addressed in the recommendations is provided (Appendices A–F).

These recommendations focus on the direct delivery of care to individual clients. However, parallel steps might need to be taken to maintain the systems required to support the provision of quality services for all clients (e.g., record-keeping procedures that preserve client confidentiality, procedures that improve efficiency and reduce clients' wait time, staff training to ensure that all clients are treated with respect, and the establishment and maintenance of a strong system of care coordination and referrals).

Client Care

Family planning services are embedded within a broader framework of preventive health services (Figure 1). In this report, health services are divided into three main categories:

- **Family planning services.** These include contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and mental health). STD/HIV and other preconception health services are considered family planning services because they improve women's and men's health and can influence a person's ability to conceive or to have a healthy birth outcome.
- **Related preventive health services.** These include services that are considered to be beneficial to reproductive health,

BOX 1. Definitions of quality terms used in this report

Accessible. The timely use of personal health services to achieve the best possible health outcomes.*

Client-centered. Care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.†

Effective. Services are based on scientific knowledge and provided to all who could benefit and are not provided to those not likely to benefit.†

Efficient. Waste is avoided, including waste of equipment, supplies, ideas, and energy.†

Equitable. Care does not vary in quality because of the personal characteristics of clients (e.g., sex, race/ethnicity, geographic location, insurance status, or socioeconomic status).†

Evidence-based. The process of integrating science-based interventions with community preferences to improve the health of populations.§

Health-care quality. The degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.†

Process. Whether services are provided correctly and completely and how clients perceive the care they receive.¶

Safe. Avoids injuries to clients from the care that is intended to help them.†

Structure. The characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure.¶

Timely. Waits and sometimes harmful delays for both those who receive and those who provide care are reduced.†

Value. The care provides good return relative to the costs involved, such as a return on investment or a reduction in the per capita cost of health care.*

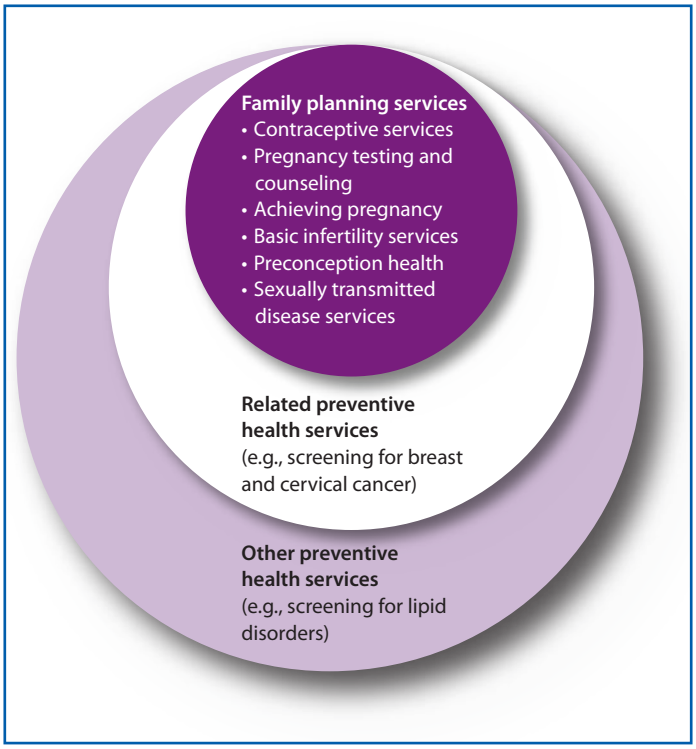
* Source: Institute of Medicine. Future directions for the national healthcare quality and disparities reports. Ulmer C, Bruno M, Burke S, eds. Washington, DC: The National Academies Press; 2010.

† Source: Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Committee on Quality of Health Care in America, ed. Washington, DC: National Academies of Science; 2001.

§ Source: Kohatsu ND, Robinson JG, Torner JC. Evidence-based public health: an evolving concept. Am J Prev Med 2004;27:417–21.

¶ Source: Donabedian A. The quality of care. JAMA 1988;260:1743–8.

FIGURE 1. Family planning and related and other preventive health services



are closely linked to family planning services, and are appropriate to deliver in the context of a family planning visit but that do not contribute directly to achieving or preventing pregnancy (e.g., breast and cervical cancer screening).

- **Other preventive health services.** These include preventive health services for women that were not included above (*6*), as well as preventive services for men. Screening for lipid disorders, skin cancer, colorectal cancer, or osteoporosis are examples of this type of service. Although important in the context of primary care, these have no direct link to family planning services.

Providers of family planning services should be trained and equipped to offer all family planning and related preventive health services so that they can provide optimal care to clients, with referral for specialist care, as needed. Other preventive health services should be available either on-site or by referral, but these recommendations do not address this category of services. Information about preventive services that are beyond the scope of this report is available at http://www.uspreventiveservicestaskforce.org.

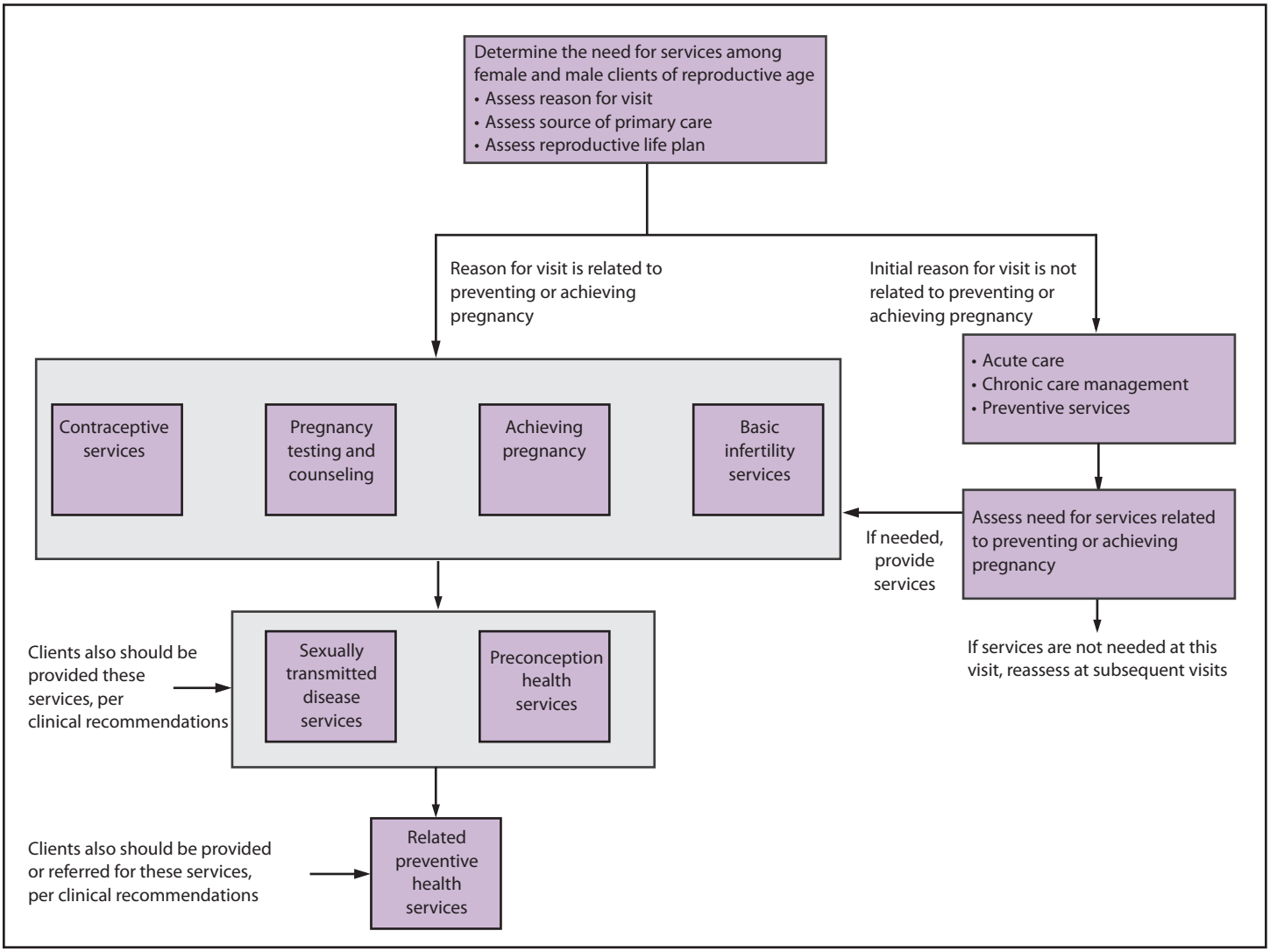
Determining the Client's Need for Services

These recommendations apply to two types of encounters with women and men of reproductive age. In the first type of encounter, the primary reason for a client's visit to a health-care provider is related to preventing or achieving pregnancy, (i.e., contraceptive services, pregnancy testing and counseling, or becoming pregnant). Other aspects of managing pregnancy (e.g., prenatal and delivery care) are not addressed in these recommendations. For clients seeking to prevent or achieve pregnancy, providers should assess whether the client needs other related services and offer them to the client. In the second type of encounter, the primary reason for a client's visit to a health-care provider is not related to preventing or achieving pregnancy. For example, the client might come in for acute care (e.g., a male client coming in for STD symptoms or as a contact of a person with an STD), for chronic care, or for another preventive service. In this situation, providers not only should address the client's primary reason for the visit but also assess the client's need for services related to preventing or achieving pregnancy.

A clinical pathway of family planning services for women and men of reproductive age is provided (Figure 2). The following questions can help providers determine what family planning services are most appropriate for a given visit.

- **What is the client's reason for the visit?** It is essential to understand the client's goals for the visit and address those needs to the extent possible.
- **Does the client have another source of primary health care?** Understanding whether a provider is the main source of primary care for a client will help identify what preventive services a provider should offer. If a provider is the client's main source of primary care, it will be important to assess the client's needs for the other services listed in this report. If the client receives ongoing primary care from another provider, the provider should confirm that the client's preventive health needs are met while avoiding the delivery of duplicative services.
- **What is the client's reproductive life plan?** An assessment should be made of the client's reproductive life plan, which outlines personal goals about becoming pregnant (*23–25*) (Box 2).The provider should avoid making assumptions about the client's needs based on his or her characteristics, such as sexual orientation or disabilities. For clients whose initial reason for coming to the service site was not related to preventing or achieving pregnancy, asking questions about his or her reproductive life plan might help identify unmet reproductive health-care needs. Identifying a need for contraceptive services might be particularly important given the high rate of unintended pregnancy in the United States.
  - If the client does not want a child at this time and is sexually active, then offer contraceptive services.
  - If the client desires pregnancy testing, then provide pregnancy testing and counseling.
  - If the client wants to have a child now, then provide services to help the client achieve pregnancy.

FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age



  – If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.

- **Does the client need preconception health services?** Preconception health services (such as screening for obesity, smoking, and mental health) are a subset of all preventive services for women and men. Preconception health care is intended to promote the health of women and men of reproductive age before conception, with the goal of improving pregnancy-related outcomes (*24*). Preconception health services are also important because they improve the health of women and men, even if they choose not to become pregnant. The federal and professional medical recommendations cited in this report should be followed when determining which preconception health services a client might need.
- **Does the client need STD services?** The need for STD services, including HIV/AIDS testing, should be considered at every visit. Many clients requesting contraceptive services also might meet the criteria for being at risk of one or more STDs. Screening for chlamydia and gonorrhea is especially important in a family planning context because these STDs contribute to tubal infertility if left untreated. STD services are also necessary to maximize preconception health. The federal recommendations cited in this report should be followed when determining which STD services a client might need. Aspects of managing symptomatic STDs are not addressed in these recommendations.
- **What other related preventive health services does the client need?** Whether the client needs related preventive health services, such as breast and cervical cancer screening for female clients, should be assessed. The federal and professional medical recommendations cited in this report should be followed when determining which related preventive health services a client might need.

BOX 2. Recommended questions to ask when assessing a client's reproductive life plan

Providers should discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, sexually transmitted disease, and preconception health services in accordance with CDC's recommendation that all persons capable of having a child should have a reproductive life plan.*

Providers should assess the client's reproductive life plan by asking the client questions such as:

- Do you have any children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?

* Source: CDC. Recommendations to improve preconception health and health care—United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006;55(No. RR-6).

The individual client's needs should be considered when determining what services to offer at a given visit. It might not be feasible to deliver all the needed services in a single visit, and they might need to be delivered over the course of several visits. Providers should tailor services to meet the specific needs of the population they serve. For example, clients who are trying to achieve pregnancy and those at high risk of unintended pregnancy should be given higher priority for preconception health services. In some cases, the provider will deliver the initial screening service but then refer to another provider for further diagnosis or follow-up care.

The delivery of preconception, STD, and related preventive health services should not become a barrier to a client's ability to receive services related to preventing or achieving pregnancy. For these clients, receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, then follow-up visits should be scheduled.

In addition, professional recommendations for how to address the needs of diverse clients, such as LGBTQ persons (*26–32*) or persons with disabilities (*33*), should be consulted and integrated into procedures, as appropriate. For example, as noted before, providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth, as recommended by the World Health Organization (*34*).

Contraceptive Services

Providers should offer contraceptive services to clients who wish to delay or prevent pregnancy. Contraceptive services should include consideration of a full range of FDA-approved contraceptive methods, a brief assessment to identify the contraceptive methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. Contraceptive counseling is defined as a process that enables clients to make and follow through on decisions about their contraceptive use. Education is an integral component of the contraceptive counseling process that helps clients to make informed decisions and obtain the information they need to use contraceptive methods correctly.

Key steps in providing contraceptive services, including contraceptive counseling and education, have been outlined (Box 3). These key steps are in accordance with the five principles of quality counseling (Appendix C). To help a client who is initiating or switching to a new method of contraception, providers should follow these steps. These steps most likely will be implemented iteratively when working with a client and should help clients adopt, change, or maintain contraceptive use.

Step 1. Establish and maintain rapport with the client. Providers should strive to establish and maintain rapport. Strategies to achieve these goals include the following:

- using open-ended questions;
- demonstrating expertise, trustworthiness, and accessibility;
- ensuring privacy and confidentiality;
- explaining how personal information will be used;
- encouraging the client to ask questions and share information;
- listening to and observing the client; and
- being encouraging and demonstrating empathy and acceptance.

Step 2. Obtain clinical and social information from the client. Providers should ask clients about their medical history to identify methods that are safe. In addition, to learn more about factors that might influence a client's choice of a contraceptive method, providers should confirm the client's pregnancy intentions or reproductive life plan, ask about the client's contraceptive experiences and preferences, and conduct a sexual health assessment. When available, standardized tools should be used.

- **Medical history.** A medical history should be taken to ensure that methods of contraception being considered by a client are safe for that particular client. For a female client, the medical history should include menstrual history (including last menstrual period, menstrual frequency, length and amount of bleeding, and other

BOX 3. Steps in providing contraceptive services, including contraceptive counseling* and education

- Establish and maintain rapport with the client.
- Obtain clinical and social information from the client.
- Work with the client interactively to select the most effective and appropriate contraceptive method.
- Conduct a physical assessment related to contraceptive use, only when warranted.
- Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow up, and confirm client understanding.

* Key principles of providing quality counseling including education have been outlined (Appendix C).

patterns of uterine/vaginal bleeding), gynecologic and obstetrical history, contraceptive use, allergies, recent intercourse, recent delivery, miscarriage, or termination, and any relevant infectious or chronic health condition and other characteristics and exposures (e.g., age, postpartum, and breastfeeding) that might affect the client's medical eligibility criteria for contraceptive methods (*35*). Clients considering combined hormonal contraception should be asked about smoking tobacco, in accordance with CDC guidelines on contraceptive use (*35*). Additional details about the methods of contraception that are safe to use for female clients with specific medical conditions and characteristics (e.g., hypertension) are addressed in previously published guidelines (*35*). For a male client, a medical history should include use of condoms, known allergies to condoms, partner use of contraception, recent intercourse, whether his partner is currently pregnant or has had a child, miscarriage, or termination, and the presence of any infectious or chronic health condition. However, the taking of a medical history should not be a barrier to making condoms available in the clinical setting (i.e., a formal visit should not be a prerequisite for a client to obtain condoms).

- **Pregnancy intention or reproductive life plan.** Each client should be encouraged to clarify decisions about her or his reproductive life plan (i.e., whether the client wants to have any or more children and, if so, the desired timing and spacing of those children) (*24*).
- **Contraceptive experiences and preferences.** Method-specific experiences and preferences should be assessed by asking questions such as, "What method(s) are you currently using, if any?"; "What methods have you used in the past?"; "Have you previously used emergency contraception?"; "Did you use contraception at last sex?"; "What difficulties did you experience with prior methods if any (e.g., side effects or noncompliance)?"; "Do you have a specific method in mind?"; and "Have you discussed method options with your partner, and does your partner have any preferences for which method you use?" Male clients should be asked if they are interested in vasectomy.
- **Sexual health assessment.** A sexual history and risk assessment that considers the client's sexual practices, partners, past STD history, and steps taken to prevent STDs (*36*) is recommended to help the client select the most appropriate method(s) of contraception. Correct and consistent condom use is recommended for those at risk for STDs. CDC recommendations for how to conduct a sexual health assessment have been summarized (Box 4).

Step 3. Work with the client interactively to select the most effective and appropriate contraceptive method. Providers should work with the client interactively to select an effective and appropriate contraceptive method. Specifically, providers should educate the client about contraceptive methods that the client can safely use, and help the client consider potential barriers to using the method(s) under consideration. Use of decision aids (e.g., computerized programs that help a client to identify a range of methods that might be appropriate for the client based on her physical characteristics such as health conditions or preferences about side effects) before or while waiting for the appointment can facilitate and maximize the utility of the time spent on this step.

Providers should inform clients about all contraceptive methods that can be used safely. Before the health-care visit, clients might have only limited information about all or specific methods of contraception (*37*). A broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents, if medically appropriate.

Providers are encouraged to present information on potential reversible methods of contraception by using a tiered approach (i.e., presenting information on the most effective methods first, before presenting information on less effective methods) (*38*,*39*). This information should include an explanation that long-acting reversible contraceptive methods are safe and effective for most women, including those who have never given birth and adolescents (*35*). Information should be tailored and presented to ensure a client-centered approach. It is not appropriate to omit presenting information on a method solely because the method is not available at the service site. If not all methods are available at the service site, it is important to have strong referral links in place to other providers to maximize opportunities for clients to obtain their preferred method that is medically appropriate.

BOX 4. Steps in conducting a sexual health assessment*

- **Practices:** Explore the types of sexual activity in which the patient engages (e.g., vaginal, anal, or oral sex).
- **Pregnancy prevention:** Discuss current and future contraceptive options. Ask about current and previous use of methods, use of contraception at last sex, difficulties with contraception, and whether the client has a particular method in mind.
- **Partners:** Ask questions to determine the number, gender (men, women, or both), and concurrency of the patient's sex partners (if partner had sex with another partner while still in a sexual relationship with the patient). It might be necessary to define the term "partner" to the patient or use other, relevant terminology.
- **Protection from sexually transmitted diseases (STDs):** Ask about condom use, with whom they do or do not use condoms, and situations that make it harder or easier to use condoms. Topics such as monogamy and abstinence also can be discussed.
- **Past STD history:** Ask about any history of STDs, including whether their partners have ever had an STD. Explain that the likelihood of an STD is higher with a past history of an STD.

* Source: CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).

For clients who have completed childbearing or do not plan to have children, permanent sterilization (female or male) is an option that may be discussed. Both female and male sterilization are safe, are highly effective, and can be performed in an office or outpatient surgery setting (*40*,*41*). Women and men should be counseled that these procedures are not intended to be reversible and that other highly effective, reversible methods of contraception (e.g., implants or IUDs) might be an alternative if they are unsure about future childbearing. Clients interested in sterilization should be referred to an appropriate source of care if the provider does not perform the procedure.

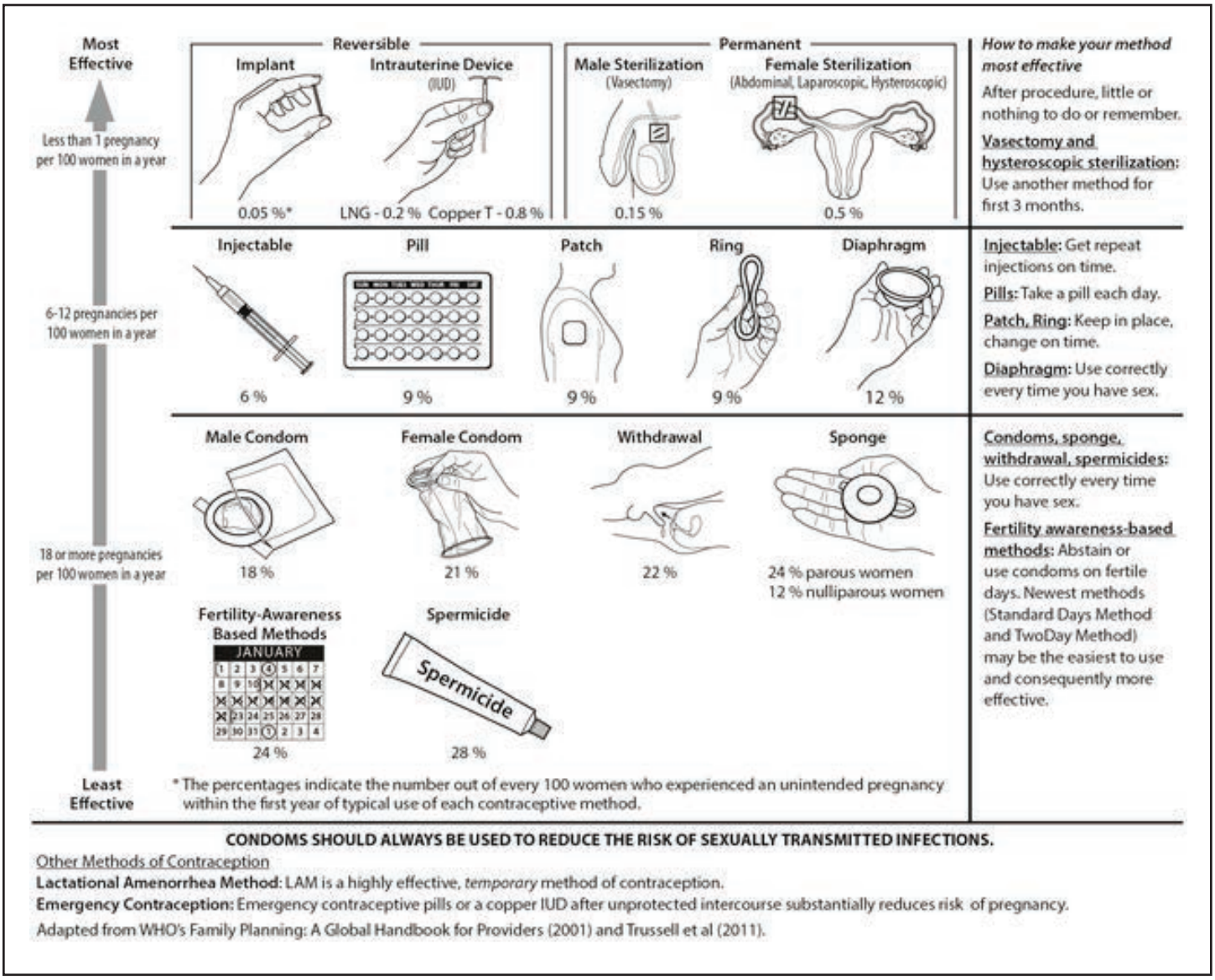
When educating clients about contraceptive methods that the clients can use safely, providers should ensure that clients understand the following:

- **Method effectiveness.** A contraceptive method's rate of typical effectiveness, or the percentage of women experiencing an unintended pregnancy during the first year of typical use, is an important consideration (Figure 3; Appendix D) (*38*,*42*).
- **Correct use of the method.** The mode of administration and understanding how to use the method correctly might be important considerations for the client when choosing a method. For example, receiving a contraceptive injection every 3 months might not be acceptable to a woman who fears injections. Similarly, oral contraceptives might not be acceptable to a woman who is concerned that she might not be able to remember to take a pill every day.
- **Noncontraceptive benefits.** Many contraceptives have noncontraceptive benefits, in addition to preventing pregnancy, such as reducing heavy menstrual bleeding. Although the noncontraceptive benefits are not generally the major determinant for selecting a method, awareness of these benefits can help clients decide between two or more suitable methods and might enhance the client's motivation to use the method correctly and consistently.
- **Side effects.** Providers should inform the client about risks and side effects of the method(s) under consideration, help the client understand that certain side effects of contraceptive methods might disappear over time, and encourage the client to weigh the experience of coping with side effects against the experience and consequences of an unintended pregnancy. The provider should be prepared to discuss and correct misperceptions about side effects. Clients also should be informed about warning signs for rare, but serious, adverse events with specific contraceptive methods, such as stroke and venous thromboembolism with use of combined hormonal methods.
- **Protection from STDs, including HIV.** Clients should be informed that contraceptive methods other than condoms offer no protection against STDs, including HIV. Condoms, when used correctly and consistently, help reduce the risk of STDs, including HIV, and provide protection against pregnancy. Dual protection (i.e., protection from both pregnancy and STDs) is important for clients at risk of contracting an STD, such as those with multiple or potentially infected partner(s). Dual protection can be achieved through correct and consistent use of condoms with every act of sexual intercourse, or correct and consistent use of a condom to prevent infection plus another form of contraception to prevent pregnancy. (For more information about preventing and treating STDs, see STD Services.)

When educating clients about the range of contraceptive methods, providers should ensure that clients have information that is medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that can be readily understood and retained. The content, format, method, and medium for delivering education should be evidence-based (see Appendix E).

When working with male clients, when appropriate, providers should discuss information about female-controlled methods

FIGURE 3. The typical effectiveness of Food and Drug Administration–approved contraceptive methods



(including emergency contraception) encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STDs, including HIV.

When working with any client, encourage partner communication about contraception, as well as understanding partner barriers (e.g., misperceptions about side effects) and facilitators (e.g., general support) of contraceptive use (*43–46*).

The provider should help the client consider potential barriers to using the method(s) under consideration. This includes consideration of the following factors:

- **Social-behavioral factors.** Social-behavioral factors might influence the likelihood of correct and consistent use of contraception (*47*). Providers should help the client consider the advantages and disadvantages of the method(s) being considered, the client's feelings about using the method(s), how her or his partner is likely to respond, the client's peers' perceptions of the method(s), and the client's confidence in being able to use the method correctly and consistently (e.g., using a condom during every act of intercourse or remembering to take a pill every day) (*37*).
- **Intimate partner violence and sexual violence.** Current and past intimate partner sexual or domestic violence might impede the correct and consistent use of contraception, and might be a consideration when choosing a method (*47–49*). For example, an IUD might

be preferred because it does not require the partner's participation. The medical history might provide information on signs of current or past violence and, if not, providers should ask clients about relationship issues that might be potential barriers to contraceptive use. In addition, clients experiencing intimate partner violence or sexual violence should be referred for appropriate care.

- **Mental health and substance use behaviors.** Mental health (e.g., depression, anxiety disorders, and other mental disorders) and substance use behaviors (e.g., alcohol use, prescription abuse, and illicit drug use) might affect a client's ability to correctly and consistently use contraception (*47*,*50*). The medical history might provide information about the signs of such conditions or behaviors, and if not, providers should ask clients about substance use behaviors or mental health disorders, such as depression or anxiety, that might interfere with the motivation or ability to follow through with contraceptive use. If needed, clients with mental health disorders or risky substance use behaviors should be referred for appropriate care.

Step 4. Conduct a physical assessment related to contraceptive use, when warranted. Most women will need no or few examinations or laboratory tests before starting a method of contraception. Guidance on necessary examinations and tests related to initiation of contraception is available (*42*). A list of assessments that need to be conducted when providing reversible contraceptive services to a female client seeking to initiate or switch to a new method of reversible contraception is provided (Table 1) (*42*). Clinical evaluation of a client electing permanent sterilization should be guided by the clinician who performs the procedure. Recommendations for contraceptive use are available (*42*). Key points include the following:

- Blood pressure should be taken before initiating the use of combined hormonal contraception.
- Providers should assess the current pregnancy status of clients receiving contraception (*42*), which provides guidance on how to be reasonably certain that a woman is not pregnant at the time of contraception initiation. In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman about to start using a contraceptive method. Routine pregnancy testing for every woman is not necessary.
- Weight measurement is not needed to determine medical eligibility for any method of contraception because all methods generally can be used among obese women. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
- Unnecessary medical procedures and tests might create logistical, emotional, or economic barriers to contraceptive access for some women, particularly adolescents and low-income women, who have high rates of unintended pregnancies (*1*,*51*,*52*). For both adolescent and adult female clients, the following examinations and tests are not needed routinely to provide contraception safely to a healthy client (although they might be needed to address other non-contraceptive health needs) (*42*):
  - pelvic examinations, unless inserting an intrauterine device (IUD) or fitting a diaphragm;
  - cervical cytology or other cancer screening, including clinical breast exam;
  - human immunodeficiency virus (HIV) screening; and
  - laboratory tests for lipid, glucose, liver enzyme, and hemoglobin levels or thrombogenic mutations.

For male clients, no physical examination needs to be performed before distributing condoms.

Step 5. Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm client understanding.

- A broad range of FDA-approved contraceptive methods should be available onsite. Referrals for methods not available onsite should be provided for clients who indicate they prefer those methods. When providing contraception, providers should instruct the client about correct and consistent use and employ the following strategies to facilitate a client's use of contraception:
  - Provide onsite dispensing;
  - Begin contraception at the time of the visit rather than waiting for next menses (also known as "quick start") if the provider can reasonably be certain that the client is not pregnant (*42*). A provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria (*42*,*53*):
    - is ≤7 days after the start of normal menses,
    - has not had sexual intercourse since the start of last normal menses,
    - has been using a reliable method of contraception correctly and consistently,
    - is ≤7 days after spontaneous or induced abortion,
    - is within 4 weeks postpartum,
    - is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum;
  - Provide or prescribe multiple cycles (ideally a full year's supply) of oral contraceptive pills, the patch, or the ring

TABLE 1. Assessments to conduct when a female client is initiating a new method of reversible contraception

	Cu-IUD and LNG-IUD	Implant	Injectable	Combined hormonal contraception	Progestin-only pills	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/height [m]^2)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Source: CDC. U.S. selected practice recommendations for contraceptive use 2013. MMWR 2013;62(No. RR-5).

Abbreviations: A = Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method; B = Class B: contributes substantially to safe and effective use, but implementation might be considered within the public health and/or service context (the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available); C = Class C: does not contribute substantially to safe and effective use of the contraceptive method; Cu-IUD = copper-containing intrauterine device; LNG-IUD = levonorgestrel releasing intrauterine device.

* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

¶ Most women do not require additional STD screening at the time of IUD insertion, if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR. 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

to minimize the number of times a client has to return to the service site;
  - Make condoms easily and inexpensively available; and
  - If a client chooses a method that is not available on-site or the same day, provide the client another method to use until she or he can start the chosen method.

- Help the client develop a plan for using the selected method. Using a method incorrectly or inconsistently and having gaps in contraceptive protection because of method switching both increase the likelihood of an unintended pregnancy (*37*). After the method has been provided, or a plan put into place to obtain the chosen method, providers should help the client develop an action plan for using the selected method.

  Providers should encourage clients to anticipate reasons why they might not use their chosen method(s) correctly or consistently, and help them develop strategies to deal with these possibilities. For example, for a client selecting oral contraceptive pills who might forget to take a pill, the provider can work with the client to identify ways to routinize daily pill taking (e.g., use of reminder systems such as daily text messages or cell phone alarms). Providers also may inform clients about the availability of emergency contraceptive pills and may provide clients an advance supply of emergency contraceptive pills on-site or by prescription, if requested.

  Side effects (e.g., irregular vaginal bleeding) are a primary reason for method discontinuation (*54*), so providers should discuss ways the client might deal with potential side effects to increase satisfaction with the method and improve continuation (*42*).

- Develop a plan for follow-up. Providers should discuss an appropriate follow-up plan with the client to meet their individual needs, considering the client's risk for discontinuation. Follow-up provides an opportunity to inquire about any initial difficulties the client might be experiencing, and might reinforce the perceived accessibility of the provider and increase rapport. Alternative modes of follow-up other than visits to the service site, such as telephone, e-mail, or text messaging, should be considered (assuming confidentiality can be assured), as needed.

  As noted previously, if a client chooses a method that is not available on-site or during the visit, the provider

should schedule a follow-up visit with the client or provide a referral for her or him to receive the method. The client should be provided another method to use until she or he can start the chosen method.

- Confirm the client's understanding. Providers should assess whether the client understands the information that was presented. The client's understanding of the most important information about her or his chosen contraceptive method should be documented in the medical record (e.g., by a checkbox or written statement).

The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about risks and benefits and appropriate method use and follow-up. If providers assess the client's understanding, then the check box or written statement can be used in place of a written method-specific informed consent form. Topics that providers may consider having the client repeat back include the following: typical method effectiveness; how to use the method correctly; protection from STDs; warning signs for rare, but serious, adverse events and what to do if they experience a warning sign; and when to return for follow-up.

Provide Counseling for Returning Clients

When serving contraceptive clients who return for ongoing care related to contraception, providers should ask if the client has any concerns with the method and assess its use. The provider should assess any changes in the client's medical history, including changes in risk factors and medications that might affect safe use of the contraceptive method. If the client is using the method correctly and consistently and there are no concerns about continued use, an appropriate follow-up plan should be discussed and more contraceptive supplies given (*42*). If the client or provider has concerns about the client's correct or consistent use of the method, the provider should ask if the client would be interested in considering a different method of contraception. If the client is interested, the steps described above should be followed.

Counseling Adolescent Clients

Providers should give comprehensive information to adolescent clients about how to prevent pregnancy (*55–57*). This information should clarify that avoiding sex (i.e., abstinence) is an effective way to prevent pregnancy and STDs. If the adolescent indicates that she or he will be sexually active, providers should give information about contraception and help her or him to choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs. Long-acting reversible contraception is a safe and effective option for many adolescents, including those who have not been pregnant or given birth (*35*).

Providers of family planning services should offer confidential services to adolescents and observe all relevant state laws and any legal obligations, such as notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, as well as human trafficking (*58,59*). Confidentiality is critical for adolescents and can greatly influence their willingness to access and use services (*60–67*). As a result, multiple professional medical associations have emphasized the importance of providing confidential services to adolescents (*68–70*).

Providers should encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health (*71–86*). Adolescents who come to the service site alone should be encouraged to talk to their parents or guardians. Educational materials and programs can be provided to parents or guardians that help them talk about sex and share their values with their child (*72,87*). When both parent or guardian and child have agreed, joint discussions can address family values and expectations about dating, relationships, and sexual behavior.

In a given year, approximately 20% of adolescent births represent repeat births (*88*), so in addition to providing postpartum contraception, providers should refer pregnant and parenting adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy (*89–94*).

Services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth as recommended by the World Health Organization (*34*).

Pregnancy Testing and Counseling

Providers of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) (*95–97*).

Pregnancy testing is a common reason for a client to visit a provider of family planning services. Approximately 65% of pregnancies result in live births, 18% in induced abortion, and 17% spontaneous fetal loss (*98*). Among live births, only 1% of infants are placed for adoption within their first month of life (*99*).

The visit should include a discussion about her reproductive life plan and a medical history that includes asking about any coexisting conditions (e.g., chronic medical illnesses, physical disability, psychiatric illness) (*95,96*). In most cases,

a qualitative urine pregnancy test will be sufficient; however, in certain cases, the provider may consider performing a quantitative serum pregnancy test, if exact hCG levels would be helpful for diagnosis and management. The test results should be presented to the client, followed by a discussion of options and appropriate referrals.

Options counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP (*95–97*). A female client might wish to include her partner in the discussion; however, if a client chooses not to involve her partner, confidentiality must be assured.

Positive Pregnancy Test

If the pregnancy test is positive, the clinical visit should include an estimation of gestational age so that appropriate counseling can be provided. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age. In addition, clients should receive information about the normal signs and symptoms of early pregnancy, and should be instructed to report any concerns to a provider for further evaluation. If ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the provider should either manage the condition or refer the client for immediate diagnosis and management.

Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.

For clients who are considering or choose to continue the pregnancy, initial prenatal counseling should be provided in accordance with the recommendations of professional medical associations, such as ACOG (*97*). The client should be informed that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife). In addition, the client should be encouraged to take a daily prenatal vitamin that includes folic acid; to avoid smoking, alcohol, and other drugs; and not to eat fish that might have high levels of mercury (*97*). If there might be delays in obtaining prenantal care, the client should be provided or referred for any needed STD screening (including HIV) and vaccinations (*36*).

Negative Pregnancy Test

Women who are not pregnant and who do not want to become pregnant at this time should be offered contraceptive services, as described previously. The contraceptive counseling session should explore why the client thought that she was pregnant and sought pregnancy testing services, and whether she has difficulties using her current method of contraception. A negative pregnancy test also provides an opportunity to discuss the value of making a reproductive life plan. Ideally, these services will be offered in the same visit as the pregnancy test because clients might not return at a later time for contraceptive services.

Women who are not pregnant and who are trying to become pregnant should be offered services to help achieve pregnancy or basic infertility services, as appropriate (see "Clients Who Want to Become Pregnant" and "Basic Infertility Services"). They also should be offered preconception health and STD services (see "Preconception Health Services" and "STD services").

Clients Who Want to Become Pregnant

Providers should advise clients who wish to become pregnant in accordance with the recommendations of professional medical organizations, such as the American Society for Reproductive Medicine (ASRM) (*100*).

Providers should ask the client (or couple) how long she or they have been trying to get pregnant and when she or they hope to become pregnant. If the client's situation does not meet one of the standard definitions of infertility (see "Basic Infertility Services"), then she or he may be counseled about how to maximize fertility. Key points are as follows:

- The client should be educated about peak days and signs of fertility, including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation.
- Women with regular menstrual cycles should be advised that vaginal intercourse every 1–2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant.
- Methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.
- It should be noted that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups per day).
- Smoking, consuming alcohol, using recreational drugs, and using most commercially available vaginal lubricants should be discouraged as these might reduce fertility.

Basic Infertility Services

Providers should offer basic infertility care as part of core family planning services in accordance with the recommendations of professional medical organizations, such as ACOG, ASRM, and the American Urological Association (AUA) (*96*,*101*,*102*).

Infertility commonly is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse (*101*). Earlier assessment (such as 6 months of regular unprotected intercourse) is justified for women aged >35 years, those with a history of oligo-amenorrhea (infrequent menstruation), those with known or suspected uterine or tubal disease or endometriosis, or those with a partner known to be subfertile (the condition of being less than normally fertile though still capable of effecting fertilization) (*101*). An early evaluation also might be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential (*102*). Infertility visits to a family planning provider are focused on determining potential causes of the inability to achieve pregnancy and making any needed referrals to specialist care (*101*,*102*). ASRM recommends that evaluation of both partners should begin at the same time (*101*).

Basic Infertility Care for Women

The clinical visit should focus on understanding the client's reproductive life plan (*24*) and her difficulty in achieving pregnancy through a medical history, sexual health assessment and physical exam, in accordance with recommendations developed by professional medical associations such as ASRM (*101*) and ACOG (*96*). The medical history should include past surgery, including indications and outcome(s), previous hospitalizations, serious illnesses or injuries, medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders), and childhood disorders; results of cervical cancer screening and any follow-up treatment; current medication use and allergies; and family history of reproductive failure. In addition, a reproductive history should include how long the client has been trying to achieve pregnancy; coital frequency and timing, level of fertility awareness, and results of any previous evaluation and treatment; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea; and sexual history, including pelvic inflammatory disease, history of STDs, or exposure to STDs. A review of systems should emphasize symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism (*101*).

The physical examination should include: height, weight, and body mass index (BMI) calculation; thyroid examination to identify any enlargement, nodule, or tenderness; clinical breast examination; and assessment for any signs of androgen excess. A pelvic examination should assess for: pelvic or abdominal tenderness, organ enlargement or mass; vaginal or cervical abnormality, secretions, or discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity. If needed, clients should be referred for further diagnosis and treatment (e.g., serum progesterone levels, follicle-stimulating hormone/luteinizing hormone levels, thyroid function tests, prolactin levels, endometrial biopsy, transvaginal ultrasound, hysterosalpingography, laparoscopy, and clomiphene citrate).

Basic Infertility Care for Men

Infertility services should be provided for the male partner of an infertile couple in accordance with recommendations developed by professional medical associations such as AUA (*102*). Providers should discuss the client's reproductive life plan, take a medical history, and conduct a sexual health assessment. AUA recommends that the medical history include a reproductive history (*102*). The medical history should include systemic medical illnesses (e.g., diabetes mellitus), prior surgeries and past infections; medications (prescription and nonprescription) and allergies; and lifestyle exposures. The reproductive history should include methods of contraception, coital frequency and timing; duration of infertility and prior fertility; sexual history; and gonadal toxin exposure, including heat. Patients also should be asked about their female partners' history of pelvic inflammatory disease, their partners' histories of STDs, and problems with sexual dysfunction.

In addition, a physical examination should be conducted with particular focus given to 1) examination of the penis, including the location of the urethral meatus; 2) palpation of the testes and measurement of their size; 3) presence and consistency of both the vas deferens and epididymis; 4) presence of a varicocele; 5) secondary sex characteristics; and 6) a digital rectal exam (*102*). Male clients concerned about their fertility should have a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

Infertility Counseling

Counseling provided during the clinical visit should be guided by information elicited from the client during the medical and reproductive history and the findings of the

physical exam. If there is no apparent cause of infertility and the client does not meet the definition above, providers should educate the client about how to maximize fertility (see "Clients Who Want to Become Pregnant"). ACOG notes the importance of addressing the emotional and educational needs of clients with infertility and recommends that providers consider referring clients for psychological support, infertility support groups, or family counseling (*96*).

Preconception Health Services

Providers of family planning services should offer preconception health services to female and male clients in accordance with CDC's recommendations to improve preconception health and health care (*24*).

Preconception health services are beneficial because of their effect on pregnancy and birth outcomes and their role in improving the health of women and men. The term preconception describes any time that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner.

Preconception health-care services for women aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management. It promotes the health of women of reproductive age before conception, and thereby helps to reduce pregnancy-related adverse outcomes, such as low birthweight, premature birth, and infant mortality (*24*). Moreover, the preconception health services recommended here are equally important because they contribute to the improvement of women's health and well-being, regardless of her childbearing intentions. CDC recommends that preconception health services be integrated into primary care visits made by women of reproductive age, such as family planning visits (*24*).

In the family planning setting, providers may prioritize screening and counseling about preconception health for couples that are trying to achieve pregnancy and couples seeking basic infertility services. Women who are using contraception to prevent or delay pregnancy might also benefit from preconception health services, especially those at high risk of unintended pregnancy. A woman is at high risk of unintended pregnancy if she is using no method or a less effective method of contraception (e.g., barrier methods, rhythm, or withdrawal), or has a history of contraceptive discontinuation or incorrect use (*38*,*39*). A woman is at lower risk of unintended pregnancy if she is using a highly effective method, such as an IUD or implant, or has an established history of using methods of contraception, such as injections, pills, patch, or ring correctly and consistently (*38*,*39*). Clients who do not want to become pregnant should also be provided preconception health services, since they are recommended by USPSTF for the purpose of improving the health of adults.

Recommendations for improving the preconception health of men also have been identified, although the evidence base for many of the recommendations for men is less than that for women (*103*). This report includes preconception health services that address men as partners in family planning (i.e., both preventing and achieving pregnancy), their direct contributions to infant health (e.g., genetics), and their role in improving the health of women (e.g., through reduced STD/HIV transmission). Moreover, these services are important for improving the health of men regardless of their pregnancy intention.

In a family planning setting, all women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid, in accordance with the USPSTF recommendation (Grade A) (*104*).

Other preconception health services for women and men should include discussion of a reproductive life plan and sexual health assessment (Boxes 2 and 4), as well as the screening services described below (*24*,*103*,*105*). Services should be provided in accordance with the cited clinical recommendations, and any needed follow up (further diagnosis, treatment) should be provided either on-site or through referral.

Medical History

For female clients, the medical history should include the reproductive history, history of poor birth outcomes (i.e., preterm, cesarean delivery, miscarriage, and stillbirth), environmental exposures, hazards and toxins (e.g., smoking, alcohol, other drugs), medications that are known teratogens, genetic conditions, and family history (*24*,*105*).

For male clients, the medical history should include asking about the client's past medical and surgical history that might impair his reproductive health (e.g., genetic conditions, history of reproductive failures, or conditions that can reduce sperm quality, such as obesity, diabetes mellitus, and varicocele) and environmental exposures, hazards and toxins (e.g., smoking) (*103*).

Intimate Partner Violence

Providers should screen women of childbearing age for intimate partner violence and provide or refer women who screen positive to intervention services, in accordance with USPSTF (Grade B) recommendations (*106*).

Alcohol and Other Drug Use

For female and male adult clients, providers should screen for alcohol use in accordance with the USPSTF recommendation (Grade B) for how to do so, and provide behavioral counseling

interventions, as indicated (*107*). Screening adults for other drug use and screening adolescents for alcohol and other drug use has the potential to reduce misuse of alcohol and other drugs, and can be recommended (*105*,*108*,*109*). However, the USPSTF recommendation for screening for other drugs in adults, and for alcohol and other drugs in adolescents, is an "I," and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of this screening (*107*,*110*).

Tobacco Use

For female and male clients, providers should screen for tobacco use in accordance with the USPSTF recommendation (*111*,*112*) for how to do so. Adults (Grade A) who use tobacco products should be provided or referred for tobacco cessation interventions, including brief behavioral counseling sessions (<10 minutes) and pharmacotherapy delivered in primary care settings (*111*). Adolescents (Grade B) should be provided intervention to prevent initiation of tobacco use (*112*).

Immunizations

For female and male clients, providers should screen for immunization status in accordance with recommendations of CDC's Advisory Committee on Immunization Practices (*113*) and offer vaccination, as indicated, or provide referrals to community providers for immunization. Female and male clients should be screened for age-appropriate vaccinations, such as influenza and tetanus–diphtheria–pertussis (Tdap), measles, mumps, and rubella (MMR), varicella, pneumococcal, and meningococcal. In addition, ACOG recommends that rubella titer be performed in women who are uncertain about MMR immunization (*108*). (For vaccines for reproductive health-related conditions, i.e., human papillomavirus and hepatitis B, see "Sexually Transmitted Disease Services.")

Depression

For all clients, providers should screen for depression when staff-assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow-up (*114*,*115*). Staff-assisted care supports are defined as clinical staff members who assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment. The lowest effective staff supports consist of a screening nurse who advises primary care clinicians of a positive screen and provides a protocol facilitating referral to behavioral therapy.

Providers also may follow American Psychiatric Association (*116*) and American Academy of Child and Adolescent Psychiatry (*117*) recommendations to assess risk for suicide among persons experiencing depression and other risk factors.

Height, Weight, and Body Mass Index

For all clients, providers should screen adult (Grade B) and adolescent (Grade B) clients for obesity in accordance with the USPSTF recommendation, and obese adults should be referred for intensive counseling and behavioral interventions to promote sustained weight loss (*118*,*119*). Clients likely will need to be referred for this service. These interventions typically comprise 12 to 26 sessions in a year and include multiple behavioral management activities, such as group sessions, individual sessions, setting weight-loss goals, improving diet or nutrition, physical activity sessions, addressing barriers to change, active use of self-monitoring, and strategizing how to maintain lifestyle changes.

Blood Pressure

For female and male clients, providers should screen for hypertension in accordance with the USPSTF's recommendation (Grade A) that blood pressure be measured routinely among adults (*120*) and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure's recommendation that persons with blood pressure less than 120/80 be screened every 2 years, and every year if prehypertensive (i.e., blood pressure 120–139/80–89) (*121*). Providers also may follow AAP's recommendation that adolescents receive annual blood pressure screening (*109*).

Diabetes

For female and male clients, providers should follow the USPSTF recommendation (Grade B) to screen for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) >135/80 mmHg (*122*).

Sexually Transmitted Disease Services

Providers should offer STD services in accordance with CDC's STD treatment and HIV testing guidelines (*36*,*123*,*124*). It is important to test for chlamydia annually among young sexually active females and for gonorrhea routinely among all sexually active females at risk for infection because they can cause tubal infertility in women if left untreated. Testing for syphilis, HIV/AIDS, and hepatitis C should be conducted as recommended (*36*,*123*,*124*). Vaccination for human papillomavirus (HPV) and hepatitis B are also important parts of STD services and preconception care (*113*).

STD services should be provided for persons with no signs or symptoms suggestive of an STD. STD diagnostic management recommendations are not included in these guidelines, so providers should refer to CDC's STD treatment guidelines

(36) when caring for clients with STD symptoms. STD services include the following steps, which should be provided at the initial visit and at least annually thereafter:

Step 1. Assess: The provider should discuss the client's reproductive life plan, conduct a standard medical history and sexual health assessment (see text box above), and check immunization status. A pelvic exam is not indicated in patients with no symptoms suggestive of an STD.

Step 2. Screen: A client who is at risk of an STD (i.e., sexually active and not involved in a mutually monogamous relationship with an uninfected partner) should be screened for HIV and the other STDs listed below, in accordance with CDC's STD treatment guidelines (*36*) and recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings (*123*). Clients also should follow CDC's recommendations for testing for hepatitis C (*124*), and the Advisory Committee on Immunization Practice's recommendations on reproductive health-related immunizations (*113*). It is important to follow these guidelines both to ensure that clients receive needed services and to avoid unnecessary screening.

Chlamydia

For female clients, providers should screen all sexually active women aged ≤25 years for chlamydia annually, in addition to sexually active women aged >25 years with risk factors for chlamydia infection (*36*). Women aged >25 years at higher risk include sexually active women who have a new or more than one sex partner or who have a partner who has other concurrent partners. Females with chlamydia infection should be rescreened for re-infection at 3 months after treatment. Pregnant women should be screened for chlamydia at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, chlamydia screening can be considered for males seen at sites with a high prevalence of chlamydia, such as adolescent clinics, correctional facilities, and STD clinics (*36*,*125*,*126*). Providers should screen men who have sex with men (MSM) for chlamydia at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of chlamydia (urethral discharge or dysuria or whose partner has chlamydia) should be tested and empirically treated at the initial visit. Males with chlamydia infection should be re-screened for reinfection at 3 months (*36*).

Gonorrhea

For female clients, providers should screen clients for gonorrhea, in accordance with CDC's STD treatment guidelines (*36*). Routine screening for *N. gonorrhoeae* in all sexually active women at risk for infection is recommended annually (*36*). Women aged <25 years are at highest risk for gonorrhea infection. Other risk factors that place women at increased risk include a previous gonorrhea infection, the presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, and drug use. Females with gonnorrhea infection should be re-screened for re-infection at 3 months after treatment. Pregnant women should be screened for gonorrhea at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, providers should screen MSM for gonorrhea at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated at the initial visit. Males with gonorrhea infection should be re-screened for reinfection at 3 months after treatment (*36*,*126*–*128*).

Syphilis

For female and male clients, providers should screen clients for syphilis, in accordance with CDC's STD treatment guidelines (*36*). CDC recommends that persons at risk for syphilis infection should be screened. Populations at risk include MSM, commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities and those living in communities with high prevalence of syphilis (*36*). Pregnant women should be screened for syphilis at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

HIV/AIDS

For female and male clients, providers should screen clients for HIV/AIDS, in accordance with CDC HIV testing guidelines (*123*). Providers should follow CDC recommendations that all clients aged 13–64 years be screened routinely for HIV infection and that all persons likely to be at high risk for HIV be rescreened at least annually (*123*). Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. CDC further recommends that screening be provided after the patient is notified that testing will be performed as part of general medical consent unless the patient declines (opt-out screening) or otherwise prohibited by state law. The USPSTF also recommends screening for HIV (Grade A) (*129*).

Hepatitis C

For female and male clients, CDC recommends one-time testing for hepatitis C (HCV) without prior ascertainment of HCV risk for persons born during 1945–1965, a population with a disproportionately high prevalence of HCV infection

and related disease. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions. These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications. Rather, they define an additional target population for testing: persons born during 1945–1965 (*124*). USPSTF also recommends screening persons at high risk for infection for hepatitis C and one-time screening for HCV infection for persons in the 1945–1965 birth cohort (Grade B) (*130*).

Immunizations Related to Reproductive Health

Female clients aged 11–26 years should be offered either human papillomavirus (HPV) 2 or HPV4 vaccine for the prevention of HPV and cervical cancer if not previously vaccinated, although the series can be started in persons as young as age 9 years (*113*); recommendations include starting at age 11–12 years and catch up vaccine among females aged 13–26 who have not been vaccinated previously or have not completed the 3-dose series through age 26. Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years and all adults who are unvaccinated and do not have any documented history of hepatitis B infection (*113*).

Male clients aged 11–21 years (minimum age: 9 years) should be offered HPV4 vaccine, if not vaccinated previously; recommendations include starting at age 11–12 years and catch up vaccine among males aged 13–21 years who have not been vaccinated previously or have not completed the 3-dose series through age 21 years; vaccination is recommended among at-risk males, including MSM and immune-compromised males through age 26 years if not vaccinated previously or males who have not completed the 3-dose series through age 26 years. Heterosexual males aged 22–26 years may be vaccinated (*131*). Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years, and all unvaccinated adults who do not have a documented history of hepatitis B infection (*113*).

Step 3. Treat: A client with an STD and her or his partner(s) should be treated in a timely fashion to prevent complications, re-infection and further spread of the infection in the community in accordance with CDC's STD treatment guidelines; clients with HIV infection should be linked to HIV care and treatment (*36*,*123*). Clients should be counseled about the need for partner evaluation and treatment to avoid reinfection at the time the client receives the positive test results. For partners of clients with chlamydia or gonorrhea, one option is to schedule them to come in with the client; another option for partners who cannot come in with the client is expedited partner therapy (EPT), as permissible by state laws, in which medication or a prescription is provided to the patient to give to the partner to ensure treatment. EPT is a partner treatment strategy for partners who are unable to access care and treatment in a timely fashion. Because of concerns related to resistant gonorrhea, efforts to bring in for treatment partners of patients with gonorrhea infection are recommended; EPT for gonorrhea should be reserved for situations in which efforts to treat partners in a clinical setting are unsuccessful and EPT is a gonorrhea treatment of last resort.

All clients treated for chlamydia or gonorrhea should be rescreened 3 months after treatment; HIV-infected females with *Trichomonas vaginalis* should be linked to HIV care and rescreened for *T. vaginalis* at 3 months. If needed, the client also should be vaccinated for hepatitis B and HPV (*113*). Ideally, STD treatment should be directly observed in the facility rather than a prescription given or called in to a pharmacy. If a referral is made to a service site that has the necessary medication available on-site, such as the recommended injectable antimicrobials for gonorrhea and syphilis, then the referring provider must document that treatment was given.

Step 4. Provide risk counseling: If the client is at risk for or has an STD, high-intensity behavioral counseling for sexual behavioral risk reduction should be provided in accordance with the USPSTF recommendation (Grade B) (*132*). One high-intensity behavioral counseling model that is similar to the contraceptive counseling model is Project Respect (*133*), which could be implemented in family planning settings. All sexually active adolescents are at risk, and adults are at increased risk if they have current STDs, had an STD in the past year, have multiple sexual partners, are in nonmonogamous relationships, or are sexually active and live in a community with a high rate of STDs.

Other key messages to give infected clients before they leave the service site include the following: a) refrain from unprotected sexual intercourse during the period of STD treatment, 2) encourage partner(s) to be screened or to get treatment as quickly as possible in accordance with CDC's STD treatment guidelines (partners in the past 60 days for chlamydia and gonorrhea, 3 to 6 months plus the duration of lesions or signs for primary and secondary syphilis, respectively) if the partner did not accompany the client to the service site for treatment, and 3) return for retesting in 3 months. If the partner is unlikely to access treatment quickly, then EPT for chlamydia or gonorrhea should be considered, if permissible by state law.

A client using or considering contraceptive methods other than condoms should be advised that these methods do not protect against STDs. Providers should encourage a client who is not in a mutually monogamous relationship with an

uninfected partner to use condoms. Patients who do not know their partners' infection status should be encouraged to get tested and use condoms or avoid sexual intercourse until their infection status is known.

Related Preventive Health Services

For many women and men of reproductive age, a family planning service site is their only source of health care; therefore, visits should include provision of or referral to other preventive health services. Providers of family planning services that do not have the capacity to offer comprehensive primary care services should have strong links to other community providers to ensure that clients have access to primary care. If a client does not have another source of primary care, priority should be given to providing related reproductive health services or providing referrals, as needed.

For clients without a primary care provider, the following screening services should be provided, with appropriate follow-up, if needed, while linking the client to a primary care provider. These services should be provided in accordance with federal and professional medical recommendations cited below regarding the frequency of screening, the characteristics of the clients that should be screened, and the screening procedures to be used.

Medical History

USPSTF recommends that women be asked about family history that would be suggestive of an increased risk for deleterious mutations in BRCA1 or BRCA2 genes (e.g., receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B) (*134*). The USPSTF also recommends that women at increased risk for breast cancer should be counseled about risk-reducing medications (Grade B) (*135*).

Cervical Cytology

Providers should provide cervical cancer screening to clients receiving related preventive health services. Providers should follow USPSTF recommendations to screen women aged 21–65 years with cervical cytology (Pap smear) every 3 years, or for women aged 30–65 years, screening with a combination of cytology and HPV testing every 5 years (Grade A) (*136*).

Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years (*136*). Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy (*96*,*137*). The need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method (*42*).

Providers should also follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STD (*96*,*97*,*138*).

Clinical Breast Examamination

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. ACOG recommends annual examination for all women aged >19 years (*108*). ACS recommends screening every 3 years for women aged 20–39 years, and annually for women aged ≥40 years (*139*). However, the USPSTF recommendation for clinical breast exam is an I, and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service (*140*).

Mammography

Providers should follow USPSTF recommendations (Grade B) to screen women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient (*140*).

Genital Examination

For adolescent males, examination of the genitals should be conducted. This includes documentation of normal growth and development and other common genital findings, including hydrocele, varicocele, and signs of STDs (*141*). Components of this examination include inspecting skin and hair, palpating inguinal nodes, scrotal contents and penis, and inspecting the perinanal region (as indicated).

Summary of Recommendations for Providing Family Planning and Related Preventive Health Services

The screening components for each family planning and related preventive health service are provided in summary checklists for women (Table 2) and men (Table 3). When considering how to provide the services listed in these recommendations (e.g., the screening components for each

service, risk groups that should be screened, the periodicity of screening, what follow-up steps should be taken if screening reveals the presence of a health condition), providers should follow CDC and USPSTF recommendations cited above, or, in the absence of CDC and USPSTF recommendations, the recommendations of professional medical associations. Following these recommendations is important both to ensure clients receive needed care and to avoid unnecessary screening of clients who do not need the services.

The summary tables describe multiple screening steps, which refer to the following: 1) the process of asking questions about a client's history, including a determination of whether risk factors for a disease or health condition exist; 2) performing a physical exam; and 3) performing laboratory tests in at-risk asymptomatic persons to help detect the presence of a specific disease, infection, or condition. Many screening recommendations apply only to certain subpopulations (e.g., specific age groups, persons who engage in specific risk behaviors or who have specific health conditions), or some screening recommendations apply to a particular frequency (e.g., a cervical cancer screening is generally recommended every 3 years rather than annually). Providers should be aware that the USPSTF also has recommended that certain screening services not be provided because the harm outweighs the benefit (see Appendix F).

When screening results indicate the potential or actual presence of a health condition, the provider should either provide or refer the client for the appropriate further diagnostic testing or treatment in a manner that is consistent with the relevant federal or professional medical associations' clinical recommendations.

Conducting Quality Improvement

Service sites that offer family planning services should have a system for conducting quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Quality improvement is the use of a deliberate and continuous effort to achieve measurable improvements in the identified indicators of quality of care, which improve the health of the community (*142*). By improving the quality of care, family planning outcomes, such as reduced rates of unintended pregnancy, improved patient experiences, and reduced costs, are more likely to be achieved (*10*,*12*,*143*,*144*).

Several frameworks for conducting quality improvement have been developed (*144*–*146*). This section presents a general overview of three key steps that providers should take when conducting quality improvement of family planning services: 1) determine which measures are needed to monitor quality; 2) collect the information needed; and 3) use the findings to make changes to improve quality (*147*). Ideally, these steps will be conducted on a frequent (optimally, quarterly) and ongoing basis. However, since quality cuts across all aspects of a program, not all domains of quality can necessarily be considered at all times. Within a sustainable system of quality improvement, programs can opt to focus on a subset of quality dimensions and their respective measures.

Determining Which Measures Are Needed

Performance measures provide information about how well the service site is meeting pre-established goals (*148*). The following questions should be considered when selecting performance measures (*143*):

- Is the topic important to measure and report? For example, does it address a priority aspect of health care, and is there opportunity for improvement?
- What is the level of evidence for the measure (e.g., that a change in the measure is likely to represent a true change in health outcomes)? Does the measure produce consistent (reliable) and credible (valid) results about the quality of care?
- Are the results meaningful and understandable and useful for informing quality improvement?
- Is the measure feasible? Can it be implemented without undue burden (e.g., captured with electronic data or electronic health records)?

Performance measures should consider the quality of the structure of services (e.g., the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure), the process by which care is provided (whether services are provided correctly and completely, and how clients perceive the care they receive), and the outcomes of that care (e.g., client behaviors or health conditions that result) (*149*). They also may assess each dimension of quality services (*10*,*13*). Examples of measures that can be used for monitoring the quality of family planning services (*150*) and suggested measures that might help providers monitor quality of care have been listed (Table 6). However, other measures have been developed that also might be useful (*151*–*153*). Service sites that offer family planning services should select, measure, and assess at least one intermediate or outcome measure on an ongoing basis, for which the service site can be accountable. Structure- and process-based measures that assess the eight dimensions of quality services may be used to better determine how to improve quality (*154*).

Collecting Information

Once providers have determined what information is needed, the next steps are to collect and use that information to improve the quality of care. Commonly used methods of data collection include the following:

TABLE 2. Checklist of family planning and related preventive health services for women

Screening components	Family planning services (provide services in accordance with the appropriate clinical recommendation): Contraceptive services*	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services†	Related preventive health services
History						
Reproductive life plan§	Screen	Screen	Screen	Screen	Screen	
Medical history§,**	Screen	Screen	Screen	Screen	Screen	Screen
Current pregnancy status§	Screen					
Sexual health assessment§,**	Screen		Screen	Screen	Screen	
Intimate partner violence §,¶,**				Screen		
Alcohol and other drug use§,¶,**				Screen		
Tobacco use§,¶	Screen (combined hormonal methods for clients aged ≥35 years)			Screen		
Immunizations§				Screen	Screen for HPV & HBV§§	
Depression§,¶				Screen		
Folic acid§,¶				Screen		
Physical examamination						
Height, weight and BMI§,¶	Screen (hormonal methods)††		Screen	Screen		
Blood pressure§,¶	Screen (combined hormonal methods)			Screen§§		
Clinical breast exam**			Screen			Screen§§
Pelvic exam§,**	Screen (initiating diaphragm or IUD)	Screen (if clinically indicated)	Screen			
Signs of androgen excess**			Screen			
Thyroid exam**			Screen			
Laboratory testing						
Pregnancy test **	Screen (if clinically indicated)	Screen				
Chlamydia§, ¶	Screen¶¶				Screen§§	
Gonorrhea§, ¶	Screen¶¶				Screen§§	
Syphilis§,¶					Screen§§	
HIV/AIDS§,¶					Screen§§	
Hepatitis C§,¶					Screen§§	
Diabetes§,¶				Screen§§		
Cervical cytology¶						Screen§§
Mammography¶						Screen§§

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

* This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59(No. RR-4).

† STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

§ CDC recommendation.

¶ U.S. Preventive Services Task Force recommendation.

** Professional medical association recommendation.

†† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

¶¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4) women who have a very high individual likelihood of STD exposure (e.g. those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

- **Review of medical records.** All records that detail service delivery activities can be reviewed, including encounters and claims data, client medical records, facility logbooks, and others. It is important that records be carefully designed, sufficiently detailed, provide accurate information, and have access restricted to protect confidentiality. The use of electronic health records can facilitate some types of medical record review.
- **Exit interview with the client.** A patient is asked (through either a written or in-person survey) to describe what happened during the encounter or their assessment of their satisfaction with the visit. Both quantitative (close-ended questions) and qualitative (open-ended questions) methods can be used. Limitations include a bias toward clients reporting higher degrees of satisfaction, and the

TABLE 3. Checklist of family planning and related preventive health services for men

Screening components and source of recommendation	Family planning services (provide services in accordance with the appropriate clinical recommendation)				Related preventive health services
	Contraceptive services*	Basic infertility services	Preconception health services†	STD services§	
History					
Reproductive life plan¶	Screen	Screen	Screen	Screen	
Medical history¶,††	Screen	Screen	Screen	Screen	
Sexual health assessment¶,††	Screen	Screen	Screen	Screen	
Alcohol & other drug use ¶,**,††			Screen		
Tobacco use¶,**			Screen		
Immunizations¶			Screen	Screen for HPV & HBV§§	
Depression¶,**			Screen		
Physical examination					
Height, weight, and BMI¶,**			Screen		
Blood pressure**,††			Screen§§		
Genital exam††		Screen (if clinically indicated)		Screen (if clinically indicated)	Screen§§
Laboratory testing					
Chlamydia¶				Screen§§	
Gonorrhea¶				Screen§§	
Syphilis¶,**				Screen§§	
HIV/AIDS¶,**				Screen§§	
Hepatitis C¶,**				Screen§§	
Diabetes¶,**			Screen§§		

Abbreviations: HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus virus; STD = sexually transmitted disease.

* No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

† The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199[6 Suppl 2]:S389–95).

§ STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

¶ CDC recommendation.

** U.S. Preventive Services Task Force recommendation.

†† Professional medical association recommendation.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

provider's behavior might be influenced if she or he knows clients are being interviewed.

- **Facility audit.** Questions about a service site's structure (e.g., on-site availability of a broad range of FDA-approved methods) and processes (e.g., skills and technical competence of staff, referral mechanisms) can be used to determine the readiness of the facility to serve clients.
- **Direct observation.** A provider's behavior is observed during an actual encounter with a client. Evaluation of a full range of competencies, including communication skills, can be carried out. A main limitation is that the observer's presence might influence the provider's performance.
- **Interview with the health-care provider.** Providers are interviewed about how specific conditions are managed. Both closed- and open-ended questions can be used, although it is important to frame the question so that the 'correct' answer is not suggested. A limitation is that providers tend to over-report their performance.

Consideration and Use of the Findings

After data are collected, they should be tabulated, analyzed, and used to improve care. Staff whose performance was assessed should be involved in the development of the data collection tools and analysis of results. Analysis should address the following questions (*155*):

- What is the performance level of the facility?
- Is there a consistent pattern of performance among providers?
- What is the trend in performance?
- What are the causes of poor performance?
- How can performance gaps be minimized?

Given the findings, service site staff should use a systematic approach to identifying ways to improve the quality of care. One example of a systematic approach to improving the quality of care is the "Plan, Do, Study, and Act" (PDSA) model (*147*,*156*), in which staff first develop a plan for improving quality, then execute the plan on a small scale, evaluate feedback to confirm or adjust the plan, and finally, make the plan

TABLE 4. Suggested measures of the quality of family planning services

Type of measure and dimension of quality	Measure	Source
Health outcome	• Unintended pregnancy • Teen pregnancy • Birth spacing • Proportion of female users at risk for unintended pregnancy who adopt or continue use of an FDA-approved contraceptive method (measured for any method; highly effective methods; or long-acting reversible methods) [Intermediate outcome]	PIMS*
Safe (Structure)	• Proportion of providers that follow the most current CDC recommendations on contraceptive safety	
Effective (Structure, or the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure)	• Site dispenses or provides on-site a full range of FDA-approved contraceptive methods to meet the diverse reproductive needs and goals of clients; short-term hormonal, long-acting reversible contraception (LARC), emergency contraception (EC). • Proportion of female users aged ≥24 years who are screened annually for chlamydial infection. • Proportion of female users aged ≥24 years who are screened annually for gonorrhea. • Proportion of users who were tested for HIV during the past 12 months. • Proportion of female users aged ≥21 years who have received a Pap smear within the past 3 years.	PIMS*
Client-centered (Process, or whether services are provided correctly and completely, and how clients perceive the care they receive)	• Proportion of clients who report the provider communicates well, shows respect, spends enough time with the client, and is informed about the client's medical history. • Proportion of clients who report that – Staff are helpful and treat clients with courtesy and respect. – His or her privacy is respected. – She or he receives contraceptive method that is acceptable to her or him.	CAHPS† RQIP§
Efficient (Structure)	• Site uses electronic health information technology or electronic health records to improve client reproductive health.	PIMS*
Timely (Structure and process)	• Average number of days to the next appointment. • Site offers routine contraceptive resupply on a walk-in basis. • Site offers on-site HIV testing (using rapid technology). • Site offers on-site HPV and hepatitis B vaccination.	PIMS*
Accessible (Structure and process)	• Site offers family planning services during expanded hours of operation. • Proportion of total family planning encounters that are encounters with ongoing or continuing users. • Proportion of clients who report that his or her care provider follows up to give test results, has up-to-date information about care from specialists, and discusses other prescriptions. • Site has written agreements (e.g., MOUs) with the key partner agencies for health care (especially prenatal care, primary care, HIV/AIDS) and social service (domestic violence, food stamps) referrals.	PIMS* CAHPS–PCMH item set on care coordination†
Equitable (Structure)	• Site offers language assistance at all points of contact for the most frequently encountered language(s).	PIMS*
Value	• Average cost per client.	CDC¶

Abbreviations: CAPHS = Agency for Healthcare Research and Quality's Consumer Assessment of Health Care Providers and Systems; FDA = Food and Drug Administration; HPV = human papillomavirus; MOU = memorandum of understanding; PIMS = Performance Information and Monitoring System; RQIP = Regional Quality Indicators Program.

* **Source:** Fowler C. Title X Family Planning Program Performance Information and Monitoring System (PIMS): Description of Proposed Performance Measures [DRAFT]. Washington, DC: Research Triangle Institute; 2012.

† **Source:** Agency for Healthcare Research and Quality. Consumer Assessment of Healthcare Providers and Systems (CAHPS). Available at https://www.cahps.ahrq.gov/default.asp.

§ **Source:** John Snow International. The Regional Quality Indicators Project (RQIP). Boston, MA: John Snow International; 2014. Available at http://www.jsi.com/JSIInternet/USHealth/project/display.cfm?ctid=na&cid=na&tid=40&id=2621.

¶ **Sources:** Haddix A, Corso P, Gorsky R. Costs. In: Haddix A, Teutsch S, Corso P, eds. Prevention effectiveness: a guide to decision analysis and economic evaluation. 2nd ed. Oxford, UK: Oxford University Press; 2003; Stiefel M, Nolan K. A guide to measuring the triple aim: population health, experience of care, and per capita cost. Cambridge, MA: Institute for Healthcare Improvements; 2012.

permanent. Examples of steps that may be taken to improve the quality of care include developing job aids, providing task-specific training for providers, conducting more patient education, or strengthening relationships with referral sites through formal memoranda of understanding (*146*).

Conclusion

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. The recommendations in this report can contribute to improved reproductive health by defining a core set of family planning

services for women and men, describing how to provide contraceptive and other family planning services to both adult and adolescent clients, and encouraging the use of the family planning visit to provide selected preventive health services for women and men. This guidance is intended to assist primary care providers to offer the family planning services that will help persons and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy.

Recommendations are updated periodically. The most recent versions are available at http://www.hhs.gov/opa.

References

1. Finer LB, Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006. Contraception 2011;84:478–85.
2. CDC. Adolescent pregnancy and childbirth—United States, 1991–2008. In: CDC. CDC health disparities and inequalities report—United States, 2011. MMWR 2011;60(Suppl; January 14, 2011):105–8.
3. Martin J, Hamilton B, Osterman J, et al. Births: final data for 2012. Natl Vital Stat Rep 2013;62(9).
4. Mathews T, Macdorman M. Infant mortality statistics from the 2010 period linked birth/infant data set. Natl Vital Stat Rep 2013:62(8).
5. US Department of Health and Human Services, Office of Population Affairs. Mission statement for the Office of Family Planning. Washington, DC: US Department of Health and Human Services; 2013. Available at http://www.hhs.gov/opa/about-opa-and-initiatives/mission.
6. Institute of medicine. Clinical preventive services for women: closing the gaps. Washington, DC: The National Academies Press; 2011. Available at http://www.nap.edu/catalog.php?record_id=13181.
7. US Department of Health and Human Services, Office of Population Affairs. Title X family planning. Washington, DC: US Department of Health and Human Services; 2013. Available at http://www.hhs.gov/opa/title-x-family-planning/index.html.
8. Frost J. U.S. women's use of sexual and reproductive health services: trends, sources of care and factors associated with use, 1995–2010. New York, NY: Guttmacher Institute; 2013.
9. US Department of Health and Human Services Coverage of certain preventive services under the Affordable Care Act: final rules. 45 CFR Parts 147 and 156. July 19, 2010. Washington, DC: US Department of Health and Human Services; 2010.
10. Institute of Medicine. Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies of Science; 2001.
11. Bruce J. Fundamental elements of the quality of care: a simple framework. Stud Fam Plann 1990;21:61–91.
12. Becker D, Koenig MA, Kim YM, Cardona K, Sonenstein FL. The quality of family planning services in the United States: findings from a literature review. Perspect Sex Reprod Health 2007;39:206–15.
13. Institute of Medicine. Future directions for the national health care quality and disparities reports. Ullmer CBM, Burke S, eds. Washington, DC: The National Academies Press; 2010.
14. Tucker CM. US Department of Health and Human Services, Advisory Committee on Minority Health. Reducing health disparities by promoting patient-centered culturally and linguistically sensitive/competent health care. Rockville, MD: US Department of Health and Human Services, Public Health Service; 2009.
15. US Department of Health and Human Services, Office of Minority Health. The national standards for culturally and linguistically appropriate services in health and health care. Washington, DC: US Department of Health and Human Services; 2012. Available at https://www.thinkculturalhealth.hhs.gov/Content/clas.asp#clas_standards.
16. Olavarria M, Beaulac J, Belanger A, Young M, Aubry T. Organizational cultural competence in community health and social service organizations: how to conduct a self-assessment. J Cult Divers 2009;16:140–50.
17. Frost J, Finer L, Tapales A. The impact of publicly funded family planning clinic services on unintended pregnancies and government cost savings. J Health Care Poor Underserved 2008;19:778–96.
18. Trussell J, Henry N, Hassan F, Prezioso A, Law A, Filonenko A. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. Contraception 2013;87:154–61.
19. Foster DG, Rostovtseva DP, Brindis CD, Biggs MA, Hulett D, Darney PD. Cost savings from the provision of specific methods of contraception in a publicly funded program. Am J Public Health 2009;99:446–51.
20. GRADE Working Group. GRADE: going from evidence to recommendations. BMJ 2008;336:1049–51.
21. Institute of Medicine. Clinical practice guidelines we can trust. Washington, DC: The National Academies Press; 2011. Available at http://www.nap.edu/catalog.php?record_id=13058.
22. US Preventive Services Task Force. USPSTF: methods and processes. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.
23. Lu M. Recommendations for preconception care. Am Fam Physician 2007;76:397–400.
24. CDC. Recommendations to improve preconception health and health care—United States. MMWR 2006;55(No. RR-6).
25. Moos M. Preconceptional health promotion: progress in changing a prevention paradigm. J Perinat Neonatal Nurs 2004;18:2–13.
26. American College of Obstetricians and Gynecologists. Committee Opinion #512: health care for transgender individuals. Obstet Gynecol 2011;118:1454–8.
27. American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. ACOG Committee Opinion No. 525: health care for lesbians and bisexual women. Obstet Gynecol 2012;119:1077–80.
28. McNair R, Hegarty K. Guidelines for the primary care of lesbian, gay and bisexual people: a systematic review. Ann Fam Med 2010;8:533–41.
29. World Professional Association for Transgender Health. Standards of care for the health of transsexual, transgender, and gender-nonconforming people. Minneapolis, MN: World Professional Association for Transgender Health; 2011.
30. The Center of Excellence for Transgender Health. Primary care protocol for transgender patient care. San Francisco, CA: University of California–San Francisco; 2011.
31. American Academy of Pediatrics. Office-based care for lesbian, gay, bisexual, transgender, and questioning youth: Policy statement and Technical report. Pediatrics 2013;132:198–203.
32. Adelson SL, American Academy of Child and Adolescent Psychiatry Committee on Quality Issues. Practice parameter on gay, lesbian or bisexual orientation, gender nonconformity, and gender discordance in children and adoelscents. J Am Acad Child Adolesc Psychiatry 2012;51:957–74.

33. Office on Women's Health. Illnesses and disabilities: sexual and reproductive health. Available at http://www.womenshealth.gov/illnesses-disabilities/your-health/sexuality-reproductive-health.cfm.
34. McIntyre P. Adolescent friendly health services: an agenda for change. Geneva, Switzerland: World Health Organization; 2002.
35. CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59(No. RR-4).
36. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).
37. Jaccard J. Careful, current, and consistent: tips to improve contraceptive use. Washington, DC: National Campaign to Prevent Teen Pregnancy; 2010.
38. Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.
39. Winner B, Peipert J, Zhao Q, et al. Effectiveness of long-acting reversible contraception. N Engl J Med 2012;366:1998–2007.
40. Beerthuizen R. State-of-the-art of non-hormonal methods of contraception: V. Female sterilisation. Eur J Contracept Reprod Health Care 2010;15:124–35.
41. Michielsen D, Beerthuizen R. State-of-the art of non-hormonal methods of contraception: VI. Male sterilisation. Eur J Contracept Reprod Health Care 2010;15:136–49.
42. CDC. U.S. Selected practice recommendations for contraceptive use 2013. MMWR 2013;62(No. RR-5).
43. Kerns J, Westhoff C, Morroni C, Murphy P. Partner influence on early discontinuation of the pill in a predominantly Hispanic population. Perspect Sex Reprod Health 2003;35:256–60.
44. Forste R, Morgan J. How relationships of US men affect contraceptive use and efforts to prevent STD. Fam Plann Perspect 1998;30:56–62.
45. Severy L, Silver S. Two reasonable people: joint decision-making in contraceptive choice and use. In: LJ S, ed. Advances in population: psychosocial perspectives. London, UK: Jessica Kingsley Publishers; 1994:207–27.
46. Grady W, Klepinger D. BIlly J, Cubbins L. The role of relationship power in couple decisions about contraception in the US. J Biosoc Sci 2010;42:307–25.
47. Jaccard J. Unlocking the contraceptive conundrum. Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregnancy; 2009.
48. Pallitto CC, Campbell JC, O'Campo P. Is intimate partner violence associated with unintended pregnancy? A review of the literature. Trauma Violence Abuse 2005;6:217–35.
49. Paterno MT, Jordan ET. A review of factors associated with unprotected sex among adult women in the United States. J Obstet Gynecol Neonatal Nurs 2012;41:258–74.
50. Rehm J, Shield KD, Joharchi N, Shuper PA. Alcohol consumption and the intention to engage in unprotected sex: systematic review and meta-analysis of experimental studies. Addiction 2012;107:51–9.
51. Harper C, Balistreri E, Boggess J, Leon K, Darney P. Provision of hormonal contraceptives without a mandatory pelvic examination: the first stop demonstration project. Fam Plann Perspect 2001;33:13–8.
52. Stormo A, Hawkins N, Cooper C, Saraiya M. The pelvic examination as a screening tool: practices of US physicians. Arch Intern Med 2011;171:2053–4.
53. Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. Adv Contracept Deliv Syst 1994;10:93–109.
54. Huber L, Hogue C, Stein A, et al. Contraceptive use and discontinuation: findings from the contraceptive history, initiation and choice study. Am J Obstet Gynecol 2006;194:1290–5.
55. CDC. Guide to community preventive services: prevention of HIV/AIDS, other STIs and pregnancy, group-based comprehensive risk reduction interventions for adolescents. Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at www.thecommunityguide.org/hiv/riskreduction.html.
56. Kirby DB, Laris BA, Rolleri LA. Sex and HIV education programs: their impact on sexual behaviors of young people throughout the world. J Adolesc Health 2007;40:206–17.
57. Oringanje C, Meremikwu MM, Eko H, Esu E, Meremikwu A, Ehiri JE. Interventions for preventing unintended pregnancies among adolescents. Cochrane Database Syst Rev 2009:CD005215.
58. English A. State minor consent laws: a summary. 3rd ed. Washington, DC: Center for Adolescent Health and the Law; 2010.
59. US Department of Health and Human Services. State requirements for reporting child abuse. Washington, DC: US Department of Health and Human Services; 2013. Available at http://www.childwelfare.gov/systemwide/laws_policies/state.
60. Guldi M. Fertility effects of abortion and birth control pill access for minors. Demography 2008;45:817–27.
61. Klein JD, McNulty M, Flatau CN. Adolescents' access to care: teenagers' self-reported use of services and perceived access to confidential care. Arch Pediatr Adolesc Med 1998;152:676–82.
62. Lehrer JA, Pantell R, Tebb K, Shafer MA. Forgone health care among U.S. adolescents: associations between risk characteristics and confidentiality concern. J Adolesc Health 2007;40:218–26.
63. Lyren A, Kodish E, Lazebnik R, O'Riordan MA. Understanding confidentiality: perspectives of African American adolescents and their parents. J Adolesc Health 2006;39:261–5.
64. Reddy DM, Fleming R, Swain C. Effect of mandatory parental notification on adolescent girls' use of sexual health care services. JAMA 2002;288:710–4.
65. Vo DX, Pate OL, Zhao H, Siu P, Ginsburg KR. Voices of Asian American youth: important characteristics of clinicians and clinical sites. Pediatrics 2007;120:e1481–93.
66. Zabin LS, Stark HA, Emerson MR. Reasons for delay in contraceptive clinic utilization. Adolescent clinic and nonclinic populations compared. J Adolesc Health 1991;12:225–32.
67. Zavodny M. Fertility and parental consent for minors to receive contraceptives. Am J Public Health 2004;94:1347–51.
68. Klein J. Achieving quality health services for adolescents: policy statement of the Committee on Adolescence, American Academy of Pediatrics. Pediatrics 2008;121:1263.
69. Ford C, English A, Sigman G. Confidential health care for adolescents: position paper for the Society for Adolescent Medicine. J Adolesc Health 2004;35:160–7.
70. American College of Obstetricians and Gynecologists. Confidentiality in adolescent health care. guidelines for adolescent health care. 2nd ed. Washington, DC: American College of Obstetricians and Gynecologists; 2011.
71. Anderson NLR, Koniak-Griffin D, Keenan CK, Uman G, Duggal BR, Casey C. Evaluating the outcomes of parent-child family life education. Sch Inq Nurs Pract 1999;13:211–38.
72. Guilamo-Ramos V, Bouris A, Jaccard J, Gonzalez B, McCoy W, Aranda D. A parent-based intervention to reduce sexual risk behavior in early adolescence: building alliances between physicians, social workers, and parents. J Adolesc Health 2011;48:159–63.

73. Blake SM, Simkin L, Ledsky R, Perkins C, Calabrese JM. Effects of a parent-child communications intervention on young adolescents' risk for early onset of sexual intercourse. Fam Plann Perspect 2001;33:52–61.
74. Brody GH, Murry VM, Gerrard M, et al. The Strong African American Families Program: translating research into prevention programming. Child Dev 2004;75:900–17.
75. Evans WD, Davis KC, Ashley OS, Blitstein J, Koo H, Zhang Y. Efficacy of abstinence promotion media messages: findings from an online randomized trial. J Adolesc Health 2009;45:409–16.
76. Forehand R, Armistead L, Long N, et al. Efficacy of a parent-based sexual-risk prevention program for African American preadolescents: a randomized controlled trial. Arch Pediatr Adolesc Med 2007;161:1123–9.
77. Haggerty KP, Skinner ML, MacKenzie EP, Catalano RF. A randomized trial of Parents Who Care: effects on key outcomes at 24-month follow-up. Prev Sci 2007;8:249–60.
78. Huston RL, Martin LJ, Foulds DM. Effect of a program to facilitate parent-child communication about sex. Clin Pediatr (Phila) 1990;29:626–33.
79. Lederman RP, Chan W, Roberts-Gray C. Sexual risk attitudes and intentions of youth aged 12–14 years: survey comparisons of parent-teen prevention and control groups. Behavioral Medicine (Washington, DC) 2004;29:155–63.
80. Lederman RP, Chan W, Roberts-Gray C. Parent-adolescent relationship education (PARE): program delivery to reduce risks for adolescent pregnancy and STDs. Behav Med 2008;33:137–43.
81. Lefkowitz ES, Sigman M, Au TK. Helping mothers discuss sexuality and AIDS with adolescents. Child Dev 2000;71:1383–94.
82. Miller BC, Norton MC, Jenson GO. Pregnancy prevention programs: Impact Evaluation of Facts and Feelings: a home-based video sex education curriculum. Fam Relat 1993;42:392–400.
83. Murry VM, Berkel C, Brody GH, Gerrard M, Gibbons FX. The Strong African American Families program: longitudinal pathways to sexual risk reduction. J Adolesc Health 2007;41:333–42.
84. Schuster MA, Corona R, Elliott MN, et al. Evaluation of Talking Parents, Healthy Teens, a new worksite based parenting programme to promote parent-adolescent communication about sexual health: randomised controlled trial. BMJ 2008;337:a308.
85. Stanton B, Cole M, Galbraith J, et al. Randomized trial of a parent intervention: parents can make a difference in long-term adolescent risk behaviors, perceptions, and knowledge. Arch Pediatr Adolesc Med 2004;158:947–55.
86. Stanton BF, Li X, Galbraith J, et al. Parental underestimates of adolescent risk behavior: a randomized, controlled trial of a parental monitoring intervention. J Adolesc Health 2000;26:18–26.
87. American Academy of Pediatrics. Parents matter: your children want to learn about the facts of life from you. Elk Grove Village, IL: American Academy of Pediatrics; ND. Available at http://www2.aap.org/visit/ParentsMatterBrochure.pdf.
88. Hamilton B. Births: final Data for 2010. National Vital Statistics Reports 2012;61(1).
89. Olds DL, Henderson CR Jr, Tatelbaum R, Chamberlin R. Improving the life-course development of socially disadvantaged mothers: a randomized trial of nurse home visitation. Am J Public Health 1988;78:1436–45.
90. Olds DL, Kitzman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: age 6 follow-up results of a randomized trial. Pediatrics 2004;114:1550–9.
91. Olds DL, Kitzman H, Hanks C, et al. Effects of nurse home visiting on maternal and child functioning: age-9 follow-up of a randomized trial. Pediatrics 2007;120:e832–45.
92. Rabin JM, Seltzer V, Pollack S. The long term benefits of a comprehensive teenage pregnancy program. Clin Pediatr (Phila) 1991;30:305–9.
93. Avellar S, Paulsell D, Sama-Miller E, Del Grosso P. Home visiting evidence of effectiveness review. Washington, DC: US Department of Health and Human Services, Office of Planning, Research and Evaluation, Administration for Children and Families; 2012.
94. Black M, Bentley M, Papas M, et al. Delaying second births among adolescent mothers: a randomized, controlled trial of a home-based mentoring program. Pediatrics 2006;118:1087–99.
95. American Academy of Pediatrics. Counseling the adolescent about pregnancy options. Pediatrics 2006;101:938–40.
96. American College of Obstetricians and Gynecologists. Guidelines for women's health care: a resource manual. 3rd ed. Washington, DC: American College of Obstetricians and Gynecologists; 2007.
97. American College of Obstetricians and Gynecologists. Guidelines for perinatal care. 6th ed. Washington, DC: American College of Obstetricians and Gynecologists; 2007.
98. Ventura S, Curtin S, Abma J, Henshaw S. Estimated pregnancy rates and rates of pregnancy outcomes for the US: 1990–2008. Natl Vital Stat Rep 2012;60(7).
99. Jones J. Adoption experiences of women and men and demand for children to adopt by women 18–44 years of age in the United States, 2002. Vital Health Stat 2008;23(7).
100. American Society for Reproductive Medicine in collaboration with the Society for Reproductive Endocrinology and Infertility. Optimizing natural fertility. Fertil Steril 2008;90(Suppl):S1–6.
101. American Society for Reproductive Medicine. Optimal evaluation of the infertile female. Fertil Steril 2006;86.
102. American Urological Association. The optimal evaluation of the infertile male: AUA best practice statement. Linthicum, MD: American Urological Association; 2010.
103. Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;6:S389–95.
104. US Preventive Services Task Force. Folic acid to prevent neural tube defects. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsnrfol.htm.
105. Jack B, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(Suppl B):S266–79.
106. US Preventive Services Task Force. Screening for intimate partner violence and abuse of elderly and vulnerable adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsipv.htm.
107. US Preventive Services Task Force. Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse. AHRQ, US Department of Health and Human Services; 2013.
108. American College of Obstetricians and Gynecologists. Committee Opinion No. 483: primary and preventive care: periodic assessments. Obstet Gynecol 2011;117:1008–15.
109. Committee on Practice and Ambulatory Medicine, Bright Futures Periodicity Schedule Workgroup. 2014 recommendations for pediatric preventive health care. Pediatrics 2014;133;568.
110. US Preventive Services Task Force. Screening for illicit drug use. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2008.

111. US Preventive Services Task Force. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspstbac2.htm.
112. US Preventive Services Task Force. Primary care interventions to prevent tobacco use in children and adolescents. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013.
113. CDC. Advisory Committee on Immunization Practices (ACIP) recommended immunization schedules for persons aged 0 through 18 years and adults aged 19 years and older—United States, 2013. MMWR 2013;62(Suppl 1):1–19.
114. US Preventive Services Task Force. Screening for depression in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsaddepr.htm.
115. US Preventive Services Task Force. Major depressive disorder in children and adolescents. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspschdepr.htm.
116. American Psychiatric Association. Practice guideline for the assessment and treatment of patients with suicidal behaviors. Am J Psychiatry 2003;160(Suppl):1–60.
117. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with suicidal behavior. J Am Acad Child Adolesc Psychiatry 2001;40(Suppl):24S–51S.
118. US Preventive Services Task Force. Screening for obesity in children and adolescents: US Preventive Services Task Force recommendation statement. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2010. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspschobes.htm.
119. US Preventive Services Task Force. Screening for and management of obesity in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2012. Available at http://www.uspreventiveservicestaskforce.org/uspstf11/obeseadult/obesers.htm.
120. US Preventive Services Task Force. Screening for high blood pressure in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2007. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspshype.htm.
121. US Department of Health and Human Services. The seventh report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Washington, DC: US Department of Health and Human Services; 2004.
122. US Preventive Services Task Force. Screening for type 2 diabetes mellitus in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2008. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsdiab.htm.
123. CDC. Revised recommendations for HIV testing of adults, adolescents and pregnant women in health care settings. MMWR 2006;55(No. RR-14).
124. CDC. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945–1965. MMWR 2012;61(No. RR-4).
125. CDC. Male chlamydia screening consultation. Atlanta, GA: US Department of Health and Human Services, DCD; 2006. Available at http://www.cdc.gov/std/chlamydia.
126. Burstein GR, Eliscu A, Ford K, et al. Expedited partner therapy for adolescents diagnosed with chlamydia or gonorrhea: a position paper of the Society for Adolescent Medicine. J Adolesc Health 2009;45:303–9.
127. American Academy of Pediatrics. Promoting healthy sexual development and sexuality. Bright Futures: guidelines for health supervision of infants, children, and adolescents. Elk Grove, IL: American Academy of Pediatrics; 2007.
128. US Preventive Services Task Force. Screening for gonorrhea. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2005. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsgono.htm.
129. US Preventive Services Task Force. Screening for HIV. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm.
130. US Preventive Services Task Force. Screening for hepatitis C virus infection in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm#recommendations.
131. CDC. Recommendations on the use of quadrivalent human papillomavirus vaccine in males—Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60:1705–8.
132. US Preventive Services Task Force. Behavioral counseling to prevent sexually transmitted infections. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2008. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsstds.htm.
133. Kamb ML, Fishbein M, Douglas JM Jr, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. JAMA 1998;280:1161–7.
134. US Preventive Services Task Force. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm.
135. US Preventive Services Task Force. Medications for risk reduction of primary breast cancer in women. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrpv.htm.
136. US Preventive Services Task Force. Screening for cervical cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2012. Available at www.uspreventiveservicestaskforce.org/uspstf11/cervcancer/cervcancerrs.htm.
137. Massad L, Einstein M, Huh W, et al. 2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. Obstet Gynecol 2013;121:829–46.
138. Braverman P, Breech L. Gynecologic examination for adolescents in the pediatric office setting. Pediatrics 2010;126:583–90.
139. Smith RA, Brooks D, Cokkinides V, Saslow D, Brawley OW. Cancer screening in the United States, 2013: a review of current American Cancer Society guidelines, current issues in cancer screening, and new guidance on cervical cancer screening and lung cancer screening. CA Cancer J Clin 2013;63:88–105.

140. US Preventive Services Task Force. Screening for breast cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrca.htm.
141. Marcell A, Bell D, Joffe A. The male genital examination: a position paper of the Society for Adolescent Health and Medicine: a position paper of the Society for Adolescent Health and Medicine. J Adolesc Health 2012;50:424–5.
142. Riley W, Moran J, Corso L, Beitsch L, Bialek R, Cofsky A. Defining quality improvement in public health. J Public Health Manag Pract 2010;16:5–7.
143. National Quality Forum. ABCs of measurement. Washington, DC: National Quality Forum; 2011. Available at http://www.qualityforum.org/Measuring_Performance/ABCs_of_Measurement.aspx.
144. Berwick D, Nolan T, Whittington J. The Trip Aim: care, health and cost. Health Aff 2008;27:759–69.
145. CDC. National Public Health Performance Standards Program. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. Available at www.cdc.gov/od/ocphp/nphpsp.
146. Berwick D. A user's manual for the IOM's "Quality Chasm" Report. Health Affairs 2002;21:80–90.
147. Langley G, Nolan K, Nolan T, Norman C, Provost L. The Improvement Guide: A practical approach to enhancing organizational performance. 2nd ed. San Francisco, CA: Jossey-Bass Publishers; 2009.
148. Government Accountability Office. Performance measurement and evaluation: definitions and relationships. Washington, DC: Government Accountability Office; 2011.
149. Donabedian A. The quality of care. JAMA 1988;260:1743–8.
150. Fowler C. Title X Family Planning Program Performance Information and Monitoring System (PIMS): description of proposed performance measures. Washington, DC: Research Triangle Institute; 2012.
151. California Family Health Council. Performance measures: guiding quality improvement for family planning services. Los Angeles, CA: California Family Health Council; 2011. Available at http://www.cfhc.org/TitleX/PerformanceMeasures/default.htm.
152. John Snow International. The Regional Quality Indicators Project (RQIP). Boston, MA: John Snow International; 2012. Available at http://www.jsi.com/JSIInternet/USHealth/project/display.cfm?ctid=na&cid=na&tid=40&id=2621.
153. Family Planning Councils of America. Performance Measurement System. Los Angeles, CA: Family Planning Councils of America; ND. Available at http://www.fpcai.org/pms.html.
154. Palmer R. Process-based measures of quality: the need for detailed clinical data in large health care databases. Ann Intern Med 1997; 127:733–8.
155. Bouchet B. Health manager's guide: monitoring the quality of primary care. Bethesda, MD: Center for Human Services; ND. Available at http://pdf.usaid.gov/pdf_docs/PNACK584.pdf.
156. Institute for Health Care Improvement. How to improve. Cambridge, MA: Institute for Health Care Improvement; 2014. Available at http://www.ihi.org/knowledge/Pages/HowtoImprove/default.aspx.

Appendix A

How the Recommendations Were Developed

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health (DRH) and the Office of Population Affairs (OPA), in consultation with a wide range of experts and key stakeholders. A multistage process that drew on established procedures for developing clinical guidelines (*1,2*) was used to develop the recommendations. In April 2010, an Expert Work Group (EWG) comprising family planning clinical providers, program administrators, representatives from relevant federal agencies, and representatives from professional medical organizations was created to advise OPA and CDC on the structure and content of the revised recommendations and to help make the recommendations more feasible and relevant to the needs of the field. This group made two key initial recommendations: 1) to examine the scientific evidence for three priority areas of focus identified as key components of family planning service delivery, (i.e., counseling and education, serving adolescents, and quality improvement); and 2) to guide providers of family planning services in the use of various recommendations for how to provide clinical care to women and men.

Developing Recommendations on Counseling, Adolescent Services, and Quality Improvement

Systematic reviews of the published literature from January 1985 through December 2010 were conducted for each priority topic to identify evidence-based and evidence-informed approaches to family planning service delivery. Standard methods for conducting the reviews were used, including the development of key questions and analytic frameworks, the identification of the evidence base through a search of the published as well as "gray literature" (i.e., studies published somewhere other than in a peer-reviewed journal), and a synthesis of the evidence in which findings were summarized and the quality of individual studies was considered, using the methodology of the U.S. Preventive Services Task Force (USPSTF) (*3*). Eight databases were searched (i.e., MEDLINE, PsychInfo, PubMed, CINAHL, Cochrane, EMBASE, POPLINE, and the U.K. National Clearinghouse Service Economic Evaluation Database) and were restricted to literature from the United States and other developed countries. Summaries of the evidence used to prepare these recommendations will appear in background papers that will be published separately.

In May 2011, three technical panels (one for each priority topic) comprising subject matter experts were convened to consider the quality of the evidence and suggest what recommendations might be justified on the basis of the evidence. CDC and OPA used this feedback to develop core recommendations for counseling, serving adolescents, and quality improvement. EWG members subsequently reviewed these core recommendations; EWG members differed from the subject matter experts in that they were more familiar with the family planning service delivery context and could comment on the feasibility and appropriateness of the recommendations as well as on their scientific justification. EWG members met to consider the core recommendations using 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences (e.g., the ability of the recommendations to have a substantial effect on health outcomes may be weighed more than the logistical challenges of implementing them) (*1*). In certain cases, when the evidence was inconclusive or incomplete, recommendations were made on the basis of expert opinion (see Appendix B). Finally, CDC and OPA staff considered the feedback from EWG members when finalizing the core recommendations and writing this report.

Developing Recommendations on Clinical Services

DRH and OPA staff members synthesized recommendations for clinical care for women and for men that were developed by >35 federal and professional medical organizations. They were assisted in this effort by staff from OPA's Office of Family Planning Male Training Center and from CDC's Division of STD Prevention, Division of Violence Prevention, Division of Immunization Services, and Division of Cancer Prevention and Control. The synthesis was needed because clinical recommendations are sometimes inconsistent with each other and can vary by the extent to which they are evidence-based. The clinical recommendations addressed contraceptive services, achieving pregnancy, basic infertility services, preconception health services, sexually transmitted disease services, and related health-care services.

An attempt was made to apply the Institute of Medicine's criteria for clinical practice guidelines when deciding which professional medical organizations to include in the review (*2*). However, many organizations did not articulate the process used to develop the recommendations fully, and many did not

conduct comprehensive and systematic reviews of the literature. In the end, to be included in the synthesis, the recommending organization had to be a federal agency or major professional medical organization that represents established medical disciplines. In addition, a recommendation had to be made on the basis of an independent review of the evidence or expert opinion and be considered a primary source that was developed for the United States.

In July 2011, two technical panels comprising subject matter experts on clinical services for women and men were convened to review the synthesis of federal and professional medical recommendations, reconcile inconsistent recommendations, and provide individual feedback to CDC and OPA about the implications for family planning service delivery. CDC and OPA used this individual feedback to develop core recommendations for clinical services. The core recommendations were subsequently reviewed by EWG members, and feedback was used to finalize the core recommendations and write this report.

Members of the technical panels recommended that contraceptive services, pregnancy testing and counseling, services to achieve pregnancy, basic infertility care, STD services, and other preconception health services should be considered family planning services. This feedback considered federal statute and regulation, CDC and USPSTF recommendations for clinical care, and EWG members' opinion.

Because CDC's preconception health recommendations include many services, the panel narrowed the range of preconception services that were included by using the following criteria: 1) the Select Panel on Preconception Care (*4*) had assigned an A or B recommendation to that service for women, which means that there was either good or fair evidence to support the recommendation that the condition be considered in a preconception care evaluation (Table 1), or 2) the service was included among recommendations made by experts in preconception health for males (*5*). Services for men that addressed health conditions that affect reproductive capacity or pregnancy outcomes directly were included as preconception health; services that addressed men's health but that were not related directly to pregnancy outcomes were considered to be related preventive health services.

The Expert Work Group noted that more preventive services are recommended than can be offered feasibly in some settings. However, a primary purpose of this report is to set a broad framework within which individual clinics will tailor services to meet the specific needs of the populations that they serve. In addition, EWG members identified specific subgroups that should have the greatest priority for preconception health services (i.e., those trying to achieve pregnancy and those at high risk of unintended pregnancy). Future operational research should provide more information about how to deliver these services most efficiently during multiple visits to clients with diverse needs.

Determining How Clinical Services Should Be Provided

Various federal agencies and professional medical associations have made recommendations for how to provide family planning services. When considering these recommendations, the Expert Work Group used the following hierarchy:

- Highest priority was given to CDC guidelines because they are developed after a rigorous review of scientific evidence. CDC guidelines tailor recommendations for higher risk individuals, (whereas USPSTF focuses on average risk individuals), who are more representative of the clients seeking family planning services.
- When no CDC guideline existed to guide the recommendations, the relevant USPSTF A or B recommendations (which indicate a high or moderate certainty that the benefit is moderate to substantial) were used. USPSTF recommendations are made on the basis of a thorough review of the available evidence.
- If neither a CDC nor a USPSTF A or B recommendation existed, the recommendations of selected major professional medical associations were considered as resources. The American Academy of Pediatrics' (AAP) Bright Futures guidelines (*6*) were used as the primary source of recommendations for adolescents when no CDC or USPSTF recommendations existed.
- For a limited number of recommendations, there were no federal or major professional medical recommendations, but the service was recommended by EWG members on the basis of expert opinion for family planning clients.

In some cases, a service was graded as an I recommendation by USPSTF for the general population (an I recommendation means that the current evidence is insufficient to assess the balance of benefits and harms of the service, so if the service is offered, patients should be informed of this fact), but either CDC, EWG members, or another organization recommended the service for women or men seeking family planning services. The situations in which this occurred and the reasons why the service was recommended despite its receiving an I recommendation by USPSTF have been summarized (Table 2). The approach used to consider the evidence and make recommendations that are used by USPSTF have been summarized (Tables 3 and 4) (*7*).

References

1. GRADE Working Group. GRADE: going from evidence to recommendations. BMJ 2008;336:1049–51.
2. Institute of Medicine. Clinical practice guidelines we can trust. Washington, DC: The National Academies Press; 2011. Available at http://www.nap.edu/catalog.php?record_id=13058.
3. US Preventive Services Task Force. USPSTF: methods and processes. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.
4. Jack BW, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(Suppl 2):S266–79.
5. Frey KA, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199(Suppl 2):S389–95.
6. Committee on Practice and Ambulatory Medicine, Bright Futures Periodicity Schedule Workgroup. 2014 recommendations for pediatric preventive health care. Pediatrics 2014;133;568.
7. US Preventive Services Task Force. Grade definitions. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm.

TABLE 1. Select Panel on Preconception Care grading system

Quality of the evidence*	
I-a	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was performed with subjects who were not pregnant.
I-b	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was done not necessarily before pregnancy.
II-1	Evidence was obtained from well-designed, controlled trials without randomization.
II-2	Evidence was obtained from well-designed cohort or case-control analytic studies, preferably conducted by more than one center or research group.
II-3	Evidence was obtained from multiple-time series with or without the intervention, or dramatic results in uncontrolled experiments.
III	Opinions were gathered from respected authorities on the basis of clinical experience, descriptive studies and case reports, or reports of expert committees.
Strength of the recommendation	
A	There is good evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
B	There is fair evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
C	There is insufficient evidence to recommend for or against the inclusion of the condition in a preconception care evaluation, but recommendation to include or exclude may be made on other grounds.
D	There is fair evidence to support the recommendation that the condition be excluded in a preconception care evaluation.
E	There is good evidence to support the recommendation that the condition be excluded in a preconception care evaluation.

Source: Jack B, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(6 Suppl 2):S266–79.

TABLE 2. Services included in these recommendations that received a U.S. Preventive Services Task Force (USPSTF) I recommendation

Service/screen	USPSTF recommendation	Why the service is recommended despite a USPSTF I recommendation
Alcohol	I for adolescents	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures* guidelines.
Other drugs	I for adolescents and adults	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures guidelines.
Clinical breast exam	I for all women	No CDC recommendation exists, but ACOG and ACS recommend conducting clinical breast exams, and the Expert Work Group endorsed the ACOG recommendation.
Chlamydia	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.
Gonorrhea	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.

Source: US Preventive Services Task Force. USPSTF recommendations. Available at http://www.uspreventiveservicestaskforce.org/recommendations.htm.
Abbreviations: AAP = American Academy of Pediatrics; ACS = American Cancer Society; ACOG = American Congress of Obstetricians and Gynecologists; STD = sexually transmitted disease.
* Source: Committee on Practice and Ambulatory Medicine, Bright Futures Periodicity Schedule Workgroup. 2014 recommendations for pediatric preventive health care. Pediatrics 2014;133;568.

TABLE 3. U.S. Preventive Services Task Force (USPSTF) grades, definitions, and suggestions for practice

Grade	Definition	Suggestions for practice
A	USPSTF recommends the service. There is high certainty that the net benefit is substantial.	This service should be offered or provided.
B	USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	This service should be offered or provided.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for a majority of persons without signs or symptoms there is likely to be only a limited benefit from this service.	This service should be offered or provided only if other considerations support the offering or providing the service in an individual patient.
D	USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Use of this service should be discouraged.
I Statement	USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	The clinical considerations section of USPSTF recommendation statement should be consulted. If the service is offered, patients should be educated about the uncertainty of the balance of benefits and harms.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

TABLE 4. Levels of certainty regarding net benefit

Level of certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as • the number, size, or quality of individual studies; • inconsistency of findings across individual studies; • limited generalizability of findings to routine primary care practice; and • lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes is insufficient because of • the limited number or size of studies, • important flaws in study design or methods, • inconsistency of findings across individual studies, • gaps in the chain of evidence, • findings not generalizable to routine primary care practice, • lack of information on important health outcomes, or • more information required to allow estimation of effects on health outcomes.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

* The US Preventive Services Task Force (USPSTF) defines certainty as the likelihood that the USPSTF assessment of the net benefit of a preventive service is correct. The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Appendix B

The Evidence, Potential Consequences, and Rationales for Core Recommendations

Sixteen core recommendations that were considered by the Expert Work Group (EWG) are presented below. Each recommendation is accompanied by a summary of the relevant evidence (full summaries of which will be published separately), a list of potential consequences of implementing the recommendation, and its rationale. When considering the recommendations, the Expert Work Group was divided into two groups (one comprising seven members and the other five members), and each group considered separate recommendations.

Definition of Family Planning Services

Recommendation: Primary care providers should offer the following family planning services: contraceptive services for women and men who want to prevent pregnancy and space births, pregnancy testing and counseling, help for clients who wish to achieve pregnancy, basic infertility services, sexually transmitted disease (STD) services and preconception health services to improve the health of women, men, and infants.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of federal statute and regulation (*1,2*), CDC clinical recommendations (*3–5*), and expert opinion.

Potential consequences: Adding preconception health services means that more women and men will receive preconception health services. The recommended services also will promote the health of women and men even if they do not have children. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered in some settings.

Rationale: Services to prevent and achieve pregnancy are core to the federal government's efforts to promote reproductive health. Adding preconception health as a family planning service is consistent with this mission; it emphasizes achieving a healthy pregnancy and also promotes adult health. Adding preconception health is also consistent with CDC recommendations to integrate preconception health services into primary care platforms (*3*). All seven EWG members agreed to this recommendation.

Preconception Health — Women

Recommendation: Preconception health services for women include the following screening services: reproductive life plan; medical history; sexual health assessment; intimate partner violence, alcohol, and other drug use; tobacco use; immunizations; depression; body mass index (BMI); blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. All female clients also should be counseled about the need to take a daily supplement of folic acid. When screening results indicate the presence of a health condition, the provider should take steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to enable clients who need services to receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services by an expert panel on preconception care for women (*6*).

Potential consequences: More women will receive specified preconception health services, which will improve the health of infants and women. The evidence base for preconception health is not fully established. There is a potential risk that a client with a positive screen will not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to the health of women and infants were thought by the panel to be greater than the costs, potential harms, and opportunity costs of providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Preconception Health — Men

Recommendation: Preconception health services for men include the following screening services: reproductive life plan; medical history; sexual health assessment; alcohol and other drug use; tobacco use; immunizations; depression; BMI; blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. When screening results indicate the presence of a health condition, the provider should take

steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to ensure that clients who need services receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services for men (*7*).

Potential consequences: More men will receive preconception health services, which might improve infant and men's health. The evidence base for preconception health is not well established and is less than that for women's preconception health. There is a risk of over-screening if recommendations are not followed. There is a potential risk that a client with a positive screen might not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to men and infant health were thought by the panel to be greater than the costs, potential harms, and opportunity costs of not providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Contraceptive Services — Contraceptive Counseling Steps

Recommendation: To help a client who is initiating or switching to a new method of contraception, providers should follow these steps, which are in accordance with the key principles for providing quality counseling: 1) establish and maintain rapport with the client; 2) obtain clinical and social information from the client; 3) work with the client interactively to select the most effective and appropriate contraceptive method for her or him; 4) provide a physical assessment related to contraceptive use, when warranted; and 5) provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm understanding.

Quality of evidence: Twenty-two studies were identified that examined the impact of contraceptive counseling in clinical settings and met the inclusion criteria. Of the 16 studies that focused on adults or mixed populations (adolescents and adults) (*8–23*), 11 found a statistically significant positive impact of counseling interventions with low (*11*,*12*,*14–16*,*18–21*), moderate (*8*), or unrated (*22*) intensity on at least one outcome of interest; study designs included two cross-sectional surveys (*14*,*22*), one pre-post study (*21*), one prospective cohort study (*8*), one controlled trial (*15*), and six randomized controlled trials (RCTs) (*11*,*12*,*16*,*18–20*). Six studies examined the impact of contraceptive counseling among adolescents (*24–29*), with four finding a statistically significant positive impact of low-intensity (*27*) or moderate-intensity (*24*,*25*,*29*) counseling interventions on at least one outcome of interest; study designs included two pre-post studies (*24*,*30*), one controlled trial (*29*), and one RCT (*27*). In addition, five studies were identified that examined the impact of reminder system interventions in clinical settings on family planning outcomes and met the inclusion criteria (*31–35*); of these, two found a statistically significant positive impact of reminder systems on perfect oral contraceptive compliance, a retrospective historical nonrandomized controlled trial that examined daily reminder email messages (*31*) and a cohort study that examined use of a small reminder device that emitted a daily audible beep (*34*). In addition, two studies examined the impact of reminder systems among depot medroxyprogesterone acetate users (DMPA) (*33*,*35*) with one, a retrospective cohort study, finding a statistically significant positive impact of receiving a wallet-sized reminder card with the date of the next DMPA injection and a reminder postcard shortly before the next injection appointment on timely DMPA injections. Statements about safety and unnecessary medical examinations and tests are made on the basis of CDC guidelines on contraceptive use (*36*,*37*).

Potential consequences: Fewer clients will use methods that are not safe for them, there will be increased contraceptive use, increased use of more effective methods, increased continuation of method use, increased use of dual methods, increased knowledge, increased satisfaction with services, and increased use of repeat or follow-up services.

Rationale: Making sure that a contraceptive method is safe for an individual client is a fundamental responsibility of all providers of family planning services. Removing medical barriers to contraceptive use is key to increasing access to contraception and helping clients prevent unintended pregnancy. Consistent use of contraceptives is needed to prevent unintended pregnancies, so appropriate counseling is critical to ensure clients make the best possible choice of methods for their unique circumstances, and are supported in continued

use of the chosen method. The principles of quality counseling, from which the steps listed in the recommendations are based, are supported by a substantial body of evidence and expert opinion. Future research to evaluate the five principles will be monitored and the recommendations modified, as needed. All seven EWG members agreed to this recommendation.

Contraceptive Services — Tiered Approach to Counseling

Recommendation: For clients who might want to get pregnant in the future and prefer reversible methods of contraception, providers should use a tiered approach to presenting a broad range of contraceptive methods (including long-acting reversible contraception such as intrauterine devices and contraceptive implants), in which the most effective methods are presented before less effective methods.

Quality of evidence: National surveys have demonstrated low rates of LARC use overall (*38,39*). However, Project CHOICE has demonstrated high uptake of long-acting reversible contraception (approximately two thirds of clients when financial barriers are removed) and a very substantial reduction in rates of unintended pregnancy (*40*). Further, a recent study of postpartum contraceptive use shows that 50% of teen mothers with a recent live birth are using long-acting reversible contraception postpartum in Colorado, which demonstrates high levels of acceptance in the context of a statewide program to remove financial barriers (*41*).

Potential consequences: Use of long-acting reversible contraception has the potential to help many more persons prevent unintended pregnancy because of its ease of use, safety, and effectiveness. Several questions were raised about ethical issues in using a tiered approach to counseling. First, is it ethical to educate about long-acting reversible contraception when the methods are not all available on-site? Second, conversely, is it ethical not to inform clients about the most effective methods? In other health service areas, the standard of care is to inform the client about the most effective treatment (e.g., blood pressure medications), so the client can make a fully informed decision, and this standard should apply in this instance as well. On the basis of historic experiences, there is a need to ensure that methods always are offered on a completely voluntary and noncoercive basis. Health-care reform might make contraceptive services more available to the majority of clients.

Rationale: Providers have an obligation to inform clients about the most effective methods available, even if they cannot provide them. Further, health-care reform will reduce the financial barriers to long-acting reversible contraception for many persons. The potential increase in use of long-acting reversible contraception and other more effective methods is likely to help reduce rates of unintended pregnancy. All seven EWG members agreed to this recommendation.

Contraceptive Services — Broad Range of Methods

Recommendation: A broad range of methods should be available on-site or through referral.

Quality of evidence: Three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Clients will be more likely to select a method that they will use consistently and correctly.

Rationale: A central tenet of quality health care is that it be client-centered. Being able to provide a client with a method that best fits her or his unique circumstances is essential for that reason. All seven EWG members agreed to this recommendation.

Contraceptive Services — Education

Recommendation: The content, format, method, and medium for delivering education should be evidence-based.

Quality of evidence: Seventeen studies were identified that met the inclusion criteria for this systematic review. Of these, 15 studies looked at knowledge of correct method use or contraceptive risks and benefits, including side effects and method effectiveness (*45–59*). All but one study (*56*) found a statistically significant positive impact of educational interventions on increased knowledge. These studies included six randomized controlled trials with low risk for bias.

Potential consequences: Clients will make more informed decisions when choosing a contraceptive method. More clients will be satisfied with the process of selecting a contraceptive method.

Rationale: Knowledge obtained through educational activities, as integrated into the larger counseling model, is a critically important precondition for the client's ability to make informed decisions. The techniques described in the recommendations have a well-established evidence base for increasing knowledge and satisfaction with services. This knowledge lays the foundation for further counseling steps that will increase the likelihood of correct and consistent use, and increased satisfaction will increase return visits to the service site, as needed. Four of seven EWG members agreed to this recommendation; three members did not express an opinion.

Contraceptive Services — Confirm Understanding

Recommendation: A check box or written statement should be available in the medical record that can be used to document that the client expressed understanding of the most important information about her/his chosen contraceptive method. The teach-back method may be used to get clients to express the most important points by repeating back messages about risks and benefits and appropriate method use and follow-up. Documentation of understanding using the teach-back method and a check box or written statement can be used in place of a written method-specific informed consent.

Quality of evidence: Two studies from outside the family planning literature (one cohort study and one controlled trial with unclear randomization) (*60,61*) and a strong recommendation by members of the Technical Panel on Counseling and Education were considered.

Potential consequences: More clients will make informed decisions, adherence to contraceptive and treatment plans will improve, and reproductive and other health conditions will be better controlled.

Rationale: Asking providers to document in the record that the client is making an informed decision will increase providers' attention to this task. This recommendation will replace a previous requirement that providers obtain method-specific informed consent from each client (in addition to a general consent form). Six of seven EWG members agreed to this recommendation.

Adolescent Services — Comprehensive Information

Recommendation: Providers should provide comprehensive information to adolescent clients about how to prevent pregnancy and STDs. This should include information about contraception and that avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs.

Quality of evidence: A systematic review was not conducted because other recent reviews were available that have shown a substantial impact of comprehensive sexual health education on reduced adolescent risk behavior (*62–66*). The evidence for abstinence-only education was more limited: CDC's Community Guide concluded that there was insufficient evidence (*67*), but the Department of Health and Human Services' Office of Adolescent Health has identified two abstinence-based programs as having evidence of effectiveness (*68*).

Potential consequences: Teens will make more informed decisions and will delay initiation of sexual intercourse. The absence of harmful effects from comprehensive sexual health education was noted.

Rationale: The benefits of informing adolescents about all ways to prevent pregnancy are substantial. Ultimately, each adolescent should make an informed decision that meets her or his unique circumstances, based on the counseling provided by the provider. Six of seven EWG members agreed to this recommendation.

Adolescent Services — Use of Long-Acting Reversible Contraception

Recommendation: Education about contraceptive methods should include an explanation that long-acting reversible contraception is safe and effective for nulliparous women (women who have not been pregnant or given birth), including adolescents.

Quality of evidence: CDC guidelines on contraceptive use (*37*) provide evidence that long-acting reversible contraception is safe and effective for adolescents and nulliparous women.

Potential consequences: More providers will encourage adolescents to consider long-acting reversible contraception; more adolescents will choose long-acting reversible contraception, resulting in reduced rates of teen pregnancy, including rapid repeat pregnancy.

Rationale: Long-acting reversible contraception is safe for adolescents (*37*). As noted above, providers should inform clients about the most effective methods available. The potential increase in use of long-acting reversible contraception and other more effective methods by adolescents is substantial and is likely to lead to further reductions in teen pregnancy. Three EWG members agreed to this recommendation; two EWG members abstained.

Adolescent Services — Confidential Services

Recommendation: Confidential family planning services should be made available to adolescents, while observing state laws and any legal obligations for reporting.

Quality of evidence: Six descriptive studies documented one or more of the following: that confidentiality is important to adolescents; that many adolescents reported they will not use reproductive health services if confidentiality cannot be assured; and that adolescents might not be honest in discussing reproductive health with providers if confidentiality cannot be assured (*69–74*). One RCT showed a slight reduction in use of services after receiving conditional confidentiality, compared with complete confidentiality (*75*). One study showed a

positive association between confidentiality and intention to use services (*73*).

Potential consequences: Consequences might include an increased intention to use services, increased use of services, and reduced rates of teen pregnancy. However, explaining the need to report under certain circumstances (rape, child abuse) might deter some adolescent clients from using services. Further, some parents/guardians might not agree that adolescents should have access to confidential services.

Rationale: Minors' rights to confidential reproductive health services are consistent with state and federal law. The risks of not providing confidential services to adolescents are great and likely to result in an increased rate of teen pregnancies. Finally, this recommendation is consistent with the recommendations of three professional medical associations that endorse provision of confidential services to adolescents (*76–78*). All seven EWG members agreed to this recommendation.

Adolescent Services — Family-Child Communication

Recommendation: Providers should encourage and promote family-child communication about sexual and reproductive health.

Quality of evidence: From the family planning literature, 16 parental involvement programs (most using an RCT study design) were found to be positively associated with at least one short-term (13 of 16 studies) or medium-term (four of seven studies) outcome (*79–94*). However, only one of these studies was linked to clinical services (*80*); others were implemented in community settings.

Potential consequences: Consequences might include increased parental/guardian involvement and communication, improved knowledge/awareness, increased intentions to use contraceptives, and the adoption of more pro-social norms that support parent-child communication about sexual health.

Rationale: The literature provides strong evidence that increased communication between a child and her/his parent/guardian will lead to safer sexual behavior among teens, and numerous community-based programs have created an evidence base for how to strengthen parents/guardians' ability to hold those conversations. Although less is known about how to do so in a clinical setting, providers can refer their clients to programs in the community, and principles from the community-based approaches can be used to help providers develop appropriate approaches in the clinical setting. Research in this area will be monitored, and the recommendations will be revised, as needed. Four of five EWG members who provided input agreed to this recommendation; one member abstained.

Adolescent Services — Repeat Teen Pregnancy

Recommendation: Providers should refer pregnant and parenting adolescents to home visiting and other programs that have been shown to provide needed support and reduce rates of repeat teen pregnancy.

Quality of evidence: Three of four studies of clinic-based programs (using retrospective case-control cohort, ecological evaluation, and prospective cohort study designs) showed that comprehensive teen pregnancy prevention programs (programs with clinical, school, case management, and community components) were associated with both medium- and long-term outcomes (*95–98*). In addition, several randomized trials of community-based home visiting programs, and an existing systematic review of the home visiting literature, demonstrated a protective impact of these programs on preventing repeat teen pregnancy and other relevant outcomes (*99–103*).

Potential consequences: Consequences might include decreased rapid repeat pregnancy and abortion rates, and increased use of contraceptives.

Rationale: There is sufficient evidence to recommend that providers link pregnant and parenting teens to community and social services that might reduce rates of rapid repeat pregnancy. Three of seven EWG members agreed to an earlier version of this recommendation. Other members wanted to remove a clause about prioritizing the contraceptive needs of pregnant/parenting teens because they felt that all clients should be treated as priority clients. This suggestion was adopted, but the EWG did not have a chance to vote again on the modified recommendation.

Contraceptive Method Availability

Recommendation: Family planning programs should stock and offer a broad a range of FDA-approved contraceptive methods so that the needs of individual clients can be met. These methods are optimally available on-site, but strong referrals can serve to make methods not available on-site real options for clients.

Quality of evidence: No research was identified that explicitly addressed the question of whether having a broad range of methods was associated with short-, medium-, or long-term reproductive health outcomes. However, as noted above, three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Consequences might include increased use of contraception and increased use of reproductive

health services. It also was noted that there are sometimes high costs to stocking certain methods (e.g., intrauterine devices and contraceptive implants).

Rationale: Having a broad range of contraceptive methods is central to client-centered care, a core aspect of providing quality services. Individual clients need to have a choice so they can select a method that best fits their particular circumstances. This is likely to result in more correct and consistent use of the chosen methods. The benefits of this recommendation were weighed more heavily than the negative outcomes (e.g., additional cost). All five EWG members agreed to this recommendation.

Youth-Friendly Services

Recommendation: Family planning programs should take steps to make services "youth-friendly."

Quality of evidence: Of 20 studies that were identified, six looked at short-, medium-, or long-term outcomes with mixed designs (one group time series, one cross-sectional, three prospective cohort, and one nonrandomized trial); protective effects were found on long-term (two of three studies), medium-term (three of three), and short-term (three of three) outcomes (*29*,*30*,*104–107*). One of these six studies (*29*), plus 13 other descriptive studies (for a total of 14 studies), presented adolescents' or providers' views on facilitators for adolescent clients in using youth-friendly family planning services. Key factors described were confidentiality (13 of 14), accessibility (11 of 14), peer involvement (three of 14), parental or familial involvement (four of 14), and quality of provider interaction (11 of 14) (*105–121*). Four of these studies (*111*,*112*,*114*,*121*) plus one other descriptive study (*108*) described barriers to clinics adopting and implementing youth-friendly family planning services.

Potential consequences: Consequences might include increased use of reproductive health services by adolescents, improved contraceptive use, use of more effective methods, more consistent use of contraception, and reduced rates of teen pregnancy. It is also likely to lead to improved satisfaction with services and greater knowledge about pregnancy prevention among adolescents. It is possible that there will be higher costs, and some uncertainty regarding the benefits due to a relatively weak evidence base.

Rationale: Existing evidence has demonstrated the importance of specific characteristics to adolescents' attitudes and use of clinical services. The potential benefits of providing youth-friendly services outweigh the potential costs and weak evidence base. All five EWG members agreed to this recommendation. Some thought that it should be cast as an example of comprehensively client-centered care, rather than an end of its own.

Quality Improvement

Recommendation: Family planning programs should have a system for quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Family planning programs should select, measure, and assess at least one outcome measure on an ongoing basis, for which the service site can be accountable.

Quality of evidence: A recent systematic review (*122*) was supplemented with 10 articles that provided information related to client and/or provider perspectives regarding what constitutes quality family planning services (*42–44*,*113*,*123–128*). These studies used a qualitative (k = 4) or cross-sectional (k = 6) study design. Ten descriptive studies identified client and provider perspectives on what constitutes quality family planning services, which include stigma and embarrassment reduction (n = 9), client access and convenience (n = 8); confidentiality (n = 3); efficiency and tailoring of services (n = 6); client autonomy and confidence (n = 5); contraceptive access and choice (n = 4); increased time of patient-provider interaction (n = 3); communication and relationship (n = 3); structure and facilities (n = 2); continuity of care (n = 2). Well-established frameworks for guiding quality improvement efforts were referenced (*122*,*129–132*).

Potential consequences: Consequences might include increased use by clients of more effective contraceptive methods, clients might be more likely to return for care, client satisfaction might improve, and there might be reduced rates of teen and unintended pregnancy, and improved spacing of births.

Rationale: Research, albeit limited, has demonstrated that quality services are associated with improved client experience with care and adoption of more protective contraceptive behavior. Further, these recommendations on quality improvement are consistent with those made by national leaders in the quality improvement field. Research is either under way or planned to validate a core set of performance measures, and the recommendations will be updated as new findings emerge. All five EWG members agreed to these recommendations.

References

1. Family Planning Services and Population Research Act of 1970, Title X. Population Research and Voluntary Family Planning Programs Project Grants and Contracts for Family Planning Services Pub. L. No. Public Law 91-572 (1970).
2. Project Grants for Family Planning Services. 42 CFR Part 59, Subpart A, (1971).
3. CDC. Recommendations to improve preconception health and health care—United States. MMWR 2006;55(No. RR-06).

4. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).
5. CDC. Revised recommendations for HIV testing of adults, adolescents and pregnant women in health care settings. MMWR 2006;55(No. RR-14).
6. Jack B, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(Supplement B):S266–79.
7. Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199(6 Suppl 2):S389–95.
8. Adams-Skinner J, Exner T, Pili C, Wallace B, Hoffman S, Leu CS. The development and validation of a tool to assess nurse performance in dual protection counseling. Patient Educ Couns 2009;76:265–71.
9. Bender SS, Geirsson RT. Effectiveness of preabortion counseling on postabortion contraceptive use. Contraception 2004;69:481–7.
10. Boise R, Petersen R, Curtis KM, et al. Reproductive health counseling at pregnancy testing: a pilot study. Contraception 2003;68:377–83.
11. Custo G, Saitto C, Cerza S, Sertoli G. The adjusted contraceptive score (ACS) improves the overall performance of behavioural and barrier contraceptive methods. Adv Contracept Deliv Syst 1987;3:367–73.
12. Gilliam M, Knight S, McCarthy M Jr. Success with oral contraceptives: a pilot study. Contraception 2004;69:413–8.
13. Langston AM, Rosario L, Westhoff CL. Structured contraceptive counseling—a randomized controlled trial. Patient Educ Couns 2010;81:362–7.
14. Lee JK, Parisi SM, Akers AY, Borrero S, Schwarz EB. The impact of contraceptive counseling in primary care on contraceptive use. J Gen Intern Med 2011;26:731–6.
15. Namerow PB, Weatherby N, Williams-Kaye J. The effectiveness of contingency-planning counseling. Fam Plann Perspect 1989;21:115–9.
16. Nobili MP, Piergrossi S, Brusati V, Moja EA. The effect of patient-centered contraceptive counseling in women who undergo a voluntary termination of pregnancy. Patient Educ Couns 2007;65:361–8.
17. Petersen R, Albright J, Garrett JM, Curtis KM. Pregnancy and STD prevention counseling using an adaptation of motivational interviewing: a randomized controlled trial. Perspect Sex Reprod Health 2007;39:21–8.
18. Proctor A, Jenkins TR, Loeb T, Elliot M, Ryan A. Patient satisfaction with 3 methods of postpartum contraceptive counseling: a randomized, prospective trial. J Reprod Med 2006;51:377–82.
19. Schunmann C, Glasier A. Specialist contraceptive counselling and provision after termination of pregnancy improves uptake of long-acting methods but does not prevent repeat abortion: a randomized trial. Hum Reprod 2006;21:2296–303.
20. Shlay JC, Mayhugh B, Foster M, Maravi ME, Baron AE, Douglas JM Jr. Initiating contraception in sexually transmitted disease clinic setting: a randomized trial. Am J Obstet Gynecol 2003;189:473–81.
21. Todres R. Effectiveness of counseling in the transmission of family planning and sexuality knowledge. J Sex Educ Ther 1990;16:279–85.
22. Weisman CS, Maccannon DS, Henderson JT, Shortridge E, Orso CL. Contraceptive counseling in managed care: preventing unintended pregnancy in adults. Womens Health Issues 2002;12:79–95.
23. Yassin AS, Cordwell D. Does dedicated pre-abortion contraception counselling help to improve post-abortion contraception uptake? J Fam Plann Reprod Health Care 2005;31:115–6.
24. Berger DK, Perez G, Kyman W, et al. Influence of family planning counseling in an adolescent clinic on sexual activity and contraceptive use. J Adolesc Health Care 1987;8:436–40.
25. Brindis CD, Geierstanger SP, Wilcox N, McCarter V, Hubbard A. Evaluation of a peer provider reproductive health service model for adolescents. Perspect Sex Reprod Health 2005;37:85–91.
26. Cowley CB, Farley T, Beamis K. 'Well, maybe I'll try the pill for just a few months...': Brief motivational and narrative-based interventions to encourage contraceptive use among adolescents at high risk for early childbearing. Fam Syst Health 2002;20:183–204.
27. Hanna KM. Effect of nurse-client transaction on female adolescents' oral contraceptive adherence. Image J Nurs Sch 1993;25:285–90.
28. Kirby D, Raine T, Thrush G, Yuen C, Sokoloff A, Potter SC. Impact of an intervention to improve contraceptive use through follow-up phone calls to female adolescent clinic patients. Perspect Sex Reprod Health 2010;42:251–7.
29. Winter L, Breckenmaker LC. Tailoring family planning services to the special needs of adolescents. Fam Plann Perspect 1991;23:24–30.
30. Brindis CD, Geierstanger SP, Wilcox N, McCarter V, Hubbard A. Evaluation of a peer provider reproductive health service model for adolescents. Perspect Sex Reprod Health 2005;37:85–91.
31. Fox MC, Creinin MD, Murthy AS, Harwood B, Reid LM. Feasibility study of the use of a daily electronic mail reminder to improve oral contraceptive compliance. Contraception 2003;68:365–71.
32. Hou MY, Hurwitz S, Kavanagh E, Fortin J, Goldberg AB. Using daily text-message reminders to improve adherence with oral contraceptives: a randomized controlled trial. Obstet Gynecol 2010;116:633–40.
33. Keder LM, Rulin MC, Gruss J. Compliance with depot medroxyprogesterone acetate: a randomized, controlled trial of intensive reminders. Am J Obstet Gynecol 1998;179:583–5.
34. Lachowsky M, Levy-Toledano R. Improving compliance in oral contraception: 'the reminder card'. Eur J Contracept Reprod Health Care 2002;7:210–5.
35. Madlon-Kay DJ. The effectiveness of a mail reminder system for depot medroxyprogesterone injections. Arch Fam Med 1996;5:234–6.
36. CDC. U.S. selected practice recommendations for contraceptive use 2013. MMWR 2013;62(No. RR-4).
37. CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59(No. RR-4).
38. Daniels K, Mosher W, Jones J. Contraceptive methods women have ever used: United States, 1982–2010. National health statistics reports; 2013;62.
39. Martinez G, Copen C, Abma J. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006–2010 National Survey of Family Growth. Vital Health Stat 2011;23(31).
40. Winner B, Peipert J, Zhao Q, et al. Effectiveness of long-acting reversible contraception. N Engl J Med 2012;366:1998–2007.
41. CDC. Vital signs: repeat births among teens—United States, 2007–2010. MMWR 2013;62:249–55.
42. Becker D, Klassen AC, Koenig MA, LaVeist TA, Sonenstein FL, Tsui AO. Women's perspectives on family planning service quality: an exploration of differences by race, ethnicity and language. Perspect Sex Reprod Health 2009;41:158–65.
43. Gilliam ML, Hernandez M. Providing contraceptive care to low-income, African American teens: the experience of urban community health centers. J Community Health 2007;32:231–44.
44. Landry DJ, Wei J, Frost JJ. Public and private providers' involvement in improving their patients' contraceptive use. Contraception 2008;78:42–51.
45. Deijen JB, Kornaat H. The influence of type of information, somatization, and locus of control on attitude, knowledge, and compliance with respect to the triphasic oral contraceptive Tri-Minulet. Contraception 1997;56:31–41.

46. Kirby D, Harvey PD, Claussenius D, Novar M. A direct mailing to teenage males about condom use: its impact on knowledge, attitudes and sexual behavior. Fam Plann Perspect 1989;21:12–8.
47. Little P, Griffin S, Kelly J, Dickson N, Sadler C. Effect of educational leaflets and questions on knowledge of contraception in women taking the combined contraceptive pill: randomised controlled trial. BMJ 1998;316:1948–52.
48. Smith LF, Whitfield MJ. Women's knowledge of taking oral contraceptive pills correctly and of emergency contraception: effect of providing information leaflets in general practice. Br J Gen Pract 1995;45:409–14.
49. Steiner MJ, Dalebout S, Condon S, Dominik R, Trussell J. Understanding risk: a randomized controlled trial of communicating contraceptive effectiveness. Obstet Gynecol 2003;102:709–17.
50. DeLamater J, Wagstaff DA, Havens KK. The impact of a culturally appropriate STD/AIDS education intervention on black male adolescents' sexual and condom use behavior. Health Educ Behav 2000;27:454–70.
51. Mason V, McEwan A, Walker D, Barrett S, James D. The use of video information in obtaining consent for female sterilisation: a randomised study. BJOG 2003;110:1062–71.
52. Schwarz EB, Gerbert B, Gonzales R. Computer-assisted provision of emergency contraception a randomized controlled trial. J Gen Intern Med 2008;23:794–9.
53. Paperny DM, Starn JR. Adolescent pregnancy prevention by health education computer games: computer-assisted instruction of knowledge and attitudes. Pediatrics 1989;83:742–52.
54. Reis J, Tymchyshyn P. A longitudinal evaluation of computer-assisted instruction on contraception for college students. Adolescence 1992;27:803–11.
55. Roberto AJ, Zimmerman RS, Carlyle KE, Abner EL, Cupp PK, Hansen GL. The effects of a computer-based pregnancy, STD, and HIV prevention intervention: a nine-school trial. Health Commun 2007;21:115–24.
56. Lindenberg CS, Solorzano RM, Bear D, Strickland O, Galvis C, Pittman K. Reducing substance use and risky sexual behavior among young, low-income, Mexican-American women: comparison of two interventions. Appl Nurs Res 2002;15:137–48.
57. Chewning B, Mosena P, Wilson D, et al. Evaluation of a computerized contraceptive decision aid for adolescent patients. Patient Educ Couns 1999;38:227–39.
58. O'Donnell L, San Doval A, Duran R, O'Donnell CR. The effectiveness of video-based interventions in promoting condom acquisition among STD clinic patients. Sex Transm Dis 1995;22:97–103.
59. Pedrazzini AE, McGowan H, Lucking L, Johanson RJ. 'The trouble with sex–it always gets in the way': an evaluation of a peer-produced teenage pregnancy video. Br J Fam Plann 2000;26:131–5.
60. McMahon SR, Rimsza ME, Bay RC. Parents can dose liquid medication accurately. Pediatrics 1997;100:330–3.
61. Schillinger D, Piette J, Grumbach K, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med 2003;163:83–90.
62. Kirby D. Comprehensive sex education: strong public support and persuasive evidence of impact, but little funding. Arch Pediatr Adolesc Med 2006;160:1182–4.
63. Guide to Community Preventive Services. Preventing HIV/AIDS, other STIs, and teen pregnancy: group-based comprehensive risk reduction interventions for adolescents. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at http://www.thecommunityguide.org/hiv/riskreduction.html.
64. Kirby D, Obasi A, Laris BA. The effectiveness of sex education and HIV education interventions in schools in developing countries. World Health Organ Tech Rep Ser 2006;938:103–50, discussion 317–41.
65. Kirby DB, Laris BA, Rolleri LA. Sex and HIV education programs: their impact on sexual behaviors of young people throughout the world. J Adolesc Health 2007;40:206–17.
66. Oringanje C, Meremikwu MM, Eko H, Esu E, Meremikwu A, Ehiri JE. Interventions for preventing unintended pregnancies among adolescents. Cochrane Database Syst Rev 2009;(4):CD005215.
67. Guide to Community Preventive Services. Preventing HIV/AIDS, other STIs, and teen pregnancy: group-based abstinence education interventions for adolescents. Atlanta, GA: US Department of Health and Human Services, CDC; 2009; Available at http://www.thecommunityguide.org/hiv/abstinence_ed.html.
68. Office of Adolescent Health. Information about effective programs for preventing teen pregnancy. Washington, DC: US Department of Health and Human Services; 2011. Available at www.hhs.gov/ash/oah/oah-initiatives/tpp/programs.html.
69. Ford CA, Thomsen SL, Compton B. Adolescents' interpretations of conditional confidentiality assurances. J Adolesc Health 2001;29:156–9.
70. Garside R, Ayres R, Owen M, Pearson VA, Roizen J. Anonymity and confidentiality: rural teenagers' concerns when accessing sexual health services. J Fam Plann Reprod Health Care 2002;28:23–6.
71. Rainey DY, Brandon DP, Krowchuk DP. Confidential billing accounts for adolescents in private practice. J Adolesc Health 2000;26:389–91.
72. Schuster MA, Bell RM, Petersen LP, Kanouse DE. Communication between adolescents and physicians about sexual behavior and risk prevention. Arch Pediatr Adolesc Med 1996;150:906–13.
73. Thomas N, Murray E, Rogstad KE. Confidentiality is essential if young people are to access sexual health services. Int J STD AIDS 2006;17:525–9.
74. Thrall JS, McCloskey L, Ettner SL, Rothman E, Tighe JE, Emans SJ. Confidentiality and adolescents' use of providers for health information and for pelvic examinations. Arch Pediatr Adolesc Med 2000;154:885–92.
75. Ford CAMS, Halpern-Felsher BL, Irwin CE Jr. Influence of physician confidentiality assurances on adolescents' willingness to disclose information and seek future health care. A randomized controlled trial. JAMA 1997;278:1029–34.
76. American College of Obstetricians and Gynecologists. Confidentiality in adolescent health care: guidelines for adolescent health care. 2nd ed. Washington, DC: American College of Obstetricians and Gynecologists; 2011.
77. American Academy of Pediatrics. Achieving quality health services for adolescents: policy statement of the Committee on Adolescence, American Academy of Pediatrics. Pediatrics 2008;121:1263.
78. Ford C, English A, Sigman G. Confidential health care for adolescents: position paper for the society for adolescent medicine. J Adolesc Health 2004;35:160–7.
79. Anderson NLR, Koniak-Griffin D, Keenan CK, Uman G, Duggal BR, Casey C. Evaluating the outcomes of parent-child family life education [including commentary by Hayman LL]. Sch Inq Nurs Pract 1999;13:211–38.
80. Guilamo-Ramos V, Bouris A, Jaccard J, Gonzalez B, McCoy W, Aranda D. A parent-based intervention to reduce sexual risk behavior in early adolescence: building alliances between physicians, social workers, and parents. J Adolesc Health;48:159–63.
81. Blake SM, Simkin L, Ledsky R, Perkins C, Calabrese JM. Effects of a parent-child communications intervention on young adolescents' risk for early onset of sexual intercourse. Fam Plann Perspect 2001;33:52–61.

82. Brody GH, Murry VM, Gerrard M, et al. The Strong African American Families Program: translating research into prevention programming. Child Dev 2004;75:900–17.
83. Evans WD, Davis KC, Ashley OS, Blitstein J, Koo H, Zhang Y. Efficacy of abstinence promotion media messages: findings from an online randomized trial. J Adolesc Health 2009;45:409–16.
84. Forehand R, Armistead L, Long N, et al. Efficacy of a parent-based sexual-risk prevention program for African American preadolescents: a randomized controlled trial. Arch Pediatr Adolesc Med 2007;161:1123–9.
85. Haggerty KP, Skinner ML, MacKenzie EP, Catalano RF. A randomized trial of Parents Who Care: effects on key outcomes at 24-month follow-up. Prev Sci 2007;8:249–60.
86. Huston RL, Martin LJ, Foulds DM. Effect of a program to facilitate parent-child communication about sex. Clin Pediatr (Phila) 1990;29:626–33.
87. Lederman RP, Chan W, Roberts-Gray C. Sexual risk attitudes and intentions of youth aged 12–14 years: survey comparisons of parent-teen prevention and control groups. Behavioral Medicine (Washington, DC) 2004;29:155–63.
88. Lederman RP, Chan W, Roberts-Gray C. Parent-adolescent relationship education (PARE): program delivery to reduce risks for adolescent pregnancy and STDs. Behav Med 2008;33:137–43.
89. Lefkowitz ES, Sigman M, Au TK. Helping mothers discuss sexuality and AIDS with adolescents. Child Dev 2000;71:1383–94.
90. Miller BC, Norton MC, Jenson GO. Impact Evaluation of Facts and Feelings: a home-based video sex education curriculum. Fam Relat 1993;42:392–400.
91. Murry VM, Berkel C, Brody GH, Gerrard M, Gibbons FX. The Strong African American Families program: longitudinal pathways to sexual risk reduction. J Adolesc Health 2007;41:333–42.
92. Schuster MA, Corona R, Elliott MN, et al. Evaluation of Talking Parents, Healthy Teens, a new worksite based parenting programme to promote parent-adolescent communication about sexual health: randomised controlled trial. BMJ 2008;337:a308.
93. Stanton B, Cole M, Galbraith J, et al. Randomized trial of a parent intervention: parents can make a difference in long-term adolescent risk behaviors, perceptions, and knowledge. Arch Pediatr Adolesc Med 2004;158:947–55.
94. Stanton BF, Li X, Galbraith J, et al. Parental underestimates of adolescent risk behavior: a randomized, controlled trial of a parental monitoring intervention. J Adolesc Health 2000;26:18–26.
95. Elster AB, Lamb ME, Tavare J, Ralston CW. The medical and psychosocial impact of comprehensive care on adolescent pregnancy and parenthood. JAMA 1987;258:1187–92.
96. Omar HA, Fowler A, McClanahan KK. Significant reduction of repeat teen pregnancy in a comprehensive young parent program. J Pediatr Adolesc Gynecol 2008;21:283–7.
97. Rabin JM, Seltzer V, Pollack S. The long term benefits of a comprehensive teenage pregnancy program. Clin Pediatr (Phila) 1991;30:305–9.
98. Stevens-Simon C, Kelly L, Kulick R. A village would be nice but...it takes a long-acting contraceptive to prevent repeat adolescent pregnancies. Am J Prev Med 2001;21:60–5.
99. Eckenrode J, Campa M, Luckey DW, et al. Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial. Arch Pediatr Adolesc Med 2010;164:9–15.
100. Olds D, Henderson CR Jr, Cole R, et al. Long-term effects of nurse home visitation on children's criminal and antisocial behavior: 15-year follow-up of a randomized controlled trial. JAMA 1998;280:1238–44.
101. Olds DL, Eckenrode J, Henderson CR Jr, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial. JAMA 1997;278:637–43.
102. Black M, Bentley M, Papas M, et al. Delaying second births among adolescent mothers: a randomized, controlled trial of a home-based mentoring program. Pediatrics 2006;118:1087–99.
103. Avellar S, Paulsell D, Sama-Miller E, Del Grosso P. Home visiting evidence of effectiveness review. Washington, DC: US Department of Health and Human Services, Office of Planning, Research and Evaluation, Administration for Children and Families; 2012.
104. Wilson S, Daniel S, Pearson J, Hopton C, Madeley R. An evaluation of a new teenage clinic and its impact on teenage conceptions in Nottingham from 1986 to 1992. Contraception 1994;50:77–86.
105. Gupta S, Hogan R, Kirkman RJ. Experience of the first pelvic examination. Eur J Contracept Reprod Health Care 2001;6:34–8.
106. Morrison A, Mackie CM, Elliott L, Elliott LM, Gruer L, Bigrigg A. The Sexual Health Help Centre: a service for young people. J Public Health Med 1997;19:457–63.
107. Herz EJ, Olson LM, Reis JS. Family planning for teens: strategies for improving outreach and service delivery in public health settings. Public Health Rep 1988;103:422–30.
108. Bethea J, Hippisley-Cox J, Coupland C, Pringle M. General practitioners' attitudes towards the provision of services to young people aged under 16: a cross-sectional survey. Qual Prim Care 2007;15:11–9.
109. Kapphahn CJ, Wilson KM, Klein JD. Adolescent girls' and boys' preferences for provider gender and confidentiality in their health care. J Adolesc Health 1999;25:131–42.
110. Wilson A, Williams R. Sexual health services: what do teenagers want? Ambul Child Health 2000;6:253–60.
111. Alberti PM, Steinberg AB, Hadi EK, Abdullah RB, Bedell JF. Barriers at the frontline: assessing and improving the teen friendliness of South Bronx medical practices. Public Health Rep 2010;125:611–4.
112. Brindis CD, Loo VS, Adler NE, Bolan GA, Wasserheit JN. Service integration and teen friendliness in practice: a program assessment of sexual and reproductive health services for adolescents. J Adolesc Health 2005;37:155–62.
113. Chambers R, Boath E, Chambers S. Young people's and professionals' views about ways to reduce teenage pregnancy rates: to agree or not agree. J Fam Plann Reprod Health Care 2002;28:85–90.
114. Cromer BA, McCarthy M. Family planning services in adolescent pregnancy prevention: the views of key informants in four countries. Fam Plann Perspect 1999;31:287–93.
115. Donovan C, Mellanby AR, Jacobson LD, Taylor B, Tripp JH; The Adolescent Working Group. Teenagers' views on the general practice consultation and provision of contraception. Br J Gen Pract 1997;47:715–8.
116. French RS. The experience of young people with contraceptive consultations and health care workers. Int J Adolesc Med Health 2002;14:131–8.
117. Hayter M. Reaching marginalized young people through sexual health nursing outreach clinics: evaluating service use and the views of service users. Public Health Nurs 2005;22:339–46.
118. Ingram J, Salmon D. 'No worries!' Young people's experiences of nurse-led drop-in sexual health services in South West England. J Res Nurs 2007;12:305–16.

119. Peremans L, Hermann I, Avonts D, Van Royen P, Denekens J. Contraceptive knowledge and expectations by adolescents: an explanation by focus groups. Patient Educ Couns 2000;40:133–41.
120. Perry C, Thurston M. Meeting the sexual health care needs of young people: a model that works? Child Care Health Dev 2008;34:98–103.
121. Russell ST, Lee FCH. Practitioners' perspectives on effective practices for Hispanic teenage pregnancy prevention. Perspect Sex Reprod Health 2004;36:142–9.
122. Becker D, Koenig MA, Kim YM, Cardona K, Sonenstein FL. The quality of family planning services in the United States: findings from a literature review. Perspect Sex Reprod Health 2007;39:206–15.
123. Becker D, Tsui AO. Reproductive health service preferences and perceptions of quality among low-income women: racial, ethnic and language group differences. Perspect Sex Reprod Health 2008;40:202–11.
124. Becker H, Stuifbergen A, Tinkle M. Reproductive health care experiences of women with physical disabilities: a qualitative study. Arch Phys Med Rehabil 1997;78:S26–33.
125. Bender SS. Attitudes of Icelandic young people toward sexual and reproductive health services. Fam Plann Perspect 1999;31:294–301.
126. Dixon-Woods M, Stokes T, Young B, Phelps K, Windridge K, Shukla R. Choosing and using services for sexual health: a qualitative study of women's views. Sex Transm Infect 2001;77:335–9.
127. Khan NS, Kirkman R. Intimate examinations: use of chaperones in community-based family planning clinics. BJOG 2000;107:130–2.
128. Fiddes P, Scott A, Fletcher J, Glasier A. Attitudes towards pelvic examination and chaperones: a questionnaire survey of patients and providers. Contraception 2003;67:313–7.
129. Bruce J. Fundamental elements of the quality of care: a simple framework. Stud Fam Plann 1990;21:61–91.
130. Donabedian A. The quality of care. JAMA 1988;260:1743–8.
131. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies of Science; 2001.
132. National Quality Forum. ABCs of measurement. Washington, DC: National Quality Forum; 2011. Available at http://www.qualityforum.org/Measuring_Performance/ABCs_of_Measurement.aspx.

Appendix C

Principles for Providing Quality Counseling

Counseling is a process that enables clients to make and follow through on decisions. Education is an integral component of the counseling process that helps clients to make informed decisions. Providing quality counseling is an essential component of client-centered care.

Key principles of providing quality counseling are listed below and may be used when providing family planning services. The model was developed in consultation with the Technical Panel on Contraceptive Counseling and Education and reviewed by the Expert Work Group. Although developed specifically for providing contraceptive counseling, the principles are broad and can be applied to health counseling on other topics. Although the principles are listed here in a particular sequence, counseling is an iterative process, and at every point in the client encounter it is necessary to determine whether it is important to readdress and emphasize a given principle.

Principles of Quality Counseling

Principle 1. Establish and Maintain Rapport with the Client

Establishing and maintaining rapport with a client is vital to the encounter and achieving positive outcomes (*1*). This can begin by creating a welcoming environment and should continue through every stage of the client encounter, including follow-up. The contraceptive counseling literature indicates that counseling models that emphasized the quality of the interaction between client and provider have been associated with decreased teen pregnancy, increased contraceptive use, increased use of more effective methods, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use (*2–5*) .

Principle 2. Assess the Client's Needs and Personalize Discussions Accordingly

Each visit should be tailored to the client's individual circumstances and needs. Clients come to family planning providers for various services and with varying needs. Standardized questions and assessment tools can help providers determine what services are most appropriate for a given visit (*6*). Contraceptive counseling studies that have incorporated standardized assessment tools during the counseling process have resulted in increased contraceptive use, increased correct use of contraceptives, and increased use of more effective methods (*2,7,8*). Contraceptive counseling studies that have personalized discussions to meet the individual needs of clients have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased use of dual-method contraceptives to prevent both sexually transmitted diseases (STDs) and pregnancy, increased quality and satisfaction with services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(4,7,9–12*).

Principle 3. Work with the Client Interactively to Establish a Plan

Working with a client interactively to establish a plan, including a plan for follow-up, is important. Establishing a plan should include setting goals, discussing possible difficulties with achieving goals, and developing action plans to deal with potential difficulties. The amount of time spent establishing a plan will differ depending on the client's purpose for the visit and health-care needs. A client plan that requires behavioral change should be made on the basis of the client's own goals, interests, and readiness for change (*13–15*). Use of computerized decision aids before the appointment can facilitate this process by providing a structured yet interactive framework for clients to analyze their available options systematically and to consider the personal importance of perceived advantages and disadvantages *(16,17*). The contraceptive counseling literature indicates that counseling models that incorporated goal setting and development of action plans have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, and increased knowledge *(2,9,18–20*). Furthermore, contraceptive counseling models that incorporated follow-up contacts resulted in decreased teen pregnancy, increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased continuation of method use, increased use of dual-method contraceptives to prevent both STDs and pregnancy, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(2,3,7,11,21,22*) . From the family planning education literature, computerized decision aids have helped clients formulate questions and have been associated with increased knowledge, selection of more effective methods, and increased continuation and compliance (*23–25*).

Principle 4. Provide Information That Can Be Understood and Retained by the Client

Clients need information that is medically accurate, balanced, and nonjudgmental to make informed decisions and follow through on developed plans. When speaking with clients or providing educational materials through any medium (e.g., written, audio/visual, or computer/web-based), the provider must present information in a manner that can be readily understood and retained by the client. Strategies for making information accessible to clients are provided (see Appendix D).

Principle 5. Confirm Client Understanding

It is important to ensure that clients have processed the information provided and discussed. One technique for confirming understanding is to have the client restate the most important messages in her or his own words. This teach-back method can increase the likelihood of the client and provider reaching a shared understanding, and has improved compliance with treatment plans and health outcomes *(26,27)*. Using the teach-back method early in the decision-making process will help ensure that a client has the opportunity to understand her or his options and is making informed choices (*28*).

References

1. Lambert M. Implications of outcome research for psychotherapy integration. In: Norcross J, Goldfind M, eds. Handbook of psychotherapy integration. New York, NY: Basic Books; 1992:94–129.
2. Adams-Skinner J, Exner T, Pili C, Wallace B, Hoffman S, Leu CS. The development and validation of a tool to assess nurse performance in dual protection counseling. Patient Educ Couns 2009;76:265–71.
3. Brindis CD, Geierstanger SP, Wilcox N, McCarter V, Hubbard A. Evaluation of a peer provider reproductive health service model for adolescents. Perspect Sex Reprod Health 2005;37:85–91.
4. Nobili MP, Piergrossi S, Brusati V, Moja EA. The effect of patient-centered contraceptive counseling in women who undergo a voluntary termination of pregnancy. Patient Educ Couns 2007;65:361–8.
5. Proctor A, Jenkins TR, Loeb T, Elliot M, Ryan A. Patient satisfaction with 3 methods of postpartum contraceptive counseling: a randomized, prospective trial. J Reprod Med 2006;51:377–82.
6. Fiore M, Jaén C, Baker T, Bailey W, Benowitz N, Curry S. Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: US Department of Health and Human Services; 2008. Available at http://www.ncbi.nlm.nih.gov/books/NBK63952.
7. Boise R, Petersen R, Curtis KM, et al. Reproductive health counseling at pregnancy testing: a pilot study. Contraception 2003;68:377–83.
8. Custo G, Saitto C, Cerza S, Sertoli G. The adjusted contraceptive score (ACS) improves the overall performance of behavioural and barrier contraceptive methods. Adv Contracept Deliv Syst 1987;3:367–73.
9. Hanna KM. Effect of nurse-client transaction on female adolescents' oral contraceptive adherence. Image J Nurs Sch 1993;25:285–90.
10. Schunmann C, Glasier A. Specialist contraceptive counselling and provision after termination of pregnancy improves uptake of long-acting methods but does not prevent repeat abortion: a randomized trial. Hum Reprod 2006;21:2296–303.
11. Shlay JC, Mayhugh B, Foster M, Maravi ME, Baron AE, Douglas JM Jr. Initiating contraception in sexually transmitted disease clinic setting: a randomized trial. Am J Obstet Gynecol 2003;189:473–81.
12. Weisman CS, Maccannon DS, Henderson JT, Shortridge E, Orso CL. Contraceptive counseling in managed care: preventing unintended pregnancy in adults. Womens Health Issues 2002;12:79–95.
13. Kaplan D. Family Counseling for all counselors. Greensboro, NC: CAPS Publications; 2003.
14. Nupponen R. What is counseling all about—basics in the counseling of health-related physical activity. Patient Educ Couns 1998; 33(Suppl):S61–7.
15. Whitlock EP, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach. Am J Prev Med 2002;22:267–84.
16. French RS, Wellings K, Cowan F. How can we help people to choose a method of contraception? The case for contraceptive decision aids. J Fam Plann Reprod Health Care 2009;35:219–20.
17. O'Connor AM, Bennett CL, Stacey D, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2009;CD001431.
18. Cowley CB, Farley T, Beamis K. "Well, maybe I'll try the pill for just a few months...": brief motivational and narrative-based interventions to encourage contraceptive use among adolescents at high risk for early childbearing. Fam Syst Health 2002;20:183–204.
19. Gilliam M, Knight S, McCarthy M Jr. Success with oral contraceptives: a pilot study. Contraception 2004;69:413–8.
20. Namerow PB, Weatherby N, Williams-Kaye J. The effectiveness of contingency-planning counseling. Fam Plann Perspect 1989;21:115–9.
21. Berger DK, Perez G, Kyman W, et al. Influence of family planning counseling in an adolescent clinic on sexual activity and contraceptive use. J Adolesc Health Care 1987;8:436–40.
22. Winter L, Breckenmaker LC. Tailoring family planning services to the special needs of adolescents. Fam Plann Perspect 1991;23:24–30.
23. Chewning B, Mosena P, Wilson D, et al. Evaluation of a computerized contraceptive decision aid for adolescent patients. Patient Educ Couns 1999;38:227–39.
24. Garbers S, Meserve A, Kottke M, Hatcher R, Chiasson MA. Tailored health messaging improves contraceptive continuation and adherence: results from a randomized controlled trial. Contraception 2012;86:536–42.
25. Garbers S, Meserve A, Kottke M, Hatcher R, Ventura A, Chiasson MA. Randomized controlled trial of a computer-based module to improve contraceptive method choice. Contraception 2012;86:383–90.
26. McMahon SR, Rimsza ME, Bay RC. Parents can dose liquid medication accurately. Pediatrics 1997;100:330–3.
27. Schillinger D, Piette J, Grumbach K, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med 2003;163:83–90.
28. National Quality Forum. Health literacy: a linchpin in achieving national goals for health and healthcare, Issue Brief #13 2009. Available at http://www.qualityforum.org/Publications/2009/03/Health_Literacy__A_Linchpin_in_Achieving_National_Goals_for_Health_and_Healthcare.aspx.

Appendix D

Contraceptive Effectiveness

Providers should counsel clients about the effectiveness of different contraceptive methods. Method effectiveness is measured as the percentage of women experiencing an unintended pregnancy during the first year of use, and is estimated for both typical and perfect use (Table).

TABLE. Percentage of women experiencing an unintended pregnancy during the first year of typical use* and the first year of perfect use† of contraception and the percentage continuing use at the end of the first year — United States

Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at 1 year§
	Typical use	Perfect use	
No method¶	85.0	85.0	
Spermicides**	28.0	18.0	42.0
Fertility awareness-based methods	24.0		47.0
Standard days method††		5.0	
2-day method††		4.0	
Ovulation method††		3.0	
Symptothermal method		0.4	
Withdrawal	22.0	4.0	46.0
Sponge			36.0
Parous women	24.0	20.0	
Nulliparous women	12.0	9.0	
Condom§§			
Female	21.0	5.0	41.0
Male	18.0	2.0	43.0
Diaphragm¶¶	12.0	6.0	57.0
Combined pill and progestin-only pill	9.0	0.3	67.0
Evra patch	9.0	0.3	67.0
NuvaRing	9.0	0.3	67.0
Depo-Provera	6.0	0.2	56.0
Intrauterine contraceptives			
ParaGard (copper T)	0.8	0.6	78.0
Mirena (LNG)	0.2	0.2	80.0
Implanon	0.05	0.05	84.0
Female sterilization	0.5	0.5	100.0
Male sterilization	0.15	0.1	100.0

Emergency Contraceptives: Emergency contraceptive pills or insertion of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.***
Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.†††
Source: Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, eds. Contraceptive technology: 20th revised ed. New York, NY: Ardent Media; 2011.

* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill, and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth corrected for underreporting of abortion. See the text for the derivation of estimates for the other methods.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

§ Among couples attempting to avoid pregnancy, the percentage of couples who continue to use a method for 1 year.

¶ The percentages becoming pregnant in columns labeled "typical use" and "perfect use" are based on data from populations in which contraception is not used and from women who cease using contraception to become pregnant. Among such populations, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage of women who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

** Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The Ovulation and 2-day methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

§§ Without spermicides.

¶¶ With spermicidal cream or jelly.

*** Ella, Plan B One-Step, and Next Choice are the only dedicated products specifically marketed for emergency contraception. The label for Plan B One-Step (1 dose is 1 white pill) says to take the pill within 72 hours after unprotected intercourse. Research has indicated that all of the brands listed here are effective when used within 120 hours after unprotected intercourse. The label for Next Choice (1 dose is 1 peach pill) says to take one pill within 72 hours after unprotected intercourse and another pill 12 hours later. Research has indicated that that both pills can be taken at the same time with no decrease in efficacy or increase in side effects and that they are effective when used within 120 hours after unprotected intercourse. The Food and Drug Administration has in addition declared the following 19 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel (1 dose is 2 white pills), Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills), Jolessa, Portia, Seasonale or Trivora (1 dose is 4 pink pills), Seasonique (1 dose is 4 light-blue-green pills), Enpresse (1 dose is 4 orange pills), Lessina (1 dose is 5 pink pills), Aviane or LoSeasonique (one dose is 5 orange pills), Lutera or Sronyx (1 dose is 5 white pills), and Lybrel (1 dose is 6 yellow pills).

††† However, for effective protection against pregnancy to be maintained, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches age 6 months.

Appendix E

Strategies for Providing Information to Clients

The client should receive and understand the information she or he needs to make informed decisions and follow treatment plans. This requires careful attention to how information is communicated. The following strategies can make information more readily comprehensible to clients:

Strategies for Providing Information to Clients

Educational materials should be provided that are clear and easy to understand. Educational materials delivered through any one of a variety of media (for example, written, audio/visual, computer/web-based) need to be presented in a format that is clear and easy to interpret by clients with a 4th to 6th grade reading level (*1–3*). Many adults have only a basic ability to obtain, process, and understand health information necessary to make decisions about their health (*4*). Making easy-to-access materials enhances informed decision-making (*1–3*). Test all educational materials with the intended audiences for clarity and comprehension before wide-scale use.

The following evidence-based tools provide recommendations for increasing the accessibility of materials through careful consideration of content, organization, formatting, and writing style:

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy),
- Toolkit for Making Written Material Clear and Effective, provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/WrittenMaterialsToolkit), and
- Health Literacy Online, provided by the Office of Disease Prevention and Health Promotion (available at http://www.health.gov/healthliteracyonline).

Information should be delivered in a manner that is culturally and linguistically appropriate. In presenting information it is important to be sensitive to the client's cultural and linguistic preferences (*5*,*6*). Ideally information should be presented in the client's primary language, but translations and interpretation services should be available when necessary. Information presented must also be culturally appropriate, reflecting the client's beliefs, ethnic background, and cultural practices. Tools for addressing cultural and linguistic differences and preferences include

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy), and
- Toolkit for Making Written Material Clear and Effective, Part 11; Understanding and using the "Toolkit Guidelines for Culturally Appropriate Translation," provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/outreach-and-education/outreach/writtenmaterialstoolkit/downloads/toolkitpart11.pdf).

The amount of information presented should be limited and emphasize essential points. Providers should focus on needs and knowledge gaps identified during the assessment. Many clients immediately forget or remember incorrectly much of the information provided. This problem is exacerbated as more information is presented (*7–9*). Limiting the amount of information presented and highlighting important facts by presenting them first improves comprehension (*10–14*).

Numeric quantities should be communicated in a way that is easily understood. Whenever possible, providers should use natural frequencies and common denominators (for example, 85 of 100 sexually active women are likely to get pregnant within 1 year using no contraceptive, as compared with 1 in 100 using an IUD or implant), and display quantities in graphs and visuals. Providers also should avoid using verbal descriptors without numeric quantities (for example, sexually active women using an IUD or implant almost never become pregnant). Finally, they should quantify risk in absolute rather than relative terms (for example, "the chance of unintended pregnancy is reduced from 8 in 100 to 1 in 100 by switching from oral contraceptives to an IUD" versus the chance of unintended pregnancy is reduced by 87%). Numeracy is more highly correlated with health outcomes than the ability to read or listen effectively (*15*). The strategies listed above can help clients interpret numeric quantities correctly (*16–28*).

Balanced information on risks and benefits should be presented and messages framed positively. In addition to discussing risks, contraindications, and warnings, providers should discuss the advantages and benefits of contraception. In presenting this information, providers should express risks and benefits in a common format (for example, do not present risks in relative terms and benefits in absolute terms), and frame messages in positive terms (for example "99 out of 100 women find this a safe method with no side effects," versus "1 out of 100 women experience noticeable side effects"). Many clients prefer to receive a balance of information on risks and benefits (*29*), and using a common format avoids bias in presentation of information (*18*,*22*,*26*,*30*). Framing messages positively increases acceptance and comprehension (*18*,*22*,*31*,*32*).

Active client engagement should be encouraged. Providers should use educational materials that encourage active information processing (e.g., questions, quizzes, fill-in-the-blank, web-based games, and activities). In addition, they should be sure the client has an opportunity to discuss the information provided, and when speaking with a client, providers should engage her or him actively. Research has indicated that interactive materials improve knowledge of contraceptive risks, benefits, and correct method use (*33–35*). Clients also value spoken information (*29*,*36*); and educational materials, when delivered by a provider, more effectively increase knowledge (*10*,*37*). In particular, presenting information in a question and answer format is more effective than simply presenting the information (*10*,*15*,*37–41*).

References

1. Centers for Medicare and Medicaid Services. Toolkit for making written material clear and effective. Baltimore, MD: Centers for Medicare and Medicaid Services; 2011.
2. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Health literacy online: A guide to writing and designing easy-to-use health Web sites. Washington, DC: US Department of Health and Human Services; 2010.
3. DeWalt D, Callahan L, Hawk V, et al. Health literacy universal precautions toolkit. AHRQ Publication No. 10–0046-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2010.
4. Kutner M, Greenberg E, Jin Y, Paulsen C. The health literacy of America's adults: results from the 2003 National Assessment of Adult Literacy (NCES 2006–483). Washington, DC: U.S. Department of Education: National Center for Education Statistics; 2006.
5. Olavarria M, Beaulac J, Belanger A, Young M, Aubry T. Organizational cultural competence in community health and social service organizations: how to conduct a self-assessment. J Cult Divers 2009;16:140–50.
6. Tucker C. Reducing health disparities by promoting patient-centered culturally and linguistically sensitive/competent health care. U.S. Department of Health and Human Services Advisory Committee on Minority Health, US Public Health Service; 2009.
7. Anderson JL, Dodman S, Kopelman M, Fleming A. Patient information recall in a rheumatology clinic. Rheumatol Rehabil 1979;18:18–22.
8. Crane JA. Patient comprehension of doctor-patient communication on discharge from the emergency department. J Emerg Med 1997;15:1–7.
9. McGuire LC. Remembering what the doctor said: organization and adults' memory for medical information. Exp Aging Res 1996;22:403–28.
10. Little P, Griffin S, Kelly J, Dickson N, Sadler C. Effect of educational leaflets and questions on knowledge of contraception in women taking the combined contraceptive pill: randomised controlled trial. BMJ 1998;316:1948–52.
11. McGee J. Toolkit for making written material clear and effective: Baltimore, MD: Centers for Medicare and Medicaid Services; 2010. Available at http://www.cms.gov/WrittenMaterialsToolkit.
12. Peters E, Dieckmann N, Dixon A, Hibbard JH, Mertz CK. Less is more in presenting quality information to consumers. Med Care Res Rev 2007;64:169–90.
13. Steiner MJ, Dalebout S, Condon S, Dominik R, Trussell J. Understanding risk: a randomized controlled trial of communicating contraceptive effectiveness. Obstet Gynecol 2003;102:709–17.
14. Berry DC, Michas IC. Rosis F. Evaluating explanations about drug prescriptions: Effects of varying the nature of information about side effects and its relative position in explanations. Psychol Health 1998;13:767–84.
15. Berkman N, Sheridan S, Donahue K, et al. Health literacy interventions and outcomes: an updated systematic review. Evidence Report/Technology Assesment No. 199. Rockville, MD: Agency for Healthcare Research and Quality; 2011.
16. Berry DC. Informing people about the risks and benefits of medicines: implications for the safe and effective use of medicinal products. Curr Drug Saf 2006;1:121–6.
17. Berry DC, Raynor DK, Knapp P, Bersellini E. Patients' understanding of risk associated with medication use: impact of European Commission guidelines and other risk scales. Drug Saf 2003;26:1–11.
18. Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ 2002;324:827–30.
19. Galesic M, Gigerenzer G, Straubinger N. Natural frequencies help older adults and people with low numeracy to evaluate medical screening tests. Med Decis Making 2009;29:368–71.
20. Garcia-Retamero R, Galesic M. Communicating treatment risk reduction to people with low numeracy skills: a cross-cultural comparison. Am J Public Health 2009;99:2196–202.
21. Garcia-Retamero R, Galesic M, Gigerenzer G. Do icon arrays help reduce denominator neglect? Med Decis Making 2010;30:672–84.
22. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. BMJ 2003;327:741–4.
23. Knapp P, Gardner PH, Raynor DK, Woolf E, McMillan B. Perceived risk of tamoxifen side effects: a study of the use of absolute frequencies or frequency bands, with or without verbal descriptors. Patient Educ Couns 2010;79:267–71.
24. Kurz-Milcke E, Gigerenzer G, Martignon L. Transparency in risk communication: graphical and analog tools. Ann N Y Acad Sci 2008;1128:18–28.
25. Lipkus IM. Numeric, verbal, and visual formats of conveying health risks: suggested best practices and future recommendations. Med Decis Making 2007;27:696–713.
26. Paling J. Strategies to help patients understand risks. BMJ 2003; 327:745–8.
27. Skolbekken JA. Communicating the risk reduction achieved by cholesterol reducing drugs. BMJ 1998;316:1956–8.
28. Visschers VH, Meertens RM, Passchier WW, de Vries NN. Probability information in risk communication: a review of the research literature. Risk Anal 2009;29:267–87.
29. Raynor DK, Blenkinsopp A, Knapp P, et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. Health Technol Assess 2007;11:iii, 1–160.
30. Fahey T, Griffiths S, Peters TJ. Evidence based purchasing: understanding results of clinical trials and systematic reviews. BMJ 1995;311:1056–9, discussion 9–60.
31. Armstrong K, Schwartz JS, Fitzgerald G, Putt M, Ubel PA. Effect of framing as gain versus loss on understanding and hypothetical treatment choices: survival and mortality curves. Med Decis Making 2002;22:76–83.
32. Gurm HS, Litaker DG. Framing procedural risks to patients: is 99% safe the same as a risk of 1 in 100? Acad Med 2000;75:840–2.
33. Paperny DM, Starn JR. Adolescent pregnancy prevention by health education computer games: computer-assisted instruction of knowledge and attitudes. Pediatrics 1989;83:742–52.
34. Reis J, Tymchyshyn P. A longitudinal evaluation of computer-assisted instruction on contraception for college students. Adolescence 1992;27:803–11.
35. Roberto AJ, Zimmerman RS, Carlyle KE, Abner EL, Cupp PK, Hansen GL. The effects of a computer-based pregnancy, STD, and HIV prevention intervention: a nine-school trial. Health Commun 2007;21:115–24.
36. Grime J, Blenkinsopp A, Raynor DK, Pollock K, Knapp P. The role and value of written information for patients about individual medicines: a systematic review. Health Expect 2007;10:286–98.

37. DeLamater J, Wagstaff DA, Havens KK. The impact of a culturally appropriate STD/AIDS education intervention on black male adolescents' sexual and condom use behavior. Health Educ Behav 2000;27:454–70.
38. McMahon SR, Rimsza ME, Bay RC. Parents can dose liquid medication accurately. Pediatrics 1997;100:330–3.
39. Belcher L, Kalichman S, Topping M, et al. A randomized trial of a brief HIV risk reduction counseling intervention for women. J Consult Clin Psychol 1998;66:856–61.
40. Eldridge GD, St Lawrence JS, Little CE, et al. Evaluation of the HIV risk reduction intervention for women entering inpatient substance abuse treatment. AIDS Educ Prev 1997;9(Suppl):62–76.
41. Jaccard J. Unlocking the contraceptive conundrum. Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregnancy; 2009. Available at http://thenationalcampaign.org/resource/unlocking-contraception-conundrum.

Appendix F

Screening Services For Which Evidence Does Not Support Screening

The following services have been given a D recommendation from the U.S. Preventive Services Task Force (USPSTF), which indicates that the potential harms of routine screening outweigh the benefits. Providers should not perform these screening services.

The USPSTF has recommended against offering the following services to women and men:

- **Asymptomatic bacteriuria:** USPSTF recommends against screening for asymptomatic bacteriuria in men and nonpregnant women (*1*).
- **Gonorrhea:** USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk of infection (*2*).
- **Hepatitis B:** USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection (*3*).
- **Herpes simplex virus (HSV):** USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults (*4*).
- **Syphilis:** USPSTF recommends against screening of asymptomatic persons who are not at increased risk of syphilis infection (*5*).

The USPSTF has recommended against offering the following services to women:

- **BRCA mutation testing for breast and ovarian cancer susceptibility:** USPSTF recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk of deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2) (*6*). However, USPSTF continues to recommend that women whose family history is associated with an increased risk of deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.
- **Breast self-examination:** USPSTF recommends against teaching breast self-examination (*7*).
- **Cervical cytology:** USPSTF recommends against routine screening for cervical cancer with cytology (Pap smear) in the following groups: women aged <21 years, women aged >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer, women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia grade 2 or 3) or cervical cancer. USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women aged <30 years (*8*).
- **Ovarian cancer:** USPSTF recommends against routine screening for ovarian cancer (*9*).

The USPSTF has recommended against offering the following services to men:

- **Prostate cancer:** USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer (*10*).
- **Testicular cancer:** USPSTF recommends against screening for testicular cancer in adolescent or adult males (*11*).

References

1. US Preventive Services Task Force. Screening for asymptomatic bacteriuria in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2008. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbact.htm.
2. US Preventive Services Task Force. Screening for gonorrhea. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2005. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsgono.htm.
3. US Preventive Services Task Force. Screening for hepatitis B infection. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2004. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspshepb.htm.
4. US Preventive Services Task Force. Screening for genital herpes: recommendation statement. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2005. Available at http://www.uspreventiveservicestaskforce.org/uspstf05/herpes/herpesrs.htm.
5. US Preventive Services Task Force. Screening for syphilis infection. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2004. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspssyph.htm.
6. US Preventive Services Task Force. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2013. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm.
7. US Preventive Services Task Force. Screening for breast cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2009. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrca.htm.
8. US Preventive Services Task Force. Screening for cervical cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2012. Available at www.uspreventiveservicestaskforce.org/uspstf11/cervcancer/cervcancerrs.htm.
9. US Preventive Services Task Force. Screening for ovarian cancer: U.S. Preventive Services Task Force reaffirmation recommendation statement. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2012. Available at http://www.uspreventiveservicestaskforce.org/uspstf12/ovarian/ovarcancerrs.htm.
10. US Preventive Services Task Force. Screening for prostate cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2012. Available at http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm.
11. US Preventive Services Task Force. Screening for testicular cancer. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2011. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspstest.htm.

Lead Authors

Loretta Gavin, PhD, Division of Reproductive Health, CDC
Susan Moskosky, MS, Office of Population Affairs, CDC

Systematic Review Authors and Presenters

Anna Brittain, MHS, Division of Reproductive Health, CDC
Marion Carter, PhD, Division of Reproductive Health, CDC
Kathryn Curtis, PhD, Division of Reproductive Health, CDC
Emily Godfrey, MD, Division of Reproductive Health, CDC
Arik V. Marcell, MD, The Johns Hopkins University and the Male Training Center
Cassondra Marshall, MPH, Division of Reproductive Health, CDC
Karen Pazol, PhD, Division of Reproductive Health, CDC
Naomi Tepper, MD, Division of Reproductive Health, CDC
Marie Tiller, PhD, MANILA Consulting Group, Inc.
Stephen Tregear, DPhil, MANILA Consulting Group, Inc.
Michelle Tregear, PhD, MANILA Consulting Group, Inc.
Jessica Williams, MPH, MANILA Consulting Group, Inc.
Lauren Zapata, PhD, Division of Reproductive Health, CDC

Expert Work Group

Courtney Benedict, MSN, Marin Community Clinics
Jan Chapin, MPH, American College of Obstetricians and Gynecologists
Clare Coleman, President and CEO, National Family Planning and Reproductive Health Association
Vanessa Cullins, MD, Planned Parenthood Federation of America
Daryn Eikner, MS, Family Planning Council
Jule Hallerdin, MN, Advisor to the Office of Population Affairs
Mark Hathaway, MD, Unity Health Care and Washington Hospital Center
Seiji Hayashi, MD, Bureau of Primary Health Care, Health Resources and Services Administration
Beth Jordan, MD, Association of Reproductive Health Professionals
Ann Loeffler, MSPH, John Snow Research and Training Institute
Arik V. Marcell, MD, The Johns Hopkins University and the Male Training Center
Tom Miller, MD, Alabama Department of Health
Deborah Nucatola, MD, Planned Parenthood Federation of America
Michael Policar, MD, State of California and UCSF Bixby Center
Adrienne Stith-Butler, PhD, Keck Center of the National Academies
Denise Wheeler, ARNP, Iowa Department of Public Health
Gayla Winston, MPH, Indiana Family Health Council
Jacki Witt, MSN, Clinical Training Center for Family Planning, University of Missouri—Kansas City
Jamal Gwathney, MD, Bureau of Primary Health Care, Health Resources and Services Administration

Technical Panel on Women's Clinical Services

Courtney Benedict, MSN, Marin Community Clinics
Janet Chapin, MPH, American College of Obstetricians and Gynecologists
Elizabeth DeSantis, MSN, South Carolina Department of Health and Environmental Control
Linda Dominguez, CNP, Southwest Women's Health
Eileen Dunne, MD, Division of STD Prevention, CDC
Jamal K. Gwathney, MD, Bureau of Primary Health Care, Health Resources and Services Administration
Jule Hallerdin, Consultant Advisor
Mark Hathaway, MD, Washington Hospital Center
Arik V. Marcell, MD, Johns Hopkins University and the Male Training Center
Cheri Moran, University of Illinois Medical Center at Chicago
Deborah Nucatola, MD, Planned Parenthood Federation of America
Michael Policar, MD, Family PACT Program - California State Office of Family Planning
Pablo Rodriguez, MD, Women's Care Inc., Providence Office
Denise Wheeler, ARNP, Iowa Department of Public Health
Jacki Witt, MSN, Clinical Training Center for Family Planning, University of Missouri—Kansas City

Technical on Men's Clinical Services

Linda Creegan, FNP, California STD/HIV Prevention Training Center
Dennis Fortenberry, MD, Indiana University School of Medicine
Emily Godfrey, MD, University of Illinois at Chicago
Wendy Grube, PhD, University of Pennsylvania School of Nursing
Arik V. Marcell, MD, The Johns Hopkins University and the Male Training Center
Elissa Meites, MD, Division of STD Prevention, CDC
Anne Rompalo, MD, Johns Hopkins University
Thomas Walsh, MD, University of Washington Medical Center
Jacki Witt, MSN, Clinical Training Center for Family Planning, University of Missouri—Kansas City
Sandra Wolf, MD, Women's Care Center, Philadelphia

Technical Panel on Adolescents

Claire Brindis, DrPH, University of California, San Francisco
Gale Burstein, MD, SUNY at Buffalo School of Medicine and Biomedical Sciences, Department of Pediatrics
Laura Davis, MA, Advocates for Youth
Patricia J. Dittus, PhD, Division of STD Prevention, CDC
Paula Duncan, MD, University of Vermont College of Medicine
Carol Ford, MD, The Children's Hospital of Philadelphia
Melissa Gilliam, MD, The University of Chicago
Mark Hathaway, MD, Unity Health Care & Washington Hospital Center
Deborah Kaplan, PhD, New York City Department of Health and Mental Hygiene
Arik V. Marcell, MD, The Johns Hopkins University and the Male Training Center
Brent C. Miller, PhD, Utah State University
Elizabeth M. Ozer, PhD, Division of Adolescent Medicine, University of California, San Francisco
John Santelli, MD, Columbia University, Mailman School of Public Health

Technical Panel on Counseling and Education

Beth Barnet, MD, University of Maryland
Betty Chewning, PhD, University of Wisconsin School of Pharmacy
Christine Dehlendorf, MD, University of California, San Francisco
Linda Dominguez, CNP, Southwest Women's Health
Jillian Henderson, PhD, University of California, San Francisco
James Jaccard, PhD, New York University
Beth Jordan, MD, Association of Reproductive Health Professionals—East
David Kaplan, PhD, American Counseling Association
Alicia Luchowski, American Congress of Obstetricians and Gynecologists
Merry-K Moos, FNP, University of North Carolina at Chapel Hill
Patricia Murphy, DrPH, University of Utah College of Nursing
Elizabeth O'Connor, PhD, Kaiser Permanente Center for Health Research
Jeff Peipert, MD, Washington University in St. Louis

Technical Panel on Quality Improvement

Davida Becker, PhD, Bixby Center for Global Reproductive Health University of California, San Francisco
Peter Briss, MD, National Center for Chronic Disease Prevention and Health Promotion, CDC
Denise Dougherty, PhD, Agency for Healthcare Research and Quality
Daryn Eikner, MS, Family Planning Council
Christina I. Fowler, PhD, RTI International
Evelyn Glass, MSPH, Consultant Advisor
Yvonne Hamby, MPH, Regional Quality Improvement and Infertility Prevention Programs
A. Seiji Hayashi, MD, Bureau of Primary Health Care, Health Resources and Services Administration
Michael D. Kogan, PhD, Health Resources and Services Administration /Maternal and Child Health Bureau
Tom Miller, MD, Alabama Department of Health
Sam Posner, PhD, National Center for Chronic Disease Prevention and Health Promotion, CDC
Donna Strobino, PhD, Johns Hopkins University
Amy Tsui, PhD, Johns Hopkins Bloomberg School of Public Health
Reva Winkler, MD, National Quality Forum

Adivsors on Community Outreach and Participation*

Paula Baraitser, MBBS, Kings College Hospital NHS Foundation Trust/Health Protection Agency
Joy Baynes, MPH, Advocates for Youth
Diane Chamberlain, California Family Health Council
Clare Coleman, National Family Planning & Reproductive Health Association
Emily Godfrey, MD, University of North Carolina and Division of Reproductive Health, CDC
Rachel Gold, MPA, Guttmacher Institute
Rachel Kachur, MPH, Division of STD Prevention, CDC
Michelle Kegler, PhD, Rollins School of Public Health, Emory
Eleanor McLellan-Lemal, PhD, Division of HIV/AIDS Prevention, CDC
Paula Parker-Sawyers, National Campaign to Prevent Teen and Unplanned Pregnancy
Denise Wheeler, MS, Iowa Department of Public Health
Gayla Winston, MPH, Indiana Family Health Council, Inc.

CDC and Office of Population Affairs Reviewers

Wanda Barfield, MD, Division of Reproductive Health, CDC
Gail Bolan, MD, Division of STD Prevention, CDC
Linda Dahlberg, PhD, Division of Violence Prevention, CDC
Patricia Dietz, PhD, Division of Reproductive Health, CDC
Sherry Farr, PhD, Division of Reproductive Health, CDC
Evelyn Glass, MSPH, Office of Population Affairs
Tamara Haegerich, PhD, Division of Violence Prevention, CDC
David Johnson, MPH, Office of Population Affairs
Pamela Kania, MS, Office of Population Affairs
Marilyn Keefe, MPH, Deputy Assistant Secretary for Population Affairs
Dmitry Kissin, MD, Division of Reproductive Health, CDC
Nancy Mautone-Smith, MSW, Office of Population Affairs
Jacqueline Miller, MD, Division of Cancer Prevention and Control, CDC
Sam Posner, PhD, National Center for Chronic Disease and Health Promotion, CDC
Cheryl Robbins, PhD, Division of Reproductive Health, CDC
Lance Rodewald, MD, Division of Immunization Services, CDC
Mona Saraiya, MD, Division of Cancer Prevention and Control, CDC
Van Tong, MPH, Division of Reproductive Health, CDC
Lee Warner, PhD, Division of Reproductive Health, CDC
Kim Workowski, MD, Division of STD Prevention, CDC

External Reviewers

Paula Braverman, MD, Department of Pediatrics at the University of Cincinnati
Claire Brindis, DrPH, University of California–San Francisco
Sarah Brown, MPH, National Campaign to Prevent Teen and Unplanned Pregnancy
Marji Gold, MD, Albert Einstein School of Medicine
Milton Kotelchuck, PhD, Massachusetts General Hospital for Children and Harvard Medical School
David Levine, MD, Morehouse School of Medicine
Pamela Murray, MD, West Virginia University School of Medicine

Competing interests for the development of these guidelines were not assessed.

* These persons made important contributions to a discussion about community outreach and participation. A decision was made to narrow the focus of this report to clinical services, so recommendations informed by the input of these persons will be published separately.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR*'s free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to *mmwrq@cdc.gov.*

All material in the *MMWR* Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

ISSN: 1057-5987

Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2017

Loretta Gavin, PhD[1]; Karen Pazol, PhD[2]; Katherine Ahrens, PhD[1]

In April 2014, CDC published "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs" (QFP), which describes the scope of services that should be offered in a family planning visit and how to provide those services (e.g., periodicity of screening, which persons are in need of services, etc.) (*1*). The sections in QFP include the following: Determining the Client's Need for Services; Contraceptive Services; Pregnancy Testing and Counseling; Clients Who Want to Become Pregnant; Basic Infertility Services; Preconception Health Services; Sexually Transmitted Disease Services; and Related Preventive Health Services. In addition, the QFP includes an appendix entitled Screening Services for Which Evidence Does Not Support Screening.

CDC and the Office of Population Affairs developed QFP recommendations by conducting an extensive review of published evidence, seeking expert opinion, and synthesizing existing clinical recommendations from CDC, agencies such as the U.S. Preventive Services Task Force (USPSTF), and professional medical associations such as the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

The scope of preventive services related to reproductive health is constantly evolving as new scientific findings are published and clinical recommendations are modified accordingly. Being knowledgeable about the most current recommendations is an important step toward providing the highest quality care to patients. To keep QFP current with the latest recommendations, CDC and the Office of Population Affairs publish occasional updates that summarize newly published clinical recommendations. The first of these updates was published in March 2016 (*2*), and covered guidelines published during April 2014–December 2015. This report summarizes recommendations from guidelines published during January 2016–April 2017. CDC and the Office of Population Affairs prepared these updates by searching for materials from CDC, USPSTF, and other professional medical organizations that had recommendations referenced in the original QFP. When updated recommendations were identified, they were evaluated for changes in implications for providing family planning care. CDC and the Office of Population Affairs determined that none of the newly published recommendations marked a substantial shift in how family planning care should be provided, and therefore did not seek additional review to consider the implications for the QFP for this update. Technical reviews from clinical experts representing a broad range of family planning providers might be appropriate for future updates.

Updated recommendations that have implications for clinical practice for family planning providers are highlighted (Box). In addition, an updated reference list for each section in the QFP is provided for all recommendations published during January 2016–April 2017, including those that did not result in any change in recommended clinical practices for family planning providers.

BOX. Updated recommendations that might have implications for clinical practice, by section heading — Providing Quality Family Planning Services: Recommendations from CDC and the U.S. Office of Population Affairs, 2017

Contraceptive Services

Medical eligibility for contraceptive use

The 2016 CDC recommendations update earlier 2010 recommendations for the use of specific contraceptive methods by women and men who have certain characteristics or medical conditions.

The 2016 updated recommendations include the following:

- Addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or taking St. John's wort.
- Revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate (UPA) for emergency contraception.
- Revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases (STDs), and human immunodeficiency virus (HIV) infection; and women who are receiving antiretroviral therapy.
- For all 2016 updated recommendations, see Tables A1 and A2: https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1_appendix.htm

Source: Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-3).

Selected practice recommendations for contraceptive use

The 2016 CDC recommendations update earlier 2013 recommendations that address a select group of common, yet sometimes complex, issues regarding initiation and use of specific contraceptive methods.

Recommendations have been updated regarding when to start regular contraception after UPA emergency contraceptive pills:

- Advise the woman to start or resume hormonal contraception no sooner than 5 days after use of UPA, and provide or prescribe the regular contraceptive method as needed. For methods requiring a visit to a health care provider, such as depo-medroxyprogesterone acetate (DMPA), implants, and intrauterine devices (IUDs), starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.
  - The woman needs to abstain from sexual intercourse or use barrier contraception for the next 7 days after starting or resuming regular contraception or until her next menses, whichever comes first.
  - Any nonhormonal contraceptive method can be started immediately after the use of UPA.
  - The woman should be advised to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

New recommendations have been made regarding medications used to ease IUD insertion:

- Misoprostol is not recommended for routine use before IUD insertion. Misoprostol might be helpful in select circumstances (e.g., in women with a recent failed insertion).
- Paracervical block with lidocaine might reduce patient pain during IUD insertion.

Source: Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-4).

Preconception Health Services

Depression

- The 2016 USPSTF recommendation for adults reaffirms the 2009 recommendation to screen all adults when staff-assisted depression care supports are in place. This replaces the 2009 recommendation regarding selective screening of adults.
- The 2016 USPSTF recommendation for adolescents aged 12–18 years reaffirms the 2009 recommendation to screen for major depressive disorder when systems are in place to ensure accurate diagnosis, effective treatment, and follow-up. The 2016 statement removes the recommendation of specific psychotherapies in recognition of decreased concern over the harms of pharmacotherapy in adolescents as long as they are adequately monitored.

Sources: US Preventive Services Task Force. Screening for depression in adults. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016.

US Preventive Services Task Force. Screening for depression in children and adolescents. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016.

Updated Reference List, by QFP Section

Determining the Client's Need for Services

American College of Obstetricians and Gynecologists' Committee on Health Care for Underserved Women. Committee opinion no. 654: reproductive life planning to reduce unintended pregnancy. Obstet Gynecol 2016;127:e66–9. https://doi.org/10.1097/AOG.0000000000001314

Contraceptive Services

Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-3).

Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-4).

American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Committee opinion no. 670: immediate postpartum long-acting reversible contraception. Obstet Gynecol 2016;128:e32–7. https://doi.org/10.1097/AOG.0000000000001587

American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice Long-Acting Reversible Contraceptive Expert Work Group. Committee opinion no. 672: clinical challenges of long-acting reversible contraceptive methods. Obstet Gynecol 2016;128:e69–77. https://doi.org/10.1097/AOG.0000000000001644

Clients Who Want to Become Pregnant

Pfeifer S, Butts S, Fossum G, et al.; Practice Committee of the American Society for Reproductive Medicine in collaboration with the Society for Reproductive Endocrinology and Infertility. Optimizing natural fertility: a committee opinion. Fertil Steril 2017;107:52–8. https://doi.org/10.1016/j.fertnstert.2016.09.029

Preconception Health Services

American College of Obstetricians and Gynecologists' Committee on Health Care for Underserved Women. Committee opinion no. 654: reproductive life planning to reduce unintended pregnancy. Obstet Gynecol 2016;127:e66–9. https://doi.org/10.1097/AOG.0000000000001314

Kim DK, Riley LE, Harriman KH, Hunter P, Bridges CB. Advisory Committee on Immunization Practices recommended immunization schedule for adults aged 19 years or older—United States, 2017. MMWR Morb Mortal Wkly Rep 2017;66:136–8. https://doi.org/10.15585/mmwr.mm6605e2

Robinson CL, Romero JR, Kempe A, Pellegrini C; Advisory Committee on Immunization Practices (ACIP) Child/Adolescent Immunization Work Group. Advisory Committee on Immunization Practices recommended immunization schedule for children and adolescents aged 18 years or younger—United States, 2017. MMWR Morb Mortal Wkly Rep 2017;66:134–5. https://doi.org/10.15585/mmwr.mm6605e1

US Preventive Services Task Force. Folic acid supplementation for the prevention of neural tube defects: preventive medication. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2017. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/folic-acid-for-the-prevention-of-neural-tube-defects-preventive-medication

US Preventive Services Task Force. Depression in adults: screening. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/depression-in-adults-screening1

US Preventive Services Task Force. Depression in children and adolescents: screening. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/depression-in-children-and-adolescents-screening1

Sexually Transmitted Disease Services

US Preventive Services Task Force. Syphilis infection in nonpregnant adults and adolescents: screening. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/syphilis-infection-in-nonpregnant-adults-and-adolescents

Related Preventive Health Services

US Preventive Services Task Force. Breast cancer: screening. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1

US Preventive Services Task Force. Gynecological conditions: periodic screening with the pelvic examination. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2017. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/gynecological-conditions-screening-with-the-pelvic-examination

Screening Services for Which Evidence Does Not Support Screening

US Preventive Services Task Force. Genital herpes infection: serologic screening. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/genital-herpes-screening1

Conflict of Interest

No conflicts of interest were reported.

[1]Office of Population Affairs, U.S. Department of Health and Human Services, Rockville, Maryland; [2]Division of Reproductive Health, CDC.

Corresponding author: Katherine Ahrens, kate.ahrens@hhs.gov, 240-453-2831.

References

1. Gavin L, Moskosky S, Carter M, et al. Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs. MMWR Recomm Rep 2014;63(No. RR-04).
2. Gavin L, Pazol K. Update: providing quality family planning services—recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR Morb Mortal Wkly Rep 2016;65:231–4. https://doi.org/10.15585/mmwr.mm6509a3

Program Review Tool (V4 - 2017) Administrative Only

8: Project Management and Administration

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered.

Section 8.1.2: Acceptance of FP Services not a Prerequisite for Eligibility or Services
A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

SR should institutionalize administrative procedures (e.g., staff training, clinical protocols, and consent forms) to ensure clients' receipt of family planning services is not used as a prerequisite to receipt of other services from the service site.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR has a written policy that prohibits their service sites, and any sub-recipient service sites from making the acceptance of family planning services a prerequisite to the receipt of any other services.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Documentation at the service site(s) (e.g., staff circulars, training curriculum) indicates staff has been informed at least once during the current project period that a client's receipt of family planning services may not be used as a prerequisite to receipt of any other services offered by the service site.	Our policies require annual reminders
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Administrative policies at service sites include a written statement that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. General consent forms or other documentation provided to clients states that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site.	Some of the FQHCs have this in a text box in EMR instead of consent

Section 8.1.3: Personnel Awareness
Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has written policies and procedures that require that all staff of the SR is informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Documentation at sub-recipients and service sites (e.g., staff circulars, training records) demonstrates that staff has been informed at least once during the current project period that they are subject to this requirement.	Annual reminders

8.2: Prohibition of Abortion

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Systems must be in place to assure adequate separation of any non-Title X activities from the Title X project. Grantee has documented processes to ensure that they and their sub-recipients are in compliance with Section 1008. Grantees should include language in sub-recipient contracts addressing this requirement.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has written policies and procedures that prohibit service sites from providing abortion as part of the Title X project.	May need to expand/change if new rules are adopted.

8.3: Structure and Management

Family planning services under a Title X grant may be offered by grantees directly and/or by sub-recipient agencies operating under the umbrella of a grantee. However, the grantee is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by sub-recipients. Where required services are provided by referral, the grantee is expected to have written agreements for the provision of services and reimbursement of costs as appropriate.

Section 8.3.1: Written Sub-Recipient Agreements and Standards
The grantee must have a written agreement with each sub-recipient and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Title X Program Requirements, as well as other applicable requirements (45 CFR parts 74 and 92).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐	Question N/A (No Sub-Recipients) ☐	1. SR staff have access to written agreements documenting that the SR is carrying out the scope of the contract in accordance with Title X and other applicable federal requirements.	

Section 8.3.2: Sub-Recipient Subcontracts
If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by the must be maintained by the sub-recipient (45 CFR parts 74 and 92).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐	Question N/A (No Sub-Recipients) ☐	1. Documentation shows the SR has received approval for all sub-recipient subcontracts.	
A	☐	☐	Question N/A (No Sub-Recipients) ☐	2. SR demonstrates that the sub-recipient is monitoring the entity for compliance with Title X requirements.	

Section 8.3.5: Sub-Recipient Inclusion in Grantee Policy Establishment
Sub-recipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5 (a)(10)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐	Question N/A (No Contracts) ☐	1. Documentation exists and may include meeting minutes, conference calls, and webinars that demonstrates that sub-recipients participate in ongoing policy and guideline development.	

8.5: Project Personnel

Title X grantees must have approved personnel policies and procedures.

Section 8.5.1: Personnel Policies

Grantees and sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has written policies and procedures in place that provide evidence that there is no discrimination in personnel administration at its organizations and within its sub-recipient network. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.	

Section 8.5.2: Cultural Competency

Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. Written SR policies and procedures that address how the project operationalizes cultural competency.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Documentation at service sites includes records of cultural competence training, in-services, client satisfaction surveys, or other documentation that supports culturally competent services.	

Section 8.5.3: Project Director

Projects must be administered by a qualified project director. Change in Status, including Absence of Principle Investigator/Project Director and Other Key Personnel requires pre-approval by the Office of Grants Management. For more information, see HHS Grants Policy Statement, 2007 Section II-54.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐	Question N/A (No Changes) ☐	1. Documentation that indicates any changes in SR project director have been submitted to IDPH via IowaGrants.gov.	

8.6: Staff Training and Project Technical Assistance

Title X Is are responsible for the training of all project staff. Technical assistance may be provided by OPA or the Regional Office.

Section 8.6.1: Personnel Training

Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR records demonstrate the assessment(s) of staff training needs and a training plan that addresses key requirements of the Title X program and priority areas.	
A	☐	☐		2. SR maintains written records of orientation, in-service and other training attendance by project personnel.	

Section 8.6.2: Training on Federal/State Reporting Requirements

The project's orientation/in-service training includes training on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape, or incest, as well as on human trafficking.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR documentation includes evidence of staff training within the current project period specific to this area which may include attendance records and certificates.	Make sure FP staff documentation is available at least every project period (3 years with annual reminders)

Section 8.6.3: Training on Minors (Family Involvement and Coercion)

The project's orientation/in-service training includes training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies ensure that staff has received training within the current project period on state-specific reporting/notification requirements.	Required training within each project period
A	☐	☐		2. Documentation includes training attendance records/certificates that indicate that training on family involvement counseling and sexual coercion counseling has been provided.	We require annual reminders and documentation, unfortunately we do not know what "training means" Reviewers here have said the reminders are sufficient.
A	☐	☐		3. SR screens all persons seeking Title X services for victimization if they are under the age of consent for sexual activity in Iowa.	NEW FOA and rules

8.7: Planning and Evaluation

Grantees must ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR collects and submits data for the Family Planning Annual Report (FPAR) in a timely, complete, and accurate manner.	

8.7 Link to QFP: Framework for Program Evaluations

When designing evaluations, projects should follow the Recommendations for Providing Quality Family Planning Services, which defines what services to provide and how to do so and thereby provides a framework by which program evaluations can be developed. Projects should also follow the QFP that defines 'quality' care and describes how to conduct quality improvement processes so that performance is monitored and improved on an ongoing basis. QI activities should be overseen by the grantee and occur at both the grantee and sub-recipient levels.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
A	Yes ☐	No ☐	1. SR demonstrates use of FPAR data to calculate for SR level the percentage of adolescent and adult women at risk of unintended pregnancy who use: (a) a most or moderately effective method of contraception, and (b) long-acting reversible methods of contraception.	
A	Yes ☐	No ☐	2. SR project records document the use of ongoing (i.e., at least annually) quality improvement processes related to the contraceptive use measure (see #1 above).	
A	Yes ☐	No ☐	3. SR demonstrates use of FPAR data to calculate for all service sites within the SR's network the percentage of adolescent and adult women at risk of unintended pregnancy who use: (a) a most or moderately effective method of contraception, and (b) long-acting reversible methods of contraception.	
A	Yes ☐	No ☐	4. SR project records document the use of ongoing (i.e., at least annually) quality improvement processes related to the contraceptive use measure across all service sites within the SR network (see #2 above), and a description of steps taken by the SR, sub-recipients and service sites in response to findings.	
A	Yes ☐	No ☐	5. SR project records demonstrate the use of data at service site level to monitor other aspects of quality care (e.g., client experience, chlamydia screening rates, timelines, and efficiency).	
A	Yes ☐	No ☐	6. SR has implemented HIT and can demonstrate how its use has increased its ability to monitor the quality of care.	

A	**Yes** ☐	**No** ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

8.7 Quality Assessment Score:	☐	**Exceptional** (All 6 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (4 – 6 Quality Indicators Evident)
	☐	**Fair** (1 – 3 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

9. Project Services and Clients

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects must provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services

9.1: Priority Clients

Priority for project services is to persons from low-income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. Data submitted to the Family Planning Annual Report by the SR demonstrates that more than half of clients served have incomes that are at or below 100% of the Federal Poverty Level (FPL).	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. SR service site(s) are located in locations that are accessible for low-income persons.	

9.2: Client Dignity

Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	1. SR ensures protection of client privacy as evidenced in their policies and confirmed by consultant observation.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. A patient bill of rights or other documentation, which outlines client's rights and responsibilities.	We don't require this

9.2 Link to QFP: Cultural Competency and Client Dignity

A core premise of Recommendations for Providing Quality Family Planning Services is that quality services are client-centered, which includes providing services in a respectful and culturally competent manner.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
A	Yes ☐	No ☐	1. The SR needs assessments or other documentation (including those of the sub-recipients) describe populations that may be in need of culturally competent care.	
A	Yes ☐	No ☐	2. The SR has written policies and procedures that require their staff to receive training in culturally competent care. This should include how to meet the needs of the following key populations: LGBTQ, adolescents, individuals with limited English-proficiency, and the disabled.	
A	Yes ☐	No ☐	3. Documentation (e.g., training records) that demonstrates staff have received training in providing culturally competent care to populations identified in the needs assessment.	
A	Yes ☐	No ☐	4. Observation of the clinic environment demonstrates that it is welcoming (i.e., Privacy, cleanliness of exam rooms, ease of access to service, fair and equitable charges for services including waiver of fees for "good cause," language assistance).	
A	Yes ☐	No ☐	5. Client surveys document that clients perceive providers and other clinic staff to be respectful.	
A	Yes ☐	No ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

9.2 Quality Assessment Score:		
	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

9.3: Non-Discriminatory Services

Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has written policies and procedures that require their service sites and any sub-contractor sites to provide service without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies or marital status, and to inform staff of this requirement on an annual basis.	
A	☐	☐		2. Documentation (e.g., staff circulars, orientation documentation, training curricula) demonstrates that staff has been informed at least once during employment that services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies or marital status.	Annual reminders documented

9.4: Availability of Social Services

Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR's needs assessment or other activities has documented the social service and medical needs of the community to be served, as well as ancillary services that are needed to facilitate clinic attendance, and identified relevant social and medical services available to help meet those needs.	
A	☐	☐	Question N/A (No Sub-Recipients) ☐	2. SR has a written policy that requires sub-recipients to develop and implement plans to address the related social service and medical needs of clients as well as ancillary services needed to facilitate clinic attendance.	SR policies
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. There is evidence of process to refer clients to relevant social and medical services agencies for example: child care agencies, transport providers, WIC programs. (Optimally signed, written collaborative agreements).	SR policies

9.5: Availability and Use of Referrals

Projects must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has a written policy to coordinate with and refer clients to other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Service sites have evidence of processes for effective referrals to relevant agencies exist, including: emergency care, HIV/AIDS care and treatment agencies, infertility specialists, and chronic care management providers, and providers of other medical services not provided on-site (Optimally signed, written collaborative agreements).	SR policies

9.8: Range of Family Planning Methods

All Projects must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents).

If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. (42 CFR 59.5(a)(1)).

9.8 Link to QFP

QFP notes the special needs of adolescent clients and recommends ways to address those needs, e.g., how to tailor contraceptive counseling for adolescents and ways to make services more youth-friendly.

QFP also notes the need to offer a broad range of contraceptive methods, and that this is an important part of providing client-centered care that respects the individual's choice. Projects should have a system in place to ensure continuous access to a broad range of FDA-approved contraceptive methods, optimally on-site.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
			1. Most or moderately effective contraceptives	
			2. Chlamydia screening rates (<25 females)	
			3. Reproductive life plan counseling sessions	
A	Yes ☐	No ☐	4. A review of the service site's FPAR data demonstrates that the proportion of males receiving family planning services is close to or above the national average.	

A / C	Yes ☐	No ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

9.8 Quality Assessment Score:		
	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

9.9: Durational Residency Requirements

Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR has a written policy stating that service sites will provide services without the imposition of any durational residence requirement or a requirement that the client be referred by a physician.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Written clinic policies explicitly address this requirement.	

9.12: Compliance with Legislative Mandates

Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

"Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR has written policy and procedures requiring their sites and all sub-contractors to inform their staff periodically that: (a) clinic staff must encourage family participation in the decision of minors to seek FP services, (b) minors must be counseled on how to resist attempts to coerce them into engaging in sexual activities, and (c) State law must be followed requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.	Annual reminders
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Documentation (e.g., staff circulars, training curricula) demonstrates that all staff has been formally informed about items 1a-c above at least once during the current project period.	May be in personnel files

10: Confidentiality

10: Confidentiality					
Every project must have safeguards to ensure client confidentiality. Information obtained by project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).					
Reviewer Code	**Met**	**Not Met**	**Sub-Recipient/ Service Site Score**	**Implementation Strategy**	**Comments**
A	☐	☐		1. The SR has a written policy requiring that all service sites and sub-contractors safeguard client confidentiality.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Documentation (e.g., staff circulars, new employee orientation documentation, training curricula) demonstrates that staff has been informed at least once during the current project period about policies related to preserving client confidentiality and privacy.	Annual reminders
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Clinical protocols and policies have statements related to client confidentiality and privacy.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. The health records system has safeguards in place to ensure adequate privacy, security and appropriate access to personal health information.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	5. There is evidence that HIPAA privacy forms are provided to clients and signed forms are collected as required.	

A	☐	☐	Site A: ___ Site B: ___ Site C: ___	6. General consent forms or other documentation at service sites state that services will be provided in a confidential manner, and note any limitations that may apply.	
				7. Fiscal Strategy	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	8. Client education materials (e.g., posters, videos, flyers) noting the client's right to confidential services are available to clients.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	9. The physical layout of the facility ensures that client services are provided in a manner that allows for confidentiality and privacy.	

11: Community Participation, Education, and Project Promotion

Title X grantees are expected to provide for community participation and education and to promote the activities of the project.

11.1: Collaborative Planning and Community Engagement					
Title X grantees and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).					
Reviewer Code	**Met**	**Not Met**	**Sub-Recipient/ Service Site Score**	**Implementation Strategy**	**Comments**
A	☐	☐		1. The SR has a written policy and procedures in place for ensuring that there is an opportunity for community participation in developing, implementing, and evaluating the project plan. Participants should include individuals who are broadly representative of the population to be served, and who are knowledgeable about the community's needs for family planning services.	Done at both grantee and SR levels
A	☐	☐		2. The community engagement plan: (a) engages diverse community members including adolescents and current clients, and (b) specifies ways that community members will be involved in efforts to develop, assess, and/or evaluate the program.	
A	☐	☐		3. Documentation demonstrates that the community engagement plan has been implemented (e.g., reports, meeting minutes, etc.).	

11.2: Community Awareness and Access

Projects must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)).

The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. Documentation demonstrates that the SR conducts periodic assessment of the needs of the community with regard to their awareness of and need for access to family planning services.	
A	☐	☐		2. SR has a written community education and service promotion plan that has been implemented (e.g., media spots/materials developed, event photos, participant logs, and monitoring reports). The plan: (a) states that the purpose is to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial, (b) promotes the use of family planning among those with unmet need, (c) utilizes an appropriate range of methods to reach the community, and (d) includes an evaluation strategy.	Generally delegated to SR
A	☐	☐		3. Documentation that evaluation has been conducted, and that program activities have been modified in response.	

11.3: Community Education

Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial (42 CFR 59.5 (b)(3).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR has developed a community education and service promotion plan that: (a) states that the purpose is to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial, (b) promotes the use of family planning among those with unmet need, (c) utilizes an appropriate range of methods to reach the community, and (d) includes an evaluation strategy.	Mostly delegated to SR, there are some activities we do with partners and meetings.
A	☐	☐		2. There is documentation that the plan has been implemented and evaluated.	

12: Information and Education Materials Approval

Every project is responsible for reviewing and approving informational and educational materials. The Information and Education (I&E) Advisory Committee may serve the community participation function if it meets the requirements, or a separate group may be identified.

12.1: Materials Review and Approval Process

Title X grantees and sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials developed or made available under the project prior to their distribution (Section 1006 (d)(2), PHS Act; 42 CFR 59.6(a)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has policies and procedures that ensure materials are reviewed prior to being made available to the clients that receive services within the project. If a SR sub-contracts for services, the SR must ensure that sub-recipients have a process in place that meets this requirement.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Committee meeting minutes demonstrate the process used to review and approve materials	Common section for findings – currency of materials, minutes, diversity and size of committee

12.2: Advisory Committee Diversity

The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. The SR has established a project advisory board that is comprised of members who are broadly representative of the population served.	Delegated to SR
A	☐	☐	Question N/A (No Sub-Recipients) ☐	2. If a SR sub-contracts for services, the SR must ensure that sub-recipients have a process in place that meets this requirement.	We also require SR to train committee members (using Title X slides, FP overview or Zoom)
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. SR (and/or sub-contractors) documentation (meeting minutes, lists of board members, etc.) demonstrates this requirement has been met.	

12.3: Advisory Committee Membership

Each Title X grantee must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6 (b)(1)). The Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR has policies and procedures addressing this element.	
A	☐	☐		2. SR maintains and updates Lists/Rosters of Advisory Committee members.	
A	☐	☐		3. SR maintains Advisory Committee written meeting minutes.	
A	☐	☐		4. Advisory committee minutes indicate that the committee is active.	

12.4: Grantee Oversight for Materials Review

The grantee may delegate I&E functions for the review and approval of materials to sub-recipient agencies; however, the oversight of the I&E review process rests with the grantee.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies and procedures indicate processes and responsibility for this element.	
A	☐	☐	Question N/A (Oversight Process Not Delegated) ☐	2. SR documentation indicates that an oversight process has been implemented by the SR.	

12.5: Advisory Committee Responsibility for Materials Review

The Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the I&E materials rests with the Advisory Committee.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies and procedures specify how the factual, technical, and clinical accuracy components of the review are assured.	
A	☐	☐	Question N/A (Review Process Not Delegated) ☐	2. SR maintains a written record of its determinations. Minutes from committee meetings must be maintained throughout the project period.	

12.6: Advisory Committee Requirements

The I&E Advisory Committee(s) must:

- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the standards of the population or community to be served with respect to such materials;
- Review the content of the material to assure that the information is factually correct;
- Determine whether the material is suitable for the population or community to which it is to be made available; and
- Establish a written record of its determinations (Section 1006(d), PHS Act; 42 CFR 59.6(b)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies and procedures document that the required elements of this section are addressed.	
A	☐	☐		2. Meeting minutes and/or review forms document that all required components are addressed.	

13: Additional Administrative Requirements

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

13.1: Facilities and Accessibility of Services

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR 84).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies assure language translation services are readily provided when needed.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Service site documentation indicates that staff is aware of policies and processes that exist to access language translation services when needed.	
A	☐	☐		3. SR policies and procedures ensure access to services for individuals with disabilities at their sites.	
A	☐	☐		4. SR maintains documentation of any accommodations made for disabled individuals.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	5. Project sites are free from obvious structural or other barriers that would prevent disabled individuals from accessing services.	

13.1 Link to QFP: Communication and Education

When developing written policies that meet these requirements, projects implement the recommendations presented in “Appendix E” of the QFP.

- Strategies that can make information more accessible for clients with Limited English Proficiency include:
- Presenting information in the client’s primary language.
- Providing translation services.

Ensure that information is culturally appropriate and reflects the client’s beliefs, ethnic background, and cultural practices.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
A	Yes ☐	No ☐	1. Educational materials are clear and easy to understand (e.g., 4th-6th grade reading level).	

A	**Yes** ☐	**No** ☐	2. Educational materials are tailored to literacy, age, and language preferences of client populations.	
A / C	**Yes** ☐	**No** ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

13.1 Quality Assessment Score:	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

13.2: Emergency Management

All grantees, sub-recipients and Title X clinics are required to have a written plan for the management of emergencies (29 CFR 1910, subpart E) and clinical facilities must meet applicable standards established by Federal State and local governments (e.g. local fire, building, and licensing codes).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR disaster plans have been developed and are available to staff.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Staff can identify emergency evacuation routes.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Staff has completed training and understands their role in an emergency or natural disaster.	
A	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. Exits are recognizable and free from barriers.	

13.3: Standards of Conduct

Projects are required to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies address this requirement.	
A	☐	☐		2. There is evidence of SR oversight of sub-recipients/service sites for compliance with this requirement.	

13.4: Human Subjects Clearance (Research)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise their Regional Office in writing of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
A	☐	☐		1. SR policies address this requirement.	
A	☐	☐		2. There is evidence of SR oversight of sub-recipients/service sites for compliance with this requirement.	

Iowa Department of Public Health

Family Planning Chart Audit Instructions

The Iowa Department of Public Health (IDPH) Family Planning Chart Audit is part of the Title X Family Planning Program quality assurance policy.

Family Planning Program Chart Audits are required for all IDPH sub-recipient (SR) agencies for Title X services as follows:

1. Each assigned SR shall submit a summary of the results and follow-up from an internal chart audit to IDPH by April 15 of each year as part of a quality assurance strategy.
2. Chart audits for each SR will be completed by IDPH staff, with or without the assistance of agency staff, every two years as part of the program monitoring schedule.

The chart audits must evaluate the care provided to a variety of types of family planning clients. The following chart audit requirements are provided:

1. A minimum of ten (10) charts shall be audited and preferably more.
2. Charts are to be randomly selected from all clinic sites for clients served within the past 12 months.
3. Of the charts audited a minimum of the following charts are required:
    - Four (4) initial charts
    - Two (2) annual charts
    - Two (2) pregnancy test charts
    - Two (2) charts that required follow-up

Iowa Department of Public Health
Family Planning Chart Audit

Agency _____ Client Identification #_____

Reviewer(s) _____ Date _____

Basic Chart Requirements	Yes	No	N/A
Client financial data is kept separate from clinical record			
No-contact status is recorded on medical chart			
No-contact status is recorded in financial section			
Confidentiality Assurance Statement is evident			
"Services are voluntary" statement is evident			

Informed Consent	Yes	No	N/A
Consent to receive services, including confidentiality statement			
Consent is updated with major change in health status or change in method			

Assessment	Yes	No	N/A
Race and Ethnicity are collected according to OMB guidelines			
Personal and family history			
Blood Pressure			
Follow-up for hypertension documented			
Height and Weight			
Hct/Hgb if indicated			
Pap Smear if indicated			
Results in record			
Abnormal results evaluated			
Follow-up or referral completed			
Pelvic exam if indicated			
Gonorrhea testing as appropriate			
Chlamydia testing as appropriate			
Breast exam as appropriate			
HIV Risk Assessment			
Client sexual, personal, family & social history updated at revisits			

Education/Counseling	Yes	No	N/A
Information given on clinic procedures and service			
Education/counseling given on specific contraceptive method			
STI prevention			
HIV education and risks			
Individual counseling as indicated (nutrition, infertility, etc.)			
Preconception counseling provided			
Pregnancy intention is assessed at all visits. Reproductive Life Plan counseling is provided as appropriate.			

For Clients Under 18 Years Old	Yes	No	N/A
Counseling on reproductive decision making			
Confidentiality			
Abstinence			
Parental involvement counseling			
Resisting coercive sexual activity counseling			

Coordination of Services	Yes	No	N/A
Scheduled revisit			
Referral is documented			
Referral is followed-up			
Follow-up on missed appointments not routine			
Client informed about the importance of follow-up			
Revisit is based on clients need for education, counseling, clinical counseling			

Infertility Services (if applicable)	Yes	No	N/A
History			
Exam, lab test			
Counseling			
Referral			

Pregnancy Diagnosis Services (if applicable)	Yes	No	N/A
History			
Pregnancy test			
Referred for prenatal care			
Counseling for all options			
Prenatal health information			
Client counseled as to importance of receiving a physical assessment as soon as possible			
If ectopic pregnancy is suspected, immediate referral is provided.			

Signature and Date	Yes	No	N/A
Every entry signed, dated including telephone encounters of medical nature			

Strengths

Areas for Improvement

Plan for follow-up monitoring:

Program Review Tool (v4-2017) Clinical Only

8.1: Voluntary Participation

Section 8.1.1: Voluntary and Non-Coercive Services

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)).

Grantees should institutionalize administrative procedures (i.e., staff training, clinical protocols, and consent forms) to ensure clients receive services on a voluntary basis.

8.1.1 Link to QFP: Client-Centered Counseling

A core premise of Recommendations for Providing Quality Family Planning Services is that quality services are client-centered, which includes providing services on a voluntary basis. The key principles of providing quality, client-centered counseling include: 1) Establish and maintain rapport with the client, 2) Assess the client's needs and personalize discussions accordingly, 3) Work with the client interactively to establish a plan, 4) Provide information that can be understood and retained by the client, and 5) Confirm client understanding. These principles are useful when developing counseling protocols that ensure voluntary participation. (See Appendix C of QFP for additional detail.)

Observation of counseling process, including I&E material provided, at service sites demonstrates that the five principles of quality counseling are utilized when providing family planning services.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
C	Yes ☐	No ☐	1. Establish and maintain rapport with the client.	
C	Yes ☐	No ☐	2. Assess the client's needs and personalize discussions accordingly.	
C	Yes ☐	No ☐	3. Work with the client interactively to establish a plan.	
C	Yes ☐	No ☐	4. Provide information that can be understood and retained by the client.	
C	Yes ☐	No ☐	5. Confirm client understanding.	
C	Yes ☐	No ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

8.1.1 Quality Assessment Score:		
	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

Section 8.1.2: Acceptance of FP Services not a Prerequisite for Eligibility or Services
A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

Grantee should institutionalize administrative procedures (e.g., staff training, clinical protocols, and consent forms) to ensure clients' receipt of family planning services is not used as a prerequisite to receipt of other services from the service site.

C	☐	☐	Site A: ___ Site B: ___ Site C: ___	1. Medical record review demonstrates that each client has signed a general consent form stating receipt of family planning services is not a prerequisite to receipt of any other services offered.	some EMRS (FQHCs) have this in text boxes but need to be certain they all contain this language

Section 8.5.4: Clinical Leadership
Projects must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐		1. SR organization demonstrates evidence that the medical/clinical services operate under the direction of a physician.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. There is evidence (e.g., medical advisory committee, board, and staff meetings) indicating involvement of the Medical Director in program operations.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Curriculum vitae of the Medical Director indicates special training or experience in family planning.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. The Medical Director approves clinic protocols.	

9.6: Clinical Protocols and Standards of Care

All grantees should assure services provided within their project operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐		1. The SR has written clinical protocols aligned with nationally recognized standards of care and signed by the medical director or physician responsible for the service site	
C	☐	☐		2. Documentation exists that all SR service sites practice with current written clinical protocols that are aligned with nationally recognized standards of care (such as QFP) and signed by the medical director or physician responsible for the service sites.	

C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Medical records document that clinical services align with approved protocols.	

9.6 Link to QFP

Grantees should follow QFP, which defines "family planning" services (i.e., contraception, pregnancy testing and counseling, achieving pregnancy, basic infertility services, STD services, preconception health services), describes what services should be offered by family planning providers, and recommends how to provide those services by citing specific Federal and professional medical associations' recommendations for clinical care.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
C	**Yes** ☐	**No** ☐	1. Written clinical protocols include the full scope of family planning services as defined in QFP including contraception, pregnancy testing, and counseling, achieving pregnancy, basic infertility, STD, and preconception health services.	
C	**Yes** ☐	**No** ☐	2. Service sites have current clinical protocols (i.e., revised within the past 12 months) that reflect the most current version of Federal and professional medical associations' recommendations for each type of service, as cited in QFP.	
C	**Yes** ☐	**No** ☐	3. Documentation that clinical staff has participated in training on QFP (e.g., training available from the Title X National Training Centers).	
C	**Yes** ☐	**No** ☐	4. A review of medical records and/or observational assessment confirms that the recommended services are provided in a manner consistent with QFP including those identified in Tables 2 and 3 on pages 22-23.	
C	**Yes** ☐	**No** ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

9.6 Quality Assessment Score:	☐	**Exceptional** (All 4 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (2 – 3 Quality Indicators Evident)
	☐	**Fair** (1 Quality Indicator Evident)
	☐	0 Quality Indicators Evident

9.7: Provision of Family Planning and Related Services

All projects must provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)).

This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐		1. The SR has written policies and procedures for the provision of medical services related to family planning as indicated in this section.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Current written (i.e., updated within the past 12 months) clinical protocols clearly indicate that the following services will be offered to female, male and adolescent clients as appropriate: a broad range of contraceptives, pregnancy testing and counseling, services to assist with achieving pregnancy, basic infertility services, STD services, and preconception health services.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Breast and cervical cancer screening are available on-site and offered to female clients.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. Written collaborative agreements with relevant referral agencies exist where possible, including emergency care, HIV/AIDS care and treatment providers, infertility specialists, primary care and chronic care management providers.	Written agreements are very difficult to come by – concerns about payment
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	5. Medical records document that clients are provided referrals when medically indicated.	

9.8: Range of Family Planning Methods

All Projects must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents).

If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. (42 CFR 59.5(a)(1)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	1. Medical record reviews demonstrate that clients are provided a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents).	Will include abstinence if rules are implemented
C	☐	☐		2. Services provided by the SR provide a broad range of effective and medically appropriate methods and services.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. A review of the current stock of contraceptive methods demonstrates that a broad range of methods, including LARCs, are available onsite (optimally) or by referral.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. Clinic protocols state that the following services will be provided to female, male, and adolescent clients as appropriate: contraception, pregnancy testing and counseling, services for achieving pregnancy, basic infertility services, STD services, and preconception health services.	

9.8 Link to QFP

QFP notes the special needs of adolescent clients and recommends ways to address those needs, e.g., how to tailor contraceptive counseling for adolescents and ways to make services more youth-friendly.

QFP also notes the need to offer a broad range of contraceptive methods, and that this is an important part of providing client-centered care that respects the individual's choice. Projects should have a system in place to ensure continuous access to a broad range of FDA-approved contraceptive methods, optimally on-site.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
C	Yes ☐	No ☐	1. All services listed in QFP are offered to female and male clients, including adolescents as specified in clinical protocols.	
C	Yes ☐	No ☐	2. A review of clinic/pharmacy records demonstrates no stock-out of any contraceptive method that is routinely offered occurred during the past 6 months.	
C	Yes ☐	No ☐	3. Documentation that clinical staff has participated in training on QFP (e.g., training available from the Title X National Training Centers).	
			4. In administrative section.	
C	Yes ☐	No ☐	5. A review of medical records confirms that adolescents have been counseled about abstinence, the use of condoms and other contraceptive methods, including LARCs.	
A / C	Yes ☐	No ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

9.8 Quality Assessment Score:		
	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

9.10: Pregnancy Diagnosis and Counseling

Projects must provide pregnancy diagnosis and counseling to all clients in need of these services (42 CFR 59.5(a)(5)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐		1. The SR has a written policy requiring its sites and all sub-contractors to provide pregnancy diagnosis and counseling services to all clients in need of these services.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Clinic inventory and medical records review demonstrates that pregnancy testing and counseling is available and offered to all clients in need of these services	

9.10 Link to QFP

Projects should follow QFP, which describes how to provide pregnancy testing and counseling services, and cites the clinical recommendations of the relevant professional medical associations.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
C	**Yes** ☐	**No** ☐	1. Written clinical protocols regarding pregnancy testing and counseling are in accordance with the recommendations presented in QFP, including reproductive life planning discussions and medical histories that include any coexisting conditions.	
C	**Yes** ☐	**No** ☐	2. Chart review demonstrates that clients with a positive pregnancy test who wish to continue the pregnancy receive initial prenatal counseling and are assessed regarding their social support.	
C	**Yes** ☐	**No** ☐	3. Chart review demonstrates that clients with a negative pregnancy test who do not want to become pregnant are offered same day contraception, if appropriate.	
C	**Yes** ☐	**No** ☐	4. Staff have received training on pregnancy counseling recommendations presented in QFP at least once during employment.	
C	**Yes** ☐	**No** ☐	5. Observation and/or medical record review demonstrates counseling recommendations in accordance with the principles presented in QFP including reproductive life planning discussions.	
C	**Yes** ☐	**No** ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

9.10 Quality Assessment Score:	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)

	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

9.11: Pregnancy Counseling Options

Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- Prenatal care and delivery;
- Infant care, foster care, or adoption; and
- Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
C	☐	☐		1. The SR has written policies and procedures to offer options counseling to pregnant women.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	2. Written clinical protocols ensure that pregnant clients are offered neutral, factual information, and non-directive counseling about all three pregnancy options except for those options that the woman does not wish to receive information, and that referrals requested by the client are provided to her.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Medical records of pregnant clients document that clients were offered the opportunity to be provided with information and counseling about all three pregnancy options, except those for which the woman did not want to receive information and counseling.	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	4. Medical records of pregnant clients document that referrals were made as requested.	This may require edits if new rules are adopted.

9.12: Compliance with Legislative Mandates

Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

"Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

Reviewer Code	Met	Not Met	Sub-Recipient/ Service Site Score	Implementation Strategy	Comments
				1. In administrative section.	
				2. In administrative section	
C	☐	☐	Site A: ___ Site B: ___ Site C: ___	3. Medical records of minors document encouragement regarding family participation in their decision to seek family planning services and counseling on how to resist attempts to being coerced into engaging in sexual activities.	

13: Additional Administrative Requirements

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

13.1: Facilities and Accessibility of Services

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate based on disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR 84).

13.1 Link to QFP: Communication and Education

When developing written policies that meet these requirements, projects implement the recommendations presented in "Appendix E" of the QFP.

- Strategies that can make information more accessible for clients with Limited English Proficiency include:
- Presenting information in the client's primary language.
- Providing translation services.

Ensure that information is culturally appropriate and reflects the client's beliefs, ethnic background, and cultural practices.

Reviewer Code	Evidence of Quality Indicator in Place?		Quality Indicator	Comments
A	Yes ☐	No ☐	1. In administrative section	
C	Yes ☐	No ☐	2. Observation demonstrates that information is presented in a way that emphasizes essential points (e.g., limits the amount of information presented appropriately).	
C	Yes ☐	No ☐	3. Observation demonstrates information on risks and benefits is communicated in a way that is easily understood (e.g., using natural frequencies and common denominators).	
C	Yes ☐	No ☐	4. Information provided during counseling is culturally appropriate and reflects the client's beliefs, ethnic background, and cultural practices.	
A	Yes ☐	No ☐	5. In administrative section.	
A / C	Yes ☐	No ☐	+ Additional quality indicators, best practices, or highly innovative approaches	**If Yes, describe:**

13.1 Quality Assessment Score:		
	☐	**Exceptional** (All 5 Quality Indicators Evident + Best Practices In Place)
	☐	**Good** (3 – 5 Quality Indicators Evident)
	☐	**Fair** (1 – 2 Quality Indicators Evident)
	☐	0 Quality Indicators Evident

Iowa Department of Public Health
Family Planning
Title X Provider Review

Agency:_____ **Provider:**_____

Reviewer:_____ **Date:**_____

VISIT TYPE:

Initial **Annual** **Bi-Annual** **Special Management Problem** **Pregnancy Diagnosis**

INITIAL VISIT HISTORICAL DATA						
	Done	**Not Done**	**Incomplete**	**Not Applicable**	**Review Only**	**Comments**
Demographic Information						
Purpose of visit						
Any present illness						
Menstrual History						
Reproductive History Female						
Obstetric						
Gynecological						
STD's/risk assessment						
Genito-urinary surgery						
Reproductive History Male						
STD's/risk assessment						
Genito-urinary surgery						
trauma, masses, infection						
Fertility						
Contraceptive History						
Sexual History						
Medical History						
Surgical History						
Hospitalizations						
Mental Health History						
Social History						
Medication use including OTC meds						
Allergies						
Immunization History						
Family History						
Substance use including ETOH, Tobacco and Illicit Drugs						
Systems review including OC, IUD, injected progestins and barrier method specific						
Nutrition assessment						
Clinician reviews above if she/he did not obtain history						

PHYSICAL EXAM INITIAL VISIT *not required for the provision of contraceptives						
	Done	Not Done	Incomplete	Not Applicable	Review Only	Comments
1. Height/Weight						
2. Vital Signs						
3. HEENT*						
4. Thyroid*						
5. Cardiovascular *						
6. Pulmonary*						
7. Breasts*						
8. Abdomen*						
9. Pelvis if indicated, including						
a. inspection of external genitalia						
b. BUS						
c. speculum exam						
d. bimanual exam						
e. rectal exam*						
10. Male exam specific including, if indicated						
a. inspection of external genitalia						
b. rectal exam as indicated						
c. palpation of prostate						
d. self exam of testes taught and documented						
11. Extremities including signs of abuse*						
12. Lymph*						
13. IUD insertion						
14. Diaphragm fit						
15. Hormone implant insertion						
16. Laboratory Data as indicated						
a. Urinalysis and/or						
b. culture and sensitivity						
c. Hgb/Hct						
d. PAP						
e. Chlamydia						
f. GC						
g. Serology						
h. Rubella						
i. TB						
j. Pregnancy Test**Error! Bookmark not defined.**						
k. Wet Mount						
17. Blood glucose						
a. Cholesterol						
18. Provider uses proper technique obtaining specimens						
19. Provider uses proper technique during any procedure						
20. Other_____						

INTERNAL VISIT HISTORICAL DATA						
	Done	**Not Done**	**Incomplete**	**Not Applicable**	**Review Only**	**Comments**
Purpose of the visit						
Menstrual History Update						
Contraceptive History Update						
General and method specific						
Interval History Update,						
including systems review						
Mental Health History Update						
Sexual History Update						
PHYSICAL EXAM INTERVAL VISIT						
Weight						
Vital Signs						
Thyroid*						
Breasts*						
Abdomen*						
Extremities*						
IUD string check and/or insertion						
Diaphragm fit check and insertion technique						
Pelvis complete*						
Rectum*						
Laboratory Data as indicated						
Other areas as indicated by the interval history						
GENERAL						
Introduces self to client						
Systematic approach to history and physical						
Culturally sensitive						
Age appropriate						
Enough time allowed for client questions						
Care is individualized						
All procedures explained in advance						
Self Breast exam taught and documented as appropriate						
Laboratory results discussed/documented						
Client privacy and confidentiality are maintained						
Universal precautions						
Reproductive Life Plan Discussed						
Provider demonstrated empathy						
Counseling is client centered						
Provider uses time effectively						
Preventive health guidelines are discussed						
Provider follows the most current CDC recommendations on contraceptive safety						

DOCUMENTATION						
	Done	**Not Done**	**Incomplete**	**Not Applicable**	**Review Only**	**Comments**
Counseling/Education documented including:						
Reproductive life plan						
preconceptual where appropriate						
Pregnancy options where appropriate						
Reproductive decision making						
Adolescent counseling if under 18						
Method specific counseling						
Substance abuse, IPV, sexual coercion						
Informed consent						
STD prevention						
HIV education						
Coordination of Services documented including:						
Referral where indicated						
Follow-up appointment						
Record signed and dated						

Please provide comments on clinician efficiency and suggestions for improving clinician/clinic efficiency or flow.

Iowa Department of Public Health
Family Planning
Agency Administrative On-Site Review

Agency:_____**Agency Staff Consulted:**_____

Reviewer:_____**Date of Review:**_____

Date of last administrative review:_____

List any recommendations and requirements from previous administrative reviews that are still unmet:

_____

_____

_____

_____

Yes	No	N/A	
			I. Organizational Chart:
☐	☐	☐	A. Documents on file are consistent with current organizational structure.
☐	☐	☐	B. Actual lines of supervision are reflected.
☐	☐	☐	C. Agency has notified the Department, in writing, of required staff changes.
			II. Agency lines of Communication and/or Management:
☐	☐	☐	A. How often are agency staff meetings held? _____
☐	☐	☐	B. How are staff minutes dispersed to staff? _____
☐	☐	☐	C. How often are meetings with subcontractors held? _____
☐	☐	☐	D. How are subcontractor meeting minutes dispersed? _____
			III. Subcontractors:
☐	☐	☐	A. Agreements, contracts, and memoranda of understanding have been signed for current grant year prior to effective date. (Check against the Subcontracts form of Agency's application)
☐	☐	☐	B. Subcontracts are in compliance with Article 5 of the General Conditions dated October 1, 2009.
☐	☐	☐	C. For Subcontracts, the qualifications and responsibilities are stipulated in the contract, or with contracted providers, as required by Americans with Disabilities Act of 1990 (ADA).

IV. Licensure:

☐ ☐ ☐ A. Agency has on file verification of current licensure status of professional staff, including contracted staff.

V. OSHA Bloodborne Pathogens Standards:

☐ ☐ ☐ A. Agency exposure control plan meets all of the OSHA Bloodborne Pathogens Standards.

☐ ☐ ☐ B. Employees directly exposed to bloodborne pathogens signed the "Hepatitis B Immunization Consent/Refusal Form".

☐ ☐ ☐ C. Agency conducts training and education (at the time of hire and annually thereafter) concerning bloodborne pathogen exposure.

☐ ☐ ☐ D. Records of training are kept for at least three years.

VI. Personnel Policies:

☐ ☐ ☐ A. Conditions of employment include recruitment, selection, termination, promotion, and compensation (including fringe benefits)

☐ ☐ ☐ B. Leave and absence.

☐ ☐ ☐ C. Grievance procedure.

☐ ☐ ☐ D. Provision for career development or continuing education.

☐ ☐ ☐ E. Nondiscrimination policy, to be consistent with Title VI of the Civil Right Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans with Disabilities Act.

☐ ☐ ☐ F. Employee orientation program.

☐ ☐ ☐ G. Employee performance evaluation.

☐ ☐ ☐ H. Policies reviewed according to the agency policy and updated as needed.

VII. Employee/Personnel Files:

☐ ☐ ☐ A. Employee performance review in employee personnel files is in compliance with Employee Performance Evaluation Policy. (Randomly select a representative sample of MCH personnel files and all Family Planning files)

☐ ☐ ☐ B. Confidentiality of personnel records are ensured in what way(s)?

_____

Locked cabinet? Yes☐ No☐

VIII. Employment Application Form:

☐ ☐ ☐ A. Form is in compliance with civil rights regulations.

☐ ☐ ☐ B. Form includes a detachable demographic data sheet.

IX. Job Description:

☐ ☐ ☐ A. Every agency position in the budget has a written job description available.

☐ ☐ ☐ B. Job descriptions delineate qualifications and responsibilities.

☐ ☐ ☐ C. Job descriptions are dated and reflect current responsibilities.

☐ ☐ ☐ D. Job descriptions are updated regularly to delineate essential functions.

X. Salary Schedule:

☐ ☐ ☐ A. Salary schedule is current.

☐ ☐ ☐ B. Salaries for budgeted positions agree with this schedule.

XI. Civil Rights:

☐ ☐ ☐ A. Contractor is in compliance with Title VI of the Civil Rights Act, the Americans with Disabilities Act of 1990 (ADA) and Section 504 of the 1973 Rehabilitation Act.

☐ ☐ ☐ 1. Agency has appointed a Section 504/ADA coordinator:

_____

☐ ☐ ☐ 2. The section coordinator has taken recommended Civil Rights training.

☐ ☐ ☐ 3. Agency is prepared and willing to provide "reasonable accommodation" to an applicant or employee who requests it.

☐ ☐ ☐ 4. Service sites have been evaluated for handicapped accessibility and have written documentation. By whom:

_____

☐ ☐ ☐ B. The agency is in compliance with Affirmative Action requirements.

☐ ☐ ☐ 1. Agency has an Equal Employment/Affirmative Action (AA) officer:

_____

☐ ☐ ☐ 2. Agency has a current Affirmative Action policy and plan.

☐ ☐ ☐ 3. The plan analyzes and compares the agency's workforce to labor.

☐ ☐ ☐ 4. Areas of under-utilization are identified. Goals, objectives, action steps, and timetables have been developed to correct these under-utilizations and revised to reflect progress.

☐ ☐ ☐ 5. The AA plan is evaluated and updated at regularly specified intervals to reflect progress. At what intervals?: _____

XII. Inventory Control:

☐ ☐ ☐ A. The Department's computerized inventory reconciles with items on site.

XIII. Fiscal Policies and Control:

☐ ☐ ☐ A. The agency fiscal year covers the following time period: _____

☐ ☐ ☐ B. The agency tracks interest earned on advances.

☐ ☐ ☐ C. The agency remits such interest, at least quarterly, to the Department.

☐ ☐ ☐ D. A system to compare actual vs. budgeted expenditures is in place.

☐ ☐ ☐ E. Monthly reports of budgeted and actual expenditures are reviewed and approved.

☐ ☐ ☐ F. Allocating administrative and/or indirect costs charged to the program has a valid methodology.

☐ ☐ ☐ 1. Cost allocation plan is current.

☐ ☐ ☐ 2. Supporting documentation is available.

☐ ☐ ☐ 3. WIC and/or MCH funds pay for a vehicle lease arrangement.

☐ ☐ ☐ 4. The terms of the lease comply with federal policies.

☐ ☐ ☐ G. Agency personnel perform all accounting functions.

☐ ☐ ☐ H. MCH billing procedures for third party payers and other funding sources are in place.

☐ ☐ ☐ I. MCH and FP programs have a sliding fee scale.

☐ ☐ ☐ J. Patient bills show total cost of services and fees based on the sliding fee scale, as applicable.

☐ ☐ ☐ K. Sliding fee scale is applied after payment from other sources is received.

☐ ☐ ☐ L. The methodology for deferring fees meets program requirements.

XIV. Time Records:

☐ ☐ ☐ A. Continuous daily time studies are maintained.

☐ ☐ ☐ B. Time records allow reporting for more than one program.

☐ ☐ ☐ C. Time records accurately reflect total distribution of work time.

☐ ☐ ☐ D. Time studies and payroll records balance.

☐ ☐ ☐ E. All agency personnel keep time records.

☐ ☐ ☐ F. Time records are maintained, signed, and utilize a dual verification system.

_____

XV. Expenditures and Documentation:

☐ ☐ ☐ A. External, agency-wide audit is conducted annually.

☐ ☐ ☐ B. Date of last Department fiscal audit: _____

☐ ☐ ☐ C. Chart of accounts is current.

☐ ☐ ☐ D. Monthly expenditure reports are prepared, signed properly, and submitted to the Department.

☐ ☐ ☐ E. Expenditures are within contractual and budgeted parameters.

☐ ☐ ☐ F. Monthly expense reports and agency ledgers match.

☐ ☐ ☐ G. All prior approval budget revisions have been submitted to the Department.

XVI: Inventory Control

☐ ☐ ☐ A. WIC's infant formula sample inventory and/or issue log is maintained in a current and accurate manner.

☐ ☐ ☐ B. A specified person has been named as responsible for maintaining the log.

XVII. In the exit interview, recommendations and requirements from this review were orally presented to management staff of:

_____

_____

_____

Requirements

Recommendations

To assist with your planning for the On-Site Review, this listing of documents should be available during the review:

- Current table(s) of organization
- Administrate and personnel policies and procedures
- Verification of current licensure status of professional staff
- Current job descriptions for each budgeted position
- Current salary schedule
- Employee performance evaluation form
- Employment application form
- Time sheets/time studies
- Affirmative action plan
- Verification of compliance with OSHA bloodborne pathogens standards and the Americans with Disabilities Act of 1990
- Clinic site accessibility evaluation documentation
- Equipment inventory list and procedures
- Fiscal policies and procedures
- Fiscal records, chart of accounts, and support documentation
- Contract and budget file
- Vehicle lease agreement
- Contracts and agreements with other providers or agencies
- Rent leases/agreements and space cost allocation plan
- Cost allocation plan for shared costs
- MCH/FP sliding fee, billing, collection and bad debt policies
- Documentation of compliance with requirements of previous reviews.

Iowa Department of Public Health Family Planning Program Sub-Recipient Agency Medical Directors

ALLEN MEMORIAL HOSPITAL, WOMEN'S HEALTH DEPARTMENT
Bilal Kaaki, MD

NEW OPPORTUNITIES, INC.
Michelle Heim, DO

CRAWFORD COUNTY HOME HEALTH AGENCY
Roger A. Davidson, MD

NORTH IOWA COMMUNITY ACTION
Rebecca Jenkins, DO

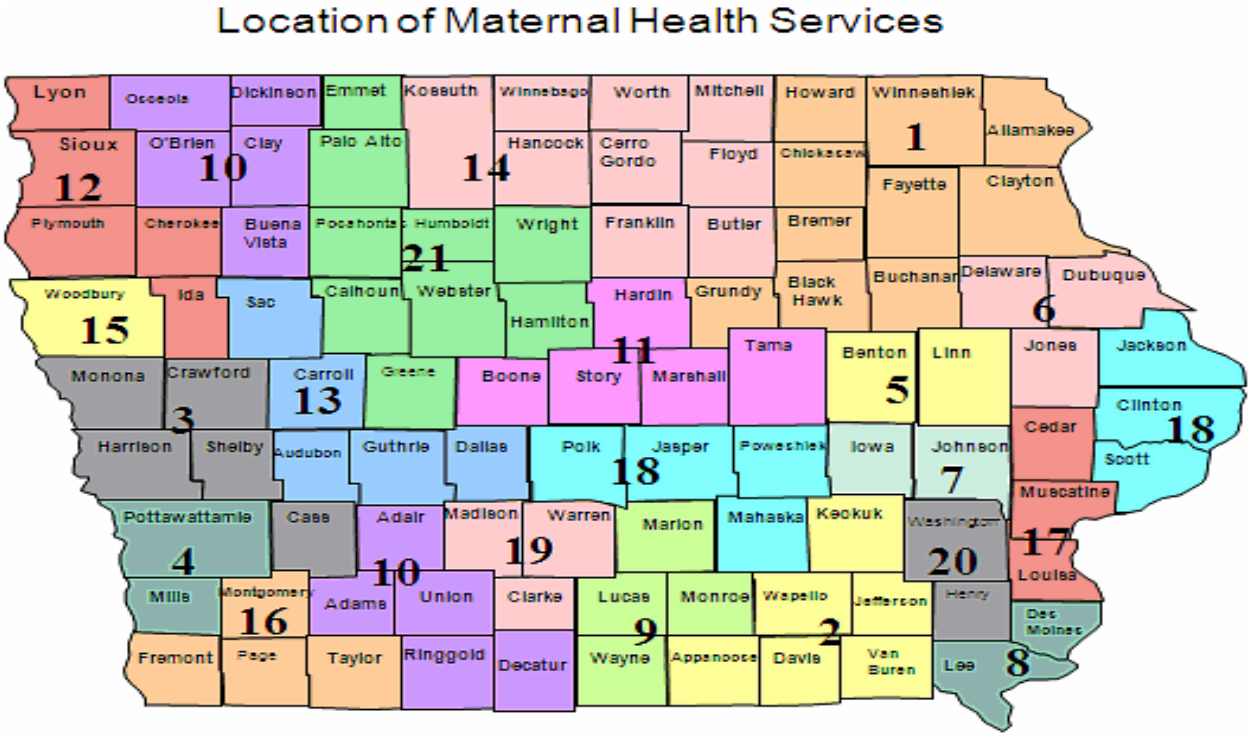
EASTERN IOWA HEALTH CENTER
Ursula Livermore, MD

RIVER HILLS COMMUNITY HEALTH CENTER
Ted Church, MD

PRIMARY HEALTH CARE, INC.
Heidi Shreck, MD

Iowa Department of Public Health
Family Planning Medical Advisory Committee
Member List

Name	Agency	Address	Email	Phone
James K Olson, MD	OB- Gyn Associates	855 A Ave. NE Cedar Rapids, Iowa	JKOlson@ob-gynassoc.com	319-368-5500
Erin Krull RN	North Iowa Comm. Action	100 1st Street NW Mason City, IA 50401	ekrull@nicao-online.org	641-423-5044 Ext. 33
Kim Fineran RN	Crawford County	1213 Garfield Avenue Harlan, IA 51537	hccmsdirector@frontiernet.net	712-263-3303
Jean Hoy, ARNP	Allen Women's Health	233 Vold Drive Waterloo, Iowa 50703	Jean.Hoy@Unitypoint.org	319-235-5098
Vickie Steffes, RN	Comm Opps/New Opps	23751 Hwy 30 PO Box 427 Carroll, IA 51401	vsteffes@newopp.org	712-792-9266 Ext 201
Pat Tucker, ARNP	River Hills Community Health Center	216 S. Market Street Ottumwa, IA 52501	ptucker@riverhillshealth.org	641-684-3013
Shawna Meyer, RN	Eastern Iowa Health Center	4251 River Center Ct. NE Cedar Rapids, IA 52302	smeyer@eihc.co	319-730-7300
Sara Kokke, CMA	Primary Health Care, Inc.	3509 E 29th Street Des Moines, Iowa 50317	skokke@phcinc.net	515-248-1600
Stephanie Trusty, RN	IDPH staff	321 East 12th Street Des Moines, IA 50319	stephanie.trusty@idph.iowa.gov	515-281-4731
Denise Wheeler, MS, ARNP	FP Coordinator IDPH	321 East 12th Street Des Moines, Iowa 50319	denise.wheeler@idph.iowa.gov	515-281-4907



Location of Maternal Health Services 2011

1. Allen Memorial Hospital
Women's Health Center
233 Vold Drive
Waterloo, IA 50703
(319) 235-5090

2. American Home Finding Association
123 East 3rd Suite 201
Ottumwa, IA 52501
(641) 682-8784 (800) 452-1098

3. Crawford County Home Health, Hospice, & PH
105 North Main Street
Denison, IA 51442
(712) 263-3303

4. Family Inc.
3501 Harry Langdon Blvd. Suite 150
Council Bluffs, IA 51503
(712) 256-9566

5. Hawkeye Area Community Action Program, Inc.
1515 Hawkeye Drive
Hiawatha, IA 52233
(319) 393-7811

6. Hillcrest Family Services
220 W. 7th Street
Dubuque, IA 52001
(563) 589-8595

7. Johnson County Public Health
855 South Dubuque Street, Suite 217
Iowa City, IA 52240
(319) 356-6040

8. Lee County Health Department
2218 Avenue H
Ft. Madison, IA 52627
(319) 372-5225 (800) 458-6672

9. Marion County Public Health
104 South Sixth Street; P.O. Box 152
Knoxville, IA 50138
(641) 828-2238

10. MATURA Action Corporation
203 West Adams Street
Creston, IA 50801
(641) 782-8431

11. Mid-Iowa Community Action, Inc.
1001 South 18th Avenue
Marshalltown, IA 50158
(641) 752-7162

12. Mid-Sioux Opportunity, Inc.
418 South Marion Street
Remsen, IA 51050
(712) 786-2001 (800) 859-2025

13. New Opportunities, Inc.
23751 Hwy 30, P.O. Box 427
Carroll, IA 51401
(712) 792-9266 (800) 642-6330

14. North Iowa Community Action Organization
100 1st Street NW; Suite 200
Mason City, IA 50401
(641) 423-5044 (800) 657-5856

15. Siouxland District Health Department
1014 Nebraska Street
Sioux City, IA 51105
(712) 279-6119 (800) 587-3005

16. Taylor County Public Health
405 Jefferson Street
Bedford, IA 50833
(712) 523-3405 (800) 425-0051

17. Trinity Muscatine Public Health
1609 Cedar Street
Muscatine, IA 52761
(563) 263-0122

18. Visiting Nurse Services of Iowa
1111 9th Street, Suite 320
Des Moines, IA 50314
(515) 288-1516

19. Warren County Health Services
301 North Buxton; Suite 203
Indianola, IA 50125
(515) 961-1074

20. Washington Co Public Health & Home Care
110 North Iowa Avenue, Suite 300
Washington, IA 52353
(319) 653-7758 (800) 655-7758

21. Webster County Health Department
330 1st Avenue North, Suite L-2
Fort Dodge, IA 50501
(515) 573-4107 (888) 289-3318

2-14-2011

CHAPTER 74
FAMILY PLANNING SERVICES

641—74.1(135) Program explanation.

The Iowa department of public health is a designated agency to operate the family planning program pursuant to an agreement with the federal government. Congress authorized grants to assist in the establishment and operation of family planning projects which offer a broad range of acceptable and effective family planning methods, including natural family planning, infertility services and services to adolescents. The majority of the funding available is from the Title X, family planning services grant, administered by the United States Department of Health and Human Services (DHHS). The purpose of the program is to promote the health of persons of reproductive age and families by providing access to family planning and reproductive health promotion services. The department, bureau of family health, enters into contracts with selected private and public agencies within the department family planning service area for the provision of family planning services. A description of the department family planning service area can be obtained from the Chief, Bureau of Family Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. The maternal and child health (MCH) advisory council assists in the development of the state plan for MCH, including children with special health care needs and family planning. The advisory council assists with the assessment of need, prioritization of services, establishment of objectives, and encouragement of public support for MCH and family planning programs. In addition, the advisory council advises the director regarding health and nutrition services for women and children supports the development of special projects and conferences and advocates for health and nutrition services for women and children. The director appoints the council membership. Membership shall include parents of and service providers for children with special health care needs. Council membership shall also include the chairs, or designees, of the department's advisory committee for perinatal guidelines and the birth defects advisory committee to ensure coordination of each committee's respective issues and priorities. The chair of the family services grantee committee or the designee of the chair may serve as an ex officio member of the council.

641—74.2(135) Adoption by reference.

Federal regulations found at 42 CFR Subpart A, Part 59, and the Program Guidelines for Project Grants for Family Planning Services shall be the regulations governing the Iowa family planning program and are incorporated by reference herein. Copies of the federal regulations adopted by reference are available from the Chief, Bureau of Family Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

641—74.3(135) Rule coverage.

These rules cover the agencies that have a contract with the department to provide family planning services and receive funds from the department for that purpose.

641—74.4(135) Definitions.

"Applicant" means a private nonprofit or public agency that seeks a contract with the department to provide family planning services and receives funds from the department for that purpose.

"Client" means an individual who receives family planning services through a contract agency.

"Contract agency or contractor" means a private nonprofit or public agency within the department family planning service area that has a contract with the department to provide family planning services and receives funds from the department for that purpose.

"Department" means the Iowa department of public health.

"DHHS" means the United States Department of Health and Human Services.

"DIA" means the Iowa department of inspections and appeals.

"Director" means the director of the Iowa department of public health.

"Family" means a group of two or more persons related by birth, marriage, or adoption or residing together. A pregnant woman is considered as two individuals when calculating the number of individuals in the family. If a pregnant woman is expecting multiple births, the family size is increased by the number expected in the multiple births.

"Family planning" means the promotion of reproductive and family health by the prevention of and planning for pregnancy, and reproductive health education.

"Health education" means services provided by a health professional to include teaching about normal anatomy and physiology, contraception, risk assessment, safety and injury prevention, signs or symptoms indicating need for medical care, and other anticipatory guidance topics.

"Health professional" means an individual who is licensed to provide health care or social services within their scope of practice.

"Health services" means services provided by family planning contract agencies.

"Medicaid" means the Medicaid program authorized by Title XIX of the Social Security Act and funded through the Iowa department of human services from DHHS.

"OMB" means the United States Department of the Treasury, Office of Management and Budget.

"Performance standards" means criteria or indicators of the quality of service provided or the capability of an agency to provide services in a cost-effective or efficient manner as defined in "Iowa Department of Public Health Family Planning Manual" and the federal regulations found at 42 CFR Subpart A, Part 59, and the Program Guidelines for Project Grants for Family Planning Services.

"Title X" means the federal requirements contained in 42 CFR Subpart A, Part 59, and the Program Guidelines for Project Grants for Family Planning Services.

"Title XX" means the combined federal and state dollars in the Social Services Block Grant allocated to pay for family planning services.

641—74.5(135) Grant application procedures for contract agencies.

Notification of the availability of funds and grant application procedures will be provided in accordance with the department rules found in 641—Chapter 176. Eligible applicants include only private nonprofit or public agencies. Private nonprofit or public agencies seeking to provide Title X family planning center services shall file a letter of intent to make application to the department no later than April 1 of the competitive year. The request for proposals shall identify the project period and the contract period. Contract agencies are selected on the basis of the grant applications submitted to the department. In the case of competing applications, the contract will be awarded to the applicant that scores the highest number of points in the review. Copies of review criteria are available from the Chief, Bureau of Family Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. All materials submitted as part of the grant application are considered public records in accordance with Iowa Code chapter 22, after a notice of award is made by the department.

641—74.6(135) Funding levels for contract agencies.

The amount of funds available to each contract agency on an annual basis shall be determined by the department using a methodology based upon dollars available, number of clients enrolled, and selected needs criteria.

641—74.7(135) Agency performance.

Contract agencies are required to provide services in accordance with these rules.

74.7(1) *Performance standards.* The department shall establish performance standards that contract agencies shall meet in the provision of public health services in addition to meeting all federal requirements. The performance standards for community-based agencies are published in the document "Iowa Department of Public Health Family Planning Manual." Copies of the performance standards are available from the Chief, Bureau of Family Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Contract agencies that do not meet the performance standards shall not be eligible for continued funding as a family planning agency unless the contract agency has secured an exception.

74.7(2) *Contract agency review.* The state agency shall review contract agency operations through use of reports and documents submitted, state-generated data reports, chart audits, on-site and clinic visits for evaluation and technical assistance.

74.7(3) *Exception.* An agency that does not meet a performance standard or fails to meet action plans as approved by the department may be granted an exception for up to one year in order to improve performance. Such an exception must be requested in writing. If granted, the approval for the exception will include the conditions necessary for the successful completion of the standard, a time frame, and additional reporting requirements. The procedures for applying for and approving an exception are outlined in the "Iowa Department of Public Health Family Planning Manual."

641—74.8(135) Reporting.

Contract agencies shall complete grant applications, a budget, expenditure reports, an annual progress report, a family planning annual report, and data forms in compliance with the terms of the contract.

641—74.9(135) Fiscal management.

All contract agencies are required to meet certain fiscal management policies.

74.9(1) *Last pay.* Family planning grant funds are considered last pay. Title XIX, Title XX and other third parties are to be billed first if the client is covered by those sources.

74.9(2) *Program income.* Program income means gross income earned by the contractor from activities in which part or all of the cost is either borne as a direct cost by a grant or counted as a direct cost toward providing services. It includes but is not limited to such income in the form of Title XIX and Title XX fees for services, third-party reimbursements, client fees, and proceeds from sales of tangible personal or real property. Program income shall be used for allowable costs of the project. Program income shall be used prior to the use of funds received from the department. Excess program income may be retained to establish a three-month operating capital. Program income shall be used during the current fiscal year or the following fiscal year. Five percent of unobligated program income may be used by the contract agency

For special purposes or projects provided such use furthers the mission of the family planning program and does not violate state rules or federal regulations governing the program.

74.9(3) *Advances.* A contract agency may request an advance up to one-sixth of its contract at the beginning of a contract year. The amount of any advance shall be deducted prior to the end of the fiscal year.

74.9(4) *Subcontracts.* Contract agencies may subcontract a portion of the project activity to another entity provided such subcontract is approved by the department. Subcontract agencies must follow the same rules, procedures, and policies as required of the contract agency by these rules and contract with the department. The contract agency is responsible for ensuring the compliance of the subcontract agency. Subcontract agencies may not subcontract these project activities with other entities.

641—74.10(135) Audits.

Every two years, each contract agency shall undergo financial audit of the family planning program. The audit shall be conducted in compliance with OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations. Each audit shall cover all unaudited periods through the end of the previous grant year. The department's audit guide should be followed to ensure an audit, which meets federal and state requirements.

641—74.11(135) Denial, suspension, revocation, or reduction of contracts with contract agencies.

The department may deny, suspend, revoke, or reduce contracts with contract agencies in accord with applicable federal regulations or contractual relationships. Notice of such action shall be in writing.

641—74.12(135) Right to appeal—contract agency.

Contract agencies may appeal denial of a contract or the suspension, revocation or reduction of an existing contract.

74.12(1) *Appeal.* The appeal shall be made in writing to the department within ten days of receipt of notification of the adverse action. Notice is to be addressed to the Director, Division of Community Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

74.12(2) *Contested case.* Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the DIA pursuant to the rules adopted by the DIA regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the DIA.

74.12(3) *Hearing.* Parties shall receive notice of the hearing in advance. The administrative law Judge shall schedule the time, place and date of the hearing so that the hearing is held as expeditiously as possible. The hearing shall be conducted according to the procedural rules of the DIA found in 481—Chapter 10, Iowa Administrative Code.

74.12(4) *Decision of administrative law judge.* The administrative law judge's decision shall be issued within 60 days from the date of request for hearing. When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final decision without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 76.17(5).

74.12(5) *Appeal to the director.* Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

74.12 (6) *Record of hearing.* Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

74.12(7) *Decision of director.* An appeal to the director shall be based on the record made at the hearing. The decision and order of the director becomes the department's final decision upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

74.12(8) *Exhausting administrative remedies.* It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final decision of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A. Petition for judicial review must be filed within 30 days after decision becomes final.

These rules are intended to implement Iowa Code section 135.11.

[Filed 6/14/83, Notice 4/27/83—published 7/6/83, effective 8/10/83]
[Filed emergency 7/1/86—published 7/16/86, effective 7/1/86]*
[Filed emergency 9/19/86—published 10/8/86, effective 9/19/86]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 1/11/96, Notice 11/8/95—published 1/31/96, effective 3/6/96]
[Filed 7/18/02, Notice 5/29/02—published 8/7/02, effective 9/11/02]
*See IAB, Inspections and Appeals Department.

CHAPTER 7

ADVANCED REGISTERED NURSE PRACTITIONERS

[Prior to 8/26/87, Nursing Board [590] Ch 7]

655—7.1 (152) Definitions.

"Advanced registered nurse practitioner (ARNP)" means a nurse with current licensure as a registered nurse in Iowa or who is licensed in another state and recognized for licensure in this state pursuant to the nurse licensure compact contained in 2000 Iowa Acts, House File 2105, section 8, and is also registered in Iowa to practice in an advanced role. The ARNP is prepared for an advanced role by virtue of additional knowledge and skills gained through a formal advanced practice education program of nursing in a specialty area approved by the board. In the advanced role, the nurse practices nursing assessment, intervention, and management within the boundaries of the nurse-client relationship. Advanced nursing practice occurs in a variety of settings, within an interdisciplinary health care team, which provide for consultation, collaborative management, or referral. The ARNP may perform selected medically delegated functions when a collaborative practice agreement exists.

"Basic nursing education" as used in this chapter is a nursing program that prepares a person for initial licensure to practice nursing as a registered nurse.

"Board" as used in this chapter means Iowa board of nursing.

"Certified clinical nurse specialist" is an ARNP prepared at the master's level who possesses evidence of current advanced level certification as a clinical specialist in an area of nursing practice by a national professional nursing certifying body as approved by the board.

"Certified nurse-midwife" is an ARNP educated in the disciplines of nursing and midwifery who possesses evidence of current advanced level certification by a national professional nursing certifying body approved by the board. The certified nurse-midwife is authorized to manage the care of normal newborns and women, antepartally, intrapartally, postpartally or gynecologically.

"Certified nurse practitioner" is an ARNP educated in the disciplines of nursing who has advanced knowledge of nursing, physical and psychosocial assessment, appropriate interventions, and management of health care, and who possesses evidence of current certification by a national professional nursing certifying body approved by the board.

"Certified registered nurse anesthetist" is an ARNP educated in the disciplines of nursing and anesthesia who possesses evidence of current advanced level certification or recertification, as applicable, by a national professional nursing certifying body approved by the board.

"Collaboration" is the process whereby an ARNP and physician jointly manage the care of a client.

"Collaborative practice agreement" means an ARNP and physician practicing together within the framework of their respective professional scopes of practice. This collaborative agreement reflects both independent and cooperative decision making and is based on the preparation and ability of each practitioner.

"Consultation" is the process whereby an ARNP seeks the advice or opinion of a physician, pharmacist, or another member of the health care team. ARNPs practicing in a noninstitutional setting as sole practitioners, or in small clinical practice groups, shall regularly consult with a licensed physician or pharmacist regarding the distribution, storage, and appropriate use of controlled substances.

"Controlled substance" is a drug, substance, or immediate precursor in Schedules I through V of **division II,**

655—7.2(152) General requirements for the advanced registered nurse practitioner.

7.2(1) *Specialty areas of nursing practice for the advanced registered nurse practitioner.* The board derives its authority to define the educational and clinical experience that is necessary to practice at an advanced registered nurse practitioner level under the provisions of Iowa Code section 152.1(6)*"d."*
The specialty areas of nursing practice for the advanced registered nurse practitioner which shall be considered as legally authorized by the board are as follows:
a. Certified clinical nurse specialist.
b. Certified nurse-midwife.
c. Certified nurse practitioner.
d. Certified registered nurse anesthetist.
7.2(2) *Supervision of fluoroscopy.* An advanced registered nurse practitioner (ARNP) shall be permitted to provide direct supervision in the use of fluoroscopic X-ray equipment, pursuant to 641—subrule 42.1(2), definition of "supervision."
a. The ARNP shall provide direct supervision of fluoroscopy pursuant to the following provisions:
(1) Completion of an educational course including content in radiation physics, radiobiology, radiological safety and radiation management applicable to the use of fluoroscopy, and maintenance of documentation verifying successful completion.
(2) Collaboration, as needed, as defined in rule 655—7.1(152).
(3) Compliance with facility policies and procedures.
b. The ARNP shall complete an annual radiological safety course whose content includes, but is not limited to, time, dose, distance, shielding and the effects of radiation.
c. The ARNP shall maintain documentation of the initial educational course and all annual radiological safety updates.
d. The initial and annual education requirements are subject to audit by the board pursuant to 655—subrule 5.2(5).

7.2(3) *Titles and abbreviations.* A registered nurse who has completed all requirements to practice as an advanced registered nurse practitioner and who is registered with the board to practice shall use the title advanced registered nurse practitioner (ARNP). Utilization of the title which denotes the specialty area is at the discretion of the advanced registered nurse practitioner.
a. No person shall practice or advertise as or use the title of advanced registered nurse practitioner for any of the defined specialty areas unless the name, title and specialty area appear on the official record of the board and on the current license.
b. No person shall use the abbreviation ARNP for any of the defined specialty areas or any other words, letters, signs or figures to indicate that the person is an advanced registered nurse practitioner unless the name, title and specialty area appears on the official record of the board and on the current license.
c. Any person found to be practicing under the title of advanced registered nurse practitioner or using the abbreviation ARNP without being registered as defined in this subrule shall be subject to disciplinary action.

7.2(4) *General education and clinical requirements.*
a. The general educational and clinical requirements necessary for recognition by the board as a specialty area of nursing practice are as follows:
(1) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills as approved by the board; or
(2) Satisfactory completion of a formal advanced practice educational program of study in a

nursing specialty area approved by the board and appropriate clinical experience as approved by the board.
b. Additional requirements. Nothing in this rule shall be construed to mean that additional general educational or clinical requirements cannot be defined in a specialty area.

7.2(5) *Application process.* A registered nurse who wishes to practice as an advanced registered nurse practitioner shall submit the following to the office of the board:
a. An advanced registered nurse practitioner application form which may be obtained from the office of the board.
b. A registration fee as established by the board.
c. A copy of the time-dated, advanced level certification by appropriate national certifying body evidencing that the applicant holds current certification in good standing; copy of official transcript directly from the formal advanced practice educational program maintaining the records necessary to document that all requirements have been met in one of the specialty areas of nursing practice as listed in subrule 7.2(1). The transcript shall verify the date of completion of the program/graduation and the degree conferred. A registered nurse may make application to practice in more than one specialty area of nursing practice.

7.2(6) *Initial registration.* The executive director or a designee shall have the authority to determine if all requirements have been met for registration as an advanced registered nurse practitioner. If it has been determined that all requirements have been met:
a. Official licensure records of the registered nurse shall denote registration as an advanced registered nurse practitioner as well as the specialty area(s) of nursing practice.
b. The registered nurse shall be issued a registration card and a certificate to practice as an ARNP which clearly denotes the name, title, specialty area(s) of nursing practice, and expiration date of registration. The expiration date shall be based on the same period of licensure to practice as a registered nurse.

7.2(7) *Registration completion.* The registered nurse shall complete the registration process within 12 months of receipt of the application materials. The board reserves the right to destroy the documents after 12 months.

7.2(8) *Denial of registration.* If it has been determined that all requirements have not been met, the registered nurse shall be notified in writing of the reason(s) for the decision. The applicant shall have the right of appeal to the Iowa board of nursing within 30 days of denial by the executive director or designee.

7.2(9) *Application process for renewal of registration.* Renewal of registration for the advanced registered nurse practitioner shall be for the same period of licensure to practice as a registered nurse. The executive director or a designee shall have the authority to determine if all requirements have been met for renewal as an advanced registered nurse practitioner. A registered nurse who wishes to continue practice as an advanced registered nurse practitioner shall submit the following at least 30 days prior to the license expiration to the office of the Iowa board of nursing:
a. Completed renewal application form.
b. Renewal fee as outlined in rule 655—3.1(17A,147,152,272C), definition of “fees.”
c. Documentation of current time-dated, advanced level certification by appropriate national certifying body.

7.2(10) *Continuing education requirements.* Continuing education shall be met as required for certification by the relevant national certifying body, as outlined in 655—subrule 5.2(3), paragraph *“e.”*

7.2(11) *Denial of renewal registration.* If it has been determined that all requirements have not

been met, the applicant shall be notified in writing of the reason(s) for the decision. Failure to obtain the renewal will result in termination of registration and of the right to practice in the advanced registered nurse practitioner specialty area(s). The applicant shall have the right of appeal to the Iowa board of nursing within 30 days of denial of the executive director or designee.

7.2(12) *Registration to practice as an advanced registered nurse practitioner restricted, revoked, or suspended.* Rescinded IAB 12/29/99, effective 2/2/00.

[**ARC 7888B**, IAB 7/1/09, effective 8/5/09]

CHAPTER 152 NURSING

Enforcement, §147.87, 147.90, 147.92 Penalty, §147.86 Examining board, support staff exception; location and powers; see § 135.11A, 135.31 Utilization and cost control review committee; § 514F.1 Authority of advanced registered nurse practitioner to prescribe drugs; limitations; see § 147.107

"Accountability" means being obligated to answer for one's acts, including the act of supervision.
"Advanced registered nurse practitioner (ARNP)" means a nurse with current licensure as a registered nurse in Iowa or who is licensed in another state and recognized for licensure in this state pursuant to the nurse licensure compact contained in 2000 Iowa Acts, House File 2105, section 8, and is also registered in Iowa to practice in an advanced role. The ARNP is prepared for an advanced role by virtue of additional knowledge and skills gained through a formal advanced practice education program of nursing in a specialty area approved by the board. In the advanced role, the nurse practices nursing assessment, intervention, and management within the boundaries of the nurse-client relationship.
Advanced nursing practice occurs in a variety of settings, within an interdisciplinary health care team, which provide for consultation, collaborative management, or referral. The ARNP may perform selected medically delegated functions when a collaborative practice agreement exists.
"Basic nursing education" means a nursing program preparing a person for initial licensure to practice nursing as a registered nurse or licensed practical nurse.
"Board" as used in this chapter means the Iowa board of nursing.
"Certified clinical nurse specialist" means an ARNP prepared at the master's level who possesses evidence of current certification as a clinical specialist in an area of nursing practice by a national professional nursing association as approved by the board.
"Certified nurse-midwife" means an ARNP educated in the disciplines of nursing and midwifery who possesses evidence of current certification by a national professional nursing association approved by the board. The certified nurse-midwife is authorized to manage the care of normal newborns and women, antepartally, intrapartally, postpartally or gynecologically.
"Certified nurse practitioner" means an ARNP educated in the disciplines of nursing who has advanced knowledge of nursing, physical and psychosocial assessment, appropriate interventions, and management of health care, and who possesses evidence of current certification by a national professional nursing association approved by the board.
"Certified registered nurse anesthetist" means an ARNP educated in the disciplines of nursing and anesthesia who possesses evidence of current certification by a national professional nursing association approved by the board.
"Competence in nursing" means having the knowledge and the ability to perform, skillfully and proficiently, the functions within the role of the licensed nurse.
"Expanded intravenous therapy certification course" means the Iowa board of nursing course required for licensed practical nurses to perform procedures related to the expanded scope of practice of intravenous therapy.
"Midline catheter" means a long peripheral catheter in which the distal end resides in the mid to upper arm, but the tip terminates no further than the axilla.
"Minimum standards" means standards of practice that interpret the legal definition of nursing as well as provide criteria against which violations of the law can be determined.
"Nursing diagnosis" means a judgment made by a registered nurse, following a nursing assessment of individuals and groups about actual or potential responses to health problems, which forms the basis for determining effective nursing interventions.
"Nursing facility" means an institution as defined in Iowa Code chapter 135C. This definition does not include acute care settings.
"Nursing process" means ongoing assessment, nursing diagnosis, planning, intervention, and evaluation.

"Peripheral intravenous catheter" means a catheter three inches or less in length.
"Peripherally inserted central catheter" means a soft flexible central venous catheter inserted into an extremity and advanced until the tip is positioned in the vena cava.
"Proximate area" means that the registered nurse analyzes the qualifications of the licensed practical nurse in relationship to nursing needs of the client in determining the appropriate distance within the building and the time necessary to be readily available to the licensed practical nurse.
"Unlicensed assistive personnel" is an individual who is trained to function in an assistive role to the registered nurse and licensed practical nurse in the provision of nursing care activities as delegated by the registered nurse or licensed practical nurse.
This rule is intended to implement Iowa Code chapter 152.

655—6.2 (152) Minimum standards of nursing practice for registered nurses.
6.2(1) The registered nurse shall recognize and understand the legal implications within the scope of nursing practice. The scope of nursing practice considered to be minimum standards of nursing practice shall not be interpreted to include those practices currently ascribed to the advanced registered nurse practitioner.
6.2(2) The registered nurse shall utilize the nursing process in the practice of nursing, consistent with accepted and prevailing practice. The nursing process is ongoing and includes:
a. Nursing assessments about the health status of an individual or group.
b. Formulation of a nursing diagnosis based on analysis of the data from the nursing assessment.
c. Planning of nursing care which includes determining goals and priorities for actions which are based on the nursing diagnosis.
d. Nursing interventions implementing the plan of care.
e. Evaluation of the individual's or group's status in relation to established goals and the plan of care.
6.2(3) The registered nurse shall conduct nursing practice by respecting the rights of an individual or group.
6.2(4) The registered nurse shall conduct nursing practice by respecting the confidentiality of an individual or group, unless obligated to disclose under proper authorization or legal compulsion.
6.2(5) The registered nurse shall recognize and understand the legal implications of accountability. Accountability includes but need not be limited to the following:
a. Performing or supervising those activities and functions which require the knowledge and skill level currently ascribed to the registered nurse and seeking assistance when activities and functions are beyond the licensee's scope of preparation.
b. Assigning and supervising persons performing those activities and functions which do not require the knowledge and skill level currently ascribed to the registered nurse.
c. Using professional judgment in assigning and delegating activities and functions to unlicensed assistive personnel. Activities and functions which are beyond the scope of practice of the licensed practical nurse may not be delegated to unlicensed assistive personnel. For the purposes of this paragraph, "unlicensed assistive personnel" does not include certified emergency medical services personnel authorized under Iowa Code chapter 147A performing nonlifesaving procedures for which those individuals have been certified and which are designated in a written job description, after the patient is observed by a registered nurse.
d. Supervising, among other things, includes any or all of the following:
(1) Direct observation of a function or activity.
(2) Assumption of overall responsibility for assessing, planning, implementing, and evaluating nursing care.
(3) Delegation of nursing tasks while retaining accountability.
(4) Determination that nursing care being provided is adequate and delivered appropriately.
e. Executing the regimen prescribed by a physician. In executing the medical regimen as prescribed by the physician, the registered nurse shall exercise professional judgment in accordance

with minimum standards of nursing practice as defined in these rules. If the medical regimen prescribed by the physician is not carried out, based on the registered nurse's professional judgment, accountability shall include but need not be limited to the following:
(1) Timely notification of the physician who prescribed the medical regimen that the order(s) was not executed and reason(s) for same.
(2) Documentation on the medical record that the physician was notified and reason(s) for not executing the order(s).
Ch 6, p.2 IAC
f. Wearing identification which clearly identifies the nurse as a registered nurse when providing direct patient care unless wearing identification creates a safety or health risk for either the nurse or the patient.

655—6.3 (152) Minimum standards of practice for licensed practical nurses.
6.3(1) The licensed practical nurse shall recognize and understand the legal implications within the scope of nursing practice. The licensed practical nurse shall perform services in the provision of supportive or restorative care under the supervision of a registered nurse or physician as defined in the Iowa Code.
6.3(2) The licensed practical nurse shall participate in the nursing process, consistent with accepted and prevailing practice, by assisting the registered nurse or physician. The licensed practical nurse may assist the registered nurse in monitoring, observing and reporting reactions to therapy.
6.3(3) The licensed practical nurse shall not perform any activity requiring the knowledge and skill ascribed to the registered nurse, including:
a. The initiation of or assessment related to procedures/therapies requiring the knowledge or skill level ascribed to the registered nurse.
b. The initiation of intravenous solutions, intravenous medications and blood components.
c. The administration of medicated intravenous solutions, intravenous medications and blood components.
d. The initiation or administration of medications requiring the knowledge or skill level currently ascribed to the registered nurse.
6.3(4) A licensed practical nurse, under the supervision of a registered nurse, may engage in the limited scope of practice of intravenous therapy. The licensed practical nurse shall be educated and have documentation of competency in the limited scope of practice of intravenous therapy. Limited scope of practice of intravenous therapy may include:
a. Addition of intravenous solutions without adding medications to established peripheral intravenous sites.
b. Regulation of the rate of nonmedicated intravenous solutions to established peripheral intravenous sites.
c. Administration of maintenance doses of analgesics via the patient-controlled analgesia pump set at a lock-out interval to established peripheral intravenous sites.
d. Discontinuation of peripheral intravenous therapy.
e. Administration of a prefilled heparin or saline syringe flush, prepackaged by the manufacturer or premixed and labeled by a registered pharmacist or registered nurse, to an established peripheral lock, in a licensed hospital, a nursing facility or a certified end-stage renal dialysis unit.
6.3(5) When nursing tasks are delegated by the registered nurse to the licensed practical nurse in a certified end-stage renal dialysis unit, the facility must have a written policy that defines the practice and written verification of the education and competency of the licensed practical nurse in accordance with the facility's written policy. Nursing tasks which may be delegated to the licensed practical nurse for the sole purpose of hemodialysis treatment include:
a. Initiation and discontinuation of the hemodialysis treatment utilizing any of the following established vascular accesses: central line catheter, arteriovenous fistula, graft.
b. Administration, during hemodialysis treatment, of local anesthetic prior to cannulation of the vascular access site.

c. Administration of prescribed dosages of heparin solution or saline solution utilized in the initiation and discontinuation of hemodialysis.
d. Administration, during hemodialysis treatment via the extracorporeal circuit, of the routine intravenous medications erythropoietin, Vitamin D Analog, intravenous antibiotic solutions prepackaged by the manufacturer or premixed and labeled by a registered pharmacist or registered nurse, and iron, excluding any iron preparation that requires a test dose. The registered nurse shall administer the first dose of erythopoietin, Vitamin D Analog, antibiotics, and iron.
6.3(6) The licensed practical nurse may provide nursing care in an acute care setting. When the nursing care provided by the licensed practical nurse in an acute care setting requires the knowledge and skill level currently ascribed to the registered nurse, a registered nurse or physician must be present in the proximate area. Acute care settings requiring the knowledge and skill ascribed to the registered nurse include, but are not limited to:
a. Units where care of the unstable, critically ill, or critically injured individual is provided.
b. General medical-surgical units.
c. Emergency departments.
d. Operating rooms. (A licensed practical nurse may assist with circulating duties when supervised by a registered nurse circulating in the same room.)
e. Postanesthesia recovery units.
f. Hemodialysis units.
g. Labor and delivery/birthing units.
h. Mental health units.
6.3(7) The licensed practical nurse may provide nursing care in a non-acute care setting. When the nursing care provided by the licensed practical nurse in a non-acute care setting requires the knowledge and skill level currently ascribed to the registered nurse, the registered nurse or physician must be present in the proximate area. The non-acute care settings requiring the knowledge and skill level ascribed to the registered nurse include, but are not limited to:
a. Community health. (Subrules 6.6(1) and 6.6(4) are exceptions to the “proximate area” requirement.)
b. School nursing. (Subrules 6.6(2) and 6.6(3) are exceptions to the “proximate area” requirement.)
c. Occupational nursing.
d. Correctional facilities.
e. Community mental health nursing.
6.3(8) The licensed practical nurse shall conduct nursing practice by respecting the rights of an individual or group.
6.3(9) The licensed practical nurse shall conduct nursing practice by respecting the confidentiality of an individual or group, unless obligated to disclose under proper authorization or legal compulsion.
6.3(10) The licensed practical nurse shall recognize and understand the legal implications of accountability. Accountability includes but need not be limited to the following:
a. Performing those activities and functions which require the knowledge and skill level currently ascribed to the licensed practical nurse and seeking assistance when activities and functions are beyond the licensee’s scope of preparation.
b. Accepting responsibility for performing assigned and delegated functions and informing the registered nurse when assigned and delegated functions are not executed.
c. Executing the medical regimen prescribed by a physician. In executing the medical regimen as prescribed by the physician, the licensed practical nurse shall exercise prudent judgment in accordance with minimum standards of nursing practice as defined in these rules. If the medical regimen prescribed by the physician is not carried out based on the licensed practical nurse’s prudent judgment, accountability shall include but need not be limited to the following:
(1) Timely notification of the physician who prescribed the medical regimen that said order(s) was not executed and reason(s) for same.

(2) Documentation on the medical record that the physician was notified and reason(s) for not executing the order(s).
d. Wearing identification which clearly identifies the nurse as a licensed practical nurse when providing direct patient care unless wearing identification creates a safety or health risk for either the nurse or the patient.
This rule is intended to implement Iowa Code chapters 152 and 152E.

655—6.4(152) Additional acts which may be performed by registered nurses.
6.4(1) A registered nurse shall be permitted to practice as a diagnostic radiographer while under the supervision of a licensed practitioner provided that appropriate training standards for use of radiation-emitting equipment are met as outlined in 641—42.1(136C).
6.4(2) A registered nurse, licensed pursuant to Iowa Code chapter 152, may staff an authorized ambulance, rescue, or first response service provided the registered nurse can document equivalency through education and additional skills training essential in the delivery of out-of-hospital emergency care. The equivalency shall be accepted when documentation has been reviewed and approved at the local level by the medical director of the ambulance, rescue, or first response service in accordance with the form adopted by the Iowa department of public health bureau of emergency medical services. An exception to this subrule is the registered nurse who accompanies and is responsible for a transfer patient.
This rule is intended to implement Iowa Code section 147A.12 and chapters 136C and 152.
655—6.5 (152) Additional acts which may be performed by licensed practical nurses.
6.5(1) A licensed practical nurse shall be permitted to supervise unlicensed assistive personnel under the provisions of Iowa Code section 152.1(4)*"b."*
a. Supervision, among other things, includes any or all of the following:
(1) Direct observation of a function or activity.
(2) Delegation of nursing tasks while retaining accountability.
(3) Determination that nursing care being provided is adequate and delivered appropriately.
b. Supervision shall be in accordance with the following:
(1) A licensed practical nurse working under the supervision of a registered nurse shall be permitted to supervise in an intermediate care facility for the mentally retarded or in a residential health care setting.
(2) A licensed practical nurse working under the supervision of a registered nurse shall be permitted to supervise in a nursing facility.
The licensed practical nurse shall be required to complete a curriculum which has been approved by the board and designed specifically for the supervision role of the licensed practical nurse in a nursing facility. The course must be presented by a board-approved nursing program or an approved provider of continuing education. Documentation of the completion of the curriculum as outlined in this subparagraph shall be maintained by the licensed practical nurse.
(3) A licensed practical nurse shall be entitled to supervise without the educational requirement outlined in subparagraph 6.5(1)*"b"*(2) if the licensed practical nurse was performing in a supervisory role on or before October 6, 1982. The licensed practical nurse being employed in a supervisory role after the enactment of these rules shall complete the curriculum outlined in subparagraph 6.5(1)*"b"*(2) within six months of employment.
(4) A licensed practical nurse working under the supervision of a registered nurse may direct the activities of other licensed practical nurses and unlicensed assistive personnel in an acute care setting in giving care to individuals assigned to the licensed practical nurse. The registered nurse must be in the proximate area.
6.5(2) A licensed practical nurse shall be permitted to practice as a diagnostic radiographer while under the supervision of a licensed practitioner provided that appropriate training standards for use of radiation-emitting equipment are met as outlined in 641—42.1(136C).
6.5(3) A licensed practical nurse shall be permitted to perform, in addition to the functions set

forth in subrule 6.3(4), procedures related to the expanded scope of practice of intravenous therapy upon completion of the board-approved expanded intravenous therapy certification course.
6.5(4) To be eligible to enroll in the course, the licensed practical nurse shall:
a. Hold a current unrestricted Iowa license or an unrestricted license in another state recognized for licensure in this state pursuant to the nurse licensure compact contained in Iowa Code chapter 152E.
b. Have documentation of 1040 hours of practice as a licensed practical nurse.
c. Be practicing in a licensed hospital, a nursing facility or a certified end-stage renal dialysis unit whose policies allow the licensed practical nurse to perform procedures related to the expanded scope of practice of intravenous therapy.
6.5(5) The course must be offered by an approved Iowa board of nursing provider of nursing continuing education. Documentation of course completion shall be maintained by the licensed practical nurse and employer.
6.5(6) The board-approved course shall incorporate the responsibilities of the licensed practical nurse when providing intravenous therapy via a peripheral intravenous catheter, a midline catheter and a peripherally inserted central catheter (PICC) to children, adults and elderly adults. When providing intravenous therapy, the LPN shall be under the supervision of a registered nurse. Procedures which may be performed if delegated by the registered nurse are as follows:
a. Initiation of a peripheral intravenous catheter for continuous or intermittent therapy using a catheter not to exceed three inches in length.
b. Administration, via a peripheral intravenous catheter, midline catheter, and a PICC line, of premixed electrolyte solutions or premixed vitamin solutions. The first dose shall be administered by the registered nurse. The solutions must be prepackaged by the manufacturer or premixed and labeled by a registered pharmacist or registered nurse.
c. Administration, via a peripheral intravenous catheter, midline catheter, and a PICC line, of solutions containing potassium chloride that do not exceed 40 meq per liter and that do not exceed a dose of 10 meq per hour. The first dose shall be administered by the registered nurse. The solutions must be prepackaged by the manufacturer or premixed and labeled by a registered pharmacist or registered nurse.
d. Administration, via a peripheral intravenous catheter, midline catheter, and a PICC line, of intravenous antibiotic solutions prepackaged by the manufacturer or premixed and labeled by a registered pharmacist or registered nurse. The first dose shall be administered by the registered nurse.
e. Maintenance of the patency of a peripheral intravenous catheter, midline catheter, and a PICC line with a prefilled heparin or saline syringe flush, prepackaged by the manufacturer or premixed by a registered pharmacist or registered nurse.
f. Changing the dressing of a midline catheter and a PICC line per sterile technique.
6.5(7) Procedures which shall not be delegated by the registered nurse to the licensed practical n nurse are as follows:
a. Initiation and discontinuation of a midline catheter or a peripherally inserted central catheter (PICC).
b. Administration of medication by bolus or IV push except maintenance doses of analgesics via a patient-controlled analgesia pump set at a lock-out interval.
c. Administration of blood and blood products, vasodilators, vasopressors, oxytoxics, chemotherapy, colloid therapy, total parenteral nutrition, anticoagulants, antiarrhythmics, thrombolytics, and solutions with a total osmolarity of 600 or greater.
d. Provision of intravenous therapy to a client under the age of 12 or any client weighing less than 80 pounds, with the exception of those activities authorized in the limited scope of practice found in subrule 6.3(4).
e. Provision of intravenous therapy in any other setting except a licensed hospital, a nursing facility and a certified end-stage renal dialysis unit, with the exception of those activities authorized in the limited scope of practice found in subrule 6.3(4).

This rule is intended to implement Iowa Code chapters 136C and 152.

655—6.6 (152) Specific nursing practice for licensed practical nurses.
6.6(1) The licensed practical nurse shall be permitted to provide supportive and restorative care in the home setting under the supervision of a registered nurse, as defined in subrule 6.2(5), or a physician. When the licensed practical nurse provides care under the supervision of the registered nurse, the initial assessment and ongoing application of the nursing process shall be provided by the registered nurse.
6.6(2) The licensed practical nurse shall be permitted to provide supportive and restorative care to a specific student in the school setting in accordance with the student's health plan when under the supervision of and as delegated by the registered nurse employed by the school district.
6.6(3) The licensed practical nurse shall be permitted to provide supportive and restorative care in a Head Start program under the supervision of a registered nurse, as defined in subrule 6.2(5), or a physician if the licensed practical nurse were in this position prior to July 1, 1985.
6.6(4) The licensed practical nurse shall be permitted to provide supportive and restorative care in a camp setting under the supervision of a registered nurse, as defined in subrule 6.2(5), or a physician. When the licensed practical nurse provides care under the supervision of the registered nurse, the initial assessment and ongoing application of the nursing process are performed by the registered nurse. The licensed practical nurse is responsible for requesting registered nurse consultation as needed.
6.6(5) The licensed practical nurse shall be permitted to provide supportive and restorative care in a county jail facility or municipal holding facility operating under the authority provided by Iowa Code chapter 356. The supportive and restorative care provided by the licensed practical nurse in such facilities shall be performed under the supervision of a registered nurse, as defined in subrule 6.2(5). The registered nurse shall perform the initial assessment and ongoing application of the nursing process. The registered nurse shall be available 24 hours per day by teleconferencing equipment, and the time necessary to be readily available on site to the licensed practical nurse shall be no greater than ten minutes. This exception to the proximate area requirement is limited to a county jail facility or municipal holding facility operating under the authority of Iowa Code chapter 356 and shall not apply in any other correctional facility.
6.6(6) The licensed practical nurse shall be permitted to conduct height, weight and hemoglobin screening and record responses to health questions asked in a standardized questionnaire under the supervision of a registered nurse in a Women, Infants and Children (WIC) clinic. A registered nurse employed by or under contract to the WIC agency will assess the competency of the licensed practical nurse to perform these functions and will be available for consultation. The licensed practical nurse is responsible for performing under the scope of practice for licensed practical nurses and requesting registered nurse consultation as needed. This exception to the proximate area requirement is limited to WIC clinics and to the services permitted in this subrule.
This rule is intended to implement Iowa Code sections 17A.3 and 152.1.
655—6.7(152) Specific nursing practice for registered nurses. A registered nurse, while circulating
in the operating room, shall provide supervision only to persons in the same operating room.
This rule is intended to implement Iowa Code section 152.1.

152.4 Appropriations.

The board may apply appropriated funds to:

1. The administration and enforcement of the provisions of this chapter and of chapter 147.
2. The elevation of the standards of the schools of nursing.
3. The promotion of educational and professional standards of nurses in this state.

Section History: Early form
[C35, § 2537-g3; C39, § 2537.3; C46, 50, 54, 58, 62, 66, 71, 73, 75, § 147.107; C77, 79, 81, § 152.4]

152.5 Education programs.

1. All programs preparing a person to be a registered nurse or a licensed practical nurse shall be approved by the board. The board shall not recognize a program unless it:

a. Is of recognized standing.

b. Has provisions for adequate physical and clinical facilities and other resources with which to conduct a sound education program.

c. Requires, for graduation of a registered nurse applicant, the completion of at least a two academic year course of study.

d. Requires, for graduation of a licensed practical nurse applicant, the completion of at least a one academic year course of study as prescribed by the board.

2. All advanced formal academic nursing education programs shall also be approved by the board.

Section History: Early form
[S13, § 2575-a29; C24, 27, 31, 35, 39, § 2564; C46, 50, 54, 58, 62, 66, 71, 73, 75, § 152.4; C77, 79, 81, § 152.5]

Section History: Recent form
95 Acts, ch 79, § 1

Internal References
Referred to in § 152.7

152.6 Licenses--professional abbreviations.

The board may license a natural person to practice as a registered nurse or as a licensed practical nurse. However, only a person currently licensed as a registered nurse in this state may use that title and the abbreviation "RN" after the person's name and only a person currently licensed as a licensed practical nurse in this state may use that title and the abbreviation "LPN" after the person's name. For purposes of this section, "currently licensed" includes persons licensed in another state and recognized for licensure in this state pursuant to the nurse licensure compact contained in section 152E.1.

Section History: Early form
[C50, 54, 58, 62, 66, 71, 73, 75, § 152.5; C77, 79, 81, § 152.6]

Section History: Recent form
2000 Acts, ch 1008, §4

152.7 Applicant qualifications.

In addition to the provisions of section 147.3, an applicant to be licensed for the practice of nursing shall have the following qualifications:

1. Be a graduate of an accredited high school or the equivalent.
2. Pass an examination as prescribed by the board.
3. Complete a course of study approved by the board pursuant to section 152.5.

For purposes of licensure pursuant to the nurse licensure compact contained in section 152E.1, the compact administrator may refuse to accept a change in the qualifications for licensure as a registered nurse or as a licensed practical or vocational nurse by a licensing authority in another state which is a party to the compact which substantially modifies that state's qualifications for licensure in effect on July 1, 2000. A refusal to accept a change in a party state's qualifications for licensure may result in submitting the issue to an arbitration panel or in withdrawal from the compact, at the discretion of the compact administrator.

Section History: Early form
[S13, § 2575-a29, -a30; C24, 27, 31, 35, 39, § 2563; C46, 50, 54, 58, 62, 66, 71, 73, 75, § 152.3; C77, 79, 81, § 152.7]

Section History: Recent form
95 Acts, ch 79, § 2; 2000 Acts, ch 1008, §5; 2000 Acts, ch 1140, §37; 2000 Acts, ch 1232, §50

Internal References
Referred to in § 152.8

152.8 Reciprocity.

Notwithstanding the provisions of sections 147.44 through 147.54, the following shall apply regarding applicants for nurse licensure possessing a license from another state:

1. A license possessed by an applicant from a state which has not adopted the nurse licensure compact contained in section 152E.1 shall be recognized by the board under conditions specified which indicate that the licensee meets all the qualifications required under section 152.7. If a foreign license is recognized, the board may issue a license by endorsement without an examination being required. Recognition shall be based on whether the foreign licensee is qualified to practice nursing. The board may issue a temporary license to a natural person who has completed the requirements of and applied for licensure by endorsement. The board shall determine the length of time a temporary license shall remain effective.

2. A license possessed by an applicant and issued by a state which has adopted the nurse licensure compact contained in section 152E.1 shall be recognized pursuant to the provisions of that section.

Section History: Early form
[C35, § 2537-g3; C39, § 2537.3; C46, 50, 54, 58, 62, § 147.107; C66, 71, 73, 75, § 147.107, 152.7; C77, 79, 81, § 152.8]

Section History: Recent form
2000 Acts, ch 1008, §6

152.9 Temporary license.

The board may issue a temporary license to a natural person who has completed the requirements of and applied for licensure by endorsement. The board shall determine the length of time a temporary license shall remain effective.

Section History: Early form
[C77, 79, 81, § 152.9]

Section History: Recent form
94 Acts, ch 1123, §1

152.10 License revocation or suspension.

1. Notwithstanding sections 147.87 to 147.89 and in addition to the provisions of sections 147.58 to 147.71, the board may restrict, suspend, or revoke a license to practice nursing or place the licensee on probation. The board may also prescribe by rule conditions of license reinstatement. The board shall prescribe rules of procedure by which to restrict, suspend, or revoke a license. These procedures shall conform to the provisions of chapter 17A.

2. In addition to the grounds stated in section 147.55, the following are grounds for suspension or revocation under subsection 1 of this section:

a. Willful violation of the rules of the board.

b. Continued practice while knowingly having an infectious or contagious disease which could be harmful to a patient's welfare.

c. Conviction for a felony in the courts of this state or another state, territory, or country if the felony relates to the practice of nursing. Conviction shall include only a conviction for an offense which if committed in this state would be deemed a felony without regard to its designation elsewhere. A certified copy of the final order or judgment of conviction or plea of guilty in this state or in another jurisdiction shall be conclusive evidence of conviction.

d. (1) Having a license to practice nursing as a registered nurse or licensed practical nurse revoked or suspended, or having other disciplinary action taken by a licensing authority of another state, territory, or country. A certified copy of the record or order of suspension, revocation, or disciplinary action is prima facie evidence of such fact.

(2) Having a license to practice nursing as a registered nurse or licensed practical nurse revoked or suspended, or having other disciplinary action taken, by a licensing authority in another state which has adopted the nurse licensure compact contained in section 152E.1 and which has communicated information relating to such action pursuant to the coordinated licensure information system established by the compact. If the action taken by the licensing authority occurs in a jurisdiction which does not afford the procedural protections of chapter 17A, the licensee may object to the communicated information and shall be afforded the procedural protections of chapter 17A.

e. Knowingly aiding, assisting, procuring, advising, or allowing a person to unlawfully practice nursing.

f. Being adjudicated mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a license for the duration of the license, unless the board orders otherwise.

g. Being guilty of willful or repeated departure from or the failure to conform to the minimum standard of acceptable and prevailing practice of nursing; however, actual injury to a patient need not be established.

h. (1) Inability to practice nursing with reasonable skill and safety by reason of illness, excessive use of alcohol, drugs, narcotics, chemicals, or other type of material or as a result of a mental or physical condition.

(2) The board may, upon probable cause, request a licensee to submit to an appropriate medical examination by a designated physician. If requested by the licensee, the licensee may also designate a physician for an independent medical examination. The reasonable costs of such examinations and medical reports to the board shall be paid by the board. Refusal or failure of a licensee to complete such examinations shall constitute an admission of any allegations relating to such condition. All objections shall be waived as to the admissibility of the examining physicians' testimony or examination reports on the grounds that they constitute privileged communication. The medical testimony or examination reports shall not be used against a registered nurse or licensed practical nurse in another proceeding and shall be confidential. At reasonable intervals, a registered nurse or licensed practical nurse shall be afforded an opportunity to demonstrate that the registered nurse or licensed practical nurse can resume the competent practice of nursing with reasonable skill and safety to patients.

Section History: Early form
[C77, 79, 81, § 152.10]

Section History: Recent form
2000 Acts, ch 1008, §7

Internal References
Referred to in § 272C.3, 272C.4, 272C.5

152.11 Investigators for nurses.

The board of nursing may appoint investigators, who shall not be members of the board, to administer and aid in the enforcement of the provisions of law related to those licensed to practice nursing. The amount of compensation for the investigators shall be determined pursuant to chapter 19A. Investigators authorized by the board of nursing have the powers and status of peace officers when enforcing this chapter and chapters 147 and 272C.

Section History: Recent form
93 Acts, ch 41, § 1

Internal References
Referred to in § 272C.5

152.12 Examination information.

Notwithstanding section 147.21, subsection 3, individual pass or fail examination results made available from the authorized national testing agency may be disclosed to the appropriate licensing authority in another state, the District of Columbia, or a territory or county, and the board-approved education program, for purposes of verifying accuracy of national data and determining program approval.

Section History: Recent form
97 Acts, ch 159, §22

CHAPTER 147
GENERAL PROVISIONS, HEALTH-RELATED PROFESSIONS

147.107 DRUG DISPENSING, SUPPLYING, AND PRESCRIBING -- LIMITATIONS.

1. A person, other than a pharmacist, physician, dentist, podiatric physician, or veterinarian who dispenses as an incident to the practice of the practitioner's profession, shall not dispense prescription drugs or controlled substances.

2. *a.* A pharmacist, physician, dentist, or podiatric physician who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the dispensing is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence. However, the physical presence requirement does not apply when a pharmacist or practitioner is utilizing an automated dispensing system or when a pharmacist is utilizing a tech-check-tech program, as defined in section 155A.3. When using an automated dispensing system the pharmacist or practitioner shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. When using a tech-check-tech program the pharmacist shall utilize an internal quality control assurance plan, in accordance with rules adopted by the board of pharmacy, that ensures accuracy for dispensing. Verification of automated dispensing and tech-check-tech accuracy and completeness remains the responsibility of the pharmacist or practitioner and shall be determined in accordance with rules adopted by the board of pharmacy, the board of medicine, the dental board, and the board of podiatry for their respective licensees.

b. A dentist, physician, or podiatric physician who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall report the fact that they dispense prescription drugs with the practitioner's respective board at least biennially.

c. A physician, dentist, or podiatric physician who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall offer to provide the patient with a written prescription that may be dispensed from a pharmacy of the patient's choice or offer to transmit the prescription orally, electronically, or by facsimile in accordance with section 155A.27 to a pharmacy of the patient's choice.

3. A physician assistant or registered nurse may supply, when pharmacist services are not reasonably available or when it is in the best interests of the patient, on the direct order of the supervising physician, a quantity of properly packaged and labeled prescription drugs, controlled substances, or contraceptive devices necessary to complete a course of therapy. However, a remote clinic, staffed by a physician assistant or registered nurse, where pharmacy services are not reasonably available, shall secure the regular advice and consultation of a pharmacist regarding the distribution, storage, and appropriate use of such drugs, substances, and devices.

4. Notwithstanding subsection 3, a physician assistant shall not

dispense prescription drugs as an incident to the practice of the supervising physician or the physician assistant, but may supply, when pharmacist services are not reasonably available, or when it is in the best interests of the patient, a quantity of properly packaged and labeled prescription drugs, controlled substances, or medical devices necessary to complete a course of therapy. However, a remote clinic, staffed by a physician assistant, where pharmacy services are not reasonably available, shall secure the regular advice and consultation of a pharmacist regarding the distribution, storage, and appropriate use of such drugs, substances, and devices. Prescription drugs supplied under the provisions of this subsection shall be supplied for the purpose of accommodating the patient and shall not be sold for more than the cost of the drug and reasonable overhead costs, as they relate to supplying prescription drugs to the patient, and not at a profit to the physician or the physician assistant. If prescription drug supplying authority is delegated by a supervising physician to a physician assistant, a nurse or staff assistant may assist the physician assistant in providing that service. Rules shall be adopted by the board of physician assistants, after consultation with the board of pharmacy, to implement this subsection.

5. Notwithstanding subsection 1 and any other provision of this section to the contrary, a physician may delegate the function of prescribing drugs, controlled substances, and medical devices to a physician assistant licensed pursuant to chapter 148C. When delegated prescribing occurs, the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each individual prescription so that the individual who dispenses or administers the prescription knows under whose delegated authority the physician assistant is prescribing. Rules relating to the authority of physician assistants to prescribe drugs, controlled substances, and medical devices pursuant to this subsection shall be adopted by the board of physician assistants, after consultation with the board of medicine and the board of pharmacy. However, the rules shall prohibit the prescribing of schedule II controlled substances which are listed as depressants pursuant to chapter 124.

6. Health care providers shall consider the instructions of the physician assistant to be instructions of the supervising physician if the instructions concern duties delegated to the physician assistant by a supervising physician.

7. Notwithstanding subsection 1, a family planning clinic may dispense birth control drugs and devices upon the order of a physician. Subsections 2 and 3 do not apply to a family planning clinic under this subsection.

8. Notwithstanding subsection 1, but subject to the limitations contained in subsections 2 and 3, a registered nurse who is licensed and registered as an advanced registered nurse practitioner and who qualifies for and is registered in a recognized nursing specialty may prescribe substances or devices, including controlled substances or devices, if the nurse is engaged in the practice of a nursing specialty regulated under rules adopted by the board of nursing in consultation with the board of medicine and the board of pharmacy.

9. Notwithstanding section 147.86, a person, including a pharmacist, who violates this section is guilty of a simple misdemeanor.

Section History: Recent Form

84 Acts, ch 1006, § 1; 88 Acts, ch 1232, § 1; 91 Acts, ch 238, § 1; 91 Acts, ch 239, § 1; 92 Acts, ch 1163, § 37; 92 Acts, ch 1183, § 10; 94 Acts, ch 1134, §1; 95 Acts, ch 108, §5; 2002 Acts, ch 1108, §13; 2003 Acts, ch 93, §3, 14; 2003 Acts, ch 108, §39; 2004 Acts, ch 1036, §8; 2004 Acts, ch 1101, § 22; 2006 Acts, ch 1094, §1; 2007 Acts, ch 10, §78; 2007 Acts, ch 218, §202; 2008 Acts, ch 1016, §1; 2008 Acts, ch 1088, §43

Referred to in § 154.1, 155A.2, 155A.4, 280.16

See also § 154.1, 155A.4

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 234.6 and 2017 Iowa Acts, House File 653, sections 90 through 92, the Department of Human Services hereby gives Notice of Intended Action to amend Chapter 7, "Appeals and Hearings," and Chapter 87, "State-Funded Family Planning Program," Iowa Administrative Code.

These amendments implement a new state Family Planning Program (FPP) in accordance with legislative guidance pursuant to 2017 Iowa Acts, House File 653, sections 90 through 92.

As a result of these amendments providers of family planning services will change as entities that provide abortions can no longer participate as a FPP provider. Providers unable to participate as an FPP provider will also be unable to participate as a point-of-service agency for eligibility determinations for FPP.

Any interested person may make written comments on the proposed amendments on or before July 25, 2017. Comments should be directed to Harry Rossander, Bureau of Policy Coordination, Department of Human Services, Hoover State Office Building, 5th Floor, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. Comments may be sent by fax to (515) 281-4980 or by email to policyanalysis@dhs.state.ia.us.

These amendments do not provide for waivers in specified situations because requests for the waiver of any rule may be submitted under the Department's general rule on exceptions at 441—1.8(17A, 217).

These amendments were also Adopted and Filed Emergency and are published herein as ARC XXXXC. The purpose of this Notice of Intended Action is to solicit public comment on that submission, the subject matter of which is incorporated by reference.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 249A.4 and 2017 Iowa Acts, House File 653, sections 90 through 92.

Iowa Department of Human Services

Information on Proposed Rules

Name of Program Specialist	Telephone Number	Email Address
Kelly Lindsay	515-281-5334	klindsa@dhs.state.ia.us

1. Give a brief summary of the rule changes:

   These amendments implement a state Family Planning Program (FPP). Updates are needed to Chapter 87 to implement FPP.

   Address errors in existing rules to correct the Federal Poverty Level limits to 300 percent for the FPP.

   Update Chapter 7 to include the FPP.

2. What is the legal basis for the change? (Cite the authorizing state and federal statutes and federal regulations):

   2017 Iowa House File 653 (HF653), sections 90-92

3. What is the reason for the Department requesting these changes?

   Implements FPP, pursuant to legislative direction.

4. What will be the effect of this rule making (who, what, when, how)?

   Providers of family planning services will change as entities that provide abortions can no longer participate as a FPP provider; providers unable to participate as an FPP provider will also be unable to participate as a point-of-service agency for eligibility determinations for FPP; the state will no longer receive Federal Financial Participation (FFP).

5. Is the change mandated by State or Federal Law?

   Yes, state law.

6. Will anyone be affected by this rule change? If yes, who will be affected and will it be to the person's (organization's) benefit or detriment?

   Members may be affected as the provider network will be different under the FPP. Entities providing abortions may be affected as they are no longer eligible to participate as a provider under the FPP.

7. What are the potential benefits of this rule?

   Members will continue to have access to and receive family planning services.

8. What are the potential costs, to the regulated community or the state of Iowa as a whole, of this rule?

   $3,383,880 has been appropriated from the general fund for the FPP

9. Do any other agencies regulate in this area? If so, what agencies and what Administrative Code sections apply?

Family Planning Council of Iowa and the Iowa Department of Public Health are the Title X grantees in Iowa. FPP providers who are also Title X agencies may participate as a point-of-service agency for determinations of eligibility for the FPP.

10. What alternatives to direct regulation in this area are available to the agency? Why were other alternatives not used?

    This change is a legislative mandate.

11. Does this rule contain a waiver provision? If not, why?

    These rules do not contain waiver provisions because waivers can be requested pursuant to the department's general rule on waivers or "exceptions to policy" at 1.8.

12. What are the likely areas of public comment?

    Opposition to excluding providers from participating in the FPP.

13. Do these rules have an impact on private-sector jobs and employment opportunities in Iowa? (If yes, describe nature of impact, categories and number of jobs affected, state regions affected, costs to employer per employee)

    Providers of family planning services may see an increase or decrease in staffing needs based on the number of individuals seeking family planning services from their agency.

Administrative Rule Fiscal Impact Statement

Date: 5/11/17

Agency: Human Services

IAC citation: 441 IAC

Agency contact: Kelly Lindsay

Summary of the rule:

To replace/update rules in Chapter 87 in accordance with the implementation of the Family Planning Program (FPP)

Fill in this box if the impact meets these criteria:

____ No fiscal impact to the state.

____ Fiscal impact of less than $100,000 annually or $500,000 over 5 years.

____ Fiscal impact cannot be determined.

Brief explanation:

Fill in the form below if the impact does not fit the criteria above:

_X_ Fiscal impact of $100,000 annually or $500,000 over 5 years.

Assumptions:

Family planning waiver expenses were projected to be $3,383,880 ($2,901,845 federal; $482,035 state) in SFY18 based on current cost and enrollment assumptions. Costs are expected to be the same under the state program, but the loss of federal Medicaid funding will require a $2,901,845 state funding increase.

Due to the loss of federal administrative match and additional costs associated with converting to a state program, administrative costs are expected to increase by approximately $200,000.

Describe how estimates were derived:

Program expenses are estimated to be $3,383,880 and are based on historical cost and enrollment trends for the family planning waiver program.

Administrative expenses are expected to be $200,000, and a portion of the $3,383,880 can be used to fund these costs if actual program costs are less than expected. Any administrative spending that cannot be covered by this allocation will be absorbed within existing appropriations. For this reason, only a $3,383,880 cost is reflected below.

Estimated Impact to the State by Fiscal Year

	Year 1 (FY18)	Year 2 (FY19)
Revenue by each source:		
General fund	$3,383,880	$3,383,880
Federal funds		
Other (specify):		
TOTAL REVENUE	**$3,383,880**	**$3,383,880**
Expenditures:		
General fund	$3,383,880	$3,383,880
Federal funds		
Other (specify):		
TOTAL EXPENDITURES	**$3,383,880**	**$3,383,880**
NET IMPACT	**$0**	**$0**

X This rule is required by state law or federal mandate.

Please identify the state or federal law:

2017 House File 653

X Funding has been provided for the rule change.

Please identify the amount provided and the funding source:

House File 653 allocates $3,383,880 for this purpose.

____ Funding has not been provided for the rule.

Please explain how the agency will pay for the rule change:

Fiscal impact to persons affected by the rule:

Providers of family planning services may see an increase or decrease in staffing needs based on the number of individuals seeking family planning services from their agency.

Fiscal impact to counties or other local governments (required by Iowa Code 25B.6):

None anticipated.

Agency representative preparing estimate: Jason Buls

Telephone number: 515-281-5764

September 29, 2017

Employees' Manual
Title 5
Chapter F

IOWA FAMILY PLANNING PROGRAM

Iowa Department of Human Services

Page

Overview **1**
Definitions 1
Designated Providers 2
Who Is Eligible for FPP Services 3

Processing FPP Applications **3**
Screening for Medicaid Eligibility 4
Obtaining Information and Verification 7
Time Limit for Eligibility Decision 7
Effective Date of Coverage 8
Notices of Decision 8
Grace Period Following the Denial of an Application 9

Eligibility Requirements **11**
Medicaid or *hawk-i* Eligibility 11
Age 12
Household Size 12
Social Security Number 13
Income 13
Countable Income 13
How to Treat Self-Employment Income 15
Determination of Self-Employment Earnings 16
Providing Child Care in the Home 17
Annualizing Income Received Irregularly 18
Deductions From Gross Income 19
Health Insurance 21
Confidentiality Good Cause 21
Residency 21
Citizenship 22
Verifying Citizenship and Identity 23
Documentation Process for State Verification Exchange System (SVES) Match 24
Inconsistent SVES Match 26
No SVES Match 27
Reasonable Opportunity Period 28
Acceptable Documentation 30
Citizenship and Identity Documentation Chart 31
Alien Status 39
Aliens Subject to Five-Year Bar 39
Aliens Exempt from Five-Year Bar 40
Establishing Qualifying Quarters 42
Sponsor Deeming 45
Verifying Qualifying Quarters 46
Alien Documentation Chart 47

Page

Ongoing Eligibility 55
Reporting Changes 55
Acting on Changes 55
Annual Recertifications 56

Covered Services 57
Family Planning Benefits 57
Family Planning-Related Benefits 57
Procedure Codes and Nomenclature 58

Billing Policies and Claim Form Instructions 58

Overview

Through a cooperative effort with the Title X family planning agencies, federally qualified health centers, rural health clinics, the Iowa Departments of Public Health and Human Services (DHS), Iowa is providing limited coverage for family planning–related services through the Family Planning Program (FPP) to:

- Persons of reproductive age with countable income at or below 300% percent of the federal poverty level; and
- Any woman who had a pregnancy end on or after January 1, 2006, and who was receiving Medicaid on the date the pregnancy ended.

The DHS FPP System establishes FPP eligibility. Staff from either the designated family planning agencies or the DHS local office may enter applicant data for the 300% group into the FPP System.

FPP eligibility for women who were receiving Medicaid at the time a pregnancy ended may be established only through entries into the FFP System by DHS staff or the Department's automated process.

Definitions

"**Applicant**" means a person for whom assistance is being requested, including at recertification.

"**Certification period**" means the time for which a person may be determined eligible for the FPP.

"**DHS**" means the Iowa Department of Human Services.

"**Grace period**" means the 14 calendar days immediately following the date of denial or the effective date of cancellation.

"**Primary care services**" means health care provided by a medical professional and with whom a member has initial or primary contact.

"**Prudent-person concept**" refers to the authority given to the clinic workers to review and analyze information given by the member and decide whether the information is sufficient for making an eligibility determination, or if further checking should be done. The "prudent person" must be vigilant, cautious, perceptive, and guided by generally sound judgment.

"**Recertification**" means establishing a new certification period when the previous period has expired and there has not been a break in assistance.

"**Reproductive age**" means a person is at least 12 years old but under the age of 55 and is capable of bearing or fathering children.

"**Timely notice**" means a written notice given at least ten calendar days before the effective date of cancellation. The timely notice period extends from the day after a notice is issued to the effective date of action. A timely notice period must be at least ten calendar days. The FPP System will determine the effective date of cancellation to ensure that all cases are closed with timely notice given.

Designated Providers

Applications may be filed at the following family planning agencies and their satellite clinics. If you need assistance locating a local provider, contact the Healthy Families toll free line at 1-800-369-2229.

- New Opportunities, 1-800-642-6330
- Edgerton Women's Health Center, 563-336-3000
- HCCMS Family Health Services, 712-263-3303
- Hillcrest Family Services, 563-583-7357
- North Iowa Community Action, 1-800-657-5856
- Primary Health Care, 515-248-1447
- Promise Community Health Center, 712-722-1700
- Webster County Health Department, 515-573-4107
- Women's Health Services, 563-652-3749
- Eastern Iowa Health Center, 319-730-7300
- River Hills Community Health Center, 641-683-5773

Family planning agencies and clinics under contract with the Department of Human Services can submit questions about the policy to the Iowa Family Planning Program help desk at IFPN@dhs.state.ia.us.

Who Is Eligible for FPP Services

Legal reference: PL 104-193; Iowa Code section 217.41B; 441 IAC 87.2(1)

Persons eligible for services through the FPP coverage group are:

- Persons who are 12 but not yet 55 years old and who have countable income at or below 300% of the federal poverty level.
- Women who have a pregnancy end while they are receiving Medicaid.

A person who is eligible for Medically Needy with a spenddown can also receive coverage under the FPP program.

Eligibility does **not** exist for FPP if one or more of the following exists:

- The person is receiving Medicaid other than Medically Needy with a spenddown. NOTE: The FPP System will identify when a person is ineligible for FPP due to existing Medicaid eligibility, but persons in the ELIAS system are not systematically checked.
- The person is under 12 or age 55 or older. **EXCEPTION:** The age requirement does not apply to those who are eligible for FPP due to a pregnancy ending while receiving Medicaid.
- The person is a non-qualified alien.
- The person is a resident of another state.
- The person's countable income exceeds 300% of federal poverty level at the time of application. **EXCEPTION:** A woman who is on Medicaid when her pregnancy ends can have income above this level.

Processing FPP Applications

Legal reference: Iowa Code section 217.41B; 441 IAC 87.3(1) and (2)

Designated family planning agencies and clinics can assist in the processing of eligibility for FPP coverage for those persons who are at or below 300% of federal poverty level.

FPP applicants applying at a designated family planning agency or clinic will complete form 470-5485 or 470-5485(S), *Family Planning Program Application*.

Applications can also be filed at a local DHS office, any facility where out-stationing activities are provided, or at any authorized Title X agency.

An application is considered filed on the date form 470-5485 or 470-5485(S), *Family Planning Program Application*, that contains a legible name, address, and signature is received by a local DHS office or authorized Title X agency.

At the time of application, give the applicant the following information:

- Comm. 20, *Your Guide to Medicaid Fee-for-Service (FFS)*. This pamphlet explains what services are available under the regular Medicaid program. Comm. 20 is available at http://dhs.iowa.gov/sites/default/files/Comm020.pdf.
- Comm. 374, *Family Planning Program Frequently Asked Questions*, available at http://dhs.iowa.gov/sites/default/files/Comm374.pdf.
- Comm. 209, *Information About Your Privacy Rights*. This notice describes how medical information is used and disclosed. It also explains how members can get access to this information. Comm. 209 is available at http://dhs.iowa.gov/sites/default/files/Comm209.pdf.
- Comm. 243, *Primary Care Access*. This pamphlet explains where a person can access primary care services in Iowa. The offices listed are either rural health clinics or federally qualified health centers that generally can provide care on a sliding fee schedule. Comm. 243 is available at http://dhs.iowa.gov/sites/default/files/Comm243.pdf.

Screening for Medicaid Eligibility

Screen the application to determine if eligibility may exist under a Medicaid coverage groups. Refer to *Desk Aids*, RC-0033 and RC-0130, for income limits for Medicaid coverage groups. Click here to see a sample of RC-0033. Click here to see a sample of RC-0130.

Explain the difference between FPP and Medicaid and let the applicant choose which coverage group to apply for. One major difference is that Medicaid will require parents to be considered in the teen's household size and the parent's income will be counted. The eligibility determination for FPP does not use the parental income for youth.

If the applicant opts for FPP, ask the applicant to sign form 470-4314, *Election of Iowa Family Planning Program*, and document the case record that the application was screened and the applicant's decision. Click here to see a sample of this form.

If the applicant wants to apply for full Medicaid benefits, the applicant may complete form 470-5170, *Application for Health Care Coverage and Help Paying Costs*. Send the completed application to the appropriate DHS office for processing within two working days of receipt. Applications can also be filed online at www.dhs.iowa.gov.

Service Area	Mailing Address
Service Area 1 Western (Council Bluffs)	Imaging Center 1 417 E Kanesville Blvd Council Bluffs, IA 51503
Service Area 2 Northern (Waterloo)	Imaging Center 2 PO Box 11000 Waterloo, IA 50704
Service Area 3 Eastern (Davenport)	Imaging Center 3 PO Box 8022 Davenport, IA 52808
Service Area 4 Cedar Rapids	Imaging Center 4 PO Box 2027 Cedar Rapids, IA 52406
Service Area 5 Des Moines	Imaging Center 5 PO Box 41130 Des Moines, IA 50311

#	County	Service Area
1	Adair	Des Moines
2	Adams	Des Moines
3	Allamakee	Northern
4	Appanoose	Cedar Rapids
5	Audubon	Western
6	Benton	Cedar Rapids
7	Black Hawk	Northern
8	Boone	Des Moines
9	Bremer	Northern
10	Buchanan	Northern
11	Buena Vista	Western
12	Butler	Northern
13	Calhoun	Northern
14	Carroll	Western
15	Cass	Western

#	County	Service Area
16	Cedar	Eastern
17	Cerro Gordo	Northern
18	Cherokee	Western
19	Chickasaw	Northern
20	Clarke	Des Moines
21	Clay	Western
22	Clayton	Northern
23	Clinton	Eastern
24	Crawford	Western
25	Dallas	Des Moines
26	Davis	Cedar Rapids
27	Decatur	Des Moines
28	Delaware	Northern
29	Des Moines	Eastern
30	Dickinson	Western

#	County	Service Area
31	Dubuque	Eastern
32	Emmet	Western
33	Fayette	Northern
34	Floyd	Northern
35	Franklin	Northern
36	Fremont	Western
37	Greene	Western
38	Grundy	Northern
39	Guthrie	Western
40	Hamilton	Northern
41	Hancock	Northern
42	Hardin	Northern
43	Harrison	Western
44	Henry	Eastern
45	Howard	Northern
46	Humboldt	Northern
47	Ida	Western
48	Iowa	Cedar Rapids
49	Jackson	Eastern
50	Jasper	Cedar Rapids
51	Jefferson	Cedar Rapids
52	Johnson	Cedar Rapids
53	Jones	Cedar Rapids
54	Keokuk	Cedar Rapids
55	Kossuth	Western
56	Lee	Eastern
57	Linn	Cedar Rapids
58	Louisa	Eastern
59	Lucas	Des Moines
60	Lyon	Western
61	Madison	Des Moines
62	Mahaska	Cedar Rapids
63	Marion	Des Moines
64	Marshall	Northern
65	Mills	Western
66	Mitchell	Northern
67	Monona	Western
68	Monroe	Cedar Rapids
69	Montgomery	Western
70	Muscatine	Eastern
71	O'Brien	Western
72	Osceola	Western
73	Page	Western
74	Palo Alto	Western
75	Plymouth	Western
76	Pocahontas	Northern
77	Polk	Des Moines
78	Pottawattamie	Western
79	Poweshiek	Cedar Rapids
80	Ringgold	Des Moines
81	Sac	Western
82	Scott	Eastern
83	Shelby	Western
84	Sioux	Western
85	Story	Des Moines
86	Tama	Cedar Rapids
87	Taylor	Western
88	Union	Des Moines
89	Van Buren	Cedar Rapids
90	Wapello	Cedar Rapids
91	Warren	Des Moines
92	Washington	Cedar Rapids
93	Wayne	Des Moines
94	Webster	Northern
95	Winnebago	Northern
96	Winneshiek	Northern
97	Woodbury	Western
98	Worth	Northern
99	Wright	Northern

Obtaining Information and Verification

Legal reference: Iowa Code section 217.41B, 441 IAC 87.3(3)

The applicant must supply complete and accurate information needed to make appropriate entries into the FPP System so that initial and ongoing eligibility can be established.

If additional information is needed, give, mail, or fax a written request to the applicant. Inform the applicant in writing of the date the information is due and the consequences for failure to supply the requested information or verification.

The applicant must supply the information within ten calendar days of the day a written request is given, mailed, or faxed to the applicant. The ten-day period begins with the first day after the written request is issued. When the tenth day falls on a nonworking day or a legal holiday, extend the due date to the next working day for which there is regular mail service.

"Supply" means the requested information or verification is received by the specified date. Additional time for providing the information can be allowed when the applicant is making every effort to obtain the information but is unable to do so within the required time and notifies you about the problem.

Make the appropriate entry into the FPP System that reflects the failure of an applicant or member to supply the requested information or refuses to provide authorization to obtain it.

Time Limit for Eligibility Decision

Legal reference: Iowa Code section 217.41B; 441 IAC 87.3(3) and (5)

Make entries into the FPP System so that the system can issue a notice of decision no later than the 45th day following the date of application. If the 45th day falls on a weekend or state holiday, process the application by making system entries no later than the next working day.

The time limit for making entries into the system can be waived in unusual circumstances such as, but not be limited to:

- When you and the applicant have made every reasonable effort to get necessary information and have not been able to do so within the time limits.
- Emergencies, such as fire or flood.
- Other conditions beyond the administrative control of the clinic.

An applicant must cooperate with the application process. This may include providing information or verification or signing documents. Failure to cooperate with the application process shall serve as a basis to deny an application.

An application cannot be denied because the 45-day period for processing it has expired. To deny the application, there must be either a failure to act on the part of the applicant or a determination of ineligibility by the FPP System.

Effective Date of Coverage

Legal reference: Iowa Code section 217.41B; 441 IAC 87.4(217) and 441 IAC 87.5(217)

The effective date of eligibility for FPP is the first day of the month an application was filed or the first day of the month all eligibility factors are met, whichever is later.

Eligibility for FPP cannot be granted for any month before the month of application.

A person found eligible for FPP is certified for a period of 12 months, unless they will meet the age limit before 12 months or if their alien status and age requires a shortened certification period.

Notices of Decision

Legal reference: Iowa Code section 217.41B; 441 IAC 7.7(217), 7.7(1), 7.7(6), 76.4(1), and 87.3(6)

The FPP System will issue a notice when:

- An application is approved, denied, or withdrawn; or
- FPP is canceled.

Clinic staff shall print two copies of form 470-4200, *Notice of Decision*. Clinic staff shall provide the applicant with a copy of the *Notice of Decision* by hand delivering or mailing to the applicant at their designated mailing address. The second copy is placed in the FPP case record.

Clinic staff must document in the case record how the *Notice of Decision* was delivered to the member.

Grace Period Following the Denial of an Application

Legal reference: Iowa Code section 217.41B; 441 IAC 87.3(3)

During the 14 calendar days immediately following the date of denial, the applicant has the opportunity to "cure" the reason for the denial of an application. A previously denied application shall be reconsidered when all information necessary to determine eligibility is provided within 14 calendar days of the date of denial.

"Day one" of the 14-day grace period is the day following the date printed on the notice of decision. If the 14th day falls on a weekend or a state holiday, the 14th day is extended to the next working day for which there is regular mail service.

This grace period may apply when an application has been denied for failure to provide requested information. If mail was returned and you were not able to locate the applicant, a new application is not required if the applicant contacts you within the 14 days, provides a current Iowa address, and eligibility can otherwise be established.

Any changes reported during the grace period that may affect eligibility must be verified when required by policy and be considered in the eligibility determination.

The effective date of eligibility is the first day of the month the original application was filed or the first day of the month in which all eligibility factors were met, whichever is later.

Based on the circumstances of your case, take the appropriate action as follows:

- **No information provided**: When no information is provided by the 14th day after the date of denial, no further action is required.
- **Partial information provided**: When some of the information is returned, but there is still information needed to determine eligibility:
  - Attempt to contact the applicant to let them know what is needed and that if the information is not received so that a decision can be made by the end of the grace period, they will need to reapply. A written request for the previously requested information is not required.
  - If the information is not provided by the end of the grace period, no further action is necessary.

- **Requested information provided and a change has occurred**: If the original requested information is provided, but the applicant also reports a change for which verification is necessary:
  - Make every effort to verify the information and inform the applicant that you cannot reconsider the application unless the change is verified by the end of the grace period. A written request for the new information is not required.
  - If the new information is not verified so that an eligibility determination can be made by the end of the 14-day grace period, make entries into the FPP System to indicate that the application is "still denied."
- **Unable to verify change within grace period**: When an additional change is reported and it is unlikely the information can be verified and eligibility established by the end of the 14-day grace period, attempt to notify the applicant to file a new application.

1. Mrs. A, an FPP applicant, fails to provide proof of wages. The worker issues a denial dated April 2. Mrs. A provides pay stubs on April 16. There have been no other changes in circumstances. The worker reopens Mrs. A's application and re-processes it.

2. Mr. B, an FPP applicant, fails to provide proof of wages. The worker issues a denial dated April 6. Mr. B provides the pay stubs on April 21. Since the 14-day grace period has expired, Mr. B must file a new application and the original denial stands.

3. Ms. C, an FPP applicant, fails to provide three pieces of requested. The worker issues a denial notice dated May 11. Ms. C provides two of the items on May 13.

   The worker attempts to contact Ms. C since not all of the items needed to determine eligibility came in. The third item is received on May 25. There have been no other changes in the household circumstances. The worker re-processes the application.

4. Mrs. D, an FPP applicant, fails to provide three pieces of requested verification. The worker issues a denial notice dated May 16. Mrs. D provides two of the items on May 17.

   The worker attempts to contact Mrs. D since not all of the items needed to determine eligibility came in. The third item is received on May 31. Since the 14-day grace period has expired, the worker issues a 'remain denied' notice. Mrs. D must file a new application.

5. Mr. E, an FPP applicant, fails to provide three pieces of requested verification. The worker issues a denial notice on April 30. Mr. E provides two of the items on May 2 and the third item on May 6.

   Mr. E also reports on May 6 that he changed jobs. The worker explains that in order for the original application to be reconsidered, Mr. E has until May 13 to provide verification of the new job; otherwise Mr. E will have to reapply.

   Mr. E provides verification of the old job ending and the beginning of the new job on May 7. The application is processed with the new information and a notice is issued informing Mr. E of the decision.

Eligibility Requirements

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(217)

Medicaid or *hawk-i* Eligibility

A person cannot be eligible for the FPP if the person is currently receiving Medicaid. Clinic staff can verify Medicaid eligibility by either:

- Calling the Eligibility Verification System (ELVS) at 1-800-338-7752 or 515-323-9639; or
- Verifying eligibility on the Internet at http://dhs.iowa.gov/ime/providers/tools-trainings-and-services
- However, a woman whose pregnancy ends while the woman is on Medicaid is eligible for FPP. This includes Medicaid eligibility through Medically Needy with a spenddown.

  EXCEPTION: FPP eligibility does not exist for a woman whose delivery was covered under the emergency coverage group.
- A teen that is enrolled in ***hawk-i*** is eligible for FPP.

EXCEPTION: A person eligible for Medically Needy with a spenddown can also be eligible for FPP.

The FPP System will identify when a person is ineligible for FPP due to existing Medicaid eligibility and will deny the application. A person who is eligible in the ELIAS system will not be included in this automated eligibility match. Workers will be notified when a newly approved FPP member is found to be Medicaid eligible.

Age

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(1)"b" and "c"

To be eligible for FPP, person must be of reproductive age, which is age 12 through 54.

Household Size

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3)"a"

The household size includes the following people living together who **are not** receiving Supplemental Security Income (SSI):

- The applicant or member,
- The applicant or member's spouse, and
- The applicant or member's dependent children.

"Dependent child" means:

- A child who is under the age of 18 regardless of school attendance; or
- A child 18 years of age who is a full-time student in high school or in an equivalent program and who is expected to graduate or complete the program before reaching 19.

1. Ms. M, age 17, lives with her parents. She has no spouse and no children. Her household size is one.

2. Ms. S, age 17, has a child age 1 and lives with her parents. Her household size is two.

3. Ms. F, age 43, lives with her husband who receives SSI. Her household size is one.

4. Ms. H, age 36, lives with her husband and two children, ages 5 and 8. One child receives SSI. Her household size is three.

Social Security Number

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(2)

A social security number is required for each person for whom FPP is being requested or received. This requirement does **not** apply to a person who is a member of a recognized religious sect who conscientiously opposes applying for or using a social security number.

Income

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(2), (3), and (5)

To be eligible for FPP, the household's countable monthly income shall not exceed the amounts shown below for a household of the same size.

House-hold Size	**Family Planning Income Limits** (300% of Federal Poverty Level)							Add for each additional person
	1	2	3	4	5	6	7	
Income Limit	$3,015	$4,060	$5,105	$6,150	$7,195	$8,240	$9,285	$1,045

Clearly document the amounts used to calculate the monthly countable income. Record the applicant's income on form 470-4073, *Iowa Family Planning Network Worksheet*. (Click here to see a sample of this form.) If the applicant reports no income, document "zero," "N/A," or "$0.00."

Keep this form along with documentation proving the household's income, such as copies of pay stubs, an employer's statement, an award letter, or the income tax return.

Countable Income

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3) and (5)

The gross income (before taxes and other deductions) received by any person included in the household size must be counted. Income received by a parent for a teen (e.g., child support, social security benefits) is not counted for the teen's eligibility unless the parent makes it available to the teen.

NOTE: Do not count earnings of an applicant or a dependent child who is aged 19 or younger and is a full-time student in high school or in an equivalent program. A person who has completed high school and is a student in postsecondary education is not eligible for this exemption; the person's earnings must be counted.

Use and project as future income all nonexempt earned and unearned income received by a person counted in the household size determination. Any of the following may be used as a guideline:

- Income received in the 30 days before receipt of an application or review form.
- Income received in a different 30-day period that is indicative of future income.
- Income received in a longer period of time that is indicative of future income.
- One pay stub that is indicative of future income.
- Self-employment tax returns or books if indicative of future income. (This may include the past three years' average.)
- Income verification obtained from the income source.

The following income is counted in determining eligibility:

- **Money, wages or salary** received for work performed as an employee is counted as earned income. This includes commissions, tips, piece-rate payments, and cash bonuses earned. Overtime pay is estimated based on the person's history of receiving this pay.

  Do not project a fifth paycheck for those who are paid weekly or a third paycheck for those who are paid biweekly.
- **Unemployment Insurance Benefits** (UIB): Count as unearned income. If UIB benefits are reduced due to recoupment, count the actual amount the person receives.
- **Child support**: Count as unearned income.
- **Social Security** and **railroad retirement** benefits are counted as unearned income.

- **Worker's compensation and disability payments** are counted as unearned income. This type of income includes compensation received periodically from private or public insurance companies for injuries incurred at work.
- **Veterans' pensions, compensation checks, and G. I. benefits** paid by the Veterans Administration to disabled members of the armed forces or to survivors of deceased veterans are counted as unearned income.
- **Alimony**: The support payment to a divorced person by a former spouse is counted as unearned income.
- **Self-employment**: Count earnings from self-employment as earned income.

How to Treat Self-Employment Income

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3) and (5)

Self-employment income policy differentiates between:

- Providing child care,
- A home-based business, and
- A non-home-based business.

A member who provides a service in the member's home or whose business office is in the home is involved in a home-based enterprise. The office does not need to be a separate room to meet this qualification.

Home-based self-employment operations include demonstration and sales of catalog and party-based products, painting, crafts, and cosmetology.

The treatment of self-employment income differs depending on whether the income and expenses are received regularly or irregularly, and whether irregular income has been received for less than a year.

Treat earnings received on a regular basis from self-employment in the same way as the earnings of an employee.

Expenses must be incurred on the same regular basis as the income; that is, if the income is received monthly, the expenses must also be incurred monthly. If expenses are incurred less often than the income (for example, insurance, license fees, etc.), annualize the self-employment income.

Self-employment received on a regular basis is any income that is anticipated to be received on a daily, weekly, biweekly, semimonthly, or monthly basis. Some types of self-employment income that may be received on a regular basis are income from:

- Baby-sitting in the member's home
- Selling catalog or party-based merchandise

Determination of Self-Employment Earnings

"Earnings from self-employment" means gross earnings minus allowable business expenses. The amount of earnings from self-employment is the income that is used in determining FPP eligibility.

- Whenever possible, use the previous year's federal income tax report to calculate monthly countable income.
- If the federal income tax report is not available, use the books or records of the business.
- If neither books nor tax records are available, do not allow any deduction for expenses related to the production of self-employment income.

Document the method used to determine income from self-employment in the case record.

Do not:

- Deduct capital gains and depreciation as business expenses;
- Offset the loss from one self-employment enterprise against the profit of another one; or
- Deduct a loss from self-employment from other income

Allowable Deduction in Determining Self-Employment Earnings	Home-Based	Non-Home-Based
Cost of inventory and supplies required for business, such as items for sale or business use	✓	✓
Wages, commissions, and costs (including cost of health insurance) for employees. When the employee is a member of the eligible group, allow the person's wages as a deduction for the self-employed person but also count the employed person's wages as income.	✓	✓
Cost of machinery and equipment in the form of rent, interest on a loan for machinery and equipment, and any insurance on such machinery and equipment	✓	✓
Interest on a home mortgage or contract payment	✓	
10% of the total gross income to cover the costs of upkeep when the work is performed in the home	✓	
The cost of rent or the interest on mortgage or contract for the business location		✓
Insurance on the real or personal property of the business		✓
The cost of any needed repairs		✓
The cost of any required travel (other than the cost of travel from the home to the business)		✓
Any other expense that is directly related to producing income for the member	✓	✓

Providing Child Care in the Home

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3) and (5)

When the member provides child care services in the member's own home, determine countable income by deducting 40% of the total gross income received to cover the cost of upkeep of the home and producing the income.

Gross income from providing child care in the member's own home includes the total payment received for the service, plus any payment received under the Child Nutrition Amendments of 1978 for the cost of providing meals to children.

However, exempt as income and as a resource any portion of the payment for the member's cost of providing meals to the member's own children in the home.

When the member claims to have expenses in excess of the 40% and asks to have actual expenses considered, determine allowable deductions according to the chart under Determination of Self-Employment Earnings.

NOTE: Use actual expenses only at the member's request and only when they exceed 40% of the gross income. This may require a computation of net income using both methods to determine which is to the member's advantage. When you use the 40% deduction, do not allow 10% deduction for upkeep.

Income received from the Child Nutrition Amendments of 1978 must be reported and verified. Tell the member about this responsibility.

NOTE: The amount you record as gross income on the FPP Worksheet is the gross amount minus the 40%.

Ms. S earns $400.00 weekly from providing child care in her home resulting in a monthly gross income of $1,600.00. Manually calculate the 40% deduction. This deduction is $640.00.

Monthly gross income	$ 1,600.00
40% deduction	- 640.00
Countable gross income	$ 960.00

On the FPP Worksheet or in the FPP system in the Earned Income section under Total, enter $960.00.

Annualizing Income Received Irregularly

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3) and (5)

When self-employment income is received on an irregular basis, average the annual income over a 12-month period, even if the income is received only within a short period in that 12 months.

Apply this policy when the income is received before or in the month of decision and expected to continue. (Do **not** consider any self-employment income received before the month of application if it is not expected to continue.)

If a member is self-employed in a business that does not produce a regular income, and the business has been in existence for less than a year, average the income over the period the business has been in existence to arrive at monthly income.

If the business has been in existence for only a short time and there is little income information, establish a reasonable estimate of income and expenses with the member's help.

After you have determined the self-employment earnings, enter the figure into the FPP System.

Deductions From Gross Income

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(3) and (5)

Reduce gross income by the following amounts before comparing income to the limit for a household of the same size. Proof of payments for court-ordered child support, alimony, or spousal support shall be documented in the case record. A court pay record may document court ordered deductions.

- 20% of gross **earned** income.
- Child or incapacitated adult care expense for work-related hours that is not paid by a third-party source such as the Child Care and Development Block Grant or the Child Care Assistance Program.
  - Up to $200 per month per child under age two
  - Up to $175 per month per adult or child age two or older
- Payments made for court-ordered child support, alimony, or spousal support.

1. Ms. S, age 17, applies for FPP. She lives with her parents who are both employed. Ms. S attends high school and works part-time at a local convenience store making $125 weekly.

   The income of her parents is not counted. The earnings Ms. S makes from her part-time job is not counted, as she is a full-time high school student.

2. Ms. M, age 15, applies for FPP. She lives with her mother, who is employed. Ms. M's father is deceased. Her mother receives Social Security benefits of $600 per month for Ms. M.

   The Social Security benefit is not counted, since Ms. M does not have access to this income. The mother's earnings are not counted. Ms. M has no income to count. Ms. M is eligible for FPP.

3. Ms. N, age 35, lives with her husband and two children. Her husband gets $300 weekly unemployment insurance benefits. The children receive Medicaid. Ms. N is eligible for FPP since the family income of $1,200 is less than 300% of the federal poverty level for a household of four.

4. The household consists of Ms. R, age 25, and her daughter, age 3. Ms. R is employed with monthly gross earned income of $1,800. Due to employment, Ms. R has a weekly child care cost of $75.

Monthly gross income	$ 1,800.00
Minus 20%	- 360.00
	$ 1,440.00
Minus child care expense	- 175.00
Countable income	$ 1,265.00

   Ms. R is eligible for FPP since her countable income is less than the 300% of the federal poverty level for a household of two.

5. Ms. D, age 42, lives with her husband and son, who dropped out of high school and who is age 17. Ms. D is unemployed, her husband receives unemployment insurance benefits of $320 per week, and her son earns $100 per week from working part time.

Monthly gross earned income	$ 400.00
Minus 20%	- 80.00
	$ 320.00
Plus unemployment benefits	+ 1,280.00
Countable income	$ 1,600.00

   Ms. D is eligible for FPP since the countable income is less than the 300% of the federal poverty level for a household of three.

Health Insurance

A person who is covered under group or private health insurance is eligible for FPP.

Confidentiality Good Cause

Legal reference: 441 IAC 9.5(7)

A person who is covered under group or private health insurance can claim good cause for not cooperating in filing a claim for health insurance if the person is fearful of the consequences.

A person can claim good cause due to confidentiality if the person is fearful of the consequences.

1. Ms. J is married and her husband has health insurance. Her husband does not want her receiving family planning services. Ms. J can claim good cause.

2. Mr. M, age 17, lives with his parents. He does not want his parents to know he is seeking family planning services. He can claim good cause.

Claiming confidentiality does not prevent correspondence from being mailed. A person must provide an alternate address or use the clinic address for mailing purposes. The alternate address must be entered in the FPP eligibility system.

Residency

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(6)

A person must be a resident of Iowa to be eligible for FPP. A child is considered a resident of the state in which the parent or other person responsible for the child's care, custody, and control resides.

Consider a person a resident of Iowa if the person meets one of the following criteria:

- The person is living in Iowa voluntarily, intends to make a home in the state, and is not in Iowa for a temporary purpose.
- The person does not receive assistance from another state and entered Iowa with a job commitment or to seek employment, whether or not the person is currently employed. In this case, the child is a resident of the state in which the caretaker is a resident.

Do not consider a person a resident of Iowa if the person is in Iowa solely on vacation (such as a child who lives with a parent in another state but spends the summer with the other parent in Iowa).

Residency continues until the member has left the state. When a person temporarily leaves the state but plans to return, do not cancel assistance based on residency requirements.

Continued maintenance of a home in Iowa or the fact that most household goods remain in the state is considered evidence of temporary absence from Iowa. However, the acceptance of employment or the enrollment of the child in school in the other state is an indication that Iowa residency may have been abandoned.

Citizenship

Legal reference: P. L. 99-603, P. L. 104-193; P. L. 111-3, Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA); 42 CFR 435.406; Iowa Code section 217.41B; 441 IAC 87.2(4)

To be eligible for FPP, a person must be one of the following:

- A U.S. **citizen**, defined as:
  - A person born in the United States,
  - A person born of parents who are citizens living outside the United States, or
  - A person granted citizenship status.

  For purposes of qualifying as a U.S. citizen, "United States" is defined as the 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the North Mariana Islands.
- A **national** of the United States, defined as a person born in American Samoa or the Swain Islands. The Independent State of Samoa (also known as Western Samoa) is not part of American Samoa, so individuals from this county are not U.S. nationals.
- A **qualified alien**. See Alien Status for more information on services and eligibility criteria.

"**Lawfully residing**" aliens may be either immigrants or nonimmigrants that the Department of Homeland Security considers long-term residents who have moved to the United States, are not required to maintain permanent residence in another country, and are allowed to remain in the United States either permanently or indefinitely.

NOTE: Persons from the Compact of Free Association States (CFAS) are not U.S. citizens or nationals. The CFAS includes the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

Persons from the CFAS retain citizenship in their country of origin but are allowed to enter and work in the United States without obtaining an immigration status. Adult CFAS citizens (ages 21 and over) **are not** eligible for FPP. However, children under age 21 who are CFAS citizens and are lawfully residing in the United States may be eligible for FPP.

Applicants must declare their citizenship or alien status as part of the application process by signing a state-approved FPP application. Applicants must also provide original documentation to verify their citizenship or alien status.

People who are not citizens or nationals by birth can become citizens through a process called "naturalization." In addition, certain children born abroad who were not U.S. citizens at the time of birth may establish citizenship automatically under the Children Citizenship Act. See Acceptable Documentation for more information about verification of automatic citizenship.

See Citizenship and Identity Documentation Chart for acceptable forms of citizenship and identity verification. See Alien Documentation Chart for information about acceptable forms of verification for alien status.

Verifying Citizenship and Identity

Legal reference: 42 CFR 435.406 and 435.407; 441 IAC 75.11(2)"f"; Sections 211(a) and 211(b)(3) of Public Law 111-3; Iowa Code section 217.41B; 441 IAC 87.2(4)

Unless specifically exempted, all FPP applicants or members claiming to be United States citizens are required to certify their citizenship and identity as a condition of eligibility. In most cases, FPP is available while the person is verifying citizenship and identity. See Reasonable Opportunity Period.

Procedure:
When acceptable proof of citizenship and identity is provided, document that both citizenship and identity have been verified by entering coding in the FPP System.

Unless the person's citizenship is verified through the automated SVES match, record the type of verification obtained from each person in the FPP System.

Make entries on the Non-Financial Information screen in the fields HOW WAS CITIZENSHIP VERIFIED and HOW WAS IDENTITY VERIFIED. Acceptable codes for each field are displayed in a drop down box.

You must maintain a file that contains copies of the documents used to verify citizenship and identity for each person approved for FPP.

Keep this documentation in the active case file unless citizenship was verified through the automated Social Security Validation Enumeration System (SVES). When citizenship is verified through the SVES match, a record of the proof will be maintained electronically and displayed on the Search Result screen.

NOTE: A person is required to provide proof of citizenship and identity only once. Once provided, proof cannot be required again as a condition of FPP eligibility unless there is a reason to question the proof that was previously provided.

Documentation Process for State Verification Exchange System (SVES) Match

Legal reference: 42 CFR 435.407; Iowa Code section 217.41B; 441 IAC 87.2(4)

Policy:
A person who attests to U.S. citizenship and provides name, social security number, and date of birth meets the citizenship and identity documentation requirements if the response to submission of this information to the Social Security Administration verifies the person's citizenship and identity.

A written request for verification shall be issued if:

- The Social Security Administration returns a response that does not verify the person's citizenship and identity.
- A response cannot be requested from the Social Security Administration because the person does not have a social security number.
- The person has previously had a 90-day reasonable opportunity period to verify citizenship for Medicaid, FPP or ***hawk-i***.

Procedure:
When processing an application, the FPP System will automatically send a request for proof of citizenship and identity to the Social Security Administration via SVES if you answer "yes" to the question "Do you want to request a SVES match?"

Do **not** request a SVES match when the Search Result screen already has a code in the US or ID fields indicating that citizenship or identity was already verified. Do **not** edit or override the HOW CITIZENSHIP WAS VERIFIED or HOW WAS IDENTITY VERIFIED fields in the Case information/Non-Financial screen when they indicate that citizenship and identity was already verified.

A SVES request for proof of citizenship and identity will **not** be sent when coding in **both** the US and ID fields indicates that verification is not needed (e.g., verification is already on file, person is an alien). When a SVES request will not be generated for a person who is required to verify citizenship and has not done so, follow the procedure under No SVES Match.

Request a SVES match **only** when processing a person who:

- Attests to U.S. citizenship,
- Has not yet had the 90-day reasonable opportunity period, and
- Is required to verified citizenship and identity but has not already done so, as indicated by coding in the Search Results screen.

When you request a SVES match for an FPP applicant or member:

- The system will update the fields US and ID to show a "?" in the Search Result screen.
- You **must** set a reminder to go back and check the status of the SVES request in **48 hours**.

You may accept proof of citizenship and identity directly from the applicant so that documentation is already on file in case the Social Security Administration is unable to verify the person's citizenship.

When the response to a SVES request for proof of citizenship and identity is a "consistent match" this verifies the person's citizenship and identity. The person has met the citizenship and identity documentation requirements.

When the SVES response reports a consistent match, the system will:

- Show the response in the Search Result screen, and
- Automatically update the coding in the US and ID fields on the person's "Search Screen" to a "+."

No further action is needed for that person's ongoing FPP case.

Inconsistent SVES Match

When the SVES response is an "inconsistent match," the person's citizenship and identity are not verified. The FPP System will generate a written request for verification of citizenship and identity to notify the person that:

- The person has 90 days to provide verification by either:
  - Correcting any errors in the name, social security number, or date of birth given to the family planning agency so that Social Security Administration (SSA) can verify the person's citizenship; or
  - Correcting any errors in the SSA's records and providing proof of citizenship and identity from SSA when this is done; or
  - Providing proof of citizenship and identity from the list of document described under Acceptable Documentation.
- If verification is not provided within 90 days:
  - FPP eligibility will end,
  - FPP will not be approved again in the future until citizenship and identity are verified.

Procedure:
When the response is received that SSA cannot verify the person's citizenship and identity, the system will automatically:

- Show the response in the Search Result screen.
- Change the code in the US and ID fields on the person's Search Result screen from "?" to "-" unless there is already a valid code in that field.
- Calculate and display the 90-day due date in the Search Result screen under field 90-DAY DATE.
- Generate form 470-4858, Request for Verification of Citizenship and Identity, and Comm. 258, Verifying Citizenship and Identity.

Set up a reminder for the date that the 90-day reasonable opportunity period is due. Manually cancel the FPP case at the end of the reasonable opportunity period if proof for citizenship and identity is not provided by the due date.

If acceptable proof is provided, record the receipt of documentation in the Search Result Edit screen under fields HOW WAS CITIZENSHIP VERIFIED and HOW WAS IDENTITY VERIFIED.

If the person has corrected errors in the SSA's records:

- Make the appropriate corrections in the Search Edit screen **and**
- Resend the request by answering "yes" to question "Do you want to request a SVES match?"
- Otherwise, enter the code indicating the corresponding document from the list provided under the drop down box.

If proof is provided but is questionable or not acceptable:

- Contact the person by phone or mail.
- Explain why the proof submitted is not acceptable and how acceptable proof can be obtained (see back of Comm. 258).
- Document phone contacts in the case file.

Cancel the person's FPP at the end of the 90-day reasonable opportunity period due to lack of proof of citizenship and identity, the system will allow timely notice.

No SVES Match

Policy:
An SVES request for proof of citizenship and identity will not be sent when:

- A "?" is coded in the US or ID fields for a person who does not have social security number.
- A request was already sent and the person's name, date of birth, social security number or sex has not been changed in the Search Result Edit screen.

A written request for verification shall be issued. FPP shall be approved during the 90-day reasonable opportunity period.

Procedure:
When proof of citizenship is required for a person but cannot be requested via SVES, a written request for proof will be system-generated. The request notifies the person that if proof of citizenship and identify is not provided within 90 days:

- FPP eligibility will end.
- FPP will not be approved again in the future until citizenship and identity is verified.

Form 470-4858, *Request for Verification of Citizenship and Identity*, and Comm. 258, *Verifying Citizenship and Identity*, will be system-generated and sent to a person who:

- Is approved on the system,
- Has an invalid SSN, and
- Has a "?" code in the US or ID fields.

If a person later provides a valid social security number, entry of the social security number will cause a request for proof of citizenship to send via SVES. However, form 470-4858, *Request for Verification of Citizenship and Identity*, will **not** be generated again, because only one 90-day reasonable opportunity period is allowed for each individual.

Cancel the person's FPP case at the end of the 90-day reasonable opportunity period due to lack of proof of citizenship and identity, the system will allow timely notice.

Reasonable Opportunity Period

Legal reference: 42 CFR 435.407; Iowa Code section 217.41B; 441 IAC 87.2(4)

Policy:
A person shall be allowed a reasonable opportunity period to obtain and provide proof of citizenship and identity. The reasonable opportunity period begins with the date a written request to provide the information is issued to the person and continues for 90 days.

FPP shall be approved during the 90-day reasonable opportunity period for applicants and shall continue for members who have not previously been required to provide proof of citizenship and identity.

FPP shall not be approved for an applicant or continued for a member who has already received a reasonable opportunity period until proof of citizenship and identity is provided.

Procedure:
Whenever possible, obtain proof of citizenship and identity through an automated SVES match with the Social Security Administration.

If you request a SVES match for an FPP applicant or member, you **must** set a reminder to go back and check the status of the SVES request in **48 hours**. If the match is **consistent**, the system will update citizenship and identity coding.

If the SVES match is **inconsistent** or **unavailable**, the system will generate form 470-4858, *Request for Verification of Citizenship and Identity*, and Comm. 258, *Verifying Citizenship and Identity*. The system will sent these forms to the member at the address recorded in the FPP System.

If the SVES match is **inconsistent**, the **system** will:

- Calculate the reasonable opportunity period and make it available for view at the Search Result screen in the FPP System under the field called 90-DATE DATE.
- The Search Result screen will display the following information:
  - SVES response
  - Issuance of form 470-4858 (yes or no)
  - 90-day due date

If the SVES match is **inconsistent**, the **worker** must:

- Set up a reminder and track the date that the reasonable opportunity period is due.
- Cancel the FPP case at the end of the reasonable opportunity period, using the "Quick Cancel" function, if proof for citizenship and identity is not provided by the due date.

If acceptable proof is provided, record the receipt of documentation in the Search Result Edit screen under fields HOW WAS CITIZENSHIP VERIFIED and HOW WAS IDENTITY VERIFIED.

To keep the system from incorrectly blocking subsequent FPP approvals, record receipt of the proof in the Search Result Edit screen even if the person is not currently in an active FPP status.

NOTE: Form 470-4858, *Request for Verification of Citizenship and Identity*, is not available for worker issuance because this would interfere with the system calculating the one 90-day reasonable opportunity period allowed for each person.

You may request a copy of this form to the FPP Help Desk, if necessary (e.g., if the member loses the original).

Acceptable Documentation

Legal reference: 42 CFR 435.407; Iowa Code section 217.41B; 441 IAC 87.2(4); P. L. 111-3

Original documents or copies certified by the issuing agency are required. "Certified" means that the document is stamped, embossed, or otherwise noted in writing by the agency responsible for maintaining the original that it is a true copy of the original. Copies or notarized copies of documents are not acceptable proof.

NOTE: Copies of original documents are acceptable only when made by the Department's employees (including staff out-stationed at other locations), or by staff authorized under contract, such as FPP providers who are authorized to take initial applications.

Documents submitted by a person whose last name has changed (e.g., due to marriage or divorce) may be accepted if the documents match in every way except the last name. If there is reason to question whether the documents belong to the same person, request an official document verifying the change (e.g., marriage license or the divorce decree).

Citizenship documents are arranged in a hierarchy from most reliable (Level 1) to least reliable (Level 4). Level 1 documents are acceptable proof of both citizenship and identity. If Level 2, Level 3, or Level 4 documents are used to verify citizenship, separate proof of identity is also required.

Obtain the most reliable record the person has available. Accept less reliable documents only when more reliable documents do not exist or cannot be obtained within the reasonable opportunity period.

When a lower-level document is available, you may accept it if a higher-level document cannot be obtained within the normal time limits for processing an application or automatic redetermination. In this situation, the higher-level document is not considered available.

There is no hierarchy of documents for identity. However, accept the three or more corroborating documents or an affidavit only as a last resort.

This chart lists documents acceptable as verification of citizenship and identity.

Citizenship and Identity Documentation Chart

Level 1: Primary Documents (verify both citizenship and identity)	
Confirmation of citizenship via SVES automated data match	U.S. citizenship and identity has been verified by the Social Security Administration based on a data match through Security Validation Enumerations System (SVES). This match can be attempted only for a person who provides a name, date of birth, and social security number.
U.S. passport	The Department of State issues U.S. passports. An expired passport may be accepted as evidence of U.S. citizenship and identity as long as it was originally issued without limitation. Do **not** accept any passport as evidence of U.S. citizenship when it was issued with a limitation. However, such a passport may be used as proof of identity. NOTE: Spouses and children were sometimes included on one passport through 1980. The citizenship and identity of all of the persons included can be established when one of these passports is presented. U.S. passports issued after 1980 show only one person.

Level 1: Primary Documents (verify both citizenship and identity)	
Documentation issued by a federally recognized Indian Tribe showing membership or enrollment in or affiliation with that Tribe. (Examples include Tribal enrollment or membership cards, a certificate of degree of Indian blood issued by the Bureau of Indian Affairs, or a Tribal census document.)	Until federal regulations are issued on satisfactory documentation for Tribes having an international border whose membership includes non-U.S. citizens, members of cross-border Tribes may use Tribal enrollment or membership documents for purposes of proving both citizenship and identity. The list of federally recognized Indian Tribes is maintained at https://www.gpo.gov/fdsys/pkg/FR-2016-05-04/pdf/2016-10408.pdf
Certificate of U.S. Citizenship (Department of Homeland Security Form N-560 or N-561)	Issued to persons whose U.S. citizenship is derived through a parent.
Certificate of Naturalization (Department of Homeland Security Form N-550 or N-570)	Issued when a person becomes a naturalized citizen.

Level 2: Secondary Documents (verify citizenship only)	
U.S. public birth certificate showing birth in: ♦ One of the 50 states or the District of Columbia ♦ American Samoa ♦ Swain's Islands ♦ Puerto Rico on or after January 13, 1941 ♦ The U.S. Virgin Islands on or after January 17, 1917 ♦ The Northern Mariana Islands after November 4, 1986 ♦ Guam on or after April 10, 1899	The state, commonwealth, territory, or local jurisdiction may issue the birth record document. The birth record must have been recorded before the person was 5 years old. Birth certificates recorded after age 5 can be used only as Level 4 documentation. If the document shows that a person was born in Puerto Rico, Guam, the Virgin Islands, or the Northern Mariana Islands before the dates listed, contact SPIRS help desk for assistance in determining whether the person is a collectively naturalized U.S. citizen.

Level 2: Secondary Documents (verify citizenship only)	
Certification of Report of Birth (Form DS-1350)	This form is issued by the Department of State to U.S. citizens who were born outside the United States and acquired U.S. citizenship at birth.
Consular Report of Birth Abroad of a U.S. Citizen (Form FS-240)	This form is issued by the Department of State via American consular offices overseas to children under the age of 18. Children born to U.S. military personnel usually have such a form.
Certification of Birth Abroad (Form FS-545)	Before November 1, 1990, Department of State consulates also issued this form with the previous version of form FS-240.
U.S. Citizen I.D. Card (Department of Homeland Security Form I-197 or the earlier version Form I-179)	Form I-179 was issued from 1960 to 1973. Then it was renumbered to form I-197 and was issued until April 7, 1983. These forms were issued to naturalized citizens living near the Canadian or Mexican border who needed identification for frequent border crossings. Although not currently issued, they are still valid.
American Indian Card (I-872) with "KIC" classification	Form I-872 is issued by the Department of Homeland Security to identify U.S. citizen members of the Texas band of Kickapoos living near the U.S./Mexico border. The "KIC" classification code and a statement on the back denote U.S. citizenship.
Northern Mariana Identification Card (I-873)	Form I-873 was issued by the former Immigration and Naturalization Service to a collectively naturalized U.S. citizen who was born in the Northern Mariana Islands before November 4, 1986. The card is no longer issued, but is still valid.

Level 2: Secondary Documents (verify citizenship only)	
Final adoption decree	The decree must show the child's name and U.S. place of birth. When an adoption is not finalized and the state in which the child was born will not release a birth certificate before final adoption, a statement from a state-approved adoption agency that shows the child's name and U.S. place of birth is acceptable. The agency must state in its certification that the source of the information is an original birth certificate.
Verification of automatic citizenship under section 320 of the Immigration and Nationality Act, also known as Child Citizenship Act	Children born outside the United States who were not U.S. citizens at the time of birth (international adoptions and certain children born abroad whose parents become naturalized citizens) may establish citizenship automatically by providing verification that at any time on or after February 27, 2001, the child met the following conditions: ♦ The child is under age 18. ♦ At least one parent is a U.S. citizen by birth or naturalization. ♦ The child is residing in the United States in the legal and physical custody of the U.S. citizen parent pursuant to a lawful admission for permanent residence. If adopted, the child was admitted as either having an immigration status of IR-3 (adopted outside the United States) or IR-4 (final adoption within the United States). The parent's status must be verified according to citizenship guidelines. The child's status for admission to the United States must be verified according to alien guidelines. The adoption must be verified by obtaining a copy of the full, final adoption decree.
Official military record of service	The document must show a U.S. place of birth (for example a DD-214).
Evidence of employment by the U.S. government civil service	The document must show employment by the U.S. government before June 1, 1976.

Level 3: Other Documents (verify citizenship only)	
Extract of hospital record on hospital letterhead that shows a U.S. place of birth	For persons aged 16 or over, the record must have been established at the time of the person's birth and the document created at least 5 years before the FPP application date. For children under age 16, the document must have been created near the time of birth or 5 years before the FPP application date. NOTE: A souvenir "birth certificate" issued by the hospital does not qualify.
Life, health, or other insurance record showing a U.S. place of birth	For persons aged 16 or over, the record must have been created at least 5 years before the FPP application date. For children under age 16, the document must have been created near the time of birth or 5 years before the FPP application date.
Religious record showing either the date of birth or the person's age when the record was made	The document must be an official record that was recorded with the religious organization in the United States within three months of birth. Caution: In questionable cases (e.g., a record recorded near a U.S. international border and the child may have been born outside the United States), the state must verify the record or document that the mother was in the United States at the time of birth.
Early school record showing a U.S. place of birth	The record must show the child's name, date of admission to the school, date of birth, U.S. place of birth, and the names and places of the person's parents.

NOTE: With the exception of written affidavits, all Level 4 documents must show a U.S. place of birth and must have been created at least five years before the application for FPP (or near the time of birth, for children under 16).

Level 4: Other Documents (verify citizenship only)	
Other documents listed that show a U.S. place of birth and were created at least five years before the FPP application date	♦ Seneca Indian tribal census record ♦ Bureau of Indian Affairs tribal census records of the Navaho Indians ♦ Roll of Alaska Natives maintained by the Bureau of Indian Affairs for persons born before December 18, 1971. (Contact SPIRS for assistance in requesting information from the Roll.) ♦ Any U.S. state's vital statistics official notification of birth registration ♦ A delayed U.S. public birth record that is recorded more than five years after the person's birth NOTE: A birth certificate recorded five years or less after the person's birth qualifies as a Level 2 document. ♦ Statement signed by the physician or midwife who was in attendance at the time of birth
Medical (clinic, doctor, or hospital) record	Medical records generally show biographical information for the person, including place of birth. The record can be used to establish U.S. citizenship when it shows a U.S. place of birth. NOTE: An immunization record maintained by a parent or school is not considered a medical record but an immunization record maintained by a clinic, doctor, or hospital is considered a medical record for this purpose.

Level 4: Other Documents (verify citizenship only)	
Affidavit signed under penalty of perjury: *Affidavit Concerning Documentation of Citizenship*, form 470-4374 *Affidavit of Citizenship*, form 470-4373	Form 470-4374 must be completed by the member or by another knowledgeable person (guardian or representative) explaining why the person does not have and cannot get any of the other documents to prove citizenship. Two people with personal knowledge of the events establishing the member's claim of citizenship must complete form 470-4373. Only one of these can be related to the person. They must also verify their own citizenship and identity. NOTE: If an affidavit is used to prove citizenship, an affidavit cannot be used to prove identity. An affidavit is the only Level 4 document that does not have to show a U.S. place of birth or have been created five years before the FPP application. It may be used for both U.S. born and naturalized citizens. It may be used only as a last resort when no other documents are available.

NOTE: Documents used to prove identity should be current. Identity documents that have recently expired may be accepted as long as there is no reason to question that they match the individual. Use the "prudent person" concept in deciding whether a document is "current" or "recently expired."

Identity Documents:	**Explanation:**
Driver's license issued by a U.S. state or territory	Acceptable if the license has a photograph of the person or identifying information such as name, age, sex, race, height, weight, or eye color.
ID card issued by a state, federal, or local government	Acceptable if the ID has the same information included on driver's licenses e.g., a photograph or other identifying information such as name, age, sex, race, height, weight, or eye color. NOTE: A voter's registration card or Canadian driver's license may not be accepted.
U.S. military card or draft record	Self-explanatory.
Cross match with a federal or state governmental, public assistance, law enforcement, or corrections agency's data system; if the agency establishes and certifies the true identity of the individuals	This includes data matches with Iowa Department of Transportation (DOT) driver's license information. Remember to print the driver's license information screen and file it in the case file as proof.
Military dependent's identification card	Acceptable if it contains the person's photograph.
School ID card with a photograph	Self-explanatory.
U.S. Coast Guard Merchant Mariner card	Self-explanatory.
U.S. passport issued with limitations	Contact the FPP help desk for any questions about the document.
For children under age 16: Clinic, doctor, hospital, or school record	School records include day care records and report cards. School records must be verified with the issuing school.
If none of the evidence of identity listed above is available, three or more corroborating documents may be accepted if the same items were not used to document citizenship. This option can be used only if the person submitted 2nd-level or 3rd-level citizenship documentation.	Documents that together reasonably corroborate a person's identity may be used, such as employer identification cards, high school or college diplomas, marriage certificates, divorce decrees, and property deeds or titles. All documents must contain the person's name and must contain consistent identifying information.

Alien Status

Legal reference: Section 121 of the Immigration and Control Act of 1986 (P. L. 99-603); P. L. 104-193; Iowa Code section 217.41B; 441 IAC 87.2(4)

Legal aliens may be eligible or ineligible for FPP, depending on their immigration status.

Aliens described under Aliens Exempt from Five-Year Bar may be eligible for FPP from the date they obtained alien status; regardless of the date they enter the United States.

Aliens described under Aliens Subject to Five-Year Bar are not eligible for five years after their date of entry. The five-year period of ineligibility begins on the date of the person's entry into the United States with one of the listed statuses.

Aliens Subject to Five-Year Bar

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(4); Public Law 104-193

Aliens listed in this section who enter the United States on or after August 22, 1996, are barred from receiving FPP and Medicaid (except emergency services) for five years.

The five-year period begins on the date the person enters the United States with one of the following statuses:

- Aliens aged 21 or over who are lawfully admitted for permanent residency (LPR).

  NOTE: Lawfully permanent residents may be required to have a sponsor and may be subject to deeming of income or resources from the sponsor. See 4-L, Sponsor Affidavits of Support and Deeming, for more information.

- Aliens aged 21 or over who are paroled into the United States under section 212(d)(5) of the Immigration and Nationality Act (INA) for a period of at least one year.

- Aliens aged 21 or over who are granted conditional entry under section 203(a)(7) of the INA as in effect before April 1, 1980.
- Battered aliens ages 21 or over under 8 USC 1641(c).

  NOTE: The five-year bar does not apply to aliens in these categories who entered the United States before August 22, 1996, or to children who are under the age of 21.

Aliens Exempt from Five-Year Bar

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(4); P. L. 104-193

Aliens with one of the following statuses are eligible for FPP from the date they obtain the status:

- Refugees admitted under section 207 of the Immigration and Nationality Act (INA).
- Aliens granted asylum under section 208 of the INA.
- Aliens whose deportation or removal is withheld under section 243(h) or section 241(b)(3) of the INA.
- Cuban or Haitian entrants under section 501(e) of the Refugee Education Assistance Act of 1980.
- Amerasian immigrants.
- Canadian born American Indians who have treaty rights to cross the United States borders with Canada and Mexico. There is an extensive list of these tribes. Contact the FPP help desk if you question whether a tribe is included.
- Aliens lawfully admitted for permanent residence who are veterans honorably discharged for reasons other than alienage and their spouses, surviving unremarried spouses, and unmarried dependent children. This includes alien spouses, surviving unremarried spouses, and unmarried dependent children of veterans who are U.S. citizens or deceased veterans.
- Aliens lawfully admitted for permanent residence who are active-duty personnel of the United States Armed Forces and their spouses, surviving unremarried spouses, and unmarried dependent children of active duty personnel who are U.S. citizens or deceased active-duty personnel.

  "Active duty" excludes temporary full-time duty for training purposes performed by members of the National Guard or Reserves.

- Aliens who entered the United States before August 22, 1996.
- Victims of trafficking with an Office of Refugee Resettlement (ORR) certification letter that has been verified by calling the trafficking verification line. **Contact the FPP help desk** for assistance.

  Trafficking victims are eligible only for eight months from the entry date in the original ORR certification letter unless ORR issues a recertification letter.

  Without the ORR certification or when the ORR certification expires, trafficking victims are not eligible for FPP unless another qualifying status is obtained.
- Iraqi and Afghan special immigrants. See 8-L, Iraqi and Afghan Special Immigrants, for specific instructions. These special immigrants are lawful permanent residents but are eligible for FPP to the same extent as refugees.
- Alien children under the age of 21 who are:
  - Aliens paroled into the United States under section 212(d)(5) of the INA for a period of at least one year;
  - Battered aliens under 8 USC 1641(c). Refer to 8-L, Battered Aliens, for more information; or
  - Aliens in one of the statuses listed following the definition of "lawfully residing" in 8-L, Alien Categories. Only children under age 21 in a lawfully residing status are qualified aliens and may be eligible for FPP, if all other eligibility requirements (including residency) are met.

  NOTE: Verification that these children continue in one of these statuses is required at each annual review. Attempt to use the documentation presented at application to verify then child's continued lawfully residing status.

  If additional documentation is needed, the household must provide proof of continued lawfully residing status for the child.

  When these lawfully residing children reach age 21, they become ineligible for FPP unless they obtain another qualified alien status.

Establishing Qualifying Quarters

Legal reference: Iowa Code section 217.41B; 441 IAC 87.2(4) and (5)

When a lawful permanent resident is not otherwise exempt from sponsor deeming, you must determine the number of qualifying quarters with which the person can be credited. A lawful permanent resident becomes exempt from sponsor deeming when credited with 40 qualifying quarters.

Each person can get up to a total of four qualifying quarters of credit each calendar year based on the person's own earnings. The person may be credited with additional quarters in a calendar year based on earnings of a parent or spouse as described in this section.

The following chart lists the amount a person had to earn to get one credit for the years 1978 and later. (For years before 1978, contact the FPP help desk for assistance.)

Amount Needed to Earn a Qualifying Quarter

Year	Earnings Needed to Get One Credit
1978	$250
1979	$260
1980	$290
1981	$310
1982	$340
1983	$370
1984	$390
1985	$410
1986	$440
1987	$460
1988	$470
1989	$500
1990	$520
1991	$540
1992	$570
1993	$590
1994	$620
1995	$630
1996	$640
1997	$670

Year	Earnings Needed to Get One Credit
1998	$700
1999	$740
2000	$780
2001	$830
2002	$870
2003	$890
2004	$900
2005	$920
2006	$970
2007	$1,000
2008	$1,050
2009	$1,090
2010	$1,120
2011	$1,120
2012	$1,130
2013	$1,160
2014	$1,200
2015	$1,220
2016	$1,260
2017	$1,300

To calculate the number of quarters for a year, divide the person's total earnings for the year by the amount needed to get one credit.

For earnings from employment, use the gross amount of earnings. For earnings from self-employment, use the amount of earnings after allowable self-employment expenses have been deducted.

Use only full quarters. Example: 2.95 quarters are rounded down to two quarters. Each person can have no more than four quarters per year. Example:

> An alien earned $5,000 gross income in 1995. ($5,000 divided by $630 = 7.936) Although the result equals over 7 quarters, the alien is credited with 4 qualifying quarters in 1995.

NOTE: Starting with January 1, 1997, do not count the income from any quarters in which an alien received any type of federal means-tested public assistance during the quarter. The quarters in a calendar year are: January through March, April through June, July through September, and October through December.

"Means-tested public assistance" includes FIP, SSI, Medicaid, and Food Assistance. Medicaid received by an individual, household, or family eligibility unit is receiving "means-tested public assistance."

This means if an alien got FIP, Food Assistance, Medicaid, or SSI in June 1997, you would subtract the person's April, May, and June earnings from the total 1997 earnings and divide the remainder to figure how many qualifying quarters the person has.

Aliens can count their spouse's quarters earned during the marriage in addition to their own quarters in order to meet the 40-quarter requirement. Use the same formula to calculate qualifying quarters earned by a parent or spouse.

For example, if each spouse had 20 quarters you would add the quarters together and the wife would be eligible for FPP.

Mr. and Mrs. Q are working in 2004. One earned $25,000 gross income and the other earned $3,000 gross income. ($25,000 divided by $900 = 27.77) ($3,000 divided by $900 = 3.33)

27.77 is converted to four quarters. 3.33 is converted to three quarters. The Qs' countable quarters are combined together to determine the qualifying quarters. Mrs. Q is credited with seven qualifying quarters for 2004.

Count the spouse's quarters earned during the marriage if the spouse is either a citizen or an alien, and either:

- The couple is currently married, or
- The couple is separated but not divorced, or
- A spouse is deceased and the surviving spouse is not remarried.

If the couple divorces, the former spouses are no longer entitled to each other's quarters. Thus, if the divorce results in the alien no longer having 40 qualifying quarters, cancel the person's FPP.

Aliens can also count the quarters earned by a parent in addition to their own quarters to meet the 40-quarter requirement. For this policy, "parent" means the natural or adoptive parent or the stepparent. Count the parent's quarters if the parent:

- Is either a citizen or an alien and
- Earned the quarters before the child turned 21. (The parent's quarters earned before the child was born also count.)

Count the quarters by a stepparent during the stepparent relationship if the relationship still exists. Death of the stepparent does not end the relationship. Do not count quarters earned before the stepparent relationship began. Do not count any quarters of the stepparent if the parent and stepparent are divorced.

Do not count quarters earned by a child toward the eligibility of a parent.

Sponsor Deeming

Legal reference: P. L. 104-193, P. L. 104-208, 20 CFR 416.1160(a), 416.1166a(d)3; 8 U.S.C. §§ 1182(a)(4), 1183a(1996); 42 U.S.C. 1396b(v) as amended by P. L. 111-3; Iowa Code section 217.41B; 441 IAC 87.2(5)

Aliens who seek admission to the United States as lawful permanent residents must establish that they will not become a "public charge." Many aliens establish that they will not become public charges by having "sponsors" who pledge to support them. An alien may have more than one sponsor.

A sponsor is a person who signs an "affidavit of support" agreeing to support an alien to help the alien obtain lawful permanent resident status.

There are three versions of the *Affidavit of Support*:

- Form I-864. This form is enforceable since December 19, 1997.
- Form I-134. This form is not enforceable.
- Form I-361. This form is enforceable and must be submitted with a petition for treatment as an Amerasian. However, deeming will not apply to persons with type of support affidavit.

Sponsor deeming is the process of considering the income and resources of the sponsor to be available to the sponsored person, whether or not the income or resources are actually made available. The sponsor deeming rules apply **only** to persons who:

- Are lawful permanent residents (LPRs) aged 21 or over,
- Applied for lawful permanent resident status on or after December 19, 1997, and
- Are sponsored by a person who signed Form I-864, *Affidavit of Support*.

NOTE: Sponsor deeming may still affect FPP eligibility of children under age 21 if an adult household member has a sponsor.

For deeming purposes, deeming will not apply when the sponsor is:

- An employer who does not sign an affidavit of support.
- An organization such as a church or service club.
- The alien's eligible or ineligible spouse or parent whose income is otherwise considered in determining the alien's FPP eligibility.

If the eligible couple separates and begins living in separate households, then the sponsor-to-alien deeming rules apply.

Verifying Qualifying Quarters

When an exception to sponsor deeming will affect the eligibility determination, the applicant or considered person is responsible for getting verification of qualifying quarters. This includes getting verification of the qualifying quarters earned by a spouse, parent, or stepparent.

In addition to verification from the Social Security Administration (SSA) office, you can use documentation such as:

- Wage stubs
- Employer's statement
- Income tax forms

If the alien does not have acceptable proof, the member is responsible for obtaining necessary verification from SSA. SSA can verify quarters starting with the year 1930.

If the alien provides verification from SSA of less than the required 40 qualifying quarters but disputes the SSA records, allow the alien an opportunity to resolve the discrepancy.

In either situation:

- Instruct the applicant in writing to obtain the necessary verification or proof of requesting the verification, or that SSA is investigating the discrepancy within ten days.

  Include in the note that the alien will be denied if the requested verification is not received by the stated due date. Also ask that the applicant let you know if more time is needed to obtain the requested verification or proof of request for the verification.

- Deny the alien if you do not receive the requested verification or proof for requesting the SSA verification or investigation by the due date (or the extended due date, if applicable).

If the member provides the requested proof, pend the application until the SSA verification is received or the SSA investigation n is completed. Periodically contact the member to check on the status of the SSA verification or investigation of the disputed qualifying quarters.

Process the FPP application upon receipt of the SSA verification or the results of the completed investigation. Include the alien in the eligible group if SSA verifies at least 40 qualifying quarters.

If the completed investigation still verifies less than 40 qualifying quarters:

- Include the alien if the date of entry was before August 22, 1996.
- Deny the alien if the date of entry is on or after August 22, 1996.

Alien Documentation Chart

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Amerasians treated as refugees	♦ Form I-551, *Permanent Resident Card* * ♦ Temporary I-551 stamp in a passport ♦ Form I-94, *Arrival/Departure Record* ♦ Any verification from the USCIS or other authoritative document All of these should have one of the following codes: AM-1, AM-2, AM-3, AM-6, AM-7, AM-8	Eligible regardless of U.S. entry date
American Indians born outside the United States	♦ Member of a federally recognized Indian tribe as defined in Section 4(e) of the Indian Self-Determination and Education Assistance Act; or ♦ Form I-551, *Permanent Resident Card**, coded S1-3, born in Canada and at least 50% American Indian, to whom the provisions of section 289 of the Immigration and Nationality Act apply. For the list of federally recognized tribes, refer to https://www.gpo.gov/fdsys/pkg/FR-2016-05-04/pdf/2016-10408.pdf	Eligible regardless of U.S. entry date

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Asylee	♦ Form I-94, *Arrival/Departure Record,* or passport stamped "asylee" or section 208. ♦ Order granting asylum issued by the USCIS, an immigration judge, the Board of Immigration Appeals, or a federal court. ♦ Forms I-688B or I-766, *Employment Authorization Document*, coded 274a.12(a)(5) or A5(a)10 or (a)3. ♦ *Refugee Travel Document* (Form I-571) along with another card identifying status. ♦ Any verification from the USCIS or other authoritative document. NOTE: If adjusted to lawful permanent resident status, Form I-551, *Permanent Resident Card,* may be coded AS-6, AS-7, or AS-8.	Eligible as of date asylum is granted
Battered alien (cannot live with abuser)	♦ Receipt or proof of filing visa petition Form I-130, *Petition for Alien Relative*, under immediate relative (IR) or second family preference (P-2) showing status as spouse; ♦ Form I-360, *Petition for Amerasian, Widow(er), or Special Immigrant*, (application to qualify as abused spouse or child under Violence Against Women Act); ♦ Form I-797, *Notice of Action,* referencing pending Form I-130, *Petition for Alien Relative,* or Form I-360, *Petition for Amerasian, Widow(er), or Special Immigrant*, or finding establishment of a prima facie case;	Children under age 21, eligible regardless of U.S. entry date. NOTE: Continued battered alien status must be verified at each annual review.

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Battered alien (cannot live with abuser) (Cont.)	♦ Receipt or other proof of filing Form I-485, *Application to Register Permanent Residence or Adjust Status,* (application for adjustment of status on basis of an immediate relative or family second preference petition or Violence Against Women Act application); ♦ Form I-688B *or* I-766, *Employment Authorization Document*, coded 274a.12(a)(10) or A10 (applicant for suspension of deportation) or 274a 12(c)(14) or C14 (individual granted deferred action status); ♦ Any documents indicating a pending suspension of deportation or cancellation of removal case, including a receipt from an immigration court indicating filing of Executive Office for Immigration Review: • Form EOIR-40, A*pplication for Suspension of Deportation* or • Form EOIR-42, A*pplication for Cancellation of Removal*; or ♦ Any verification from the USCIS or other authoritative document.	Adults (age 21 and over): ♦ Barred for five years if entered United States **on or after** 8/22/96 ♦ Eligible if entered United States **before** 8/22/96 See 8-L, Battered Aliens, for more information.
Conditional entrants (not used since 1980)	♦ I-94, *Arrival/Departure Record*, or other document indicating status as "conditional entrant," "Seventh Preference" Section 203(a)(7), or P7, or ♦ Any verification from the USCIS or other authoritative document.	Eligible because entered the United States **before** 8/22/96

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Cuban or Haitian entrants (treated as refugees)	♦ Form I-94, *Arrival/Departure Record*, with a stamp indicating "Cuban/ Haitian entrant" (rare; not used since 1980), any notation indicating "parole," or any documents indicating pending exclusion or deportation proceedings; ♦ Any documents indicating a pending asylum application, such as a receipt from the USCIS indicating filing of Form I-589, *Application for Asylum and for Withholding of Removal*; ♦ Forms I-688B or I-766, *Employment Authorization Document*, coded 274a.12(c)(8) or CI; or ♦ Any verification from the USCIS or other authoritative document. NOTE: Persons who have adjusted to lawful permanent resident status may have Form I-551, *Permanent Resident Card*, coded with CH-6, CU-6, CU-7, LB-2, LB-6, or LB-7.	Eligible regardless of U.S. entry date
Deportation or removal withheld	♦ Form I-94, *Arrival/Departure Record*, or passport stamped "section 243(h)" or "section 241(b)(3)"; ♦ Order granting withholding of deportation or removal issued by the USCIS, an immigration judge, the Board of Immigration Appeals, or a federal court; ♦ Forms I-688B or I-766, *Employment Authorization Document*, coded 274a.12(a)(10) or A10; ♦ Form I-571, *Refugee Travel Document*, with another card showing status; ♦ Any verification from the USCIS or other authoritative document.	Eligible regardless of U.S. entry date

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Iraqi or Afghan special immigrants (Lawful permanent residents, treated as refugees)	♦ Form I-551, *Permanent Resident Card**, showing Iraqi or Afghan nationality with any of the following status codes: • SI1, SI2, SI3, SI6, SI7, SI9, or • SQ1, SQ2, SQ3, SQ6, SQ7, SQ9 ♦ Iraqi or Afghan passport with an immigrant visa stamp noting admitted under a status code listed and date of entry noted on passport or Form I-94, *Arrival/Departure Record*.	Eligible regardless of U.S. entry date
Lawfully residing immigrants or nonimmigrants	♦ Form I-94, *Arrival/Departure Record*; ♦ Forms I-688B or I-766, *Employment Authorization Document*; or ♦ Any verification from the USCIS or other authoritative document. NOTE: The specific section of the law or a designation by USCIS must appear on the document indicating the alien is in one of the statuses listed following the definition of "lawfully residing."	Children under age 21, eligible regardless of U.S. entry date. NOTE: Continued lawfully residing status must be verified at each annual review. Adults age 21 and over, ineligible regardless of U.S. entry date.

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Lawful permanent residents (LPRs)	♦ Form I-551, Permanent Resident Card; * NOTE: Form I-551 annotated with certain codes indicates the person originally entered the United States under another status and later adjusted to lawful permanent resident. Eligibility for these persons must be determined based on the original status upon entry. These statuses and codes are: • Amerasian (AM-1, AM-2, AM-3, AM-6, AM-7, AM-8), • Asylee (AS-6, AS-7, AS-8), • Canadian-born American Indian (S1-3), • Cuban or Haitian (CH-6, CU-6, CU-7, LB-2, LB-6, LB-7), • Parolee (LA), or • Refugee (R8-6, RE-6, RE-7, RE-8, RE-9). ♦ Form I-327, Permit to Reenter the United States; ♦ Form I-94, Arrival/Departure Record, with a temporary I-551 stamp; ♦ Foreign passport stamped showing temporary evidence of lawful permanent resident or I-551 status; ♦ Form I-181, Memorandum of Creation of Lawful Permanent Residence, with approval stamp; ♦ Order issued by the USCIS, an immigration judge, the Board of Immigration Appeals, or a federal court granting registry, suspension of deportation, cancellation of removal, or adjustment of status; or ♦ Any verification from the USCIS or other authoritative document	Children under age 21, eligible regardless of U.S. entry date. NOTE: Continued LPR status must be verified at each annual review. Adults (age 21 and older) with proof of 40 qualifying quarters, eligible regardless of U.S. entry date Adults (age 21 and over) without 40 qualifying quarters: ♦ Barred for five years if entered United States **on or after** 8/22/96 ♦ Eligible if entered United States **before** 8/22/96

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Parolees NOTE: Must have been paroled for at least one year	♦ Form I-94, *Arrival/Departure Record*, indicating "parole" or "PIP" or "212(d)(5)," or other language indicating parole status; ♦ Forms I-688B or I-766, *Employment Authorization Document*, coded A4 or C11 [274a.12(a)(4), 274a.12(c)(11)]; or ♦ Any verification from the USCIS or other authoritative document. ♦ If adjusted to lawful permanent resident status, may have Form I-551, *Permanent Resident Card** (some may be coded LA).	Children under age 21, eligible regardless of U.S. entry date. NOTE: Continued parolee status must be verified at each annual review. Adults (age 21 and over): ♦ Barred for five years if entered United States **on or after** 8/22/96 ♦ Eligible if entered United States **before** 8/22/96
Refugees	♦ Form I-94, *Arrival/Departure Record,* or passport stamped "refugee" or section 207; ♦ Forms I-688B or I-766, *Employment Authorization Document*, coded 274a.12(a)(3) or A3; ♦ Form I-571, *Refugee Travel Document*, with another card verifying status; or ♦ Any verification from the USCIS or other authoritative document. NOTE: If adjusted to lawful permanent resident status, Form I-551, *Permanent Resident Card*,* may be coded R8-6, RE-6, RE-7, RE-8 or RE-9.	Eligible regardless of U.S. entry date

Alien Status	Acceptable Documentation of Alien Status	Eligibility Status
Veterans or active duty personnel (lawful permanent residents) (Includes some family members of these persons. See Aliens Exempt from Five-Year Bar.)	♦ Form I-551, Permanent Resident Card; * ♦ Form I-327, Permit to Reenter the United States; ♦ Foreign passport stamped showing temporary evidence of lawful permanent resident or I-551 status; ♦ Form I-181, Memorandum of Creation of Lawful Permanent Residence with approval stamp; ♦ Order issued by the USCIS, an immigration judge, the Board of Immigration Appeals, or a federal court granting registry, suspension of deportation, cancellation of removal, or adjustment of status; or ♦ Any verification from the USCIS or other authoritative document.	Eligible regardless of U.S. entry date
Victims of Trafficking	♦ Original certification letter for adults or letter for children issued by the Office of Refugee Resettlement (ORR) and validated by calling the trafficking verification line at (866) 401-5510. NOTE: SAVE does not have information about a person's status as a victim of trafficking.	Eligible only for 8 months from entry date in original ORR certification; eligibility may continue if ORR issues recertification
Other (legal or illegal)	The person is undocumented or presents documents that indicate the person's alien status is one **other than** those specifically listed under Aliens Subject to Five-Year Bar or under Aliens Exempt from Five-Year Bar.	Ineligible regardless of U.S. entry date

Documentation of alien status is issued by the U.S. Citizenship and Immigration Services (USCIS), part of the Department of Homeland Security. Older documents were issued by the Immigration and Naturalization Service (INS).

Ongoing Eligibility

Reporting Changes

Legal reference: 42 CFR 435.916(b) and (c); Iowa Code section 217.41B; 441 IAC 87.6(217)

The member or someone acting on the member's behalf must report the following:

- There is a change in mailing or living address,
- The woman becomes pregnant,
- The person is no longer capable of bearing or fathering children (e.g., had sterilization surgery, hysterectomy, vasectomy, etc.),
- Medicaid eligible, except women who have a pregnancy end while they are receiving Medicaid, or
- Turning 55 years old.

Acting on Changes

Legal reference: Iowa Code section 217.41B; 441 IAC 87.6(217)

A person found to be income-eligible upon application or at the annual recertification shall remain income-eligible for 12 months regardless of any change in income or household size.

FPP eligibility ends if any of the following occur. The person:

- Becomes pregnant;
- Is no longer capable of bearing or fathering children;
- Moves from Iowa;
- Gains Medicaid eligibility, except women who have a pregnancy end while they are receiving Medicaid; or
- Turns age 55. EXCEPTION: The age requirement does not apply to those who are eligible for FPP due to a pregnancy ending while receiving Medicaid.

1. Ms. D is approved for FPP in January. In March, Ms. D receives a promotion that results in her countable income being over 300% of the federal poverty level. Ms. D remains eligible for FPP through December since her increased income is disregarded for the remainder of her 12-month certification period.

2. Mr. L is approved for FPP in January because his countable income does not exceed 300% of federal poverty level for a household of two, Mr. L and his wife. Mr. L has countable income of $2,000 and his wife has no income.

   In May, Mr. L's wife moves out. Mr. L's income is now over the limit for a household size of one, but he continues to be eligible for FPP for the remainder of the 12-month certification period.

3. Ms. B is approved for FPP with a January–December certification period. Ms. B reports on October 5 that she moved to Illinois. Ms. B's FPP eligibility is canceled effective November 1.

Annual Recertifications

Legal reference: Iowa Code section 217.41B; 441 IAC 87.3(4)

Recertification is the process to establish a new certification period when the existing period is about to end. Form 470-4071, *Family Planning Program Review*, will be system-generated to the FPP member at least 30 days before the end of the certification period. Click here to see a sample of this form.

A person filing a timely form 470-4071, *Family Planning Program Review*, and who is determined eligible, will have a new 12-month certification period established beginning with the month following the last month of the previous certification period.

If form 470-4071, *Family Planning Program Review*, is not completed and received by the end of the certification period, the person must reapply, using form 470-5485 or 270-5485(S), *Family Planning Program Application*, and be determined eligible in order to establish a new certification period. Eligibility does not continue if a review is not completed.

Covered Services

Services covered under FPP are more limited than what is payable through Medicaid coverage groups.

Family Planning Benefits

Family planning services and supplies are limited to those services and supplies whose primary purpose is family planning and which are provided in a family planning setting. Family planning services and supplies include:

- Approved methods of contraception;
- Sexually transmitted infection (STI) or sexually transmitted disease (STD) testing, Pap smears and pelvic exams;
- Drugs, supplies, or devices related to women's health services described above that are prescribed by a health care provider; and
- Contraceptive management, patient education, and counseling.

The laboratory tests done during an initial family planning visit for contraception may include a Pap smear, screening tests for STIs or STDs, or pregnancy test. Additional screening tests may be performed depending on the method of contraception desired and the protocol established by the clinic, program or provider.

Additional laboratory tests may be needed to address a family planning problem or need during an inter-periodic family planning visit for contraception.

Family Planning-Related Benefits

"Family planning-related services and supplies" are defined as those services provided as part of or as follow-up to a family planning visit.

Such services are provided because a "family planning-related" problem was defined or diagnosed during a routine or periodic family planning visit.

Examples of family planning-related services and supplies include:

- Colposcopy and procedures done with or during a colposcopy or repeat Pap smear performed as a follow-up to an abnormal Pap smear that was done as part of a routine periodic family planning visit.

- Drugs for the treatment of STIs or STDs, except for HIV/AIDS and hepatitis, when the STI or STD is identified or diagnosed during a routine periodic family planning visit. A follow-up visit or encounter for the treatment or drugs and subsequent follow-up visits to rescreen for STIs or STDs based on the Centers for Disease Control and Prevention guidelines may be covered.
- Drugs or treatment for vaginal infections or disorders, other lower genital tract and genital skin infections or disorders, and urinary tract infections, where these conditions are identified or diagnosed during a routine periodic family planning visit. A follow-up visit or encounter for the treatment or drugs may also be covered.
- Other medical diagnosis, treatment, and preventative services that are routinely provided pursuant to family planning services in a family planning setting.
- Treatment of major complications arising from a family planning procedure, such as:
  - Treatment of a perforated uterus due to an intrauterine device insertion;
  - Treatment of severe menstrual bleeding caused by a Depo-Provera injection requiring a dilation and curettage; or
  - Treatment of surgical or anesthesia-related complications during a sterilization procedure.

Procedure Codes and Nomenclature

Only procedure codes and diagnosis codes that are allowed under the FPP will be reimbursed. **Both** the procedure code **and** the diagnosis code must be on the list for services to be payable. Please refer to the Iowa Family Planning Covered Services coverage chart.

Billing Policies and Claim Form Instructions

Family planning services are billed on the federal forms CMS-1500, *Health Insurance Claim Form*, or UB-04, *Claim Form*, depending on the type of provider billing the services.

Refer to the *FAMILY PLANNING SERVICES PROVIDER MANUAL* or the *ACUTE HOSPITAL SERVICES PROVIDER MANUAL* for guidance on the type of claim form that should be completed for the provider type billing the service and an explanation of the corresponding *Remittance Advice*.

CHAPTER 148C

PHYSICIAN ASSISTANTS

Enforcement, §147.87, 147.90, 147.92

Penalty, general, §147.86

Drug dispensing, supplying, and prescribing; limitations, rules, see § 147.107 and 91 Acts, ch 238, § 2

148C.1 Definitions.

1. *"Approved program"* means a program for the education of physician assistants which has been accredited by the American medical association's committee on allied health education and accreditation or its successor, by the commission on accreditation of allied health educational programs or its successor, or by the accreditation review commission on education for the physician assistant or its successor.
2. *"Board"* means the board of physician assistants created under **chapter 147**.
3. *"Department"* means the Iowa department of public health.
4. *"Licensed physician assistant"* means a person who is licensed by the board to practice as a physician assistant under the supervision of one or more physicians. *"Supervision"* does not require the personal presence of the supervising physician at the place where medical services are rendered except insofar as the personal presence is expressly required by **this chapter** or required by rules of the board adopted pursuant to **this chapter**.
5. *"Physician"* means a person who is currently licensed in Iowa to practice medicine and surgery or osteopathic medicine and surgery. Notwithstanding **this subsection**, a physician supervising a physician assistant practicing in a federal facility or under federal authority shall not be required to obtain licensure beyond licensure requirements mandated by the federal government for supervising physicians.
6. *"Physician assistant"* means a person who has successfully completed an approved program and passed an examination approved by the board or is otherwise found by the board to be qualified to perform medical services under the supervision of a physician.
7. *"Trainee"* means a person who is currently enrolled in an approved program.

[C73, 75, 77, 79, §148B.1; C81, §148C.1]

88 Acts, ch 1225, §15; 2003 Acts, ch 93, §6 – 8, 14; 2004 Acts, ch **1101, §23**; 2007 Acts, ch **10, §105**; 2008 Acts, ch **1088, §141**

148C.2 Approved programs.

The department shall issue certificates of approval for programs for the education and training of physician assistants, which meet board standards. In developing criteria for program approval, the board shall give consideration to and encourage the utilization of equivalency and proficiency testing and other mechanisms whereby full credit is given to trainees for past education and experience in health fields. Rules shall be adopted pursuant to this chapter setting forth standards to insure that such programs operate in a manner, which does not endanger the health and welfare of patients who receive services within the scope of the program. The board shall review the quality of curriculum, faculty, and the facilities of such programs and shall approve the issuance of certificates of approval.

Rules shall be adopted pursuant to this chapter setting forth the fees to be charged in connection with the application for and issuance of certificates of approval under this section.

Section History: Early form

[C73, 75, 77, 79, § 148B.2; C81, § 148C.2]

Section History: Recent form

88 Acts, ch 1225, §16

148C.3 Registration--licensure.

148C.3 Licensure.

1. The board shall adopt rules to govern the licensure of physician assistants. An applicant for licensure shall submit the fee prescribed by the board and shall meet the requirements established by the board with respect to each of the following:

a. Academic qualifications, including evidence of graduation from an approved program. A physician assistant who is not a graduate of an approved program, but who passed the national commission on certification of physician assistants' physician assistant national certifying examination prior to 1986, is exempt from this graduation requirement.

b. Evidence of passing the national commission on the certification of physician assistants' physician assistant national certifying examination or an equivalent examination approved by the board.

c. Hours of continuing medical education necessary to become or remain licensed.

2. Rules shall be adopted by the board pursuant to **this chapter** requiring a licensed physician assistant to be supervised by physicians. The rules shall provide that not more than two physician assistants shall be supervised by a physician at one time. The rules shall also provide that a physician assistant shall notify the board of the identity of the physician assistant's supervising physician and of any change in the status of the supervisory relationship.

3. A licensed physician assistant shall perform only those services for which the licensed physician assistant is qualified by training or not prohibited by the board.

4. The board may issue a temporary license under special circumstances and upon conditions prescribed by the board. A temporary license shall not be valid for more than one year and shall not be renewed more than once.

5. The board may issue an inactive license under conditions prescribed by rules adopted by the board.

6. The board shall adopt rules pursuant to **this section** after consultation with the board of medicine.

[C73, 75, 77, 79, §148B.3; C81, §148C.3; 82 Acts, ch 1005, §5]
88 Acts, ch 1225, §17; 2003 Acts, ch 93, §9, 14; 2004 Acts, ch **1101, §24**; 2007 Acts, ch **10, §106**

148C.4 Services performed by assistants.

148C.4 Services performed by physician assistants.

1. A physician assistant may perform medical services when the services are rendered under the supervision of a physician. A physician assistant student may perform medical services when the services are rendered within the scope of an approved program. For the purposes of **this section**, "*medical services when the services are rendered under the supervision of a physician*" includes making a pronouncement of death for a patient whose death is anticipated if the death occurs in a licensed hospital, a licensed health care facility, a Medicare-certified home health agency, or a Medicare-certified hospice program or facility, with notice of the death to a physician and in accordance with the directions of a physician.

2. *a*. Notwithstanding **subsection 1**, a physician assistant licensed pursuant to **this chapter** or authorized to practice in any other state or federal jurisdiction who voluntarily and gratuitously, and other than in the ordinary course of the physician assistant's employment or practice, responds to a need for medical care created by an emergency or a state or local disaster may render such care that the physician assistant is able to provide without supervision as described in **this section** or with such supervision as is available.

b. A physician who supervises a physician assistant providing medical care pursuant to **this subsection** shall not be required to meet the requirements of rules adopted pursuant to **section 148C.3, subsection 2**, relating to supervision by physicians. A physician providing physician assistant supervision pursuant to **this subsection** or a physician assistant, who voluntarily and gratuitously, and other than in the ordinary course of the physician assistant's employment or practice, responds to a need for medical care created by an emergency or a state or local disaster shall not be subject to criminal liability by reason of having issued or executed the orders for such care, and shall not be liable for civil damages for acts or omissions relating to the issuance or execution of the orders unless the acts or omissions constitute recklessness.

[C73, 75, 77, 79, §148B.4; C81, §148C.4]
88 Acts, ch 1225, §18; 2001 Acts, ch 113, §1; 2003 Acts, ch 93, §10, 14; 2009 Acts, ch **41, §263**

148C.8 Right to delegate.

Nothing in **this chapter** affects or limits a physician's existing right to delegate various medical tasks to aides, assistants or others acting under the physician's supervision or direction, including orthopedic physician's assistant technologists. Such aides, assistants, orthopedic physician's assistant technologists, and others who perform only those tasks which can be so delegated shall not be required to qualify as physician assistants under **this chapter**.

[C73, 75, 77, 79, §148B.8; C81, §148C.8]
88 Acts, ch 1225, §22

The provisions of chapter 147, not otherwise inconsistent with the provisions of this chapter, shall apply to the provisions of this chapter.

Section History: Early form
[C73, 75, 77, 79, § 148B.10; C81, § 148C.10]

Definition of child and child abuse (see also DHS Guide for Mandatory Reporters)

232.68 Definitions.

The definitions in section 235A.13 are applicable to this part 2 of division III. As used in sections 232.67 through 232.77 and 235A.12 through 235A.23, unless the context otherwise requires:

1. *"Child"* means any person under the age of eighteen years.
2. *"Child abuse"* or *"abuse"* means:

a. Any non accidental physical injury, or injury which is at variance with the history given of it, suffered by a child as the result of the acts or omissions of a person responsible for the care of the child.

b. Any mental injury to a child's intellectual or psychological capacity as evidenced by an observable and substantial impairment in the child's ability to function within the child's normal range of performance and behavior as the result of the acts or omissions of a person responsible for the care of the child, if the impairment is diagnosed and confirmed by a licensed physician or qualified mental health professional as defined in section 622.10.

c. The commission of a sexual offense with or to a child pursuant to chapter 709, section 726.2, or section 728.12, subsection 1, as a result of the acts or omissions of the person responsible for the care of the child. Notwithstanding section 702.5, the commission of a sexual offense under this paragraph includes any sexual offense referred to in this paragraph with or to a person under the age of eighteen years.

d. The failure on the part of a person responsible for the care of a child to provide for the adequate food, shelter, clothing or other care necessary for the child's health and welfare when financially able to do so or when offered financial or other reasonable means to do so. A parent or guardian legitimately practicing religious beliefs who does not provide specified medical treatment for a child for that reason alone shall not be considered abusing the child, however this provision shall not preclude a court from ordering that medical service be provided to the child where the child's health requires it.

e. The acts or omissions of a person responsible for the care of a child which allow, permit, or encourage the child to engage in acts prohibited pursuant to section 725.1. Notwithstanding section 702.5, acts or omissions under this paragraph include an act or omission referred to in this paragraph with or to a person under the age of eighteen years.

f. An illegal drug is present in a child's body as a direct and foreseeable consequence of the acts or omissions of the person responsible for the care of the child.

g. The person responsible for the care of a child has, in the presence of the child, as defined in section 232.2, subsection 6, paragraph *"p"*, manufactured a dangerous substance, as defined in section 232.2, subsection 6, paragraph *"p"*, or in the presence of the child possesses a product containing ephedrine, its salts, optical isomers, salts of optical isomers, or pseudoephedrine, its salts, optical isomers, salts of optical isomers,

with the intent to use the product as a precursor or an intermediary to a dangerous substance.
h. The commission of bestiality in the presence of a minor under section 717C.1 by a person who resides in a home with a child, as a result of the acts or omissions of a person responsible for the care of the child.
2A. *"Child protection worker"* means an individual designated by the department to perform an assessment in response to a report of child abuse.
3. *"Confidential access to a child"* means access to a child, during an assessment of an alleged act of child abuse, who is alleged to be the victim of the child abuse. The access may be accomplished by interview, observation, or examination of the child. As used in this subsection and this part:
a. "Interview" means the verbal exchange between the child protection worker and the child for the purpose of developing information necessary to protect the child. A child protection worker is not precluded from recording visible evidence of abuse.
b. "Observation" means direct physical viewing of a child under the age of four by the child protection worker where the viewing is limited to the child's body other than the genitalia and pubes. *"Observation"* also means direct physical viewing of a child aged four or older by the child protection worker without touching the child or removing an article of the child's clothing, and doing so without the consent of the child's parent, custodian, or guardian. A child protection worker is not precluded from recording evidence of abuse obtained as a result of a child's voluntary removal of an article of clothing without inducement by the child protection worker. However, if prior consent of the child's parent or guardian, or an ex parte court order, is obtained, *"observation"* may include viewing the child's unclothed body other than the genitalia and pubes.
c. "Physical examination" means direct physical viewing, touching, and medically necessary manipulation of any area of the child's body by a physician licensed under chapter 148 or 150A.
4. *"Department"* means the state department of human services and includes the local, county and regional offices of the department.
5. *"Health practitioner"* includes a licensed physician and surgeon, osteopath, osteopathic physician and surgeon, dentist, optometrist, podiatric physician, or chiropractor; a resident or intern in any of such professions; a licensed dental hygienist, a registered nurse or licensed practical nurse; a physician assistant; and an emergency medical care provider certified under section 147A.6.
6. *"Mental health professional"* means a person who meets the following requirements:
a. Holds at least a master's degree in a mental health field, including, but not limited to, psychology, counseling, nursing, or social work; or is licensed to practice medicine pursuant to chapter 148, 150, or 150A.
b. Holds a license to practice in the appropriate profession.
c. Has at least two years of post degree experience, supervised by a mental health professional, in assessing mental health problems and needs of individuals used in providing appropriate mental health services for those individuals.

7. *"Person responsible for the care of a child"* means:
a. A parent, guardian, or foster parent.
b. A relative or any other person with whom the child resides and who assumes care or supervision of the child, without reference to the length of time or continuity of such residence.
c. An employee or agent of any public or private facility providing care for a child, including an institution, hospital, health care facility, group home, mental health center, residential treatment center, shelter care facility, detention center, or child care facility.
d. Any person providing care for a child, but with whom the child does not reside, without reference to the duration of the care.
8. *"Registry"* means the central registry for child abuse information established in section 235A.14.

Section History: Early form

[C66, 71, 73, 75, 77, § 235A.2; C79, 81, § 232.68]

Section History: Recent form

83 Acts, ch 96, § 157, 159; 84 Acts, ch 1207, § 1, 2; 85 Acts, ch 173, § 2; 86 Acts, ch 1177, § 1; 87 Acts, ch 153, § 1, 2; 89 Acts, ch 24, § 1; 89 Acts, ch 89, § 16; 89 Acts, ch 230, § 3, 4; 93 Acts, ch 76, §1; 93 Acts, ch 93, § 2; 94 Acts, ch 1130, §1, 2; 95 Acts, ch 41, § 24; 95 Acts, ch 108, § 17; 95 Acts, ch 182, § 7; 96 Acts, ch 1092, § 2; 97 Acts, ch 35, §4, 5, 25; 97 Acts, ch 176, §1; 2001 Acts, ch 46, §2; 2001 Acts, ch 131, §1

Footnotes

For the fiscal year beginning July 1, 2002, the department shall utilize service areas and service area administrators in lieu of regions and regional administrators; see 2002 Acts, 2nd Ex, ch 1003, §132, 151, and governor's item veto message

232.69 Mandatory and permissive reporters -- training required. (See DHS Guide for Mandatory Reporters)

1. The classes of persons enumerated in this subsection shall make a report within twenty-four hours and as provided in section 232.70, of cases of child abuse. In addition, the classes of persons enumerated in this subsection shall make a report of abuse of a child who is under twelve years of age and may make a report of abuse of a child who is twelve years of age or older, which would be defined as child abuse under section 232.68, subsection 2, paragraph *"c"* or *"e"*, except that the abuse resulted from the acts or omissions of a person other than a person responsible for the care of the child.

a. Every health practitioner who in the scope of professional practice, examines, attends, or treats a child and who reasonably believes the child has been abused. Notwithstanding section 139A.30, this provision applies to a health practitioner who receives information confirming that a child is infected with a sexually transmitted disease.

b. Any of the following persons who, in the scope of professional practice or in their employment responsibilities, examines, attends, counsels, or treats a child and reasonably believes a child has suffered abuse:

(1) A social worker.

(2) An employee or operator of a public or private health care facility as defined in section 135C.1.

(3) A certified psychologist.

(4) A licensed school employee, certified para-educator, or holder of a coaching authorization issued under section 272.31.

(5) An employee or operator of a licensed child care center, registered child development home, head start program, family development and self-sufficiency grant program under section 217.12, or healthy opportunities for parents to experience success--healthy families Iowa program under section 135.106.

(6) An employee or operator of a substance abuse program or facility licensed under chapter 125.

(7) An employee of a department of human services institution listed in section 218.1.

(8) An employee or operator of a juvenile detention or juvenile shelter care facility approved under section 232.142.

(9) An employee or operator of a foster care facility licensed or approved under chapter 237.

(10) An employee or operator of a mental health center.

(11) A peace officer.

(12) A counselor or mental health professional.

2. Any other person who believes that a child has been abused may make a report as provided in section 232.70.

3. *a.* For the purposes of this subsection, *"licensing board"* means an examining board designated in section 147.13, the board of educational examiners created in section 272.2, or a licensing board as defined in section 272C.1.

b. A person required to make a report under subsection 1, other than a physician whose professional practice does not regularly involve providing primary health care to children, shall complete two hours of training relating to the identification and reporting of child abuse within six months of initial employment or self-employment involving the examination, attending, counseling, or treatment of children on a regular basis. Within one month of initial employment or self-employment, the person shall obtain a statement of the abuse reporting requirements from the person's employer or, if self-employed, from the department. The person shall complete at least two hours of additional child abuse identification and reporting training every five years.
c. If the person is an employee of a hospital or similar institution, or of a public or private institution, agency, or facility, the employer shall be responsible for providing the child abuse identification and reporting training. If the person is self-employed, employed in a licensed or certified profession, or employed by a facility or program that is subject to licensure, regulation, or approval by a state agency, the person shall obtain the child abuse identification and reporting training as provided in paragraph *"d"*.
d. The person may complete the initial or additional training requirements as part of any of the following that are applicable to the person:
(1) A continuing education program required under chapter 272C and approved by the appropriate licensing or examining board.
(2) A training program using a curriculum approved by the abuse education review panel established by the director of public health pursuant to section 135.11.
(3) A training program using such an approved curriculum offered by the department of human services, the department of education, an area education agency, a school district, the Iowa law enforcement academy, or a similar public agency.
e. A licensing board with authority over the license of a person required to make a report under subsection 1 shall require as a condition of licensure that the person is in compliance with the requirements for abuse training under this subsection. The licensing board shall require the person upon licensure renewal to accurately document for the licensing board the person's completion of the training requirements. However, the licensing board may adopt rules providing for waiver or suspension of the compliance requirements, if the waiver or suspension is in the public interest, applicable to a person who is engaged in active duty in the military service of this state or of the United States, to a person for whom compliance with the training requirements would impose a significant hardship, or to a person who is practicing a licensed profession outside this state or is otherwise subject to circumstances that would preclude the person from encountering child abuse in this state.
f. For persons required to make a report under subsection 1 who are not engaged in a licensed profession that is subject to the authority of a licensing board but are employed by a facility or program subject to licensure, registration, or approval by a state agency, the agency shall require as a condition of renewal of the facility's or program's licensure, registration, or approval, that such persons employed by the facility or program are in compliance with the training requirements of this subsection.
g. For peace officers, the elected or appointed official designated as the head of the agency employing the peace officer shall ensure compliance with the training requirements of this subsection.

h. For persons required to make a report under subsection 1 who are employees of state departments and political subdivisions of the state, the department director or the chief administrator of the political subdivision shall ensure the persons' compliance with the training requirements of this subsection.

Information for Mandatory Reporters

Mandatory Reporters need to be aware of a change in Iowa law relative to infants, which refers to a child less than 1 year of age, born with and identified as being affected by substance abuse.

As of July 1, 2017, health care providers involved in the delivery or care of an infant affected by any substance abuse or withdrawal symptoms resulting from prenatal drug exposure or Fetal Alcohol Spectrum Disorder will be required to notify the department via the Child Abuse Hotline number 1-800-362-2178. Prior to this, only infants born positive for an illegal substance in the child's body were required to be reported.

This change in Iowa law is the result of new federal legislation. Public Law 114-198, the Comprehensive Addiction and Recovery Act of 2016 (CARA), was passed on July 22, 2016. The intent of this legislation is to address the problem of opioid addiction and to assist states in handling infants born with a substance abuse disorder.

The Iowa Department of Human Services has implemented policies and procedures to address the needs of these infants and their families. When a Child In Need of Assistance assessment is initiated, the DHS worker will consult with the health care provider to confirm that the infant is affected by substance abuse, withdrawal symptoms or Fetal Alcohol Spectrum Disorder. Once confirmed, a Safe Plan of Care will be developed. The health care provider will be asked to review the plan and agree that the concerns and needs of the child and family have been identified and are addressed.

If DHS is notified by a health practitioner that an infant is substance-affected and additional information is provided that constitutes a child abuse allegation, the department shall commence a Child Abuse Assessment rather than a Child in Need of Assistance assessment. A Safe Plan of Care will still be developed as previously indicated.

Additional information related to the CARA legislation can be found at the following website:
www.acf.hhs.gov

Section History: Early form

[C66, 71, 73, 75, 77, § 235A.3; C79, 81, § 232.69]

Section History: Recent form

83 Acts, ch 96, § 157, 159; 84 Acts, ch 1279, § 4, 6; 85 Acts, ch 173, §3--5; 87 Acts, ch 153, § 3; 88 Acts, ch 1238, § 1; 89 Acts, ch 89, § 17; 89 Acts, ch 230, § 5; 89 Acts, ch 265, § 40; 94 Acts, ch 1130, §3; 97 Acts, ch 85, §1; 99 Acts, ch 192, §27, 33; 2000 Acts, ch 1066, §42; 2001 Acts, ch 122, §2, 3; 2002 Acts, ch 1142, §1, 31

Footnotes

For future amendments to this section effective July 1, 2003, see 2002 Acts, ch 1047, §2, 20
2002 amendment to subsection 1, paragraph b, subparagraph (5), is effective October 1, 2002; applicability to providers; 2002 Acts, ch 1142, §31

232.70 Reporting procedure. – see also DHS Guide for Mandatory Reporters

1. Each report made by a mandatory reporter, as defined in section 232.69, subsection 1, shall be made both orally and in writing. Each report made by a permissive reporter, as defined in section 232.69, subsection 2, may be oral, written, or both.
2. The employer or supervisor of a person who is a mandatory or permissive reporter shall not apply a policy, work rule, or other requirement that interferes with the person making a report of child abuse.
3. The oral report shall be made by telephone or otherwise to the department of human services. If the person making the report has reason to believe that immediate protection for the child is advisable, that person shall also make an oral report to an appropriate law enforcement agency.
4. The written report shall be made to the department of human services within forty-eight hours after such oral report.
5. Upon receipt of a report the department shall do all of the following:
a. Immediately, upon receipt of an oral report, make a determination as to whether the report constitutes an allegation of child abuse as defined in section 232.68.
b. Notify the appropriate county attorney of the receipt of the report.
6. The oral and written reports shall contain the following information, or as much thereof as the person making the report is able to furnish:
a. The names and home address of the child and the child's parents or other persons believed to be responsible for the child's care;
b. The child's present whereabouts if not the same as the parent's or other person's home address;
c. The child's age;
d. The nature and extent of the child's injuries, including any evidence of previous injuries;
e. The name, age and condition of other children in the same home;
f. Any other information which the person making the report believes might be helpful in establishing the cause of the injury to the child, the identity of the person or persons responsible for the injury, or in providing assistance to the child; and
g. The name and address of the person making the report.
7. A report made by a permissive reporter, as defined in section 232.69, subsection 2, shall be regarded as a report pursuant to this chapter whether or not the report contains all of the information required by this section and may be made to the department of human services, county attorney, or law enforcement agency. If the report is made to any agency other than the department of human services, such agency shall promptly refer the report to the department of human services.
8. If a report would be determined to constitute an allegation of child abuse as defined under section 232.68, subsection 2, paragraph *"c"* or *"e"*, except that the suspected abuse resulted from the acts or omissions of a person other than a person responsible for the care of the child, the department shall refer the report to the appropriate law enforcement agency having jurisdiction to investigate the allegation. The department shall refer the report orally as soon as practicable and in writing within seventy-two hours of receiving the report.

9. Within twenty-four hours of receiving a report from a mandatory or permissive reporter, the department shall inform the reporter, orally or by other appropriate means, whether or not the department has commenced an assessment of the allegation in the report.

Section History: Early form

[C66, 71, 73, 75, 77, § 235A.4; C79, 81, § 232.70]

Section History: Recent form

83 Acts, ch 96, § 157, 159; 87 Acts, ch 153, § 4; 97 Acts, ch 176, §2, 17; 2000 Acts, ch 1137, §4, 14; 2001 Acts, ch 122, §4

Footnotes

2000 amendment applies to disclosures of information made on or after April 21, 2000, related to child abuse reported before, on, or after that date; 2000 Acts, ch 1137, §14

CHAPTER 709

SEXUAL ABUSE

[P]
Victim counselor privilege; see §915.20A

709.1 Sexual abuse defined.
709.1A Incapacitation.
709.2 Sexual abuse in the first degree.
709.3 Sexual abuse in the second degree.
709.4 Sexual abuse in the third degree.
709.5 Resistance to sexual abuse.
709.6 Jury instructions for offenses of sexual abuse.
709.7 Detention in brothel. Repealed by 2010 Acts, ch 1043, §3.
709.8 Lascivious acts with a child.
709.9 Indecent exposure.
709.10 Sexual abuse — evidence.
709.11 Assault with intent to commit sexual abuse.
709.12 Indecent contact with a child.
709.13 Child in need of assistance complaints.
709.14 Lascivious conduct with a minor.
709.15 Sexual exploitation by a counselor, therapist, or school employee.
709.16 Sexual misconduct with offenders and juveniles.
709.17 Repealed by 98 Acts, ch 1090, §80, 84. See §915.44.
709.18 Sexual abuse of a corpse.
709.19 No-contact order upon defendant's release from jail or prison.
709.20 Sexual abuse — no-contact order. Repealed by 2006 Acts, ch 1101, §21. See §664A.3.
709.21 Invasion of privacy — nudity.
709.22 Prevention of further sexual assault — notification of rights.

709.1 Sexual abuse defined.

Any sex act between persons is sexual abuse by either of the persons when the act is performed with the other person in any of the following circumstances:

1. The act is done by force or against the will of the other. If the consent or acquiescence of the other is procured by threats of violence toward any person or if the act is done while the other is under the influence of a drug inducing sleep or is otherwise in a state of unconsciousness, the act is done against the will of the other.

2. Such other person is suffering from a mental defect or incapacity which precludes giving consent, or lacks the mental capacity to know the right and wrong of conduct in sexual matters.

3. Such other person is a child.

[C51, §2581, 2583; R60, §4204, 4206; C73, §3861, 3863; C97, §4756, 4758; C24, 27, 31, 35, 39, §**12966, 12967;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, §698.1, 698.3; C79, 81, §709.1]

84 Acts, ch 1188, §1; 99 Acts, ch 159, §1

[P] Definition of sex act, §702.17

709.1A Incapacitation.

As used in this chapter, *"incapacitated"* means a person is disabled or deprived of ability, as follows:

1. *"Mentally incapacitated"* means that a person is temporarily incapable of apprising or controlling the person's own conduct due to the influence of a narcotic, anesthetic, or intoxicating substance.

2. *"Physically helpless"* means that a person is unable to communicate an unwillingness to act because the person is unconscious, asleep, or is otherwise physically limited.

3. *"Physically incapacitated"* means that a person has a bodily impairment or handicap that substantially limits the person's ability to resist or flee.

99 Acts, ch 159, §2

709.2 Sexual abuse in the first degree.

A person commits sexual abuse in the first degree when in the course of committing sexual abuse the person causes another serious injury.

Sexual abuse in the first degree is a class "A" felony.

[C51, §2581; R60, §4204; C73, §3861; C97, §4756; C24, 27, 31, 35, 39, §**12966;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, §698.1; C79, 81, §709.2]

[P] Definition of forcible felony, §702.11

709.3 Sexual abuse in the second degree.

A person commits sexual abuse in the second degree when the person commits sexual abuse under any of the following circumstances:

1. During the commission of sexual abuse the person displays in a threatening manner a dangerous weapon, or uses or threatens to use force creating a substantial risk of death or serious injury to any person.

2. The other person is under the age of twelve.

3. The person is aided or abetted by one or more persons and the sex act is committed by force or against the will of the other person against whom the sex act is committed.

Sexual abuse in the second degree is a class "B" felony.

[C51, §2581; R60, §4204; C73, §3861; C97, §4756; C24, 27, 31, 35, 39, §**12966;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, §698.1; C79, 81, §709.3]

84 Acts, ch 1188, §2; 99 Acts, ch 159, §3

[P] Definition of forcible felony, §702.11

[P] Definition of sex act, §702.17

709.4 Sexual abuse in the third degree.

A person commits sexual abuse in the third degree when the person performs a sex act under any of the following circumstances:

1. The act is done by force or against the will of the other person, whether or not the other person is the person's spouse or is cohabiting with the person.

2. The act is between persons who are not at the time cohabiting as husband and wife and if any of the following are true:

a. The other person is suffering from a mental defect or incapacity which precludes giving consent.

b. The other person is twelve or thirteen years of age.

c. The other person is fourteen or fifteen years of age and any of the following are true:

(1) The person is a member of the same household as the other person.

(2) The person is related to the other person by blood or affinity to the fourth degree.

(3) The person is in a position of authority over the other person and uses that authority to coerce the other person to submit.

(4) The person is four or more years older than the other person.

3. The act is performed while the other person is under the influence of a controlled substance, which may include but is not limited to flunitrazepam, and all of the following are true:

a. The controlled substance, which may include but is not limited to flunitrazepam, prevents the other person from consenting to the act.

b. The person performing the act knows or reasonably should have known that the other person was under the influence of the controlled substance, which may include but is not limited to flunitrazepam.

4. The act is performed while the other person is mentally incapacitated, physically incapacitated, or physically helpless.

Sexual abuse in the third degree is a class "C" felony.

[C51, §2581, 2583; R60, §4204, 4206; C73, §3861, 3863; C97, §4756, 4758; C24, 27, 31, 35, 39, §**12966, 12967;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, §698.1, 698.3; C79, 81, §709.4]

89 Acts, ch 138, §3; 94 Acts, ch 1128, §1; 97 Acts, ch 78, §1; 99 Acts, ch 159, §4

[P] Definition of forcible felony, see §702.11

[P] Definition of sex act, see §702.17

709.5 Resistance to sexual abuse.

Under the provisions of this chapter it shall not be necessary to establish physical resistance by a person in order to establish that an act of sexual abuse was committed by force or against the will of the person. However, the circumstances surrounding the commission of the act

may be considered in determining whether or not the act was done by force or against the will of the other.

[C79, 81, §709.5]

99 Acts, ch 159, §5

709.6 Jury instructions for offenses of sexual abuse.

No instruction shall be given in a trial for sexual abuse cautioning the jury to use a different standard relating to a victim's testimony than that of any other witness to that offense or any other offense.

[C79, 81, §709.6]

709.7 Detention in brothel. Repealed by 2010 Acts, ch 1043, § 3.

709.8 Lascivious acts with a child.

It is unlawful for any person sixteen years of age or older to perform any of the following acts with a child with or without the child's consent unless married to each other, for the purpose of arousing or satisfying the sexual desires of either of them:

1. Fondle or touch the pubes or genitals of a child.
2. Permit or cause a child to fondle or touch the person's genitals or pubes.
3. Solicit a child to engage in a sex act or solicit a person to arrange a sex act with a child.
4. Inflict pain or discomfort upon a child or permit a child to inflict pain or discomfort on the person.

Any person who violates a provision of this section involving an act included in subsection 1 or 2 shall, upon conviction, be guilty of a class "C" felony. Any person who violates a provision of this section involving an act included in subsection 3 or 4 shall, upon conviction, be guilty of a class "D" felony.

[S13, §4938-a; C24, 27, 31, 35, 39, §**13184;** C46, 50, 54, 58, 62, 66, 71, 73, §725.2; C75, 77, §725.10; C79, 81, §709.8]

85 Acts, ch 181, §1; 96 Acts, ch 1062, §1; 2000 Acts, ch 1165, §1; 2005 Acts, ch 158, §35

[P] Definition of sex act, §702.17

709.9 Indecent exposure.

A person who exposes the person's genitals or pubes to another not the person's spouse, or who commits a sex act in the presence of or view of a third person, commits a serious misdemeanor, if:

1. The person does so to arouse or satisfy the sexual desires of either party; and
2. The person knows or reasonably should know that the act is offensive to the viewer.

[C79, 81, §709.9]

[P] Definition of sex act, §702.17

709.10 Sexual abuse — evidence.

1. When an alleged victim of sexual abuse consents to undergo a sexual abuse examination and to having the evidence preserved, a sexual abuse evidence collection kit must be collected and properly stored with the law enforcement agency under whose jurisdiction the offense occurred or with the agency collecting the evidence to ensure that the chain of custody is complete and sufficient.

2. If an alleged victim of sexual abuse has not filed a complaint and a sexual abuse evidence collection kit has been completed, the kit must be stored by the law enforcement agency for a minimum of ten years. In addition, if the alleged victim does not want their name recorded on the sexual abuse collection kit, a case number or other identifying information shall be assigned to the kit in place of the name of the alleged victim.

2004 Acts, ch 1055, §1

709.11 Assault with intent to commit sexual abuse.

Any person who commits an assault, as defined in section 708.1, with the intent to commit sexual abuse is guilty of a class "C" felony if the person thereby causes serious injury to any person and guilty of a class "D" felony if the person thereby causes any person a bodily injury

other than a serious injury. The person is guilty of an aggravated misdemeanor if no injury results.

[81 Acts, ch 204, §6]

709.12 Indecent contact with a child.

A person eighteen years of age or older is upon conviction guilty of an aggravated misdemeanor if the person commits any of the following acts with a child, not the person's spouse, with or without the child's consent, for the purpose of arousing or satisfying the sexual desires of either of them:

1. Fondle or touch the inner thigh, groin, buttock, anus, or breast of the child.
2. Touch the clothing covering the immediate area of the inner thigh, groin, buttock, anus, or breast of the child.
3. Solicit or permit a child to fondle or touch the inner thigh, groin, buttock, anus, or breast of the person.
4. Solicit a child to engage in any act prohibited under section 709.8, subsection 1, 2, or 4.

The provisions of this section shall also apply to a person sixteen or seventeen years of age who commits any of the enumerated acts with a child who is at least five years the person's junior, in which case the juvenile court shall have jurisdiction under chapter 232.

[81 Acts, ch 204, §7]

85 Acts, ch 181, §2; 88 Acts, ch 1252, §4

709.13 Child in need of assistance complaints.

During or following an investigation into allegations of violations of this chapter or of chapter 726 or 728 involving an alleged victim under the age of eighteen and an alleged offender who is not a person responsible for the care of the child, anyone with knowledge of the alleged offense may file a complaint pursuant to section 232.83 alleging the child to be a child in need of assistance. In all cases, the complaint shall be filed by any peace officer with knowledge of the investigation when the peace officer has reason to believe that the alleged victim may require treatment as a result of the alleged offense and that the child's parent, guardian, or custodian will be unwilling or unable to provide the treatment.

88 Acts, ch 1252, §5

709.14 Lascivious conduct with a minor.

It is unlawful for a person over eighteen years of age who is in a position of authority over a minor to force, persuade, or coerce a minor, with or without consent, to disrobe or partially disrobe for the purpose of arousing or satisfying the sexual desires of either of them.

Lascivious conduct with a minor is a serious misdemeanor.

89 Acts, ch 105, §2

709.15 Sexual exploitation by a counselor, therapist, or school employee.

1. As used in this section:

a. "Counselor or therapist" means a physician, psychologist, nurse, professional counselor, social worker, marriage or family therapist, alcohol or drug counselor, member of the clergy, or any other person, whether or not licensed or registered by the state, who provides or purports to provide mental health services.

b. "Emotionally dependent" means that the nature of the patient's or client's or former patient's or client's emotional condition or the nature of the treatment provided by the counselor or therapist is such that the counselor or therapist knows or has reason to know that the patient or client or former patient or client is significantly impaired in the ability to withhold consent to sexual conduct, as described in subsection 2, by the counselor or therapist.

For the purposes of subsection 2, a former patient or client is presumed to be emotionally dependent for one year following the termination of the provision of mental health services.

c. "Former patient or client" means a person who received mental health services from the counselor or therapist.

d. "Mental health service" means the treatment, assessment, or counseling of another

person for a cognitive, behavioral, emotional, mental, or social dysfunction, including an intrapersonal or interpersonal dysfunction.

e. *"Patient or client"* means a person who receives mental health services from the counselor or therapist.

f. *"School employee"* means a practitioner as defined in section 272.1.

g. *"Student"* means a person who is currently enrolled in or attending a public or nonpublic elementary or secondary school, or who was a student enrolled in or who attended a public or nonpublic elementary or secondary school within thirty days of any violation of subsection 3.

2. Sexual exploitation by a counselor or therapist occurs when any of the following are found:

a. A pattern or practice or scheme of conduct to engage in any of the conduct described in paragraph *"b"* or *"c"*.

b. Any sexual conduct, with an emotionally dependent patient or client or emotionally dependent former patient or client for the purpose of arousing or satisfying the sexual desires of the counselor or therapist or the emotionally dependent patient or client or emotionally dependent former patient or client, which includes but is not limited to the following: kissing; touching of the clothed or unclothed inner thigh, breast, groin, buttock, anus, pubes, or genitals; or a sex act as defined in section 702.17.

c. Any sexual conduct with a patient or client or former patient or client within one year of the termination of the provision of mental health services by the counselor or therapist for the purpose of arousing or satisfying the sexual desires of the counselor or therapist or the patient or client or former patient or client which includes but is not limited to the following: kissing; touching of the clothed or unclothed inner thigh, breast, groin, buttock, anus, pubes, or genitals; or a sex act as defined in section 702.17.

Sexual exploitation by a counselor or therapist does not include touching which is part of a necessary examination or treatment provided a patient or client by a counselor or therapist acting within the scope of the practice or employment in which the counselor or therapist is engaged.

3. Sexual exploitation by a school employee occurs when any of the following are found:

a. A pattern or practice or scheme of conduct to engage in any of the conduct described in paragraph *"b"*.

b. Any sexual conduct with a student for the purpose of arousing or satisfying the sexual desires of the school employee or the student. Sexual conduct includes but is not limited to the following: kissing; touching of the clothed or unclothed inner thigh, breast, groin, buttock, anus, pubes, or genitals; or a sex act as defined in section 702.17.

Sexual exploitation by a school employee does not include touching that is necessary in the performance of the school employee's duties while acting within the scope of employment.

4. *a.* A counselor or therapist who commits sexual exploitation in violation of subsection 2, paragraph *"a"*, commits a class "D" felony.

b. A counselor or therapist who commits sexual exploitation in violation of subsection 2, paragraph *"b"*, commits an aggravated misdemeanor.

c. A counselor or therapist who commits sexual exploitation in violation of subsection 2, paragraph *"c"*, commits a serious misdemeanor. In lieu of the sentence provided for under section 903.1, subsection 1, paragraph *"b"*, the offender may be required to attend a sexual abuser treatment program.

5. *a.* A school employee who commits sexual exploitation in violation of subsection 3, paragraph *"a"*, commits a class "D" felony.

b. A school employee who commits sexual exploitation in violation of subsection 3, paragraph *"b"*, commits an aggravated misdemeanor.

91 Acts, ch 130, §2; 92 Acts, ch 1163, §119; 92 Acts, ch 1199, §2 – 6; 2003 Acts, ch 180, §65; 2004 Acts, ch 1086, §102

709.16 Sexual misconduct with offenders and juveniles.

1. An officer, employee, contractor, vendor, volunteer, or agent of the department of corrections, or an officer, employee, or agent of a judicial district department of correctional

services, who engages in a sex act with an individual committed to the custody of the department of corrections or a judicial district department of correctional services commits an aggravated misdemeanor.

2. An officer, employee, contractor, vendor, volunteer, or agent of a juvenile placement facility who engages in a sex act with a juvenile placed at such facility commits an aggravated misdemeanor.

For purposes of this subsection, a *"juvenile placement facility"* means any of the following:

a. A child foster care facility licensed under section 237.4.

b. Institutions controlled by the department of human services listed in section 218.1.

c. Juvenile detention and juvenile shelter care homes approved under section 232.142.

d. Psychiatric medical institutions for children licensed under chapter 135H.

e. Substance abuse facilities as defined in section 125.2.

3. An officer, employee, contractor, vendor, volunteer, or agent of a county who engages in a sex act with a prisoner incarcerated in a county jail commits an aggravated misdemeanor.

91 Acts, ch 219, §21; 98 Acts, ch 1094, §1

709.17 Repealed by 98 Acts, ch 1090, § 80, 84. See § 915.44.

709.18 Sexual abuse of a corpse.

1. A person commits sexual abuse of a human corpse if the person knowingly and intentionally engages in a sex act, as defined in section 702.17, with a human corpse.

2. A person who violates this section commits a class "D" felony.

96 Acts, ch 1006, §1; 2007 Acts, ch 91, §2; 2010 Acts, ch 1074, §4
[T] Section amended

709.19 No-contact order upon defendant's release from jail or prison.

1. Upon the filing of an affidavit by a victim, or a parent or guardian on behalf of a minor who is a victim, of a crime that is a sexual offense in violation of section 709.2, 709.3, 709.4, 709.8, 709.9, 709.11, 709.12, 709.14, 709.15, or 709.16, that states that the presence of or contact with the defendant whose release from jail or prison is imminent or who has been released from jail or prison continues to pose a threat to the safety of the victim, persons residing with the victim, or members of the victim's immediate family, the court shall enter a temporary no-contact order which shall require the defendant to have no contact with the victim, persons residing with the victim, or members of the victim's immediate family.

2. A temporary restraining order issued under this section shall expire at such time as the court directs, not to exceed ten days from the date of issuance. The court, for good cause shown before expiration of the order, may extend the expiration date of the order for up to ten days, or for a longer period agreed to by the adverse party.

3. Upon motion of the party, the court shall issue a no-contact order which shall require the defendant to have no contact with the victim, persons residing with the victim, or members of the victim's immediate family if the court, after a hearing, finds by a preponderance of the evidence, that the defendant poses a threat to the safety of the victim, persons residing with the victim, or members of the victim's immediate family.

4. A no-contact order shall set forth the reasons for the issuance of the order, be specific in terms, and describe in reasonable detail the purpose of the order.

5. The court shall set the duration of the no-contact order for the period it determines is necessary to protect the safety of the victim, persons residing with the victim, or members of the victim's immediate family, but the duration shall not be set for a period in excess of one year from the date of the issuance of the order. The victim, at any time within ninety days before the expiration of the order, may apply for a new no-contact order under this section.

6. Violation of a no-contact order issued under this section constitutes contempt of court and may be punished by contempt proceedings.

2002 Acts, ch 1085, §1; 2003 Acts, ch 108, §113

709.20 Sexual abuse — no-contact order. Repealed by 2006 Acts, ch 1101, § 21. See § 664A.3.

709.21 Invasion of privacy — nudity.

1. A person who knowingly views, photographs, or films another person, for the purpose of arousing or gratifying the sexual desire of any person, commits invasion of privacy if all of the following apply:

a. The other person does not have knowledge about and does not consent or is unable to consent to being viewed, photographed, or filmed.

b. The other person is in a state of full or partial nudity.

c. The other person has a reasonable expectation of privacy while in a state of full or partial nudity.

2. As used in this section:

a. "*Full or partial nudity*" means the showing of any part of the human genitals or pubic area or buttocks, or any part of the nipple of the breast of a female, with less than fully opaque covering.

b. "*Photographs or films*" means the making of any photograph, motion picture film, videotape, or any other recording or transmission of the image of a person.

3. A person who violates this section commits a serious misdemeanor.

2004 Acts, ch 1099, §1

709.22 Prevention of further sexual assault — notification of rights.

1. If a peace officer has reason to believe that a sexual assault as defined in section 915.40 has occurred, the officer shall use all reasonable means to prevent further violence including but not limited to the following:

a. If requested, remaining on the scene of the alleged sexual assault as long as there is a danger to the victim's physical safety without the presence of a peace officer, including but not limited to staying in the dwelling unit or residence when it is the scene of the alleged sexual assault, or if unable to remain on the scene, assisting the victim in leaving the scene.

b. Assisting a victim in obtaining medical treatment necessitated by the sexual assault, including providing assistance to the victim in obtaining transportation to the emergency room of the nearest hospital.

c. Providing a victim with immediate and adequate notice of the victim's rights. The notice shall consist of handing the victim a document that includes the telephone numbers of shelters, support groups, and crisis lines operating in the area and contains a copy of the following statement written in English and Spanish; asking the victim to read the statement; and asking whether the victim understands the rights:

(1) You have the right to ask the court for help with any of the following on a temporary basis:

(a) Keeping your attacker away from you, your home, and your place of work.

(b) The right to stay at your home without interference from your attacker.

(c) The right to seek a no-contact order under section 664A.3 or 915.22, if your attacker is arrested for sexual assault.

(2) You have the right to register as a victim with the county attorney under section 915.12.

(3) You have the right to file a complaint for threats, assaults, or other related crimes.

(4) You have the right to seek restitution against your attacker for harm to you or your property.

(5) You have the right to apply for victim compensation.

(6) You have the right to contact the county attorney or local law enforcement to determine the status of your case.

(7) If you are in need of medical treatment, you have the right to request that the officer present assist you in obtaining transportation to the nearest hospital or otherwise assist you.

(8) You have the right to a sexual assault examination performed at state expense.

(9) You have the right to request the presence of a victim counselor, as defined in section 915.20A, at any proceeding related to an assault including a medical examination.

(10) If you believe that police protection is needed for your physical safety, you have the right to request that the officer present remain at the scene until you and other affected parties can leave or until safety is otherwise ensured.

2. A peace officer is not civilly or criminally liable for actions taken in good faith pursuant to this section.

2005 Acts, ch 158, §45; 2006 Acts, ch 1101, §15; 2008 Acts, ch 1068, §1; 2009 Acts, ch 133, §176, 177

CHILD ABUSE:

A Guide
for Mandatory Reporters

To make a report of suspected
child abuse,
call the toll-free 24-hour hotline:

1-800-362-2178

Comm. 164

July 1, 2011

Table of Contents

Child Abuse Overview **1**
National Data 2
Iowa Response 3

Am I a Mandatory Reporter of Child Abuse? **5**
Health 6
Education 7
Child Care 8
Mental Health 8
Law Enforcement 8
Others Required to Report 9

How Do I Report Child Abuse? **9**
Reporting Procedures 10
Waiver of Confidentiality 11
Immunity From Liability 12
Sanctions for Failure to Report Child Abuse 12
Sanctions for Reporting False Information 12
Indicators of Possible Child Abuse 13

What Is Child Abuse Under Iowa Law? **15**
Child 15
Caretaker 16
Educators as Caretakers 17
Children as Caretakers 17
Physical Abuse 18
Mental Injury 18
Sexual Abuse 19
Denial of Critical Care 20
Child Prostitution 22
Presence of Illegal Drugs 22
Manufacturing or Possession of a Dangerous Substance 23
Bestiality in the Presence of a Minor 24
Allows Access by a Registered Sex Offender 24
Allows Access to Obscene Material 24

How Does DHS Respond? 24
Intake 24
Reports from Multiple Reporters 25
Time Frame for Deciding Whether to Accept a Report for Assessment 25
Accepted Intakes 26
Rejected Intakes 26
Case Assignment 28
Evaluation of the Alleged Abuse 28
Observation of the Alleged Child Victim 28
Interviews with Subjects of the Report and Other Sources 29
Gathering Documentation 30
Evaluation of the Safety of and Risk to the Child 31
Determination if Abuse Occurred 32
Determination if Report Is Placed on the Child Abuse Registry 32
Assessment of Family's Strengths and Needs 34
Preparation of Reports and Forms 35

What Happens After the Assessment? 37
Service Recommendations and Referrals 37
Removal of a Child 39
Removal by Ex Parte Court Order 39
Removal of a Child by a Peace Officer or a Physician 41
Removal With Parent's Consent 43
Juvenile Court Hearings 44
Child in Need of Assistance 44

How Is Child Abuse Information Treated? 47
Protective Disclosure 47
Disposition of Reports 47
Requests for Correction and Appeals 48
Access to Child Abuse Information 49
Civil and Criminal Liability Regarding Child Abuse Information 51

What Training Do Mandatory Reporters Need? 52

Review Questions 54

Safe Haven for Newborns 62

Report of Suspected Child Abuse 63

Child Abuse Overview

Child abuse is not a new phenomenon. The abuse and neglect of children has been documented for more than two thousand years. However, attempts to prevent child abuse are relatively new.

The first documented legal response to child abuse in the United States occurred in 1874. The New York Society for the Prevention of Cruelty to Animals pleaded in court to have an eight-year-old child removed from her abusive and neglectful environment. Since there were no child abuse laws, the Society argued that the child was, in fact, an animal, and should be provided the same protection as other animals. During the last few decades of the 1800s, societies to protect children from cruelty were formed in many states.

The next movement to protect children came as the result of several pediatricians publishing articles about children suffering multiple fractures and brain injuries at the hands of their caretakers. In 1961, Dr. C. Henry Kempe, then president of the American Academy of Pediatrics, held a conference on the "battered child syndrome," in which he outlined a "duty" to the child to prevent "repetition of trauma." The Battered Child Syndrome Conference resulted in many states passing laws to protect children from physical abuse.

Child abuse is now recognized as a problem of epidemic proportions. Child abuse has serious consequences that may remain as indelible pain throughout the victim's lifetime. The violence and negligence of parents and caretakers serve as a model for children as they grow up. The child victims of today, without protection and treatment, may become the child abusers of tomorrow.

As with any social issue, child abuse is a problem for the entire community. Achieving the goals of protective services requires the coordination of many resources. Each professional group and agency involved with a family assumes responsibility for specific elements of the child protective service process.

National Data

Nationally, the 2008 "Child Maltreatment Report," published by the U.S. Department of Health and Human Services Children's Bureau, indicates that an estimated 3.3 million reports of child abuse involving 6 million children were made to child protection agencies that year, and that approximately 63% were accepted for investigation or assessment.

One-fourth of the investigations and assessments (25%) confirmed child abuse. There were an estimated 794,000 victims of child abuse nationwide. The rate of victimization was 10.3 per 1,000 children. The highest victimization rates were for the birth to age 1 group (21.7 per 1,000 children). There was no prior history of victimization for 75% of all victims.

National studies continue to indicate that only about one-third of maltreated children are reported to child protection agencies. Significant numbers of victims remain unidentified without protection and treatment.

In 1985, the U.S. Surgeon General declared family violence to be a national epidemic. At that time, an estimated 3.3 million children were exposed to violence by a family member against a mother or female caretaker. The U.S. Advisory Board on Child Abuse and Neglect found domestic violence to be the single major precursor to child abuse and neglect fatalities in the United States. Child abuse is 15 times more likely to occur in homes where adult domestic violence is present.

According to the *Effective Intervention in Domestic Violence & Child Maltreatment Cases: Guide for Policy and Practice*, published by the National Council of Juvenile and Family Court Judges in 1999, "domestic violence perpetrators do not victimize only adults. Recent reviews of more than two decades of studies have revealed that in families where women are abused, many of their children also are maltreated.

According to the Iowa Attorney General's Office, Crime Victim Assistance Division, from January 1995 through April 2010, 209 Iowans have been killed in domestic abuse homicides. During that period:

- 138 women were killed by their spouse, former spouse, boyfriend, or intimate partner;
- 24 men were killed by their partners;
- 46 bystanders were killed, including 25 children;
- 168 minor children survived the murder of their mother or father; and
- 67 children were present at the scene of a parent's murder.

Although many adults believe they have protected their child from exposure to domestic violence, 80% to 90% of children in those homes can give detailed descriptions of the violence experienced in their families. (Doyne, S. Bowermasyer, J. & Meloy, R. (1999). "Custody Disputes Involving Domestic Violence: Making Children's Needs a Priority," *Juvenile & Family Court Journal*, 50, (2)).

The U.S. Advisory Board on Child Abuse suggests that domestic violence may be the single major precursor to child fatalities in this country.

Varying by samples selected and types of data gathered, the majority of these studies have found that a substantial proportion, ranging from 30 to 60 percent, of battered mothers' children also are maltreated. Children who are abused physically or sexually or witness violence tend to exhibit more developmental, cognitive, emotional, and social behavior problems, including depression and increased aggression, than other children."

Iowa Response

Iowa's child abuse reporting law, Iowa Code sections 232.67 through 232.75, was initially enacted in 1978 and has been amended several times since then. The intent of the law is to identify children who are victims of abuse. The law also provides for a professional assessment to determine if abuse has occurred. Accompanying the assessment are protective services designed to protect, treat, and prevent further maltreatment.

The purpose of the Iowa law is to provide the greatest possible protection to children by encouraging the reporting of suspected child abuse. The state respects the bond between parent and child. However, the state does assert the right to intervene for the general welfare of the child when there is a clear and present danger to the child's health, welfare, and safety. The state does not intend to interfere with reasonable parental discipline and child-rearing practices that are not injurious to the child.

According to Iowa statute, the Department of Human Services (DHS) has the responsibility to assess reports of suspected child abuse. DHS is the agency designated by law to receive reports of suspected child abuse and neglect.

In calendar year 2009, DHS accepted 25,814 reports for assessment. After completing the assessment of the allegations, DHS confirmed that abuse occurred in 8,867 (34%) of the assessed reports. There were 12,442 child victims named in the confirmed and founded reports. Some children suffered multiple types of abuse or repeat maltreatment. These results represent a rate of 15.6 per 1,000 Iowa children abused for 2009.

Iowa Confirmed Child Abuse in Calendar Year 2006 - 2009

	Percentage of Total Confirmed or Founded Abuse			
Type of Abuse	**2006**	**2007**	**2008**	**2009**
Denial of critical care	77.2%	78.87%	79.4%	81.0%
Physical abuse	10.0%	9.35%	10.8%	9.0%
Presence of illegal drugs	7.2%	6.63%	3.86%	3.6%
Sexual abuse	4.1%	3.81%	3.86%	3.8%
Cohabitation with registered sex offender*	0.7%	0.84%	1.11%	0.6%
Manufacturing or possession of dangerous substance with intent to manufacture	0.5%	0.34%	0.67%	0.45%
Mental injury	0.1%	0.12%	0.20%	0.1%
Child prostitution	0.0%	0.0%	0.0%	0.0%
Bestiality in the presence of a minor	0.0%	0.0%	0.0%	0.0%

* This type of abuse was revised by legislative action effective July 1, 2009, to allow access by a registered sex offender.

Source: DHS Division of Results-Based Accountability reports of child abuse allegations that were confirmed or founded in calendar years 2006, 2007, 2008, and 2009. (**Note:** A victim may have suffered more than one type of abuse.)

DHS works closely with physicians, nurses, educators, mental health practitioners, law enforcement agencies, and the judiciary. These parties are involved in the identification, reporting, assessment, and treatment of cases of child maltreatment. Ultimately, children can be kept safer from abuse and neglect through increased community ownership, responsibility, and involvement. One entity (whether legislators, DHS, physicians, educators, or local law enforcement) alone cannot eliminate “child abuse.” The safety of children depends upon how well communities support families, organize basic systems, and make inclusive decisions about available resources.

Partnerships that involve parents, neighbors, and grassroots community groups, in addition to public agencies and non-profit organizations, create community ownership, responsibility, and involvement. The vision of partnerships has evolved with the realization that “one size does not fit all.” Through partnerships, its citizens define a community’s needs, and services can be tailored to the particular needs and strengths of individual communities.

The child abuse reporting law is only one type of Iowa statute designed to deal with child abuse. Juvenile justice laws authorize the court to provide protection for children through supervision in their own homes or in substitute care. Criminal laws are separate from the child abuse reporting and juvenile justice laws. Criminal laws provide for prosecution of alleged perpetrators in cases where a criminal act has been committed.

Am I a Mandatory Reporter of Child Abuse?

Iowa law defines classes of people who must make a report of child abuse within 24 hours when they reasonably believe a child has suffered abuse. These "mandatory reporters" are professionals who have frequent contact with children, generally in one of six disciplines:

Health	Education	Child care
Mental health	Law enforcement	Social work

- All licensed physicians and surgeons.
- Physician assistants.
- Dentists.
- Licensed dental hygienists.
- Optometrists.
- Podiatrists.
- Chiropractors.
- Residents or interns in any of the professions listed above.
- Registered nurses.
- Licensed practical nurse.
- Basic and advanced emergency medical care providers.

Any of the following persons who, in the scope of professional practice or in their employment responsibilities, examines, attends, counsels, or treats a child:

- A social worker.
- An employee or operator of a public or private health care facility as defined in Iowa Code section 135C.1.
- A certified psychologist.
- A licensed school employee, certified paraeducator, or holder of a coaching authorization issued under Iowa Code section 272.31, or an instructor employed by a community college.

- An employee or operator of a licensed child care center, registered child development home, Head Start program, Family Development and Self-Sufficiency Grant program under Iowa Code section 216A.107, or Healthy Opportunities for Parents to Experience Success – Healthy Families Iowa program under Iowa Code section 135.106.
- An employee or operator of a licensed substance abuse program or facility licensed under Iowa Code Chapter 125.
- An employee of an institution operated by DHS listed in Iowa Code section 218.1.
- An employee or operator of a juvenile detention or juvenile shelter care facility approved under Iowa Code section 232.142.
- An employee or operator of a foster care facility licensed or approved under Iowa Code Chapter 237.
- An employee or operator of a mental health center.
- A peace officer.
- A counselor or mental health professional.
- An employee or operator of a provider of services to children funded under a federally approved medical assistance home- and community-based services waiver.

The employer or supervisor of a person who is a mandatory reporter shall not apply a policy, work rule, or other requirement that interferes with the person making a report of child abuse.

Clergy members are not considered to be mandatory reporters unless they are functioning as social workers, counselors, or another role described as a mandatory reporter. If a member of clergy provides counseling services to a child, and the child discloses an abuse allegation, then the clergy member is mandated to report as a counselor. (The counseling is provided to a child during the scope of the reporter's profession as a counselor, not clergy.)

Health

Health service professionals play many roles in the recognition and treatment of child abuse, including the recognition of the abuse, reporting the suspected abuse, crisis intervention, and long-term treatment.

Health services personnel are often the first line of defense in the early detection of child abuse. Most health professionals who treat children are required to be mandatory reporters of child abuse.

Health care professionals are often called upon to work collaboratively with many other disciplines, including social work, education, law enforcement, and the courts to ensure a multi-disciplinary approach to the recognition and treatment of child abuse.

A health care practitioner may, if medically indicated, take or cause to be taken, a radiological examination, physical examination, or other medical test of the child or take photographs, which would provide medical indications for the child abuse assessment.

A physician has the authority to keep a child in custody without a court order and without the consent of a parent, guardian, or custodian, provided that the child is in a circumstance or condition that presents an imminent danger to the child's life or health. However, the physician must orally notify the court within 24 hours. The ability to take or keep a child in custody is unique to physicians and peace officers.

Education

Educators may spend more hours per day with children than their families. That's why the role of educators is vital in the mandatory reporting process. All licensed school employees, teachers, coaches and paraeducators are mandatory reporters.

The involvement of educators in the reporting of child abuse is mandated or supported by federal standards and regulations and state laws, policies and procedures. Each of these government levels provides authority for, encourages, or mandates educator involvement in the reporting process by stating what is required of the educator and how that obligation is to be fulfilled.

The primary authority at the federal level is the Federal Family Education Rights and Privacy Act (FERPA) of 1974. FERPA, which governs the release of information from school records, does not bar the reporting of suspected child abuse by educators.

In the majority of cases, educators will be relying not on school records, but on their own personal knowledge and observations when reporting child abuse. Because no school records are involved in these cases, FERPA does not apply.

In a small number of cases, it may be necessary to consult school records to determine whether a report of child abuse should be made. Ordinarily parental consent is required before information contained in school records can be released. However, there are exceptions that can apply in cases of child abuse.

Some local school systems and boards of education have enacted school policies and procedures regarding child abuse reporting. The policies and procedures support state law with regard to reporting and often provide internal mechanisms to be followed when a report of child abuse is made.

Local school policy may specify that parents be notified when the school makes a report of child abuse. If so, notify DHS of that local policy when making the report of child abuse.

Sometimes local procedure may require that administrative staff be notified when a report of child abuse is made and a copy of the written report be filed.

Child Care

Child care providers play a critical role in keeping children safe. It is very important for them to report when they suspect child abuse. Child care providers include child care staff, foster parents, and residential care personnel. All of these people are mandatory reporters. A child care provider who suspects that a child has been abused should report that to DHS and to the licensing worker.

Mental Health

Mental health professionals are often trusted with intimate information about children and families. This makes their role critical when reporting child abuse. All counseling providers, even those who are self-employed, are mandatory reporters of child abuse in regard to the child they counsel.

Law Enforcement

Law enforcement officers play a very important role in protecting our children from child abuse. Law enforcement officers are seen as a symbol of public safety. They are in an excellent position to raise community awareness about child abuse.

Law enforcement officers often encounter situations that involve child abuse. For example, on domestic calls or during drug arrests the officer may learn of information that constitutes an allegation of child abuse. Children residing in homes where methamphetamine is being manufactured or where precursors are present constitutes an allegation of child abuse as well as possible criminal charges. Law enforcement is mandated to report to DHS.

Law enforcement officers who suspect child abuse in the line of duty are required to report that abuse to the Department of Human Services as soon as they suspect it. Law enforcement officers need to follow the same procedures as all mandatory reporters in reporting child abuse.

Law enforcement and child protective services may need to work together. Sometimes child protective service workers must visit isolated, dangerous locations and deal with unstable, violent, or substance abusing individuals.

Generally, child protective service workers do not have on-site communications (radio, car phone, etc.), weapons, or special training in self-protection. It is often necessary for law enforcement personnel to accompany child protective workers to conduct their assessment. Failure to have proper backup may have unfortunate consequences to both the child protection worker and the child that may have been abused.

Law enforcement has the power to arrest and to enforce any standing orders of the court. When it is necessary to remove a child from the child's home, law enforcement officers are often called upon for assistance. Law enforcement has the general authority to take custody of children.

Law enforcement is often able to react to emergency situations faster than child protective service. Law enforcement is also available 24 hours a day, while the child protection worker after hour response is limited in some communities.

Others Required to Report

Some employers may have specific policies that require certain training and reporting procedures regarding child abuse for their staff, even when they are not by law considered mandatory reporters. Reporters who by law are not considered mandatory reporters will be considered permissive reporters regardless of the employer's requirements.

Iowa Administrative Code 441--175.23(2) mandates certified adoption investigators and DHS income maintenance workers to report suspected abuse. Income maintenance workers and certified adoption investigators are "mandated," not mandatory reporters. As such, they are not required to make a written report, although they may do so if they wish. They receive the same information and notices as permissive reporters. They are not entitled to written notification that the assessment has been completed nor to a copy of information placed on the Registry. However, they may receive a copy of the report if they have another role with the child that allows access to the summary.

How Do I Report Child Abuse?

Call 1-800-362-2178. According to Iowa Code section 232.70, if you are a mandatory reporter of child abuse and you suspect a child has been abused, you need to report it to the Department of Human Services. The law requires you to report suspected child abuse to DHS orally within 24 hours of becoming aware of the situation. You must also make a report in writing within 48 hours after your oral report. The employer or supervisor of a person who is a mandatory or permissive reporter shall not apply a policy, work rule, or other requirement that interferes with the person making a report of child abuse.

As a mandatory reporter, you are also required to make an **oral report to law enforcement** if you have reason to believe that immediate protection of the child is necessary.

The law requires the reporting of suspected child abuse. It is not the reporter's role to validate the abuse. The law does not require you to have proof that the abuse occurred before reporting. The law clearly specifies that reports of child abuse must be made when the person reporting "reasonably believes a child has suffered abuse."

Reports are made in terms of the child's possible condition, not in terms of an accusation against parents. A report of child abuse is not an accusation, but a request to determine whether child abuse exists and begin the helping process.

Making a report of child abuse may be difficult. You may have doubts about whether the circumstances merit a report, how the parents will react, what the outcome will be, and whether or not the report will put the child at greater risk. The best way to minimize the difficulty of reporting is to:

- Be knowledgeable about the reporting requirements, and
- Be aware of the Department's intake criteria and the response that is initiated by making a report.

Within 24 hours of receiving your report, you will be orally notified whether or not the report has been accepted or rejected. Within five working days, you will also be sent form 470-3789, *Notice of Intake Decision*, indicating whether the report of child abuse was accepted or rejected.

Reporting Procedures

If you see a child that is in **imminent danger**, immediately contact **law enforcement**, to provide immediate assistance to the child. Law enforcement is the only profession that can take a child into custody in that situation. After you have notified law enforcement, then call DHS.

To report a suspected case of child abuse:

- Call 1-800-362-2178.
- Then, follow up by making a written report within 24 hours.

Oral and written reports should contain the following information, if it is known:

- The names and home address of the child and the child's parents or other persons believed to be responsible for the child's care.
- The child's present whereabouts.
- The child's age.
- The nature and extent of the child's injuries, including any evidence of previous injuries.
- The name, age, and condition of other children in the same household.
- Any other information that you believe may be helpful in establishing the cause of the abuse or neglect to the child.
- The identity of the person or persons responsible for the abuse or neglect to the child.
- Your name and address.

A sample copy of form 470-0665, *Report of Suspected Child Abuse*, is included at the end of this Guide. This form is available from the DHS website (http://www.dhs.state.ia.us). This specific form is not required, but you may use it as a guide in making a report of child abuse.

If you suspect sexual abuse of a child under the age of 12 by a non-caretaker, you are required by law to make a report of child abuse to DHS. If the child is aged 12 or older, you may report the sexual abuse by a non-caretaker but you are not required by law to do so. DHS must report all sexual abuse allegations to law enforcement within 72 hours.

Waiver of Confidentiality

The issues of confidentiality and privileged communication are often areas of concern for mental health and health service professionals. Rules around confidentiality and privileged communication are waived during the child abuse assessment process (once a report of child abuse becomes a case).

Iowa Code section 232.71B indicates that the Department may request information from any person believed to have knowledge of a child abuse case. County attorneys, law enforcement officers, social services agencies, and all mandatory reporters (whether or not they made the report of suspected abuse) are obligated to cooperate and assist with the child abuse assessment upon the request of the Department.

Confidentiality is waived in Iowa Code section 232.74, which reads:

> Sections 622.9 (on communication between husband and wife) and 622.10 (on communication in professional confidence) and any statute or rule of evidence which excludes or makes privileged the testimony of health practitioners or mental health professionals as to confidential communications do not apply to evidence regarding a child's injuries or the cause of the injuries in any judicial proceeding, civil or criminal, resulting from a report of child abuse.

Physician privilege is waived in cases of suspected child abuse. Physicians are allowed to share whatever information is necessary with the Department of Human Services to facilitate a thorough assessment.

It is a good idea to let your clients know your status as a child abuse reporter at the onset of treatment. This will help establish an open relationship and minimize the client's feelings of betrayal if a report needs to be made. Making a child abuse referral does not necessarily mean that your relationship with the child and family will end, especially when you are able to support the family during the assessment process.

When possible, discuss the need to make a child abuse report with the family. However, be aware that there are certain situations where if the family is warned about the assessment process, the child may be at risk for further abuse, or the family may leave with the child.

In situations where you are not required to make a child abuse report, ethically you need to address these concerns in a therapeutic setting. Refer to your Professional Code of Ethics for further clarification on issues surrounding child abuse.

Immunity From Liability

Iowa Code section 232.73 provides immunity from any civil or criminal liability which might otherwise be incurred when a person participates in good faith in:

- Making a report, photographs, or x-rays,
- Performing a medically relevant test, or
- Assisting in an assessment of a child abuse report.

A person has the same immunity with respect to participation in good faith in any judicial proceeding resulting from the report or relating to the subject matter of the report.

As used in this section and section 232.77, "medically relevant test" means a test that produces reliable results of exposure to cocaine, heroin, amphetamine, methamphetamine, or other illegal drugs, or their combinations or derivatives, including a drug urine screen test.

Sanctions for Failure to Report Child Abuse

Iowa Code section 232.75 provides for civil and criminal sanctions for failing to report child abuse. Any person, official, agency, or institution required by this chapter to report a suspected case of child abuse who knowingly and willfully fails to do so is guilty of a simple misdemeanor.

Any person, official, agency, or institution required by Iowa Code section 232.69 to report a suspected case of child abuse who knowingly fails to do so, or who knowingly interferes with the making of such a report in violation of section 232.70, is civilly liable for the damages proximately caused by such failure or interference.

Sanctions for Reporting False Information

The act of reporting false information regarding an alleged act of child abuse to DHS or causing false information to be reported, knowing that the information is false or that the act did not occur, is classified as simple misdemeanor under Iowa Code section 232.75, subsection 3.

If DHS receives a fourth report which identifies the same child as a victim of child abuse and the same person as the alleged abuser or which is from the same person, and DHS determined that the three earlier reports were entirely false or without merit, DHS may:

- Determine that the report is again false or without merit due to the report's spurious or frivolous nature.
- Terminate its assessment of the report.
- Provide information concerning the reports to the county attorney for consideration of criminal charges.

Indicators of Possible Child Abuse

The following physical and behavioral indicators are listed as signs of possible child abuse for you to consider in making your report. These indicators need to be evaluated in the context of the child's environment. The presence of one or more of these symptoms does not necessarily prove abuse. These lists are examples and are not all-inclusive.

Physical Indicators

- Bruises and welts on the face, lips, mouth, torso, back, buttocks, or thighs in various stages of healing
- Bruises and welts in unusual patterns reflecting the shape of the article used (e.g., electric cord, belt buckle) or in clusters indicating repeated contact
- Bruises on infant, especially facial bruises
- Subdural hematomas, retinal hemorrhages, internal injuries
- Cigarette burns, especially on the soles, palms, backs or buttocks
- Immersion burns (sock-like, glove-like, doughnut-shaped) on buttocks or genitalia
- Burns patterned like an electric element, iron or utensil
- Rope burns on arms, legs, neck or torso
- Fractures of the skull, nose, ribs or facial structure in various stages of healing
- Multiple or spiral fractures
- Unexplained (or multiple history for) bruises, burns or fractures
- Lacerations or abrasions to the mouth, frenulum, lips, gums, eyes or external genitalia
- Bite marks or loss of hair
- Speech disorders, lags in physical development, ulcers
- Asthma, severe allergies or failure to thrive
- Consistent hunger, poor hygiene, inappropriate dress
- Consistent lack of supervision; abandonment

- Unattended physical or emotional problems or medical needs
- Difficulty in walking or sitting
- Pain or itching in the genital area
- Bruises, bleeding or infection in the external genitalia, vaginal or anal areas
- Torn, stained or bloody underclothing
- Frequent urinary or yeast infections
- Venereal disease, especially in pre-teens
- Pregnancy
- Substance abuse – alcohol or drugs
- Positive test for presence of illegal drugs in the child's body

Behavior Indicators

- Afraid to go home; frightened of parents
- Alcohol or drug abuse
- Apprehensive when children cry, overly concerned for siblings
- Begging, stealing or hoarding food
- Behavioral extremes, such as aggressiveness or withdrawal
- Complaints of soreness, uncomfortable movement
- Constant fatigue, listlessness or falling asleep in class
- Delay in securing or failure to secure medical care
- Delinquent, runaway or truant behaviors
- Destructive, antisocial or neurotic traits, habit disorders
- Developmental or language delays
- Excessive seductiveness or promiscuity
- Extended stays at school (early arrival and late departure)
- Extreme aggression, rage, or hyperactivity
- Fear of a person or an intense dislike of being left with someone
- Frequently absent or tardy from school or drops out of school or sudden school difficulties
- History of abuse or neglect provided by the child
- Inappropriate clothing for the weather
- Massive weight change
- Indirect allusions to problems at home such as, "I want to live with you"
- Lack of emotional control, withdrawal, chronic depression, hysteria, fantasy or infantile behavior

- Lags in growth or development
- Multiple or inconsistent histories for a given injury
- Overly compliant, passive, undemanding behavior; apathy
- Poor peer relationships; shunned by peers
- Poor self-esteem, self-devaluation, lack of confidence or self-destructive behavior
- Role-reversal behavior or overly dependent behavior; states there is no caretaker
- Suicide attempts
- Unusual interest in or knowledge of sexual matters, expressing affection in inappropriate ways
- Wary of adult contacts, lack of trust, uncomfortable with or threatened by physical contact or closeness

What Is Child Abuse Under Iowa Law?

DHS has the legal authority to conduct an assessment of child abuse when it is alleged that:

- The victim is a child.
- The child is subjected to one or more of the nine categories of child abuse defined in Iowa Code section 232.68:
  - Physical abuse
  - Mental injury
  - Sexual abuse
  - Denial of critical care
  - Child prostitution
  - Presence of illegal drugs
  - Manufacturing or possession of a dangerous substance
  - Bestiality in the presence of a minor
  - Allows access by a registered sex offender
  - Allows access to obscene material
- The abuse is the result of the acts or omissions of the person responsible for the care of the child.

Child

A **child** is defined in Iowa Code section 232.68 as any person under the age of 18 years.

The victim of child abuse is a person under the age of 18 who has suffered one or more of the categories of child abuse as defined in Iowa law (physical abuse, mental injury, sexual abuse, denial of critical care, child prostitution, presence of illegal drugs, manufacturing or possession of a dangerous substance or bestiality in the presence of a minor.

Caretaker

A perpetrator of child abuse must be a person responsible for the care of a child. A **person responsible for the care of a child** is defined in Iowa Code section 232.68 as:

a. Parent, guardian, or foster parent.

b. A relative or any other person with whom the child resides and who assumes care or supervision of the child, without reference to the length of time or continuity of such residence.

c. An employee or agent of any public or private facility providing care for a child, including an institution, hospital, health care facility, group home, mental health center, residential treatment center, shelter care facility, detention center, or child care facility.

d. Any person providing care for a child, but with whom the child does not reside, without reference to the duration of the care.

A person who assumes responsibility for the care or supervision of the child may assume such responsibility through verbal or written agreement, or implicitly through the willing assumption of the caretaking role.

Perpetrators of child abuse come from all walks of life, races, religions, and nationalities. They come from all professions and represent all levels of intelligence and standards of living. There is no single social strata free from incidents of child abuse.

Abusive parents may show disregard for the child's own needs, limited abilities, and feelings. Many abusive parents believe that children exist to satisfy parental needs and that the child's needs are unimportant. Children who don't satisfy the parent's needs may become victims of child abuse.

Sexual abusers may have deviant personality traits and behaviors that can result in sexual contact with a child. Sexual abuse perpetrators sometimes use threats, bribery, coercion or force to engage a child in sexual activity. They violate the trust that a child inherently places in them for care and protection, and exploit the power and authority of their position as a trusted caretaker in order to sexually misuse a child. Often the child is threatened or warned "not to tell," creating a conspiracy of silence about the abuse.

Educators as Caretakers

Normally teachers are not considered caretakers in the teaching and supervising of children. **Note:** If there is an accusation of child abuse (physical abuse, sexual abuse or child prostitution) by an employee in the school district, every school district will have policies and procedures in place which they will follow.

Iowa Code section 280.17 requires that "board of directors of a public school and the authorities in control of a nonpublic school prescribe procedures, in accordance with the guidelines contained in the model policy developed by the Department of Education in consultation with the Department of Human Services, and adopted by the Department of Education, for handling reports of child abuse, alleged to have been committed by an employee or agent of the public or nonpublic school."

The jurisdiction established by 281 Iowa Administrative Code 102.3, for reports of child abuse alleged to have been committed by an employee or agent of a public or nonpublic school, is "acts of the school employee on school grounds, on school time, on a school-sponsored activity, or in a school-related context."

There are times when an educator may be in the role of a caretaker and outside the jurisdiction of the school. For example, a teacher could be considered a caretaker if the teacher is responsible for supervising a child on an overnight trip.

DHS will review reports of child abuse alleged to have been committed by an employee or agent of a public or nonpublic school to determine if a joint assessment with school investigative personnel is appropriate. Where jurisdiction is unclear or there are other extenuating circumstances, DHS may initiate an assessment.

Children as Caretakers

Children are sometimes caretakers for other children and may be responsible for abusing a child in their care. Children may be in a caretaker role, for example, as a baby-sitter. An adult caretaker may be considered responsible if they delegated care responsibilities to an inappropriate minor caregiver.

A mandatory reporter who suspects that abuse has occurred when one child is caring for another is required by law to make a child abuse report. DHS will then determine if any action should be taken.

Physical Abuse

"Physical abuse" is defined as any non-accidental physical injury, or injury which is at variance with the history given of it, suffered by a child as the result of the acts or omissions of a person responsible for the care of the child.

Common indicators could include unusual or unexplained burns, bruises, or fractures. Health services personnel should be especially alert to cases of child abuse where inconsistent histories are presented. Inconsistent histories can take the form of an explanation that does not fit the degree or type of injury to the child, or where the story or explanation of the injury changes over time.

Some indicators of child abuse are not visible on the child's body. Many times there are no physical indicators of abuse. A child's behavior can change as a result of abuse. Health services personnel need to be alert to possible behavioral indicators of abuse and if they believe those to be present, they are required to make a report. Behavioral indicators include behaviors such as:

- Extreme aggression.
- Withdrawal.
- Seductive behaviors.
- Being uncomfortable with physical contact or closeness.

Mental Injury

"Mental injury" is defined as any mental injury to a child's intellectual or psychological capacity as evidenced by an observable and substantial impairment in the child's ability to function within the child's normal range of performance and behavior as the result of the acts or omissions of a person responsible for the care of the child, if the impairment is diagnosed and confirmed by a licensed physician or qualified mental health professional as defined in Iowa Code section 622.10.

Examples of mental injury may include:

- **Ignoring** the child and failing to provide necessary stimulation, responsiveness, and validation of the child's worth in normal family routine.
- **Rejecting** the child's value, needs, and request for adult validation and nurturance.
- **Isolating** the child from the family and community; denying the child normal human contact.
- **Terrorizing** the child with continual verbal assaults, creating a climate of fear, hostility, and anxiety, thus preventing the child from gaining feelings of safety and security.

- **Corrupting** the child by encouraging and reinforcing destructive, antisocial behavior until the child is so impaired in socioemotional development that interaction in normal social environments is not possible.
- **Verbally assaulting** the child with constant, excessive name-calling, harsh threats, and sarcastic put downs that continually "beat down" the child's self-esteem with humiliation.
- **Overpressuring** the child with subtle but consistent pressure to grow up fast and to achieve too early in the areas of academics, physical or motor skills, or social interaction, which leaves the child feeling that he or she is never quite good enough.

Sexual Abuse

"Sexual abuse" is defined as the commission of a sexual offense with or to a child pursuant to Iowa Code Chapter 709, Iowa Code section 726.2, or Iowa Code section 728.12, subsection 1, as a result of the acts or omissions of the person responsible for the care of the child.

Notwithstanding Iowa Code section 702.5, the commission of a sexual offense under this paragraph includes any sexual offense referred to in this paragraph with or to a person under the age of 18 years.

There are several subcategories of sexual abuse:

- First-degree sexual abuse
- Second-degree sexual abuse
- Third-degree sexual abuse
- Lascivious acts with a child
- Indecent exposure
- Assault with intent to commit sexual abuse
- Indecent contact with a child
- Lascivious conduct with a minor
- Incest
- Sexual exploitation by a counselor or therapist
- Sexual exploitation of a minor
- Sexual misconduct with offenders and juveniles
- Invasion of privacy (nudity)

Behavioral indicators of sexual abuse could include things such as excessive knowledge of sexual matters beyond their normal developmental age or seductiveness. Physical indicators of sexual abuse could include things such as bruised or bleeding genitalia, venereal disease, or even pregnancy.

Denial of Critical Care

"Denial of critical care" is defined as the failure on the part of a person responsible for the care of a child to provide for the adequate food, shelter, clothing, medical or mental health treatment, supervision, or other care necessary for the child's health and welfare when financially able to do so or when offered financial or other reasonable means to do so.

Note: What most people think of as an issue of "neglect" is covered under the child abuse category of "denial of critical care."

A parent or guardian legitimately practicing religious beliefs who does not provide specified medical treatment for a child for that reason alone shall not be considered abusing the child. However, this does not preclude a court from ordering that medical service be provided to the child where the child's health requires it.

Denial of critical care includes the following eight sub-categories:

- **Failure to provide adequate food and nutrition** to such an extent that there is danger of the child suffering injury or death.
- **Failure to provide adequate shelter** to such an extent that there is danger of the child suffering injury or death.
- **Failure to provide adequate clothing** to such an extent that there is danger of the child suffering injury or death.
- **Failure to provide adequate health care** to such an extent that there is danger of the child suffering serious injury or death.
- **Failure to provide the mental health care** necessary to adequately treat an observable and substantial impairment in the child's ability to function.
- **Gross failure to meet the emotional** needs of the child necessary for normal development evidenced by the presence of an observable and substantial impairment in the child's ability to function within the normal range of performance and behavior.
- **Failure to provide proper supervision** of a child which a reasonable and prudent person would exercise under similar facts and circumstances, to such an extent that the failure resulted in direct harm or created a risk of harm to the child or there is danger of the child suffering injury or death.

  This definition includes cruel and undue confinement of a child and the dangerous operation of a motor vehicle when the person responsible for the care of the child is driving recklessly or driving while intoxicated with the child in the vehicle.

Other situations that fall under this subcategory include:

- Illegal drug usage by the caretaker of a child

  When you make an allegation of denial of critical care because a child lacks proper supervision due to illegal drug usage by a caretaker you may be asked questions to help DHS determine the type of drug and the degree of risk to the child.

  Some illegal drugs may have a greater impact on the supervision abilities of the caretaker than others. For example, methamphetamine usage by a child's caretaker has inherent risks to the child given the known effects of methamphetamines. DHS will consider the known effect of the drug named and other information to assess risk to the child's safety. You may be asked about the child's access to the drugs and about the caretaker's use of drugs, being under the influence of drugs while supervising or transporting child, dealing drugs, possession of weapons etc.

- Children home alone

  DHS receives many inquiries each year regarding when a child can be left home alone safely. Iowa law does not define an age that is appropriate for a child to be left alone. Each situation is unique. Examples of questions to help determine whether there are safety concerns for the child include:

  - Does the child have any physical disabilities?
  - Could the child get out of the house in an emergency?
  - Does the child have a phone and know how to use it?
  - Does the child know how to reach the caretaker?
  - How long will the child be left home alone?
  - Is the child afraid to be left home alone?
  - Does the child know how to respond to an emergency such as fire or injury?

- Lice and truancy

  Head lice and truancy are often reported as child abuse allegations. However, the endangerment does not generally rise to the level that must be present to constitute a child abuse allegation.

  If other conditions are present or the situation poses a risk to the child's health and welfare, it should be reported as child abuse. Even if the report is rejected for assessment, other services may be offered to the child and family.

♦ **Failure to respond to the infant's life-threatening conditions** by failing to provide treatment which in the treating physician's judgment will be most likely to be effective in ameliorating or correcting all conditions.

This subcategory or the denial of critical care abuse type is also known as "withholding of medically indicated treatment." The type of treatments included are appropriate nutrition, hydration, and medication.

The term does not include the failure to provide treatment other than appropriate nutrition, hydration, and medication to an infant when, in the treating physician's medical judgment, any of the following circumstances apply:

- The infant is chronically and irreversibly comatose.
- The provision of treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant.
- The provision of the treatment would be virtually futile in terms of the survival of the infant and the treatment itself under the circumstances would be inhumane.

Child Prostitution

"Child prostitution" is defined as the acts or omissions of a person responsible for the care of a child which allow, permit, or encourage the child to engage in acts prohibited pursuant to Iowa Code section 725.1. Notwithstanding Iowa Code section 702.5, acts or omissions under this paragraph include an act or omission referred to in this paragraph with or to a person under the age of 18 years.

Note: "Prostitution" is defined as a person who sells or offers for sale the person's services as a partner in a sex act, or who purchases or offers to purchase such services.

Presence of Illegal Drugs

"Presence of illegal drugs" is defined as occurring when an illegal drug is present in a child's body as a direct and foreseeable consequence of the acts or omissions of the person responsible for the care of the child.

Iowa Code section 232.77 states that, "If a health practitioner discovers in a child physical or behavioral symptoms of the effect of exposure to cocaine, heroin, amphetamine, methamphetamine, or other illegal drugs or combination or derivatives thereof, which were not prescribed by a health practitioner, or if the health practitioner has determined through examination of the natural mother of the child that the child was exposed in utero, the health practitioner may perform or cause to be performed a medically relevant test as defined section 232.73, on the child. The practitioner shall report any positive results of such a test on the child to the department. The department shall begin an assessment pursuant to section 232.71B upon receipt of such a report."

"Illegal drugs" are defined as cocaine, heroin, amphetamine, methamphetamine, other illegal drugs (including marijuana), or combinations or derivatives of illegal drugs which were not prescribed by a health practitioner.

Examples of situations that may result in a determination of this type of abuse:

- An infant is born with illegal drugs present in the infant's system as determined by a medical test. The illegal drugs were present in the infant's body due to the illegal drug usage by the mother before the baby's birth.
- A three-year-old child tests positive for illegal drugs due to exposure to the illegal drugs when the child's caretakers used illegal drugs in the child's home.

Manufacturing or Possession of a Dangerous Substance

"Manufacturing or possession of a dangerous substance" is defined in Iowa Code section 232.2, subsection 6, paragraph p, as occurring when the person responsible for the care of a child:

- Has manufactured a dangerous substance in the presence of the child, or
- Knowingly allows the manufacture of a dangerous substance by another person in the presence of a child, or
- Possesses a product containing ephedrine, its salts, optical isomers, salts of optical isomers, or pseudoephedrine, its salts, optical isomers, salts of optical isomers, with the intent to use the product as a precursor or an intermediary to a dangerous substance in the presence of the child.

For the purposes of this definition, "in the presence of a child" means the manufacture or possession occurred:

- In the physical presence of a child, or
- In a child's home, on the premises, or in a motor vehicle located on the premises, or
- Under other circumstances in which a reasonably prudent person would know that the manufacture or possession may be seen, smelled, or heard by a child.

Iowa Code section 232.2, subsection 6, paragraph p, defines "dangerous substance" as:

- Amphetamine, its salts, isomers, or salts of its isomers.
- Methamphetamine, its salts, isomers, or salts of its isomers.
- A chemical or combination of chemicals that poses a reasonable risk of causing an explosion, fire, or other danger to the life or health of people who are in the vicinity while the chemical or combination of chemicals is used or is intended to be used in any of the following:
  - The process of manufacturing an illegal or controlled substance.
  - As a precursor in the manufacturing of an illegal or controlled substance.
  - As an intermediary in the manufacturing of an illegal or controlled substance.

  Note: DHS must report this type of allegation to law enforcement, as this is a criminal act.

Bestiality in the Presence of a Minor

Bestiality in the presence of a minor is defined as the commission of a sex act with an animal in the presence of a minor as defined in Iowa Code section 717C.1 by a person who resides in a home with a child, as the result of the acts or omissions of a person responsible for the care of the child. **Note:** DHS must report this type of allegation to law enforcement, as this is a criminal act.

Allows Access by a Registered Sex Offender

It is child abuse if a caretaker-knowingly allows unsupervised access to a child by a registered sex offender or allows a registered sex offender to have custody or control of a child up to age 14 or a child up to age 18 if the child has a mental or physical disability. The exceptions are if the registered sex offender is the caretaker' spouse or is a minor child of the caretaker. **Note:** DHS must report this type of allegation to law enforcement, as this is a criminal act under child endangerment.

Allows Access to Obscene Material

This type of abuse is defined as a caretaker knowingly allowing a child access to obscene material, exhibiting obscene material to a child, or disseminating obscene material to a child, as defined in Iowa Code Section 728.1.

How Does DHS Respond?

A DHS child abuse assessment consists of the following processes:

- Intake
- Case assignment
- Evaluation of the alleged abuse
- Determining if abuse occurred
- Placing a report on the Child Abuse Registry
- Assessment of family strengths and needs
- Preparing forms and reports

Intake

The purpose of intake is to obtain information to ensure that reports of child abuse meeting the criteria for assessment are accepted and reports that do not meet the legal requirements are appropriately rejected. DHS policy is to accept a report when there is insufficient information to reject it.

The first step in this process is to initiate safeguards for children who are at risk or have been abused. DHS staff will ask questions of the reporter, record necessary information, and discern between significant and extraneous information.

Information gathered at intake includes:

- The allegation of child abuse
- The identify and location of the child, parents or caretakers
- The safety of and risk to the child
- The identity and location of the person allegedly responsible for the abuse
- That person's access to children
- Information regarding the mandatory reporter

The supervisor is responsible for ensuring that accurate information is documented.

While it is helpful to be familiar with child abuse definitions to make a report, knowing the definitions and terminology is not essential. DHS will determine the type of abuse being alleged. It may be possible to make reasonable inferences that would cause a report to be accepted for assessment based upon the description of what occurred, so detail and accurate information is essential.

You may be contacted when:

- Your initial report is made through a written report of child abuse.
- Any of the information in your initial report is unclear or incomplete.
- Information in your initial report is called into question once the assessment is initiated.
- The written report you submit contains new or different information from that provided in your oral report of child abuse.

Reports from Multiple Reporters

When more than one mandatory reporter reasonably suspects abuse involving the same incident, the mandatory reporters, may jointly make a written report to DHS.

When more than one reporter separately makes a report of suspected child abuse on the same incident, and the first report is currently being assessed, DHS will advise the subsequent reporters that the report of child abuse they are making has already been accepted as a case.

Time Frame for Deciding Whether to Accept a Report for Assessment

The DHS decision on whether to accept or reject a report of child abuse is to be made within a **1-hour or 12-hour** time frame from receipt of the report, depending on the information which is provided and the level of risk to the child:

- When a report indicates that the child has suffered a "**high-risk**" injury or there is an **immediate threat** to the child, the Department acts immediately to address the child's safety. The decision to accept the report of child abuse is made within **one hour** from receipt of the report.

- When the report **does not meet the criteria** to be accepted, such as the person alleged responsible is not a caretaker, but the report alleges the child is at **high risk**, DHS still acts immediately to address the child's safety (by calling law enforcement, for example). A supervisor reviews and approves the decision to reject the report of child abuse within **one hour** from receipt of the report.
- When a report indicates that the child has been abused, but it is not considered a "high risk" injury or there is **no immediate threat** to the child, DHS still acts promptly. The decision to accept the report of child abuse and supervisory approval on that decision are made within **12 hours** from receipt of the report.
- When the report **does not meet the criteria** to be accepted, such as the person alleged responsible is not a caretaker, and the report alleges the child is not considered to be at "high risk," a supervisor reviews and approves the decision to reject the report of child abuse within **12 hours** from receipt of the report.

Accepted Intakes

When your report meets the criteria for assessment, DHS will inform you that the report of child abuse has been accepted as a case within 24 hours of receiving the report. DHS may provide this oral notification at the time that the report is made if the report is accepted immediately.

If your report is not accepted immediately because further consultation is required with a supervisor, you will be informed that further consultation is needed before a decision can be made, and someone will be calling you back with the decision.

Rejected Intakes

DHS must obtain sufficient information to be able to determine if a report meets the intake criteria. A supervisor reviews the report and makes the final determination about rejecting the report for assessment.

If your report is rejected, DHS will:

- Contact law enforcement if a child's safety appears to be in jeopardy.
- Orally notify you that the report has been rejected within 24 hours of receipt.
- Send you a written notice indicating the decision to reject the report within five working days of its receipt, using form 470-3789, *Notice of Intake Decision*, which includes instructions on what to do if you disagree with the decision.
- Provide a copy of intake information to the county attorney within five working days of its receipt.

You will be advised that:

- The report is being rejected for one or more of the following reasons:
  - The reported victim is not a child.
  - The person alleged to have abused the child is not a caretaker.
  - The reported abuse does not fall within the definition of child abuse.
- The report will be screened for a possible "child in need of assistance" assessment to determine if juvenile court action is necessary. The family may apply for services through DHS if there is a founded child abuse report or a juvenile court order.
- You may inform the family of services available in the community.

If you become aware of circumstances where you believe that the child is **imminently likely** to be abused or neglected, report this to DHS. These may include, but are not limited to, a child born into a family in which:

- The court has previously adjudicated another child to be a child in need of assistance due to abuse;
- The court has terminated parental rights to a child; or
- The parent has relinquished rights with respect to a child due to child abuse.

DHS may seek an ex parte **removal order** if it appears that the newborn's immediate removal is necessary to avoid **imminent danger** to the child's life or health.

When intake information does not meet the legal definition of child abuse, but a criminal act to a child is alleged, DHS refers the report to the appropriate law enforcement agency.

If the intake information alleges sexual abuse of a child by a person who is not a "caretaker," DHS refers the report to law enforcement verbally and also submits the referral information in writing within 72 hours of receiving the report.

The DHS Intake Unit keeps a copy of intake information for rejected reports of child abuse for three years, then destroys it.

Rejected intake information is not considered "child abuse information." It is governed by the same provisions of confidentiality as DHS service case records. If a subject of a report requests information about a rejected intake involving the subject, DHS will provide a copy of the rejected intake to the subject, if it is available, after removing the name of the reporter.

If you become aware of new information after your report has been rejected, make a new report to DHS.

Case Assignment

When a report indicates that the child has suffered a "high risk" injury or there is an immediate threat to the child, DHS must act immediately to address the child's safety. The case must be assigned **immediately**.

When a report indicates that the child has been abused but it is not considered a "high risk" injury or there is no immediate threat to the child, DHS must still act promptly. The case must be assigned within **12 hours from receipt of the report**.

The primary purpose of the assessment is to take action to protect and safeguard the child by evaluating the safety of and risk to the child named in the report and any other children in the same home as the parents or other person responsible for their care.

If DHS staff believe at any time during the assessment that there is an immediate threat because of abuse, they will immediately contact the proper authorities and communicate these concerns. This may include any or all of the following:

- Law enforcement
- Juvenile court
- Physicians

DHS staff have contact with the family in all assessments. Other assessment activities vary, depending upon the evaluation of the child's safety and the family's strengths and needs.

Evaluation of the Alleged Abuse

During the evaluation process, DHS gathers information about the allegations of child abuse, as well as the strengths and needs of the family, through:

- Observing the alleged child victim
- Interviewing subjects of the report and other sources
- Gathering documentation
- Evaluating the safety of and risk to the child

Observation of the Alleged Child Victim

The purpose of observation of the alleged victim is to address the safety of the child and determine if the child has visible symptoms of abuse. Careful and timely observation of the child is most relevant to physical abuse allegations. Observation may also be relevant in assessments involving allegations of denial of critical care, particularly failure to provide adequate food, shelter, or clothing.

Requirements for observations depend on the level of risk to the child posed by the allegation, as follows:

- **1 hour** when the report involves an immediate threat or high risk to the child's safety.
- **24 hours** when the report doesn't involve immediate threat or high risk to the child but the person alleged responsible has access to the child.
- **96 hours** when the report doesn't involve an immediate threat or high risk to the child and the person alleged responsible clearly does not have access to the child.

Whenever possible, the child protection worker attempts to observe and interview the child named in the report when interviewing the parents. When the worker must observe and interview a child named in the report away from the parental home, attempts are made to obtain parental consent.

Interviews with Subjects of the Report and Other Sources

DHS staff interview the child to gather information not only regarding the abuse allegations, but also about the child's immediate safety, the risk of abuse, the parents, the person allegedly responsible for the abuse, and the family.

Other siblings may be interviewed to determine if they have experienced abuse, to evaluate their vulnerability, to gather corroborating information regarding the alleged child victim, and to gather information to assist in the risk assessment.

During an assessment, DHS may interview parents who are not alleged to have abused the child to find out what they know about the alleged abuse, gather information related to the risk of abuse; and determine their capacity to protect the child.

Iowa law requires that the person allegedly responsible for abuse be offered an opportunity (when the person's whereabouts are known) to be interviewed and respond to the allegations, but the person may decline the interview. The information is used to determine if abuse occurred, as well as to measure the risk this person may present to the alleged victim, other children, or others residing in the household.

DHS may contact and interview other people who may have relevant information to share regarding the report of the alleged abuse and the assessment of the safety of and risk to the child. During an assessment, physicians are asked to contact DHS immediately when:

- The parents or caretakers fail to take the child to the scheduled appointment.
- There is any confirmation or evidence of physical abuse.
- The child has other medical conditions that require immediate medical attention.

Professional consultation may be sought, including the use of multidisciplinary teams, or child protection assistance teams or child protection centers when a determination is needed which is outside the Department's professional scope. For example, a worker may be able to identify a child who is underweight, but "failure to thrive" is a diagnosis that only a physician can make.

Multidisciplinary teams consist of professionals practicing in medicine, public health, mental health, social work, child development, education, law, juvenile probation, law enforcement, nursing, domestic violence and substance abuse counseling.

These teams function as an advisory and consultation group to aid child protection workers in resolving issues related to a case during the assessment phase. They may also assist in identifying treatment plans. Counties or multi-county areas with 50 or more reports of child abuse annually are required to develop multidisciplinary teams.

Child protection assistance teams are convened by the county attorney and involve DHS, law enforcement and the county attorney to consult on cases involving a forcible felony against a child younger than age 14 by a person responsible for the care of the child and child sexual abuse. The team may consult with other professionals in specified disciplines.

The county attorney is to establish a team for each county unless two or more county attorneys agree to establish a single team for a multicounty area. The team may consult with or include juvenile court officers, medical and mental health professions, physicians or other hospital-based health professions, court appointed special advocates, guardian ad litem and members of a multidisciplinary team created by DHS for child abuse assessments.

DHS has established agreements with multiple child protection centers across the state of Iowa. These centers assist child protection workers in assessment of reports of child abuse. In most cases, these centers provide medical evaluations and psychosocial assessments of the victim when there are allegations of sexual abuse or serious physical abuse.

Other evaluative information is sometimes obtained through textbooks, scholarly journals, or other publications.

Gathering Documentation

Documentation gathered during the assessment process is used to assist in determining if the information contained with the report of child abuse is accurate, to complete the assessment of family strengths, and developing a plan of action.

Iowa Code section 232.71B indicates that any mandatory reporter, the county attorney, any law enforcement agency, and any social service agency in the state shall cooperate and assist in the assessment upon the request of the DHS.

In addition to information gathered through interviews, the child protective worker may take photographs or secure photographs taken by others to show injuries to the child or to document conditions in the household. Common sources for photographic documentation are police departments and hospitals.

DHS by law may request the criminal history of a person alleged to be responsible for abuse. Information suggesting that a record check is advisable may include allegations of sexual abuse, domestic violence, or abuse of alcohol or other drugs.

DHS may use medical reports and records that are relevant to the report of child abuse, including X-rays, findings of physical or sexual abuse examinations, reports from interviews and examinations at a child protection center and medically relevant tests related to the presence of illegal drugs within a child's body.

DHS may use audiotapes, videotapes, and other electronic recording media to document observations or conversations.

Evaluation of the Safety of and Risk to the Child

The evaluation of a child's safety is an ongoing activity that continues during the entire assessment process. A safety analysis focuses on the current situation. A child is considered "safe" when the evaluation of all available information leads to the conclusion that the child will not be abused in the current living arrangement.

If a child is determined not to be safe, DHS takes action to address safety concerns. This may include (but is not limited to) any of the following active steps:

- Provision of safety services.
- Provision of family safety, risk, and permanency services.
- Removal of a child from the home.
- Placement of child with relatives.
- Removal of person allegedly responsible for the abuse from the home.

The assessment of the risk of abuse to the child is based on the following factors:

- Severity of the incident or condition.
- Chronicity of the incident or condition.
- The child's age, medical condition, mental and physical maturity, and functioning.

- Attitude of the person allegedly responsible for the abuse regarding its occurrence.
- Current resources, services, and supports available to the family that can meet the family's needs and increase protection for the child.
- Special events, situations, or circumstances that may have created immediate stress, tension, or anxiety in the family or household.
- Access of the person allegedly responsible for the abuse to the child.
- Willingness and ability of the parent, or caretaker not responsible for the abuse, to protect the child from further abuse.

Determination if Abuse Occurred

After gathering necessary information from observations, interviews and documentation, and after assessing the credibility of subjects of the report, collateral contacts and information, DHS must determine whether or not abuse occurred. Each category or subcategory of child abuse requires that specific criteria be met in order to conclude that abuse occurred.

This determination is based on a "preponderance" of credible evidence, defined as greater than 50% of the credible evidence gathered. The child protective worker must make one of the following conclusions regarding a report of child abuse:

- **Not confirmed:** Based on the credible evidence gathered, DHS determines that there is not a preponderance of available credible evidence that abuse did occur.
- **Confirmed** (but not placed on the Child Abuse Registry): Based on a preponderance of all of the credible evidence available to DHS, the allegation of abuse is confirmed; however, the abuse will not be placed on the Child Abuse Registry.
- **Founded:** Based on a preponderance of credible evidence available to DHS, the allegation of abuse is confirmed and it is the type of abuse that requires placement on the Child Abuse Registry.

Determination if Report Is Placed on the Child Abuse Registry

After a decision is made that a report of child abuse is confirmed, DHS makes a determination about whether the report must be placed on the Child Abuse Registry.

When a report of child abuse is placed on the Child Abuse Registry, the child's name, the names of the child's parents, and the name of the perpetrator of the abuse are all entered into the Registry. Placing the name of a person responsible for the abuse of a child on the Registry may affect employment, registration, and licensure opportunities for that person.

"Founded" reports must be placed on the Child Abuse Registry. A report that is not confirmed cannot be placed on the Registry. A report of child abuse that is confirmed must be placed on the Registry as a founded report under any of the following circumstances:

- **Physical abuse**, when one or more of the following criteria are met:
  - The injury was not minor.
  - The injury was not isolated.
  - The injury is likely to reoccur.
- **Denial of critical care** by:
  - Failure to provide adequate food and nutrition.
  - Failure to provide adequate shelter.
  - Failure to provide adequate health care.
  - Failure to provide adequate mental health care.
  - Gross failure to meet emotional needs.
  - Failure to respond to an infant's life-threatening condition.
  - Failure to provide proper supervision, **when** one or more of the following criteria are met:
    - The risk of injury was not minor.
    - The risk of injury was not isolated.
    - The risk of injury is likely to reoccur.
  - Failure to provide adequate clothing, **when** one or more of the following criteria are met:
    - The risk of injury was not minor.
    - The risk of injury was not isolated.
    - The risk of injury is likely to reoccur.
- **Mental injury**.
- **Presence of illegal drugs**.
- **Child prostitution**.
- **Sexual abuse committed by a person age 14 or older** at the time of the abuse.
- **Manufacturing or possession of dangerous substances with the intent to use the product as a precursor or intermediary**.
- **Bestiality in the presence of a minor**.
- **Allows access by a registered sex offender.**
- **Allows access to obscene material.**

Also, the report shall be **founded** when:

- The case was referred for juvenile or criminal court action. DHS may recommend court action for an adjudication, removal, or redisposition on an existing court case.
- Within 12 months of the report, the county attorney or juvenile court initiated **court action that resulted in an adjudication or criminal conviction**. (This could result in change in determination of placement on the Registry for a report not previously placed on the Registry.)The same person has been confirmed responsible for abuse in the **last 18 months**. If there is any prior report, the current assessment will be placed on the Registry if abuse is confirmed, because the abuse occurrence was not isolated.
- The person responsible for the abuse **continues to pose a danger** to the child named or another child. This is determined by assessing if the abuse was minor, isolated, and unlikely to reoccur. If the incident does not meet these three criteria, then the person may continue to pose a danger to the child named or to another child and the incident will be placed on the Registry.

In summary, all confirmed reports of abuse will be placed on the Registry as founded reports except for:

- Denial of critical care through failure to provide proper supervision, when the endangerment of the child was minor, isolated and unlikely to reoccur.
- Denial of critical care through failure to provide adequate clothing, when the endangerment of the child was minor, isolated and unlikely to reoccur.
- Physical abuse, when the injury to the child was minor, isolated and unlikely to reoccur.

Assessment of Family's Strengths and Needs

The assessment process requires an evaluation of the family's functioning, strengths, and needs. The family's participation is essential. Information is gathered from family members to identify strengths, possible rehabilitation needs of the child and family, and develop the plan of action. The process usually includes a visit to the home.

As part of the evaluation of the family functioning, the Department gathers information on:

- Home environment
- Parent or caretaker characteristics
- Child characteristics
- Domestic violence and substance abuse
- Social and environmental characteristics

Preparation of Reports and Forms

There are several reports and forms which are generated as a result of an assessment being initiated providing notification and other relevant information to reporters, subjects of the report, the county attorney and juvenile court.

- **Notice of Intake Decision**

  The *Notice of Intake Decision* provides written notification to all mandatory and permissive reporters about whether or not a report of child abuse was accepted or rejected for assessment. This form is completed and mailed to the reporter within five working days of the receipt of a report.

- **Parental Notification**

  The *Parental Notification* form provides written notice to the parents of a child who is the subject of a child abuse assessment within five working days of commencing an assessment. Both custodial and noncustodial parents are notified if their whereabouts are known. DHS is required by law to issue this notification. Only the court may waive issuance of the notice.

- **Child Protective Assessment Summary**

  The *Child Protective Services Assessment Summary* provides documentation of efforts to assess the abuse allegations and to assess the child and family functioning. The *Child Protective Services Assessment Summary* is available to the mandatory reporter who made the report, upon request. The custodial and noncustodial parents are provided a copy of the summary at the completion of the assessment. The safety and risk assessment can be released only with the permission of the subjects.

  The Summary includes report and disposition information divided in several sections.

  - **Abuse reported.** This section includes the allegations reported, including the name of the child subject, the person alleged to be responsible, and the type of abuse reported; and any additional allegations received while the assessment is being conducted.
  - **Assessment of child safety.** This section includes an assessment of the immediate safety of the child, actions taken to address safety issues, and an assessment of future risk to the child.
  - **Summary of contacts.** This section includes family and child identification, with a list of household members by name, and relationship to one another. It describes the date and time the child subject was observed; the rationale for using confidential access, if applicable; and the physical evidence pertaining to the abuse allegations. It identifies those interviewed (by name, date, and time), including collateral contacts and a summary of their remarks.

This section describes DHS efforts to locate and interview the person alleged to be responsible for the abuse and the documents DHS requested and examined pertaining to the abuse allegations. It includes information about all previous confirmed incidents of child abuse (both founded and confirmed not placed on Registry) involving any subjects of the current assessment and relevant information from any previous DHS contact with the child or family.

- **Determination as to whether abuse occurred.** This section includes documentation to support whether abuse did or did not occur; the identification of the type of abuse that occurred, if any, and its severity or significance; and the identification of the child and the person responsible for the abuse.
- **Rationale for placement or non-placement on the Registry.** This section specifies why the report is or is not being placed on the Child Abuse Registry. Specific circumstances that require placement of the report on the Registry are documented.
- **Recommendation for juvenile court action.** This section contains specific recommendations to the county attorney regarding the initiation (or continuation) of juvenile court action, along with the rationale to support the recommendation.
- **Recommendation for criminal court action.** This section contains specific recommendations to the county attorney regarding the initiation of any criminal prosecution and rationale for this recommendation, reference to any joint assessment with law enforcement, and the current status of a criminal investigation, when charges have already been filed.

♦ **Notice of Child Abuse Assessment**

The *Notice of Child Abuse Assessment* is issued to the parents, guardians, custodians of the child, noncustodial parent, child, person alleged to be responsible for the abuse, as well as the mandatory reporter, when applicable, a facility administrator and other child protection workers who assisted in completing the assessment, if any. The *Notice*:

- Indicates that the assessment process is concluded and whether the allegations of abuse were founded, confirmed or not confirmed.
- Lists the recommendation for services and juvenile or criminal court.
- Provides information regarding confidentiality provisions related to child abuse assessment information and how to request an appeal hearing.
- Provides information on how to obtain copies of the *Child Protective Assessment Services Summary*. Mandatory reporters may use the notice form to request a copy of the written summary of the assessment of their allegations of abuse.

What Happens After the Assessment?

By the close of the child protective assessment process, the child protection worker will determine the family's eligibility and need for services. The eligibility for services is based on age of the child, the risk of abuse or reabuse, and the finding of child abuse assessment. DHS provides protective services to abused and neglected children and their families without regard to income when there is a founded child abuse report or with a court order. Community resources provide rehabilitative services for the prevention and treatment of child abuse to children and families.

Service Recommendations and Referrals

During or at the conclusion of a child abuse assessment, the department may recommend information, information and referral, community care referral, or services provided by the department. If it is believed that treatment services are necessary for the protection of the abused child or other children in the home, juvenile court intervention shall be sought.

- **Information or information and referral.** Families with children of any age that have confirmed or not confirmed abuse and low risk of abuse shall be provided either information and referral or information when:
  - No service needs are identified, and the worker recommends no service; or
  - Service needs are identified, and the worker recommends new or continuing services to the family to be provided through informal supports; or
  - Service needs are identified, and the worker recommends new or continuing services to the family to be provided through community agencies.
- **Referral to community care.** With the exception of families of children with an open department service case, court action pending, or abuse in an out-of-home setting, a referral to community care shall be offered to:
  - Families with children whose abuse is not confirmed that have moderate to high risk of abuse when service needs are identified and the worker recommends community care.
  - Families with children that have confirmed but not founded abuse and moderate or high risk of abuse when service needs are identified and the worker recommends community care.
  - Families with children with founded abuse, a victim child six years of age or older, and a low risk of repeat abuse when service needs are identified and the worker recommends community care.

  Note: "Community care" means child and family-focused services and supports provided to families referred from the department. Services shall be geared toward keeping the children in the family safe from abuse and neglect; keeping the family intact; preventing the need for further intervention by the department, including removal of the child from the home; and building ongoing linkages to community-based resources that improve the safety, health, stability, and well-being of families served.

- **Referral for department services.** Families with children that have founded abuse and moderate to high risk of abuse and families with victim children under age six that have founded abuse and low risk of abuse shall be offered department services on a voluntary basis.
  - The worker shall recommend new or continuing treatment services to the family to be provided by the department, either directly or through contracted agencies.
  - Families refusing voluntary services shall be referred for a child in need of assistance action through juvenile court.

DHS services such as homemaker services, parenting classes, respite child care, foster care, financial assistance, psychological and psychiatric services, and sexual abuse treatment may be provided and may be provided without court involvement if the parent consents to services. Other interventions can be ordered by a court.

Juvenile court intervention may be sought in order to intervene on an emergency basis to place the child in protective custody by removing the child from the home or by seeking adjudication of the child to place the child under the protective supervision of the juvenile court with the child remaining in the care and custody of the parent.

The child protective assessment worker continuously evaluates the safety and risk to the child while conducting the assessment of allegations of abuse. The assessment worker may consider alternatives to the removal of a child if the child would be provided adequate protection. Options may include:

- Bringing protective relatives to the child's home while the parents leave the home.
- Initiating public health nurse or visiting nurse services.
- Initiating homemaker services or family safety, risk, and permanency services.
- Implementing intensive services, such as family preservation.
- Placing the child in voluntary foster or shelter care.
- Placing the child voluntarily with relatives or friends.
- Obtaining a court order requiring that the person responsible for the abuse leave the home, when other family members are willing and able to adequately protect the child.

When the juvenile court orders the person alleged responsible for the abuse to vacate the child's residence, a child in need of assistance petition must be filed within three days. If there are concerns about the person having contact with the child following the person's removal from the home, a "no contact" order through the county attorney may be requested.

Removal of a Child

Iowa laws provide for a child to be placed in protective custody in various situations. DHS does not have a statutory authority to simply "remove" a child from a parent or other caretaker. The procedures for a child to be placed in protective custody are outlined in Iowa Code sections 272.78 through 232.79A.

Assessment workers do not have the legal authority to remove children from their home without a court order or parental consent. Only a peace officer or a physician treating a child may remove a child without a court order if the child's immediate removal is necessary to avoid imminent danger to the child's life or health. There are four legal procedures for the emergency temporary removal of a child:

- Emergency removal by an ex parte court order
- Emergency removal of the child by a peace officer
- Emergency removal of the child by a physician
- With parent's consent

Removal by Ex Parte Court Order

A child may be taken into custody following the issuance of an **ex parte court order** pursuant to Iowa Code section 232.78, which states:

1. The juvenile court may enter an ex parte order directing a peace officer or a juvenile court officer to take custody of a child before or after the filing of a petition under Chapter 232 provided all of the following apply:

    a. The person responsible for the care of the child is absent, or though present, was asked and refused to consent to the removal of the child and was informed of an intent to apply for an order under this section, or there is reasonable cause to believe that a request for consent would further endanger the child, or there is reasonable cause to believe that a request for consent will cause the parent, guardian, or legal custodian to take flight with the child.

    b. It appears that the child's immediate removal is necessary to avoid imminent danger to the child's life or health. The circumstances or conditions indicating the presence of such imminent danger shall include but are not limited to any of the following:

        (1) The refusal or failure of the person responsible for the care of the child to comply with the request of a peace officer, juvenile court officer, or child protection worker for such person to obtain and provide to the requester the results of a physical or mental examination of the child. The request for a physical examination of the child may specify the performance of a medically relevant test.

(2) The refusal or failure of the person responsible for the care of the child or a person present in the person's home to comply with a request of a peace officer, juvenile court officer, or child protection worker for such a person to submit to and provide to the requester the results of a medically relevant test of the person.

c. There is not enough time to file a petition and hold a hearing under [Iowa Code] section 232.95.

d. The application for the order includes a statement of the facts to support the findings specified in paragraphs a, b, and c.

2. The person making the application for an order shall assert facts showing there is reasonable cause to believe that the child cannot either be returned to the place where the child was residing or placed with the parent who does not have physical care of the child.

3. Except for good cause shown or unless the child is sooner returned to the place where the child was residing or permitted to return to the child care facility, a petition shall be filed under this chapter within three days or the issuance of the order.

4. The juvenile court may enter an order authorizing a physician or hospital to provide emergency medical or surgical procedures before the filing of a petition under Chapter 232 provided:

   a. Such procedures are necessary to safeguard the life and health of the child; and

   b. There is not enough time to file a petition under this chapter and hold a hearing as provided in section 232.95.

5. The juvenile court, before or after the filing of a petition under Chapter 232, may enter an ex parte order authorizing a physician or hospital to conduct an outpatient physical examination of a child, or authorizing a physician…, a psychologist…, or a community mental health center… to conduct an outpatient mental examination of a child, if necessary to identify the nature, extent, and cause of injuries to the child, provided all the following apply:

   a. The parent, guardian, or legal custodian is absent, or though present, was asked and refused to provide written consent to the examination.

   b. The juvenile court has entered an ex parte order directing the removal of the child from the child's home or a child care facility under this section.

   c. There is not enough time to file a petition and to hold a hearing as provided in section 232.98.

6. Any person who may file a petition under Chapter 232 may apply for an order for temporary removal, or the court on its own motion may issue such an order. An appropriate person designated by the court shall confer with a person seeking the removal order, shall make every reasonable effort to inform the parent or other person legally responsible for the child's care of the application, and shall make such inquiries as will aid the court in disposing of such application.

The person designated by the court shall file with the court a complete written report providing all details of the designee's conference with the person seeking the removal order, the designee's efforts to inform the parents or other person legally responsible for the child's care of the application, any inquiries made by the designee to aid the court in disposing of the application, and all information the designee communicated to the court. The report shall be filed within five days of the date of the removal order.

If the court does not designate any appropriate person who performs the required duties, notwithstanding section 234.39 or any other provision of law, the child's parent shall not be responsible for paying the cost of care and services for the duration of the removal order.

7. Any order entered authorizing temporary removal of a child must include both of the following:
   a. A determination made by the court that continuation of the child in the child's home would be contrary to the welfare of the child. Such a determination must be made on a case-by-case basis. The grounds for the court's determination must be explicitly documented and stated in the order. However, preserving the safety of the child must be the court's paramount consideration. If imminent danger to the child's life or health exists at the time of the court's consideration, the determination shall not be a prerequisite to the removal of the child.
   b. A statement informing the child's parent that the consequences of a permanent removal may include termination of the parent's rights with respect to the child.

If deemed appropriate by the court, upon being informed that there has been an emergency removal or keeping of a child without a court order, the court may enter an order in accordance with section 232.78.

Removal of a Child by a Peace Officer or a Physician

A child may be taken into custody without a court order pursuant to Iowa Code section 232.79, which indicates that:

1. A peace officer or juvenile court officer may take a child into custody, a physician treating a child may keep the child in custody, or a juvenile court officer may authorize a peace officer, physician, or medical security personnel to take a child into custody, without a court order as required under section 232.78 and without the consent of a parent, guardian, or custodian provided that both of the following apply:
   a. The child is in a circumstance or condition that presents an imminent danger to the child's life or health.
   b. There is not enough time to apply for an order under section 232.78.

2. If a person authorized by this section removes or retains custody of a child, the person shall:

   a. Bring the child immediately to a place designated by the rules of the court for this purpose, unless the person is a physician treating the child and the child is or will presently be admitted to a hospital.

   b. Make every reasonable effort to inform the parent, guardian, or custodian of the whereabouts of the child.

   c. In accordance with court-established procedures, immediately orally inform the court of the emergency removal and the circumstances surrounding the removal.

   d. Within 24-hours of orally informing the court of the emergency removal in accordance with paragraph "c," inform the court in writing of the emergency removal and the circumstances surrounding the removal.

3. Any person, agency, or institution acting in good faith in the removal or keeping of a child pursuant to this section, and any employer of or person under the direction of such a person, agency, or institution, shall have immunity from any civil or criminal liability that might otherwise be incurred or imposed as the result of such removal or keeping.

4. a. When the court is informed that there has been an emergency removal or keeping of a child without a court order, the court shall direct the department of human services or the juvenile probation department to make every reasonable effort to communicate immediately with the child's parent or parents or other person legally responsible for the child's care.

   Upon locating the child's parent or parents or other person legally responsible for the child's care, the department of human services or the juvenile probation department shall, in accordance with court-established procedures, immediately orally inform the court. After orally informing the court, the department of human services or the juvenile probation department shall provide to the court written documentation of the oral information.

   b. The court shall authorize the department of human services or the juvenile probation department to cause a child thus removed or kept to be returned if it concludes there is not an imminent risk to the child's life and health in so doing.

   If the department of human services or the juvenile probation department receives information which could affect the court's decision regarding the child's return, the department of human services or the juvenile probation department, in accordance with court established procedures, shall immediately orally provide the information to the court. After orally providing the information to the court, the department of human services or the juvenile probation department shall provide to the court written documentation of the oral information.

If the child is not returned, the department of human services or the juvenile probation department shall forthwith cause a petition to be filed within three days after the removal.

c. If deemed appropriate by the court, upon being informed that there has been an emergency removal or keeping of a child without a court order, the court may enter an order in accordance with section 232.78.

5. When there has been an emergency removal or keeping of a child without a court order, a physical examination of the child by a licensed medical practitioner shall be performed within 24-hours of such removal, unless the child is returned to the child's home within 24-hours of the removal.

A child without adult supervision may be taken into custody pursuant to Iowa Code section 232.79A, which indicates that:

If a peace officer determines that a child does not have adult supervision because the child's parent, guardian, or other person responsible for the care of the child has been arrested and detained or has been unexpectedly incapacitated, and that no adult who is legally responsible for the care of the child can be located within a reasonable period of time, the peace officer shall attempt to place the child with an adult relative of the child, an adult person who cares for the child, or another adult person who is known to the child. The person with whom the child is placed is authorized to give consent for emergency medical treatment of the child and shall not be held liable for any action arising from giving the consent.

Upon the request of the peace officer, the Department shall assist in making the placement. The placement shall not exceed a period of 24-hours and shall be terminated when a person who is legally responsible for the care of the child is located and takes custody of the child.

If a person who is legally responsible for the care of the child cannot be located within the 24-hour period or a placement in accordance with this section is unavailable, the provisions of section 232.79 shall apply. If the person with whom the child is placed charges a fee for the care of the child, the fee shall be paid from funds provided in the appropriation to the Department for protective child care.

Removal With Parent's Consent

A parent, guardian, or custodian may voluntarily consent to placement of a child in foster care. Voluntary placement must be for less than a 30-day period. Court action will be sought if the child can not be returned home.

A voluntary placement may be appropriate when the need for placement is expected to be short-term, such as during the parent's illness or for crisis intervention. When a parent must be out of the home for a time-limited period, make every effort to help the family find relatives or friends who can assume temporary responsibility for the child as an alternative to foster care placement.

Juvenile Court Hearings

Juvenile court hearings are held when children are removed from their parent's custody or when treatment or DHS supervision of abused or neglected children is necessary because the parents are unwilling or unable to provide such treatment or supervision.

Parents are notified immediately if their child is placed in other care. A petition for a hearing must be filed with the juvenile court within three days of the removal of a child from a parent's care. A juvenile court hearing is held promptly in order to review the need for continued protection of the child through shelter care. Parents are provided the opportunity at the shelter care hearing to present evidence that their child can be returned home without danger of injury or harm.

The court ensures that the parent's and the children's rights will be protected. An attorney will be appointed to represent the child's best interest in these cases. The attorney representing the child is called the guardian ad litem. The court may also appoint a court-appointed special advocate (CASA) to assist in informing the court regarding child's progress and recommendations.

The parents have a right to legal counsel. If they cannot afford an attorney, the court will appoint one.

Additional hearings are held if the court determines that the child needs its protection. At each hearing, the court reviews the efforts of the parents to remedy problems and the services arranged for or provided by DHS to help the parents and children.

Child in Need of Assistance

A child in need of assistance is defined in Iowa Code section 232.2, subsection 6, as: an unmarried child:

a. Whose parent, guardian or other custodian has abandoned or deserted the child.

b. Whose parent, guardian, other custodian, or other member of the household in which the child resides has physically abused or neglected the child, or is imminently likely to abuse or neglect the child.

c. Who has suffered or is imminently likely to suffer harmful effects as a result of either of the following:

   (1) Mental injury caused by the acts of the child's parent, guardian, or custodian.

   (2) The failure of the child's parent, guardian, custodian, or other member of the household in which the child resides to exercise a reasonable degree of care in supervising the child.

   (3) The child's parent, guardian, or custodian, or the person responsible for the care of the child, as defined in section 232.68, has knowingly disseminated or exhibited obscene material to the child as defined in section 728.1.

d. Who has been, or is imminently likely to be, sexually abused by the child's parent, guardian, custodian, or other member of the household in which the child resides.

e. Who is in need of medical treatment to cure, alleviate, or prevent serious injury or illness and whose parent, guardian or custodian is unwilling or unable to provide such treatment.

f. Who is in need of treatment to cure or alleviate serious mental illness or disorder, or emotional damage as evidenced by severe anxiety, depression, withdrawal, or untoward aggressive behavior toward self or others and whose parent, guardian, or custodian is unwilling to provide such treatment.

g. Whose parent, guardian, or custodian fails to exercise a minimal degree of care in supplying the child with adequate food, clothing, or shelter and refuses other means made available to provide such essentials.

h. Who has committed a delinquent act as a result of pressure, guidance, or approval from a parent, guardian, custodian, or other member of the household in which the child resides.

i. Who has been the subject of or a party to sexual activities for hire or who poses for live display or for photographic or other means of pictorial reproduction or display which is designated to appeal to the prurient interest and is patently offensive; and taken as a whole, lacks serious literary, scientific, political, or artistic value.

j. Who is without a parent, guardian, or other custodian.

k. Whose parent, guardian, or other custodian, for good cause desires to be relieved of the child's care and custody.

l. Who for good cause desires to have the child's parents relieved of the child's care and custody.

m. Who is in need of treatment to cure or alleviate chemical dependency and whose parent, guardian, or custodian is unwilling or unable to provide such treatment.

n. Whose parent's or guardian's mental capacity or condition, imprisonment, or drug or alcohol abuse results in the child not receiving adequate care.

o. In whose body there is an illegal drug present as a direct and foreseeable consequence of the acts or omissions of the child's parent, guardian, or custodian. The presence of the drug shall be determined in accordance with a medically relevant test as defined in section 232.73.

p. Whose parent, guardian, or custodian does any of the following: Unlawfully manufactures a dangerous substance in the presence of a child. Knowingly allows such manufacture by another person in the presence of a child, or in the presence of a child possesses a product containing ephedrine, its salts, optical isomers, salts of optical isomers, or pseudoephedrine, its salts, optical isomers, salts of optical isomers, with the intent to use the product as a precursor or an intermediary to a dangerous substance.

(1) For the purposes of this paragraph "p," "in the presence of a child" means the physical presence of a child during the manufacture or possession, the manufacture or possession occurred in a child's home, on the premises, or in a motor vehicle located on the premises, or the manufacture or possession occurred under other circumstances in which a reasonably prudent person would know that the manufacture or possession may be seen, smelled, or heard by a child.

(2) For the purpose of this paragraph "p," "dangerous substance" means any of the following:

(a) Amphetamine, its salts, isomers, or salts of its isomers.
(b) Methamphetamine, its salts, isomers, or salts of its isomers.
(c) A chemical or combination of chemicals that poses a reasonable risk of causing an explosion, fire, or other danger to the life or health of persons who are in the vicinity while the chemical or combination of chemicals is used or is intended to be used in any of the following:

(i) The process of manufacturing an illegal or controlled substance.
(ii) As a precursor in the manufacturing of an illegal or controlled substance.
(iii) As an intermediary in the manufacturing of an illegal or controlled substance.

q. Who is a newborn infant whose parent has voluntarily released custody of the child in accordance with Chapter 233.

How Is Child Abuse Information Treated?

Iowa Code section 235A.15 provides that confidentiality of child abuse information shall be maintained, except as specifically authorized.

Under Iowa law, "child abuse information" includes any or all of the following data maintained by DHS in a manual or automated data storage system and individually identified:

- Report data, including information pertaining to an assessment of an allegation of child abuse in which DHS has determined the alleged abuse meets the definition of child abuse.
- Assessment data, including information pertaining to the DHS evaluation of a family.
- Disposition data, including information pertaining to an opinion or decision as the occurrence of child abuse.

Note: Iowa Code section 232.71B, subsection 2, directs that DHS shall not reveal the identity of the reporter of child abuse in the written notification to parents or otherwise.

The Department shall withhold the name of the person who made the report of suspected child abuse. Only the court may allow the release of that person's name.

Protective Disclosure

Iowa Code allows for DHS to disclose that an individual is listed on the child abuse registry, the dependent adult abuse registry or is required to register for the sexual offender registry when it is necessary for the protection of a child. The disclosure can only be made to persons who are subjects of a child abuse assessment.

Disposition of Reports

Iowa law limits access to child abuse information to specific individuals and entities depending on placement of the Child Abuse Registry. All subjects of the report and their attorneys have access to:

- Information contained within the Child Protective Services Assessment Summary.
- Correspondence or written information that pertains to *Child Protective Services Assessment Summary*.

A copy of the entire *Child Protective Services Assessment Summary* is automatically provided to subjects, including but not limited to the custodial and noncustodial parents.

If a person with access to the *Child Protective Services Assessment Summary* as a result of the current assessment does not have access to all information listed from previous summaries, the inaccessible information is deleted before providing the summary to that person.

Note: The safety assessment, safety plan, and family risk assessment are considered assessment data, and its dissemination by law is more restrictive.

A person who is the subject of a child abuse report may also receive a copy of the *Child Protective Services Assessment Summary* for that report by submitting a request to the Department. Subjects may use either the *Request for Child Abuse Information* or the *Notice of Child Abuse Assessment* to make this request.

Mandatory reporters may request a founded report using either form. They will receive a *Notice of Child Abuse Assessment* when the assessment report is completed as the reporter of the abuse. Mandatory reporters may also request founded reports when they are providing care or treatment to a child victim, their families or the person responsible for the abuse.

All other requesters must use the *Request for Child Abuse Information* to request a copy of the assessment report.

Requests for Correction and Appeals

A subject (child, parent, guardian or legal custodian, alleged perpetrator) who feels there is incorrect or erroneous information contained in the *Child Protective Services Assessment Summary*, or who disagrees with its conclusions, may request a correction of the report.

The subject must submit a written request within six months of the completion of the *Child Protective* must submit a written request within six months of the completion of the *Child Protective Assessment Summary*. Requests must be sent to:

Appeals Section
1305 E Walnut St, 5th Floor
Des Moines, Iowa 50319-0114

An administrative hearing and or a prehearing is then scheduled. At the evidentiary hearing, the matter will be heard before an administrative law judge. The administrative law judge may also uphold, modify, or overturn the finding.

A requester who is not satisfied with the decision of the administrative law judge may appeal the matter the district court.

Access to Child Abuse Information

Another function of the Child Abuse Registry is approval of the dissemination of child abuse information to persons authorized to receive this information. Iowa Code section 235A.17 indicates that an authorized recipient of child abuse information shall not redisseminate the information to anyone else.

Access to child abuse information is authorized for:

- Subjects of a report (child, parent, guardian or legal custodian, alleged perpetrator)
- The attorney for any subject
- An employee or agent of DHS who is responsible for assessment of the report of child abuse
- Other DHS personnel when necessary for the performance of their official duties and functions
- The mandatory reporter who reported the abuse
- The county attorney
- The juvenile court

Access to child abuse information is also authorized to persons involved in an assessment of child abuse (such as a health practitioner or mental health professional, a law enforcement officer, or a multidisciplinary team).

Access to certain child abuse information is authorized to individuals, agencies, or facilities providing care to a child named in a report that includes:

- A facility licensing authority
- A person or agency responsible for the care of a child victim or perpetrator
- An administrator of a psychiatric medical institution
- An administrator of a child foster care facility
- An administrator of a registered or licensed child care facility
- The superintendent of the Iowa Braille and Sightsaving School
- The superintendent of the School for the Deaf
- An administrator of a community mental health center
- An administrator of an agency providing services under a county management plan
- An administrator of a facility or program operated by the state, city or county providing direct care to children for applicant and employee record checks

- An administrator of an agency providing Medicaid home- and community-based waiver services for applicant and employee record checks
- An administrator of a child care resource and referral agency under contract with DHS
- An administrator of a hospital for applicant and employee record checks

Access to child abuse information is also authorized under some circumstances related to judicial and administrative proceedings, such as:

- The juvenile court
- A juvenile court officer
- A Court appointed special advocate
- An expert witness at any stage of an appeal hearing
- A district court
- A probation or parole officer
- An adult correctional officer
- Each board of examiners and licensing board
- A court or agency hearing an appeal for correction of child abuse information
- The Department of Justice for review by the prosecutor's review committee or the commitment of sexually violent predators

Access to certain child abuse information is also authorized to others under certain circumstances, including:

- A person conducting bona fide child abuse research
- DHS personnel for official duties
- A DHS employee for record checks of state operated institutions employees
- A DHS registration or licensing employee
- A DHS adoption worker
- The attorney for DHS
- A certified adoption investigator
- A certified adoption worker
- A child protection agency from another state for investigative, treatment or adoptive or foster care placement services
- Foster care review boards, or to conduct a record check evaluation

- The Board of Educational Examiners
- A legally authorized protection and advocacy agency
- The Iowa Board for the Treatment of Sexual Offenders
- A licensed child placing agency for adoptive placement
- The superintendent or designee of school district, or authorities for a nonpublic school, for employee and volunteer record checks
- Department of Inspections and Appeals for applicants for employment

Civil and Criminal Liability Regarding Child Abuse Information

According to Iowa Code section 235A.20, any aggrieved person may institute a civil action for damages under Iowa Code Chapter 669 or 670 or to restrain the dissemination of child abuse information in violation of Iowa Code Chapter 232.

Any recipient proven to have disseminated child abuse information or to have requested and received such information in violation of Chapter 232, shall be liable for actual damages and exemplary damages for each violation. The recipient shall also be liable for court costs, expenses, and reasonable attorney's fees incurred by the party bringing the action.

The same penalties apply to any employee of the Department who knowingly destroys investigation or assessment data, except in accordance with rules established for retention of child abuse information under Iowa Code section 235A.18.

Also, according to Iowa Code section 235A.21, the following people are guilty of a serious misdemeanor under the Iowa criminal code:

- Any person who willfully requests, obtains, or seeks to obtain child abuse information under false pretenses.
- Any person who willfully communicates or seeks to communicate child abuse information to any agency or person except in accordance with Iowa Code sections 235A.15 and 235A.17.
- Any person connected with any research authorized pursuant to Iowa Code section 235A.15 who willfully falsifies child abuse information or any records relating to child abuse information.

Any person who knowingly, but without criminal purpose, communicates, or seeks to communicate child abuse information except in accordance with sections 235A.15 and 235A.17 shall be guilty of a simple misdemeanor.

What Training Do Mandatory Reporters Need?

Mandatory reporters are required by law to complete two hours of training during their first six months of employment and two hours every five years thereafter.

The 2001 Iowa General Assembly established the requirement for the creation of a panel for the "review and approval" of mandatory reporter training curricula. The Director of the Department of Public Health convened a panel to satisfy the mandate of the legislation.

People who work in position classifications that under law make the person a mandatory reporter of child or dependent adult abuse but do not have a mandatory reporter training curriculum approved by a licensing or examining board must acquire training approved by the panel. The website for information is (http://www.idph.state.ia.us/dir_off/abuseeducation/default.htm).

Mandatory report training curricula must be approved by the Abuse Education Review Panel to satisfy the Iowa Code mandated training requirement. Licensed professionals are required to complete training that is required and approved by their respective licensing and examining boards or approved by the Abuse Education Review Panel.

Iowa Code subsection 232.69(3) states that:

a. For the purposes of this section, "licensing board" means an examining board designated in [Iowa Code] section 147.13, the Board of Educational Examiners created in [Iowa Code] section 272.2, or a licensing board as defined in [Iowa Code] section 272C.1.

b. A person required to make a report under subsection 1, other than a physician whose professional practice does not regularly involve providing primary health care to children, shall complete two hours of training relating to the identification and reporting of child abuse within six months of initial employment or self-employment involving the examinations, attending, counseling, or treatment of children, on a regular basis.

   Within one month of initial employment or self-employment, the person shall obtain a statement of the abuse reporting requirements from the person's employer or, if self-employed, from the department. The person shall complete at least two hours of additional child abuse identification and reporting training every five years.

c. If the person is an employee of a hospital or similar institution, or of a public or private institution, agency, or facility, the employer shall be responsible for obtaining the child abuse identification and reporting training.

   If the person is self-employed, employed in a licensed or certified profession, or employed by a facility or program that is subject to licensure, regulation, or approval by a state agency, the person shall obtain the child abuse identification and reporting training as provided in paragraph "d."

d. The person may complete the initial or additional training requirements as part of any of the following that are applicable to the person:

(1) A continuing education program required under [Iowa Code] Chapter 272C and approved by the appropriate licensing or examining board.

(2) A training program using a curriculum approved by the abuse education review panel established by the Director of Public Health pursuant to [Iowa Code] section 135.11.

(3) A training program using such an approved curriculum offered by the Department of Human Services, the Department of Education, an area education agency, a school district, the Iowa Law Enforcement Academy, or a similar public agency.

e. A licensing board with authority over the license of a person required to make a report shall require as a condition of licensure that the person is in compliance with the requirements for abuse training under this subsection. The licensing board shall require the person upon licensure renewal to accurately document for the licensing board the person's completion of the training requirements.

However, the licensing board may adopt rules providing for waiver or suspension of the compliance requirements, if the waiver or suspension is in the public interest, applicable to a person who is engaged in active duty in the military service of this state or of the United States, to a person for whom compliance with the training requirements would impose a significant hardship, or to a person who is practicing a licensed profession outside this state or is otherwise subject to circumstances that would preclude the person from encountering child abuse in this state.

f. For persons required to make a report who are not engaged in a licensed profession that is subject to the authority of a licensing board but are employed by a facility or program subject to licensure, registration, or approval by a state agency, the agency shall require as a condition of renewal of the facility's or program's licensure, registration, or approval, that such persons employed by the facility or program are in compliance with the training requirements of this section.

g. For peace officers, the elected or appointed official designated as the head of the agency employing the peace office shall ensure compliance with the training requirements of this section.

h. For persons who are employees of state departments and political subdivisions of the state, the department director or the chief administrator of the political subdivision shall ensure the persons' compliance with the training requirements of this section.

Review Questions

You have been provided with all of the information necessary to carry out all duties and responsibilities required of a mandatory reporter of child abuse. The following review questions are provided to emphasize key points in this Guide.

Q) *In what year was the child abuse reporting law initially enacted?*

A) 1978

Q) *What is the purpose of the child abuse reporting law?*

A) The child abuse reporting law is to provide protection to children by encouraging the reporting of suspected abuse.

Q) *Which state agency is responsible for providing protective services to children?*

A) The Department of Human Services.

Q) *Who are mandatory reporters of child abuse?*

A) Professionals who have frequent contact with children in the course of their work are considered to be mandatory reporters.

Q) *What fields are mandatory reporters typically employed in?*

A) Health, law enforcement, child care, education, mental health, and social work.

Q) *What training is required for mandatory reporters of child abuse?*

A) All mandatory reporters are required to complete two hours of approved training relating to the identification and reporting of child abuse within six months of initial employment or self-employment. All mandatory reporters are also required to complete at least two hours of additional child abuse identification and reporting training every five years.

Q) *What is the definition of child by Iowa law?*

A) Any person under the age of 18 years.

Q) *Who are typical perpetrators of child abuse?*

A) Perpetrators of child abuse come from all walks of life, races, religions, and nationalities.

Q) *When does DHS have the legal authority to conduct assessments of child abuse?*

A) When the victim is a child, the alleged victim is subjected to one or more of the eight categories of child abuse, and the abuse is the result of the acts or omissions of the person responsible for the care of the child.

Q) *Who are people "responsible for the care of a child"?*

A)
- A parent, guardian, or foster parent.
- A relative or any other person with whom the child resides, and who assumes care or supervision of the child, without reference to the length of time or continuity of such residence.

- An employee or agent of any public or private facility providing care for a child, including an institution, hospital, health care facility, group home, mental health center, residential treatment center, shelter care facility, detention center, or child care facility.
- Any person providing care for a child, but with whom the child does not reside, without reference to the duration of the care.

A person who assumes responsibility for the care or supervision of a child may assume this responsibility through verbal or written agreement, or implicitly through the willing assumption of the caretaking role.

Q) *When is an educator considered a caretaker for a child?*

A) A teacher could be assessed as a person responsible for child abuse if the teacher is acting in a caretaking role, for example having supervision responsibilities for a child on an overnight trip.

Q) *Can children be in a caretaker role?*

A) Yes, a child can be a person responsible for abuse when the child is acting in a caretaker role for another child, such as a baby-sitting situation.

Q) *What are the ten categories of child abuse?*

A)
1. Physical abuse
2. Sexual abuse
3. Child prostitution
4. Mental injury
5. Denial of critical care
6. Presence of illegal drugs
7. Manufacturing or possession of a dangerous substance
8. Bestiality in the presence of a minor
9. Allows access by a registered sex offender
10. Allows access to obscene material

Q) *What is the definition of physical abuse?*

A) Any non-accidental physical injury, or injury which is at variance with the history given of it, suffered by a child as the result of the acts or omissions of a person responsible for the care of the child.

Q) *What is the definition of mental injury?*

A) Any mental injury to a child's intellectual or psychological capacity, as evidenced by an observable and substantial impairment in the child's ability to function within the child's normal range of performance and behavior, as the result of the acts or omissions of a person responsible for the care of the child, if the impairment is diagnosed and confirmed by a licensed physician or qualified mental health professional.

Q) *What are some examples of mental injury?*

A)
- Ignoring the child and failing to provide necessary stimulation, responsiveness, and validation of the child's worth in normal family routine.
- Rejecting the child's value, needs, and requests for adult validation and nurturance.
- Isolating the child from the family and community; denying the child normal human contact.

- Terrorizing the child with continual verbal assaults, creating a climate of fear, hostility, and anxiety and preventing the child from gaining feelings of safety and security.
- Corrupting the child by encouraging and reinforcing destructive, antisocial behavior until the child is so impaired in socioemotional development that interaction in normal social environments is not possible.
- Verbally assaulting the child with constant, excessive name-calling, harsh threats, and sarcastic put-downs that continually "beat down" the child's self-esteem with humiliation.
- Overpressuring the child with subtle but consistent pressure to grow up fast and to achieve too early in the areas of academics, physical/motor skills, and social interaction, which leaves the child feeling that he or she is never quite good enough.

Q) *What is the definition of sexual abuse?*

A) The commission of a sexual offense with or to a child as a result of the acts or omissions of the person responsible for the care of the child. The commission of a sexual offense includes any sexual offense with or to a person under the age of 18 years.

Q) *What is the definition of denial of critical care?*

A) The failure on the part of a person responsible for the care of a child to provide for the adequate food, shelter, clothing, medical or mental health treatment, supervision, or other care necessary for the child's health and welfare when financially able to do so or when offered financial or other reasonable means to do so.

Q) *What are the eight subcategories of denial of critical care?*

A)
1. Failure to provide adequate food and nutrition.
2. Failure to provide adequate shelter.
3. Failure to provide adequate clothing.
4. Failure to provide adequate health care.
5. Failure to provide mental health care.
6. Gross failure to meet emotional needs.
7. Failure to provide proper supervision.
8. Failure to respond to an infant's life-threatening condition.

Q) *What questions are helpful in determining if a child should be left home alone*?

A)
- Does the child have any physical, mental, or emotional disabilities?
- Could the child get out of the house alone in an emergency and have a safe place to go?
- Does the child have a phone and know how to use it?
- Does the child know how to reach the child's caretaker?
- How long will the child be left home alone?
- Is the child afraid to be left home alone?
- Does the child know how to respond to an emergency such as fire or injury?

Q) *What is the definition of child prostitution?*

A) Child prostitution is the acts or omissions of a person responsible for the care of a child which allow, permit, or encourage the child to engage in acts of prostitution when the child is under the age of 18 years.

Q) *What is the definition of presence of illegal drugs?*

A) Presence of illegal drugs is when an illegal drug is present in a child's body as a direct and foreseeable consequence of the acts or omissions of the person responsible for the child's care.

Q) *What is the definition of manufacturing or possession of a dangerous substance?*

A) The person responsible for the care of a child manufactured a dangerous substance or, in the presence of the child, possesses a product containing ephedrine, its salts, optical isomers, salts of optical isomers, or pseudoephedrine, its salts, optical isomers, salts of optical isomers with the intent to use the product as a precursor or an intermediary to a dangerous substance.

Q) *What are the time frames a mandatory reporter must follow when making a report of child abuse?*

A) If you suspect a child has been abused, you need to report it orally to DHS within 24 hours of becoming aware of the situation. Within 48 hours after that, you need to make a written report to DHS.

Q) *What should you do if you see a child that is in imminent danger?*

A) Immediately contact law enforcement, then contact DHS.

Q) *What information should be in any oral or written reports of child abuse?*

A)
- The names and home address of the child and the child's parents or other persons believed to be responsible for the child's care.
- The child's present whereabouts.
- The child's age.
- The nature and extent of the child's injuries including any evidence of previous injuries.
- The name, age, and condition of other children in the same household.
- Any other information that you believe may be helpful in establishing the cause of the abuse or neglect to the child.
- The identity of the person or persons responsible for the abuse or neglect to the child.
- Your name and address.

Q) *How should a mandatory reporter deal with confidentiality issues?*

A) Rules around confidentiality and privileged communication are waived during the assessment process.

Q) *Are mandatory reporters liable for any damages occurring because of a report of child abuse?*

A) No, Iowa law states that any person participating in good faith in making a report of child abuse shall have immunity from any civil or criminal liability which might otherwise be incurred or imposed. The person shall have the same immunity with respect to participation in good faith in any judicial proceeding resulting from the report or relating to the subject matter of the report.

Q) *What happens if a mandatory reporter fails to make a report of child abuse?*

A) Under Iowa law there are civil and criminal sanctions for failing to report child abuse. Any person, official, agency or institution, who knowingly and willfully fails to make a report of child abuse or who knowingly interferes with the making of such a report is guilty of a simple misdemeanor and is civilly liable for the damages proximately caused by such failure or interference.

Q) *What happens if someone knowingly makes a false report of child abuse?*

A) A person who reports or causes to be reported to DHS false information regarding an alleged act of child abuse, knowing that the information is false or that the act did not occur, commits a simple misdemeanor.

If DHS receives more than three reports from the same person or which identify the same child as a victim of child abuse or the same person as the alleged abuser, and DHS determines the reports to be entirely false or without merit, DHS shall provide information concerning the reports to the county attorney for consideration of criminal charges.

Q) *What is involved in a child abuse assessment?*

A) A child abuse assessment consists of:

- Intake
- Case assignment
- Evaluation of the alleged abuse
- Determination of whether abuse occurred
- Decision on placing a report on the Child Abuse Registry
- Assessment of family's strengths and needs
- Preparation of reports and forms

Q) *When are head lice or truancy appropriate for a child abuse assessment?*

A) The endangerment caused by head lice or truancy does not generally rise to the level that must be present in order to constitute a child abuse allegation. If other conditions are present or the situation poses a risk to the child's health and welfare, it should be reported as child abuse. Even if the report is rejected for assessment, other services may be offered to the child and family.

Q) *What is the mandatory reporter's role in the observation of a child during the assessment process?*

A) When the observation of a child needs to take place at the school or in a child care facility, the administrator of the facility or school is required by law to provide the child protection worker with confidential access to the child.

Q) *Who will know the name of the person making a report of child abuse?*

A) DHS will safeguard the reporter's identity during the assessment process. However, the reporter should be aware that continued confidentiality cannot be guaranteed if the report results in juvenile, civil, or criminal court action.

Q) *Who will be interviewed during a child abuse assessment?*

A) Interviews whenever possible will be conducted with:

- The alleged child victim
- The parents and other adults in the household
- The alleged perpetrator
- Collateral sources, witnesses, or other parties with information

Q) *What types of information may be gathered during a child abuse assessment?*

A) Documentation gathered may include, but is not limited to, descriptions, photographs, medical reports and records, reports from child protection centers, and any other pertinent reports, such as mental health center evaluations, treatment records, criminal records, law enforcement reports, and audio and video tapes.

Q) *What are child protection centers?*

A) There are several child protection centers throughout the state. These centers assist child protection workers in assessing some reports of child abuse. In most cases, these centers provide medical evaluation and psychosocial assessments of the victim when there are allegations of sexual abuse.

Q) *What is the role of multidisciplinary teams?*

A) Multidisciplinary teams, exist in counties that have more than 50 reports of child abuse annually. These teams function as an advisory and consultation group to aid child protection workers in resolving issues related to a case during the assessment process.

Q) *What are the conclusions of an assessment based on?*

A) The conclusions of an assessment are based on an evaluation of all of the information gathered during the assessment, including physical evidence, documentary evidence, observations, and interviews of the victim, perpetrator and others.

Q) *What are the conclusions a child protective worker may reach at the completion of an assessment?*

A) At the completion of the assessment, the worker must make one of the following conclusions: Abuse is not confirmed, abuse is confirmed (but not placed on the Child Abuse Registry), or abuse is founded (confirmed and placed on the Child Abuse Registry).

Q) *What do the conclusions mean?*

A) Not confirmed means that, based on the credible evidence gathered, the Department determined that there was not a preponderance of evidence that abuse did occur.

Confirmed (but not placed on the Child Abuse Registry) means that, based on a preponderance of all of the credible evidence available to the Department, the allegation of abuse is confirmed; however, the abuse will not be placed on the Child Abuse Registry.

Founded (confirmed and placed on the Child Abuse Registry) means that, based on a preponderance of all of the credible evidence available to the Department, the allegation of abuse is confirmed and it is placed on the Child Abuse Registry.

Q) *What types of abuse are confirmed but not placed on the Child Abuse Registry?*

A) This applies only to two types of abuse, a physical abuse where the injury was nonaccidental and minor, isolated, and unlikely to reoccur and denial of critical care (lack of proper supervision or lack of adequate clothing) where the risk to the child's health and welfare was minor, isolated and is unlikely to reoccur.

If the abuse was minor, isolated, and unlikely to reoccur the abuse may not be placed on the Registry.

Q) *What types of abuse are founded and placed on the Child Abuse Registry?*

A) Most confirmed reports are placed on the registry as founded reports. This includes:

- All cases referred for juvenile or criminal court action
- Physical abuse when the injury was not minor or isolated or is likely to reoccur
- All mental injury
- All sexual abuse unless the perpetrator is under the age of 14 and does not pose a danger to other children
- Denial of critical care when the injury was not minor, or isolated or is likely to reoccur
- All child prostitution
- All presence of illegal drugs
- When the perpetrator continues to pose a threat; or a prior confirmed abuse incident occurred
- Manufacturing or possession of a dangerous substance
- Bestiality in the presence of a minor
- Allows access by a registered sex offender
- Allows access to obscene material

Q)*What does a "preponderance" of the evidence mean?*

A) A preponderance of the evidence is defined as greater than 50% of the evidence gathered.

Q) What notifications can the mandatory reporter expect to receive from DHS?

A) Oral notification of intake decision within 24 hours of making the report, written notification of intake decision sent within 5 working days, outcome notification of assessment sent within 20 working days, and a copy of the founded abuse report if requested.

Q) *When do parents receive notification that a child abuse assessment is being conducted?*

A) Written notification will be given to custodial and noncustodial parents within five working days that an assessment is being conducted.

Q) *Who receives notification that the assessment is completed and what the outcome is?*

A) Notification of the completion of the assessment and the outcome will be given to juvenile court, the county attorney, all subjects of the report (the alleged child victim, custodial and non-custodial parents, and the alleged perpetrator), and the mandatory reporter.

Q) *Do mandatory reporters receive a copy of the assessment report automatically?*

A) No, the report is automatically provided to juvenile court, the county attorney, the child, and the custodial and non-custodial parent.

Q) *How do mandatory reporters receive a copy of the assessment report?*

A) Mandatory reporters may request child abuse information regarding a specific report. Any request should be made using the *Request for Child Abuse Information* form provided by DHS or the *Notice of Child Abuse Assessment* that is sent to the mandatory reporter when the assessment is completed.

Q) *What is the Child Abuse Registry?*

A) The Child Abuse Registry was established by Iowa law and is maintained by the Department of Human Services. The Child Abuse Registry serves several functions. It gathers information about child abuse cases in Iowa, records repeat occurrences of child abuse, records dissemination of child abuse, collects information for appeals, and provides background checks for certain professionals.

Q) *How long are the subjects of a founded abuse report on the Registry?*

A) Subjects of a founded abuse reports are placed on the Registry for ten years from the most recent report.

Q) *Who has access to child abuse information?*

A) Iowa law states that the DHS shall not reveal the identity of the reporter of child abuse in the written notification to parents or otherwise. Only the court may require DHS to release the reporter's name. The reporter's name could be released during other judicial actions. The information on the Child Abuse Registry is confidential and can be accessed by authorized entities , agencies or individuals specified in law.

Q) *Who can take protective custody of a child?*

A) Iowa law provides juvenile court with the ability to enter an "ex parte order" directing a peace officer to take custody of a child. When the child is in a circumstance or condition that presents an imminent danger to the child's life or health, and there isn't time to file for a court order, the law provides for a peace officer to take a child into custody or a physician treating a child to keep the child in custody without the consent of the parent, guardian, or custodian.

Q) *When does juvenile court become involved?*

A) Juvenile court hearings are held when children are removed from their parents' custody, or when treatment or state supervision of abused or neglected children is necessary because the parents are unwilling or unable to provide such treatment or supervision.

Q) *When are people responsible for abuse criminally prosecuted?*

A) Criminal prosecution of a person responsible for child abuse is at the discretion of the county attorney.

Q) *When does law enforcement become involved in a child abuse assessment?*

A) Law enforcement may become involved in a child abuse assessment at any time. Cases of child prostitution, homicide, sexual abuse, and severe trauma require a joint assessment by law enforcement personnel and the DHS.

Safe Haven for Newborns

What is the Safe Haven Act?

Iowa has joined 30 other states in creating safe havens for infants. The Newborn Safe Haven Act (Iowa Code Chapter 233) is a law that allows parents (or another person who has the parent's authorization) to leave an infant up to 14 days old at a hospital or health care facility without fear of prosecution for abandonment.

What Is a Safe Haven?

A "safe haven" is an institutional health facility, which is defined according to the Act to be:

- A "hospital" as defined in Iowa Code section 135B.1, including a facility providing medical or health services that is open 24 hours per day, 7 days per week and is a hospital emergency room; or
- A "health care facility" as defined in Iowa Code section 135C.1, including a residential care facility, a nursing facility, an intermediate care facility for persons with mental illness, or an intermediate care facility for persons with mental retardation.

Immunity

The Act provides immunity from prosecution for abandonment for a parent (or a person acting with the parent's authorization) who leaves an infant at a hospital or health care facility.

The Act provides immunity from civil or criminal liability for hospitals, health care facilities, and persons employed by those facilities that perform reasonable acts necessary to protect the physical health and safety of the infant.

More Information

You can get more information by:

- Going to the Department's web site at: http://www.dhs.iowa.gov/Consumers/Safety_and_Protection/Safe_Haven.html
- Reading the Safe Haven Act, Iowa Code Chapter 233. The Code of Iowa is available at public libraries or on line at: http://www.legis.state.ia.us/IowaLaw.html

NEWBORN INFANT CUSTODY RELEASE PROCEDURES (NEWBORN SAFE HAVEN ACT)

233.1 Newborn **safe haven** Act - definitions.
233.2 Newborn infant custody release procedures.
233.3 Immunity.
233.4 Rights of parents.
233.6 Education and public information.

Iowa Department of Human Services

REPORT OF SUSPECTED CHILD ABUSE

This form may be used as the written report which the law requires all mandated reporters to file with the Department of Human Services following an oral report of suspected child abuse. If your agency has a report form or letter format which includes all of the information requested on this form, you may use the agency format in place of this form.

Fill in as much information under each category as is known. Submit the completed form within 48 hours of making the oral report to the Centralized Intake Unit, PO Box 4826, Des Moines, Iowa 50305.

FAMILY INFORMATION

Name of child	Age	Date of birth
Address	City	State
Phone	School	Grade level
Name of parent or guardian	Phone *(if different from child's)*	
Address *(if different from child's)*		

OTHER CHILDREN IN THE HOME

NAME	BIRTH DATE	CONDITION

INFORMATION ABOUT SUSPECTED ABUSE

In this section, indicate the date of suspected abuse; the nature, extent and cause of the suspected abuse; the persons thought to be responsible for the suspected abuse; evidence of previous abuse; and other pertinent information needed to conduct the assessment. Use the back of this form if necessary to complete the information requested above and to identify individuals who have been informed of the child abuse report, such as building administrator, supervisor, etc.

REPORTER INFORMATION

Name and title or position	
Office address	
Phone	Relationship to child
Names of other mandatory reporters who have knowledge of the abuse	
Signature of reporter	Date

728.12 Sexual exploitation of a minor.

1. It shall be unlawful to employ, use, persuade, induce, entice, coerce, solicit, knowingly permit, or otherwise cause or attempt to cause a minor to engage in a prohibited sexual act or in the simulation of a prohibited sexual act. A person must know, or have reason to know, or intend that the act or simulated act may be photographed, filmed, or otherwise preserved in a negative, slide, book, magazine, computer, computer disk, or other print or visual medium, or be preserved in an electronic, magnetic, or optical storage system, or in any other type of storage system. A person who commits a violation of this subsection commits a class "C" felony. Notwithstanding section 902.9, the court may assess a fine of not more than fifty thousand dollars for each offense under this subsection in addition to imposing any other authorized sentence.

2. It shall be unlawful to knowingly promote any material visually depicting a live performance of a minor engaging in a prohibited sexual act or in the simulation of a prohibited sexual act. A person who commits a violation of this subsection commits a class "D" felony. Notwithstanding section 902.9, the court may assess a fine of not more than twenty-five thousand dollars for each offense under this subsection in addition to imposing any other authorized sentence.

3. It shall be unlawful to knowingly purchase or possess a negative, slide, book, magazine, computer, computer disk, or other print or visual medium, or an electronic, magnetic, or optical storage system, or any other type of storage system which depicts a minor engaging in a prohibited sexual act or the simulation of a prohibited sexual act. A person who commits a violation of this subsection commits an aggravated misdemeanor for a first offense and a class "D" felony for a second or subsequent offense. For purposes of this subsection, an offense is considered a second or subsequent offense if, prior to the person's having been convicted under this subsection, any of the following apply:

a. The person has a prior conviction or deferred judgment under this subsection.

b. The person has a prior conviction, deferred judgment, or the equivalent of a deferred judgment in another jurisdiction for an offense substantially similar to the offense defined in this subsection. The court shall judicially notice the statutes of other states that define offenses substantially similar to the offense defined in this subsection and that therefore can be considered corresponding statutes.

4. This section does not apply to law enforcement officers, court personnel, licensed physicians, licensed psychologists, or attorneys in the performance of their official duties.

[C79, 81, §728.12]

83 Acts, ch 167, §4; 86 Acts, ch 1176, §1 – 3; 89 Acts, ch 263, §3; 2001 Acts, ch 17, §4; 2003 Acts, ch 65, §1, 2

THOMAS J. MILLER
ATTORNEY GENERAL

Iowa Department of Justice

ADDRESS REPLY TO:
Licensing & Administrative Law
1305 E. Walnut Street
Des Moines, IA 50319
Telephone: 515/281-5164
Fax: 515/281-4209
www.IowaAttorneyGeneral.org

TO: Iowa Department of Public Health, Division Directors
FROM: Heather L. Adams, Assistant Attorney General HLA
DATE: April 3, 2015
RE: Minor Consent Laws

The following memorandum contains a compilation and summary of Iowa laws which govern the ability of a minor to independently consent to medical care, treatment, and services. This summary may be shared with IDPH programs, staff, and contractors. Please note that if IDPH employees have questions about applying these laws to a specific factual situation they should request that the issue be discussed at our next regularly scheduled AAG/Division meeting, if time allows, or contact me directly if immediate attention is required. If IDPH contractors have questions about the application of the following laws they should contact legal counsel for that agency or organization to receive guidance.

Definition of Minor. Iowa law generally provides that any person under the age of eighteen is a minor. However, persons who are married prior to the age of eighteen and persons who are incarcerated as adults are deemed to have attained the age of majority and may consent to medical care, services, and treatment:

> The period of minority extends to the age of eighteen years, but all minors attain their majority by marriage. A person who is less than eighteen years old, but who is tried, convicted, and sentenced as an adult and committed to the custody of the director of the department of corrections shall be deemed to have attained the age of majority for purposes of making decisions and giving consent to medical care, related services, and treatment during the period of the person's incarceration.

Iowa Code § 599.1. *See also* Iowa Code §§ 135L.1(7), 600A.2(12), 600A.2B(1), 728.1(4).

Iowa statutory and common law also recognize majority for "emancipated" minors, defined for purposes of legal settlement as those minors who are absent from the parental home with the consent of the parents, are self supporting, and have assumed a new relationship inconsistent with being part of the family of the

parents. Iowa Code § 252.16(4); *see also* Iowa Code chapter 232C; Vaupel v. Bellach, 154 N.W.2d 149 (Iowa 1967). A minor will not be found to be emancipated solely on the basis of becoming pregnant or giving birth to a child. Bedford v. Bedford, 752 N.W.2d 34, 2008 WL 681138 (Iowa App. 2008). Minors who have been adjudicated as emancipated do not need parental consent to receive medical, dental, or psychiatric care. Iowa Code § 232C.4.

Consent Generally Required from Parent or Guardian. Under general common law, a health care provider must obtain the consent of a minor's parent or guardian in order to render medical care, treatment or services to a minor. Courts have recognized limited exceptions to the general rule of parental consent. In addition, the Iowa legislature has enacted several statutory provisions which expressly authorize minors to provide independent consent to receive medical care, treatment, and services.

The purpose behind these minor consent statutes is to encourage minors to receive medical care they might not otherwise receive if they had to obtain consent from a parent or guardian. Every state legislature including Iowa's has enacted statutory exceptions to override the common law parental consent rule and give minors the legal authority to consent to some types of medical care for certain diseases, conditions, and situations.

Health Care Services for which Minors may Consent.

A minor may consent to the following health care services without the permission or consent of his or her parents or guardians:

Contraceptive Services

In Iowa minors are expressly authorized to consent to receive contraceptive services. A health care provider is not required to obtain consent from a parent or guardian prior to providing contraceptive services to a minor.

The relevant portion of the text of the law provides as follows:

> A person may apply for…contraceptive services…directly to a licensed physician and surgeon, an osteopathic physician and surgeon, or a family planning clinic. ….The minor shall give written consent to …receive the services[.] Such consent is not subject to later disaffirmance by reason of minority.[1]

[1] This sentence means that a minor's consent may not be later subject to challenge or repudiation by the minor or any other person on the ground that the person was a minor at the time he or she consented to the service.

Iowa Code § 141A.7(3). *See also* Carey v. Population Services, International, 431 U.S. 678 (1977); Title X Family Planning Program.

Emergency Care

Health care providers (including physicians, physician designees, ARNPs, PAs, RNs, LPNs, and emergency medical care providers) are not required to obtain parental consent prior to rendering "emergency medical, surgical, hospital, or health services" to a minor, if the parent or guardian is not "reasonably available." Iowa Code § 147A.10(2).

HIV/AIDS Care

Iowa law authorizes a minor to give consent to receive services, screening, testing, and treatment for HIV/AIDS, and provides that the consent of a parent or guardian is not required to provide these services. However, the law does require that a minor must be informed prior to testing that if the test result is positive the minor's legal guardian shall be informed by the testing facility.

The text of the law provides as follows:

> A person may apply for...screening or treatment for HIV infection and other sexually transmitted diseases directly to a licensed physician and surgeon, an osteopathic physician and surgeon, or a family planning clinic. Notwithstanding any other provision of law, however, a minor shall be informed prior to testing that, upon confirmation according to prevailing medical technology of a positive HIV-related test result, the minor's legal guardian is required to be informed by the testing facility. Testing facilities where minors are tested shall have available a program to assist minors and legal guardians with the notification process which emphasizes the need for family support and assists in making available the resources necessary to accomplish that goal. However, a testing facility which is precluded by federal statute, regulation, or centers for disease control and prevention guidelines from informing the legal guardian is exempt from the notification requirement. The minor shall give written consent to these procedures and to receive the services, screening, or treatment. Such consent is not subject to later disaffirmance by reason of minority.

Iowa Code § 141A.7(3).

Non-medical Services

Certain public health services provided to minors may not require parental consent if the service does not constitute medical care or treatment. For example, providing educational services to minors under the WIC program does not constitute medical care or treatment and therefore does not require consent from a parent or guardian.

Sexually Transmitted Diseases – Prevention, Diagnosis and Treatment

Iowa law authorizes a minor to provide consent for medical services related to the prevention, diagnosis, or treatment of a sexually transmitted disease. Minors are able to provide consent for prevention services, such as the hepatitis B vaccine, and for treatment for STD's, including chlamydia, gonorrhea, hepatitis B and hepatitis C, human papillomavirus (HPV), and syphilis. A health care provider is not required to obtain consent from a parent or guardian prior to providing these services to a minor.

The text of the law provides as follows:

> A minor shall have the legal capacity to act and give consent to provision of medical care or services to the minor for the prevention, diagnosis, or treatment of a sexually transmitted disease or infection by a hospital, clinic, or health care provider. Such medical care or services shall be provided by or under the supervision of a physician licensed to practice medicine and surgery or osteopathic medicine and surgery, a physician assistant, or an advanced registered nurse practitioner. Consent shall not be subject to later disaffirmance by reason of such minority. The consent of another person, including but not limited to the consent of a spouse, parent, custodian, or guardian, shall not be necessary.

Iowa Code § 139A.35.

Substance Abuse Treatment

Iowa law authorizes a minor to consent to substance abuse treatment. A substance abuse facility or a physician or physician's designee providing substance abuse treatment or rehabilitative services is not required to obtain consent from a parent or guardian prior to providing these services to a minor.

The text of the law provides as follows:

> A substance abuser or chronic substance abuser may apply for voluntary treatment or rehabilitation services directly to a facility or to a licensed physician and surgeon or osteopathic physician and surgeon. If the proposed patient is a minor or an incompetent person, a parent, a legal guardian or other legal representative may make the application. The licensed physician and surgeon or osteopathic physician and surgeon or any employee or person acting under the direction or supervision of the physician and surgeon or osteopathic physician and surgeon, or the facility shall not report or disclose the name of the person or the fact that treatment was requested or has been undertaken to any law enforcement officer or law enforcement agency; nor shall such information be admissible as evidence in any court, grand jury, or administrative proceeding unless authorized by the person seeking treatment. If the person seeking such treatment or rehabilitation is a minor who has personally made application for treatment, the fact that the minor sought treatment or rehabilitation or is receiving treatment or rehabilitation services shall not be reported or disclosed to the parents or legal guardian of such minor without the minor's consent, and the minor may give legal consent to receive such treatment and rehabilitation.

Iowa Code § 125.33(1).

Tobacco Cessation Services

Minors twelve years of age or older may consent to receive tobacco cessation services from IDPH's Quitline provider. The text of the law provides as follows:

> A minor who is twelve years of age or older shall have the legal capacity to act and given consent to the provision of tobacco cessation coaching services pursuant to a tobacco cessation telephone and internet-based program approved by the department. Consent shall not be subject to later disaffirmance by reason of such minority. The consent of another person, including but not limited to the consent of a spouse, parent, custodian, or guardian, shall not be necessary.

Iowa Code § 142A.11 (2013).

Victim Medical and Mental Health Services

A minor who is the victim of sexual abuse or assault may receive medical and mental health services without the prior consent or knowledge of the minor's parent or guardian under certain circumstances. The text of the law provides as follows:

> "Victim" means a child under the age of eighteen who has been sexually abused or subjected to any other unlawful sexual conduct under chapter 709 [sexual abuse statute] or 726 [incest and child endangerment statute] or who has been the subject of a forcible felony.
>
> A professional licensed or certified by the state to provide immediate or short-term medical services or mental health services to a victim may provide the services without the prior consent or knowledge of the victim's parents or guardians.
>
> Such a professional shall notify the victim if the professional is required to report an incidence of child abuse involving the victim pursuant to section 232.69.

Iowa Code § 915.35(1), (2) & (3).

<u>Other Health-Care Related Minor Consent Laws</u>

Abortion -- Parental Notification Requirements Regarding Pregnant Minors -- Iowa Code chapter 135L

Anatomical Gifts by Minors – Iowa Code chapter 142C

Donation of Blood by Minors – Iowa Code § 599.6

Inpatient Mental Health Services for Minors -- Iowa Code § 229.2(1)

State Resource Centers – Voluntary Admissions – Minors – Iowa Code § 222.13A

726.2 Incest.

A person, except a child as defined in section 702.5, who performs a sex act with another whom the person knows to be related to the person, either legitimately or illegitimately, as an ancestor, descendant, brother or sister of the whole or half blood, aunt, uncle, niece, or nephew, commits incest. Incest is a class "D" felony.

[R60, §4367 – 4369; C73, §4030; C97, §4936; C24, 27, 31, 35, 39, §**12978;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, §704.1; C79, 81, §726.2]

86 Acts, ch 1105, §1

232.69 Mandatory and permissive reporters — training required.

1. The classes of persons enumerated in this subsection shall make a report within twenty-four hours and as provided in section 232.70, of cases of child abuse. In addition, the classes of persons enumerated in this subsection shall make a report of abuse of a child who is under twelve years of age and may make a report of abuse of a child who is twelve years of age or older, which would be defined as child abuse under section 232.68, subsection 2, paragraph *"c"* or *"e"*, except that the abuse resulted from the acts or omissions of a person other than a person responsible for the care of the child.

a. Every health practitioner who in the scope of professional practice, examines, attends, or treats a child and who reasonably believes the child has been abused. Notwithstanding section 139A.30, this provision applies to a health practitioner who receives information confirming that a child is infected with a sexually transmitted disease.

b. Any of the following persons who, in the scope of professional practice or in their employment responsibilities, examines, attends, counsels, or treats a child and reasonably believes a child has suffered abuse:

(1) A social worker.

(2) An employee or operator of a public or private health care facility as defined in section 135C.1.

(3) A certified psychologist.

(4) A licensed school employee, certified para-educator, holder of a coaching authorization issued under section 272.31, or an instructor employed by a community college.

(5) An employee or operator of a licensed child care center, registered child development home, head start program, family development and self-sufficiency grant program under section 216A.107, or healthy opportunities for parents to experience success – healthy families Iowa program under section 135.106.

(6) An employee or operator of a substance abuse program or facility licensed under chapter 125.

(7) An employee of a department of human services institution listed in section 218.1.

(8) An employee or operator of a juvenile detention or juvenile shelter care facility approved under section 232.142.

(9) An employee or operator of a foster care facility licensed or approved under chapter 237.

(10) An employee or operator of a mental health center.

(11) A peace officer.

(12) A counselor or mental health professional.

(13) An employee or operator of a provider of services to children funded under a federally approved medical assistance home and community-based services waiver.

2. Any other person who believes that a child has been abused may make a report as provided in section 232.70.

3. *a.* For the purposes of this subsection, *"licensing board"* means a board designated in section 147.13, the board of educational examiners created in section 272.2, or a licensing board as defined in section 272C.1.

b. A person required to make a report under subsection 1, other than a physician whose professional practice does not regularly involve providing primary health care to children, shall complete two hours of training relating to the identification and reporting of child abuse within six months of initial employment or self-employment involving the examination, attending, counseling, or treatment of children on a regular basis. Within one month of initial employment or self-employment, the person shall obtain a statement of the abuse reporting requirements from the person's employer or, if self-employed, from the department. The person shall complete at least two hours of additional child abuse identification and reporting training every five years.

c. If the person is an employee of a hospital or similar institution, or of a public or private institution, agency, or facility, the employer shall be responsible for providing the child abuse identification and reporting training. If the person is self-employed, employed in a licensed or certified profession, or employed by a facility or program that is subject to

licensure, regulation, or approval by a state agency, the person shall obtain the child abuse identification and reporting training as provided in paragraph *"d"*.

d. The person may complete the initial or additional training requirements as part of any of the following that are applicable to the person:

(1) A continuing education program required under chapter 272C and approved by the appropriate licensing board.

(2) A training program using a curriculum approved by the abuse education review panel established by the director of public health pursuant to section 135.11.

(3) A training program using such an approved curriculum offered by the department of human services, the department of education, an area education agency, a school district, the Iowa law enforcement academy, or a similar public agency.

e. A licensing board with authority over the license of a person required to make a report under subsection 1 shall require as a condition of licensure that the person is in compliance with the requirements for abuse training under this subsection. The licensing board shall require the person upon licensure renewal to accurately document for the licensing board the person's completion of the training requirements. However, the licensing board may adopt rules providing for waiver or suspension of the compliance requirements, if the waiver or suspension is in the public interest, applicable to a person who is engaged in active duty in the military service of this state or of the United States, to a person for whom compliance with the training requirements would impose a significant hardship, or to a person who is practicing a licensed profession outside this state or is otherwise subject to circumstances that would preclude the person from encountering child abuse in this state.

f. For persons required to make a report under subsection 1 who are not engaged in a licensed profession that is subject to the authority of a licensing board but are employed by a facility or program subject to licensure, registration, or approval by a state agency, the agency shall require as a condition of renewal of the facility's or program's licensure, registration, or approval, that such persons employed by the facility or program are in compliance with the training requirements of this subsection.

g. For peace officers, the elected or appointed official designated as the head of the agency employing the peace officer shall ensure compliance with the training requirements of this subsection.

h. For persons required to make a report under subsection 1 who are employees of state departments and political subdivisions of the state, the department director or the chief administrator of the political subdivision shall ensure the persons' compliance with the training requirements of this subsection.

[C66, 71, 73, 75, 77, §235A.3; C79, 81, §232.69]

83 Acts, ch 96, §157, 159; 84 Acts, ch 1279, §4, 6; 85 Acts, ch 173, §3 – 5; 87 Acts, ch 153, §3; 88 Acts, ch 1238, §1; 89 Acts, ch 89, §17; 89 Acts, ch 230, §5; 89 Acts, ch 265, §40; 94 Acts, ch 1130, §3; 97 Acts, ch 85, §1; 99 Acts, ch 192, §27, 33; 2000 Acts, ch 1066, §42; 2001 Acts, ch 122, §2, 3; 2002 Acts, ch 1047, §2, 20; 2002 Acts, ch 1142, §1, 31; 2005 Acts, ch 121, §2; 2007 Acts, ch 10, §164, 165; 2008 Acts, ch 1072, §3

2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors

L. Stewart Massad, MD, Mark H. Einstein, MD, Warner K. Huh, MD, Hormuzd A. Katki, PhD, Walter K. Kinney, MD, Mark Schiffman, MD, Diane Solomon, MD, Nicolas Wentzensen, MD, and Herschel W. Lawson, MD, for the 2012 ASCCP Consensus Guidelines Conference

From Washington University School of Medicine, St. Louis, Missouri; Albert Einstein College of Medicine, New York, New York; University of Alabama School of Medicine, Birmingham, Alabama; Division of Cancer Epidemiology and Genetics and Division of Cancer Prevention, National Cancer Institute, Bethesda, Maryland; The Permanente Medical Group, Sacramento, California; and Emory University School of Medicine, Atlanta, Georgia

■ **ABSTRACT:** A group of 47 experts representing 23 professional societies, national and international health organizations, and federal agencies met in Bethesda, MD, September 14–15, 2012, to revise the 2006 American Society for Colposcopy and Cervical Pathology Consensus Guidelines. The group's goal was to provide revised evidence-based consensus guidelines for managing women with abnormal cervical cancer screening tests, cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ (AIS) following adoption of cervical cancer screening guidelines incorporating longer screening intervals and co-testing. In addition to literature review, data from almost 1.4 million women in the Kaiser Permanente Northern California Medical Care Plan provided evidence on risk after abnormal tests. Where data were available, guidelines prescribed similar management for women with similar risks for CIN 3, AIS, and cancer. Most prior guidelines were reaffirmed. Examples of updates include: Human papillomavirus–negative atypical squamous cells of undetermined significance results are followed with co-testing at 3 years before return to routine screening and are not sufficient for exiting women from screening at age 65 years; women aged 21–24 years need less invasive management, especially for minor abnormalities; postcolposcopy management strategies incorporate co-testing; endocervical sampling reported as CIN 1 should be managed as CIN 1; unsatisfactory cytology should be repeated in most circumstances, even when HPV results from co-testing are known, while most cases of negative cytology with absent or insufficient endocervical cells or transformation zone component can be managed without intensive follow-up. ■

These guidelines are being published simultaneously in *Obstetrics & Gynecology* and the *Journal of Lower Genital Tract Disease*. The complete algorithms are published in the *Journal of Lower Genital Tract Disease* and are also available on the web site of the American Society for Colposcopy and Cervical Pathology (http://www.asccp.org/).

The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health or U.S. federal government.Corresponding author: L. Stewart Massad, MD Division of Gynecologic Oncology, Washington University School of Medicine, 4911 Barnes-Jewish Hospital Plaza, St. Louis, MO 63110; e-mail: massadl@wudosis.wustl.edu.

Financial Disclosure

Dr. Massad has served as an expert witness. Dr. Huh has served as a consultant to Roche. Dr. Schiffman has researched reagents for Qiagen and Roche. The other authors did not report any potential conflicts of interest.

By 2001, revised Bethesda system terminology for reporting cervical cytology results and the availability of findings from a recent randomized trial of strategies for managing minor cervical cytologic abnormalities had created the need for a standard approach to managing women with abnormal cervical cytology and cervical cancer precursors (1–3). In response, the American Society for Colposcopy and Cervical Pathology (ASCCP) initiated

© 2013, American Society for Colposcopy and Cervical Pathology

a process that developed comprehensive, evidence-based consensus guidelines to aid clinicians in managing women with abnormal cervical cytology, cervical intraepithelial neoplasia (CIN), and adenocarcinoma in situ (AIS) (4, 5). Although those guidelines became the standard for managing women with abnormal cervical cytology and cancer precursors, the need for revisions became apparent. A second consensus conference in 2006 aligned management of minor cytologic abnormalities and CIN 1, incorporated follow-up results of the ASCUS-LSIL Triage Study (ALTS), identified strategies for management of positive human papillomavirus (HPV) DNA tests, and established guidelines for management of adolescents and young women (6, 7).

As updated in 2001, the Bethesda System also defined terminology for cytologic specimen adequacy, and ASCCP developed management guidelines for women with unsatisfactory cytology results and for those with negative results but limited endocervical/transformation zone (EC/TZ) component (8). These guidelines were updated in 2008 (9) but were not validated by a national consensus conference.

Previous guidelines remain valid, but knowledge has advanced. Screening has changed. In 2012, national organizations published guidelines embracing longer screening intervals and a later age to start screening (10, 11). Co-testing with cytology and HPV testing at 5-year intervals is now the preferred or acceptable strategy for cervical cancer screening for women aged 30–64 years (10, 11). Clinicians should benefit from guidance on how to incorporate co-testing into management of women with cervical abnormalities.

In addition, new evidence to guide decisions about management of abnormal screening tests and CIN and AIS emerged in 2012 from analyses of the large clinical database at the Kaiser Permanente Northern California Medical Care Plan (KPNC), conducted in collaboration with scientists from the National Cancer Institute (NCI) (12). This new evidence fills gaps in the 2006 guidelines. For example, prior management guidelines relied heavily on data from ALTS, which provided evidence on initial management of women with minor cytologic abnormalities. Results were extrapolated to provide guidelines on management of women with more severe cytologic abnormalities and post-colposcopy follow-up. The newer evidence from KPNC analyses allows validation or modification of prior guidelines in specific areas. The size of the KPNC database also allows age-based stratification of data for some types of abnormalities. While these observational data from a single U.S. region may limit generalizability and the lack of follow-up beyond 8 years may limit long-term risk estimates, publication of comparable analyses from similarly large databases soon is unlikely.

Finally, additional data have emerged in specific areas. Human papillomavirus genotyping tests have been approved; these have been recommended as an option for specific clinical scenarios to guide triage to colposcopy. More information is also available to guide management of women with unsatisfactory cytology.

In response, ASCCP conducted a consensus process to update the management of abnormal co-testing results and cytology with specimen adequacy limitations, the initial management of abnormal screening test results, options for postcolposcopy management, management of women aged 21–24 years, and other issues. This report details the consensus guidelines developed through this process.

METHODS

The process for the 2012 consensus guidelines was similar to that for the previous guidelines (4–7). Initially the ASCCP Practice Committee defined questions for the 2012 consensus process. A steering committee of nationally recognized experts in cervical cancer prevention was nominated and canvassed for additional questions. At the March 2012 ASCCP Biennial Scientific Meeting, conference attendees presented suggestions for guidelines review. Organizations that participated in the 2006 guidelines development process were solicited to nominate representatives to the revision process and also were asked to identify questions for review. Participants and participating organizations are listed in Appendix A.

A multifaceted process was used to evaluate the evidence and resolve identified issues. Five working groups were created, chaired by steering committee members and including delegates from participating organizations. For some working groups, the MEDLINE database was queried using relevant key words for English-language articles published after 2005, the date of the last consensus conference review (see Appendix 1, available online at http://links.lww.com/LGT/A9). Potentially relevant abstracts from identified articles were reviewed. Reports were rated according to the strength and quality of relevant evidence.

Other working groups focused on analyses of outcomes risk from a database of 1.4 million women cared for at KPNC and followed from January 1, 2003 to December 31, 2010. The primary outcome of interest in these analyses was CIN 3+ (CIN 3, AIS, and cancer). Cancer was used as an outcome when risk was high and CIN 2+ (CIN 3+ and

CIN 2) was used when the number of CIN 3+ events was low. Applying the concepts of "similar management for similar risks," risks were benchmarked to those for accepted management strategies. Since delegates considered zero cancer risk unattainable and CIN 3+ a reasonable proxy for cancer risk, acceptable risks were considered to be those approximating CIN 3+ risk 3 years after negative cytology or 5 years after negative co-testing. In brief, immediate colposcopy was recommended when the 5-year risk of CIN 3+ in the KPNC cohort exceeded 5%, a 6-month to 12-month return for risk of 2–5%, a 3-year return for risk of 0.1–2%, and a 5-year return interval for risk comparable to co-testing in women without a history of abnormality, or 0.1%. (12).

Draft guidelines developed by the working groups were posted to the ASCCP web site, and comments were solicited from collaborating organizations and the public. Draft guidelines revised in light of public comments were presented to a consensus conference convened September 14–15, 2012, at the Natcher Conference Center on the campus of the National Institutes of Health in Bethesda, MD. Draft guidelines and supporting evidence were presented, discussed, revised as needed, and adopted by at least 66% of voting delegates using electronic voting devices.

The terminology used in the updated guidelines is similar to prior versions, and the two-part rating system is the same (Table 1). Ratings are given in parentheses throughout the guidelines. The terms *recommended, preferred, acceptable, and unacceptable* are used in the guidelines to describe various interventions. A new term, "*not recommended*," was added to describe management strategies with weak evidence against their use but only marginal risk for adverse consequences. The strength rating of a recommendation was based on the quality of evidence supporting it but incorporated other factors, including potential for harm if an intervention did not occur and potential complications from a given intervention.

For cytologic classification and assessment of cytology specimen adequacy, the 2001 Bethesda System was used (1). For histologic classification, a two-tiered system was employed. Low-grade lesions were termed CIN 1 and high-grade lesions were termed CIN 2 or CIN 3. Some pathologists do not distinguish CIN 2 from CIN 3, and these undifferentiated high-grade lesions are termed CIN 2,3.

Table 1. Rating the Recommendations

Strength of recommendation*	
A	Good evidence for efficacy and substantial clinical benefit support recommendation for use.
B	Moderate evidence for efficacy or only limited clinical benefit supports recommendation for use.
C	Evidence for efficacy is insufficient to support a recommendation for or against use, but recommendations may be made on other grounds.
D	Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use.
E	Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use.
Quality of evidence*	
I	Evidence from at least one randomized, controlled trial.
II	Evidence from at least one clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), or from multiple time-series studies, or dramatic results from uncontrolled experiments.
III	Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.
Terminology used for recommendations†	
Recommended	Good data to support use when only one option is available.
Preferred	Option is the best (or one of the best) when there are multiple options.
Acceptable	One of multiple options when there is either data indicating that another approach is superior or when there are no data to favor any single option.
Not recommended	Weak evidence against use and marginal risk for adverse consequences.
Unacceptable	Good evidence against use.

* Modified from Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. Infectious Diseases Society of America. Clin Infect Dis 1994;18:421. 98. Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001;32:851–4.
† The assignment of these terms represents an opinion ratified by vote during the 2012 consensus conference.

GUIDING PRINCIPLES

Participants at the consensus conference affirmed that the 2006 ASCCP guidelines for the management of abnormal cervical cancer screening tests (6) and CIN or AIS (7) remain valid, with the exception of the specific areas reviewed. Those earlier guidelines have been combined with current revisions in this document to provide comprehensive recommendations for management. Changes are summarized in Box 1.

Cervical cancer prevention is a process with benefits and harms. Risk cannot be reduced to zero with currently available strategies, and attempts to achieve zero risk may result in unbalanced harms, including overtreatment. As noted in a 2011 consensus conference on cervical cancer screening (10), optimal prevention strategies should identify those HPV-related abnormalities likely to progress to invasive cancers while avoiding destructive treatment of abnormalities not destined to become cancerous. Adopted management strategies provide what participants considered an acceptable level of risk of failing to detect high-grade neoplasia or cancer in a given clinical situation. Where data were available,

Box 1. Essential Changes From Prior Management Guidelines*

- Cytology reported as negative but lacking endocervical cells can be managed without early repeat.
- CIN 1 on endocervical curettage should be managed as CIN 1, not as a positive ECC.
- Cytology reported as unsatisfactory requires repeat even if HPV negative.
- Genotyping triages HPV-positive women with HPV type 16 or type 18 to earlier colposcopy only after negative cytology; colposcopy is indicated for all women with HPV and ASC-US, regardless of genotyping result.
- For ASC-US cytology, immediate colposcopy is not an option. The serial cytology option for ASC-US incorporates cytology at 12 months, not 6 months and 12 months, and then if negative, cytology every 3 years.
- HPV-negative and ASC-US results should be followed with co-testing at 3 years rather than 5 years.
- HPV-negative and ASC-US results are insufficient to allow exit from screening at age 65 years.
- The pathway to long-term follow-up of treated and untreated CIN 2+ is more clearly defined by incorporating co-testing.
- More strategies incorporate co-testing to reduce follow-up visits. Pap-only strategies are now limited to women younger than 30 years, but co-testing is expanded even to women younger than 30 years in some circumstances. Women aged 21-24 years are managed conservatively.

CIN, cervical intraepithelial neoplasia; ECC, endocervical curettage; HPV, human papillomavirus; ASC-US, atypical squamous cells of undetermined significance.
**Prior management guidelines were from the "2006 Consensus Guidelines for the Management of Women With Abnormal Cervical Screening Tests" (6). Prior guidelines not changed were retained.*

similar management strategies were prescribed for similar levels of risk (12, 13). Guidelines cannot be developed for all situations. Clinical judgment should always be applied when applying guidelines to individual patients. This is especially true for guidelines based on less robust evidence.

In 2012, the Lower Anogenital Squamous Terminology (LAST) Project created new terminology for HPV-related lesions of the lower genital tract (14). However, delegates to the current consensus process determined that this classification does not yet have a sufficiently robust outcomes evidence base to allow elucidation of risk-based management guidelines (see Box 2).

Algorithms detailing the different management recommendations are available at the ASCCP web site (www.asccp.org/consensus2012). A glossary of terms used in the guidelines is in Appendix B.

In the 2006 ASCCP guidelines,(6,7) several pathways concluded by returning women to "routine screening." This term was not defined, but in 2006, screening guidelines prescribed cytology at shorter intervals than now recommended. Current 2011 screening guidelines recommend either 3-year cytology intervals or, for women aged 30–64 years, 5-year co-testing intervals (10, 11). These multi-year intervals are safe only when risk for the development of CIN 3+ during the years between testing is low (10, 11). For example, women aged 30–64 years with a negative co-test have a 5-year risk of CIN 3+ of only 8/10,000 (12). Although this low level of risk can be achieved among women with negative screening histories, for those with some abnormalities, risk for CIN 3+ remains elevated for years, even after treatment and even after initial negative surveillance. After some abnormalities, current follow-up data are insufficient to define a pathway to return to 5-year routine screening intervals because even with treatment, risk does not fall to a level consistent with 5-year retesting.

When, how, and even whether to perform endocervical sampling is controversial. Endocervical brushing has better sensitivity than curettage with similar specificity, better tolerance, and fewer insufficient samples, although grading may be more difficult because stroma is rarely sampled with brushing (15, 16). Either is acceptable for endocervical sampling. In 2006, working groups assessing management of cytology reported as atypical squamous cells of undetermined significance (ASC-US) and low-grade squamous intraepithelial lesions (LSIL) defined indications for endocervical sampling, guidance that should be valid for women with cytology results of atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesions (ASC-H) and high-grade squamous intraepithelial lesions (HSIL) as well.

Management strategies incorporate HPV testing based on studies using validated HPV assays. Management based on results of HPV tests not similarly validated may not result in intended outcomes and may risk patient harm. These guidelines are intended for use only with HPV tests that have been analytically and clinically validated with proven acceptable reproducibility, clinical sensitivity, specificity, and positive and negative predictive values for cervical cancer and verified precancer (CIN 2+), as documented by U.S. Food and Drug Administration (FDA) licensing and approval or publication in peer-reviewed scientific literature. Testing should be restricted to high-risk (oncogenic) HPV types (mainly 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59), and in these guidelines "HPV testing" refers only to testing for high-risk

Box 2.

A recent consensus conference (the Lower Anogenital Squamous Terminology [LAST] Project convened by the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology) adopted a two-tier terminology that incorporates ancillary tests and other criteria to distinguish indeterminate lesions as high grade or low grade. Until a comprehensive evidence review and consensus guidelines development process can be conducted, histopathology results reported as low-grade squamous intraepithelial lesions (LSIL) should be managed as cervical intraepithelial neoplasia (CIN) 1 and those reported as high-grade squamous intraepithelial lesions (HSIL) should be managed as CIN 2,3 (14).

(oncogenic) HPV types. Testing for low-risk (nononcogenic) HPV types has no role in the evaluation of women with abnormal cervical cytologic results.

Both ablation and excision effectively treat CIN. Randomized trials comparing different modalities show similar efficacy (17–20). Efficacy rates range from 90% to 95%, and most failures occur within 2 years (21), although cancers can develop up to 20 years after treatment (22). Margin status is a convenient predictor of recurrence and a traditional risk marker, although it does not appear to be an independent risk factor (23, 24). Nonsurgical therapies, including topical agents and therapeutic vaccines, remain investigational.

A wide variety of follow-up approaches have been described for women treated for CIN, incorporating cytology, HPV testing, and colposcopy alone or in combination at intervals from 3 months to annually. HPV testing is more sensitive but less specific than cytology in posttreatment follow-up and it may result in earlier diagnosis of persistent or recurrent disease (25). Protocols for follow-up after treatment of CIN have not been evaluated as primary interventions in randomized trials.

Under the 2011 screening guidelines, women followed after positive HPV tests but negative cytology were referred to colposcopy only if they had LSIL or more severe cytology or a positive HPV test during surveillance co-testing (10). However, only 0.04% of all women aged 30-64 years in the KPNC database had HPV-negative ASC-US after an HPV-positive, cytology negative result (26), so referring these women for colposcopy will burden care systems minimally. Thus, for simplicity, current guidelines recommend colposcopy for any positive HPV test or any abnormal cytology during follow-up.

Studies of the effect of treatment on future pregnancy are conflicting, although many indicate an approximately two-fold increase in preterm delivery risk (27–29). Although not proven, this is presumed to result from deficient cervical stroma, and risk appears to increase with the volume and number of excisions (30). However, many studies were done in countries where loop excisions are performed with larger loop sizes and deeper excisions than most U.S. clinicians employ. Studies linking ablative treatments to preterm delivery are even more limited and conflicting. Women with CIN may be at increased risk for preterm delivery even when untreated. Nevertheless, because pregnancy complications can be devastating, the potential benefits of treatment should be balanced against the risk to future pregnancies. Young women have high regression rates for cervical disease and low cancer risk (31–33). The term "young women" indicates those who after counseling by their clinicians consider risk to future pregnancies from treating cervical abnormalities to outweigh risk for cancer during observation of those abnormalities. No specific age threshold is intended.

In 2006, guidelines recommended less aggressive management for adolescents with cervical abnormalities (6, 34), but these are now moot because the 2011 screening guidelines recommend not screening adolescents (10, 11). Delegates to the 2012 consensus conference considered less intensive management for other young women with abnormal cytology. Cervical cancer risk remains low through age 25 years (35), HPV is common (36), and lesions often regress (37). The annual incidence of cervical cancer among U.S. women aged 21–24 years is 1.4/100,000, and almost 55,000 cytology tests must be obtained for every cervical cancer diagnosed in this age group (35). This level of risk is 10-fold higher than risk in adolescents and appears to be high enough to justify screening yet is low enough to allow observation for minor cytologic abnormalities. Guidelines for women aged 21–24 years can be extrapolated to adolescents inadvertently screened.

Interventions for abnormal screening tests and CIN or AIS have other consequences that are not easily measurable. Women experience emotional distress when receiving abnormal cytology and HPV test results, when having colposcopy even when findings are normal, and when undergoing cervical treatment. Emotional distress is usually prompted by uncertainty and anticipation of the unknown (38). Many management strategies incorporate follow-up with HPV testing, which can elicit feelings of stigma and shame when positive despite the near-ubiquitous frequency of HPV infection (39, 40). The anxiety and time required for visits to manage abnormal cytology can adversely affect relationships, work-related and school activities, and family matters (41). These potential harms reinforce the concept that colposcopy and other interventions should be avoided when risk for CIN 3+ is low and when identified lesions are likely to resolve.

In the 2001 guidelines (4), separate recommendations for ASC-US management were developed for women infected with human immunodeficiency virus and other immunosuppressive conditions. Data review in 2006 eliminated these separate guidelines. Immunosuppressed women with abnormal results should be managed in the same manner as immunocompetent women.

Guidelines on management apply only to women undergoing routine screening with adequate visualization of the cervix and directed sampling with acceptable collection instruments. They also apply only to women identified with abnormalities during screening. Women with postcoital or unexplained abnormal vaginal bleeding, pelvic pain, abnormal discharge, or a visible lesion merit individualized evaluations.

Consensus guidelines from the ASCCP have international influence. However, they are tailored to the opportunistic cervical cancer screening system of the United States, with specific terminology, diagnostic criteria, pathways to colposcopic training, patient expectations and adherence, and medical–legal risks. Clinicians elsewhere must consider the guidelines in light of their own context and adapt management accordingly.

MANAGEMENT OF ABNORMAL SCREENING TESTS

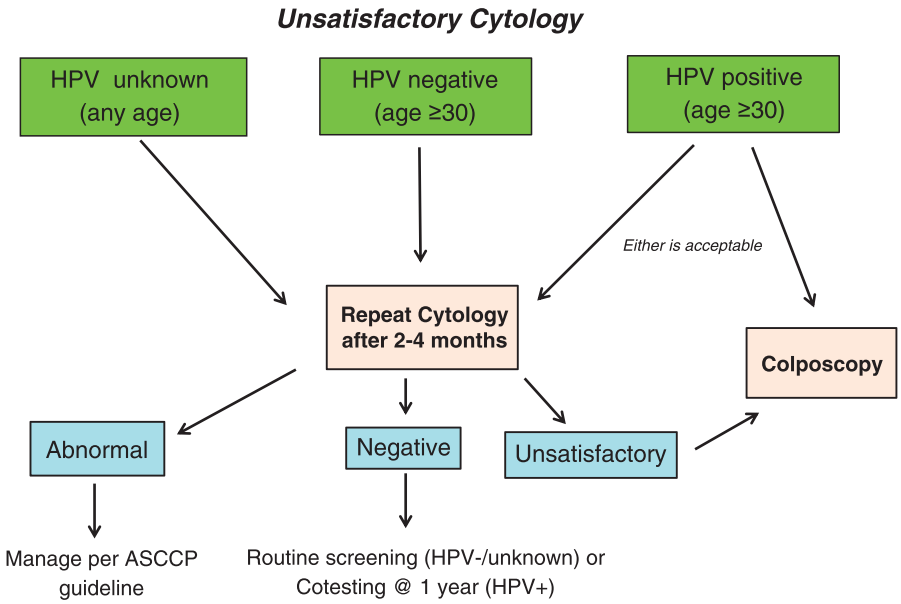
Unsatisfactory Cytology

Cytology results are unsatisfactory for 1% or less across all preparation types (42, 43). Unsatisfactory cytology specimens are unreliable for detecting epithelial abnormalities. However, most studies that found a higher risk of disease among women with unsatisfactory cytology employed conventional Pap tests that can be rendered unsatisfactory by obscuring blood, inflammation, or other processes (44, 45). Now that most U.S. cytology is done using liquid-based media, which can control for most obscuring factors in processing, unsatisfactory results arise largely from insufficient squamous cells (46). Evidence is sparse governing management of women with unsatisfactory cytology obtained as part of co-testing, although risk for high-grade disease in women with negative HPV tests appears to be low (47). Unsatisfactory results arise largely from insufficient squamous cells (48). Some currently available HPV tests lack a control for epithelial cellularity, so a negative HPV test cannot be relied, upon as the HPV test may be falsely negative because of an insufficient sample.

Specimen collection techniques to minimize unsatisfactory cytology have not changed since the last guideline (9). Extended-tip spatulas, spatulas plus brushes, and brooms all appear effective (49, 50). When two devices are used, the ectocervical device should be used first.

Management of Women With Unsatisfactory Cytology (Fig. 1)

For women with an unsatisfactory cytology result and no, unknown, or a negative HPV test result, repeat cytology in 2–4 months is recommended (BIII). Triage using reflex HPV testing is not recommended (BIII). Treatment to resolve atrophy or obscuring inflammation when a specific infection is present is acceptable (CIII).



© Copyright , 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

Figure 1.

For women aged 30 years and older who are co-tested and have unsatisfactory cytology and a positive HPV test, repeat cytology in 2–4 months or colposcopy is acceptable (BII). Colposcopy is recommended for women with two consecutive unsatisfactory cytology tests (CIII).

Cytology Reported as Negative but With Absent or Insufficient EC/TZ Component

Cytology reported as negative but with absent or insufficient EC/TZ component has adequate cellularity for interpretation but lacks endocervical or metaplastic cells, suggesting that the squamocolumnar junction may not have been adequately sampled. This raises concern for missed disease. Recently reported rates of cytology results reported as negative but with absent or insufficient EC/TZ component have ranged from 10% to 20% and are higher in older women (51, 52). Prior guidelines recommended early repeat cytology (8, 9). However, while women with absent or insufficient EC/TZ component have fewer concurrent cytologic abnormalities, they do not have a higher risk for CIN 3+ over time than women with a satisfactory EC/TZ component, as would be expected if true precancers had been missed. Instead, the lower rate of cytologic abnormality appears to occur because women whose cytology lacks a satisfactory EC/TZ component are older, and older women have lower CIN 3+ risk (53). A recent meta-analysis found that negative cytology had good specificity and negative predictive value despite absent or insufficient EC/TZ component (54). HPV testing appears to be independent of transformation zone sampling (55) and offers an added margin of safety for women aged 30–64 years now that co-testing is the preferred screening strategy for that age group. An absent EC/TZ component is not associated with an increased incidence of cervical disease after treatment of CIN 2+ (56).

Management of Women With Cytology Reported as Negative but With Absent or Insufficient EC/TZ Component (Fig. 2)

For women aged 21–29 years with negative cytology and absent or insufficient EC/TZ component, routine screening is recommended. HPV testing is unacceptable (BIII).

For women aged 30 years and older with cytology reported as negative and with absent or insufficient EC/TZ component and no or unknown HPV test result, HPV testing is preferred (BIII). Repeat cytology in 3 years is acceptable if HPV testing is not performed (BIII). If the HPV test is done and is negative, return to routine screening is recommended (BIII). If the HPV test is positive, repeating both tests in 1 year is acceptable (BIII). Genotyping is also acceptable; if HPV type 16 or type 18 is present, colposcopy is

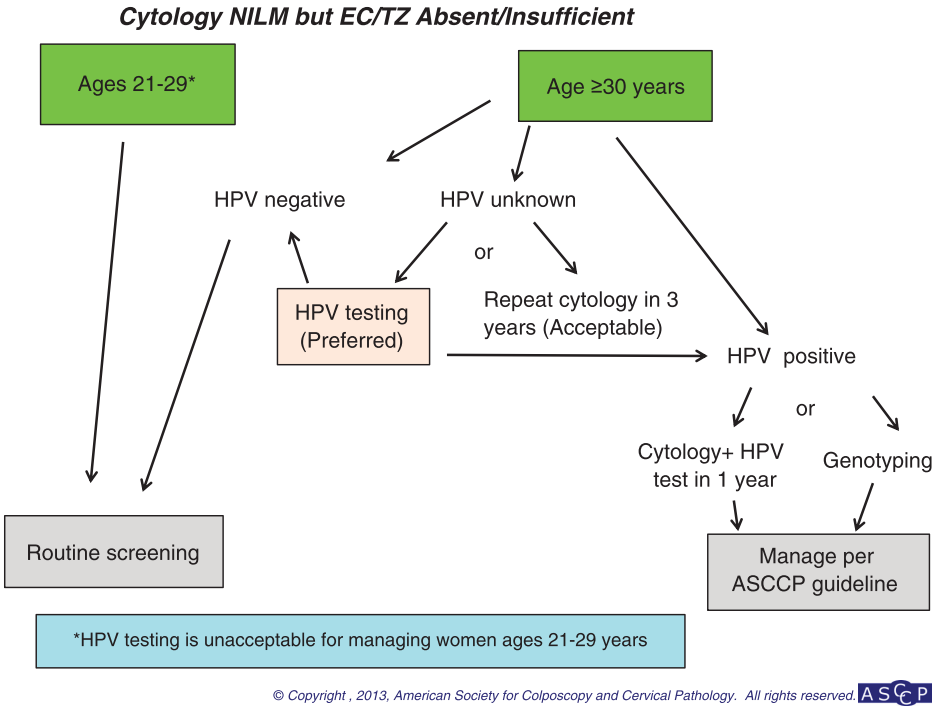


Figure 2.

recommended (BII). If HPV type 16 and type 18 are absent, repeat co-testing in 12 >months is recommended (BIII).

Negative Cytology With a Positive HPV Test

Although not indicated for younger women, co-testing is the preferred screening strategy for women aged 30–64 years (10). Despite negative cytology, women with oncogenic HPV are at higher risk for later CIN 3+ than women with negative HPV tests (57). The risk of CIN 3+ in HPV positive but cytology negative women is sufficient to justify early return for retesting. Persistent HPV positivity increases risk still further (58, 59). However, most HPV infections are cleared, substantially reducing risk of CIN 3+ (60), so observing women to allow clearance is attractive. Nevertheless, CIN 3+ does occur during observation, requiring guidelines to balance risks arising from intervention for HPV that may yet be cleared against the risks of disease. This is true even for women with HPV infections but negative cytology. In the KPNC cohort, the CIN 3+ risk for every co-test result obtained after an initial HPV-positive but cytology-negative result was higher than risk associated with that co-test result in women with prior negative screening (58).

Women with HPV-16 are at particular risk for CIN 3+. Human papillomavirus-18 merits special consideration because of its association with cervical adenocarcinomas, which are less efficiently detected by cytology than squamous cancers.

Management of Women Testing HPV Positive but Cytology Negative (Fig. 3)

For women 30 years of age and older with HPV-positive but cytology-negative co-testing, repeat co-testing at 1 year is acceptable (BII). At the 1-year repeat co-test, if the HPV test is positive or cytology is ASC-US or worse, colposcopy is recommended (BII). If the 1-year repeat co-test result is HPV negative and cytology negative, repeat co-testing in 3 years is recommended (BII).

HPV genotyping is also acceptable. If HPV-16 or HPV-18 tests are positive, colposcopy is recommended (BII). If HPV-16 and HPV-18 tests are negative, repeat co-testing in 1 year is recommended (BII).

Atypical Squamous Cells of Undetermined Significance (ASC-US)

ASC-US is the most common cytologic abnormality, but it carries the lowest risk of CIN 3+, partly because one third to two thirds are not HPV-associated (2, 26). In ALTS, three management strategies performed similarly and were included in subsequent guidelines (3, 4, 6). Compared with colposcopy for all ASC-US, reflex testing followed by colposcopy for HPV-positive women was preferred because it identified most CIN 3 lesions yet referred many fewer women to colposcopy (3). ALTS was conducted before the 2001 Bethesda system update, which separated ASC-H cytology from the ASC-US category. For this and other reasons, the observed 3%

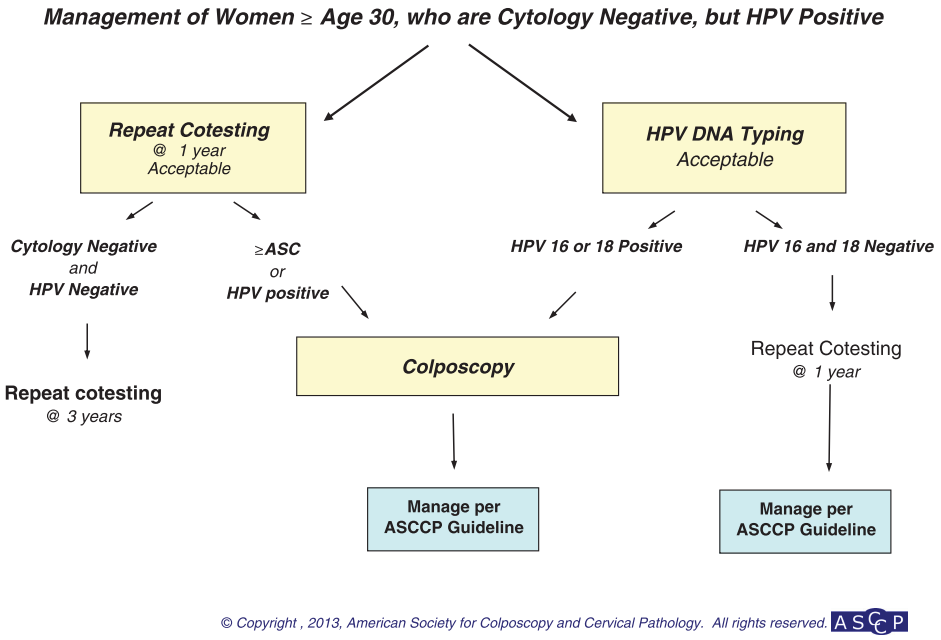


Figure 3.

5-year risk of CIN 3+ after ASC-US among women aged 30 years and older in the KPNC cohort was lower than the 2-year risk seen in ALTS. In fact, risk was low enough to justify annual rather than semiannual cytology as sufficiently sensitive to identify women with CIN 3+ (61).

Recent 2011 screening guidelines recommended that women with HPV-negative ASC-US co-testing results be managed with routine follow-up (10). This was based on an earlier analysis of a smaller KPNC dataset. Analysis of an expanded dataset found that while the absolute risk of CIN 3+ was low after HPV-negative ASC-US, it was more comparable to CIN 3+ risk among women with negative cytology alone than those with a negative co-test (26), suggesting a 3-year interval for follow-up. In addition, women over 60 years of age with HPV-negative ASC-US had a higher risk for cervical cancer during follow-up than women with negative co-testing, suggesting that they need continued screening.

Triage using HPV genotyping was considered. Women with ASC-US who also had HPV-16 or HPV-18 detected had approximately twice the risk of CIN 3+ as women with ASC-US and high-risk HPV types other than 16 or 18 (61–63). Nevertheless, KPNC data showed that the risk for CIN 3+ in both groups exceeded the threshold for colposcopy (26). HPV-16/18 genotyping of HPV-positive women with ASC-US did not appear to lead to different management.

No new information that would change the 2006 guidelines was identified on ASC-US in pregnant or postmenopausal women.

Management of Women with ASC-US (Fig. 4)

For women with ASC-US cytology, reflex HPV testing is preferred (BI). For women with HPV-negative ASC-US, whether from reflex HPV testing or co-testing, repeat co-testing at 3 years is recommended (BII). For women with HPV-positive ASC-US, whether from reflex HPV testing or co-testing, colposcopy is recommended (BI). When colposcopy does not identify CIN in women with HPV-positive ASC-US, co-testing at 12 months is recommended (BII). If the co-test is HPV negative and cytology negative, return for age-appropriate testing in 3 years is recommended (BII). If all tests are negative at that time, routine screening is recommended (BIII). It is recommended that HPV testing in follow-up after colposcopy not be performed at intervals of less than 12 months (EIII).

For women with ASC-US cytology and no HPV result, repeat cytology at 1 year is acceptable (BII). If the result is ASC-US or worse, colposcopy is recommended; if the result is negative, return to cytology testing at 3-year intervals is recommended (BII).

Endocervical sampling is preferred for women in whom no lesions are identified (BII) and for those with an

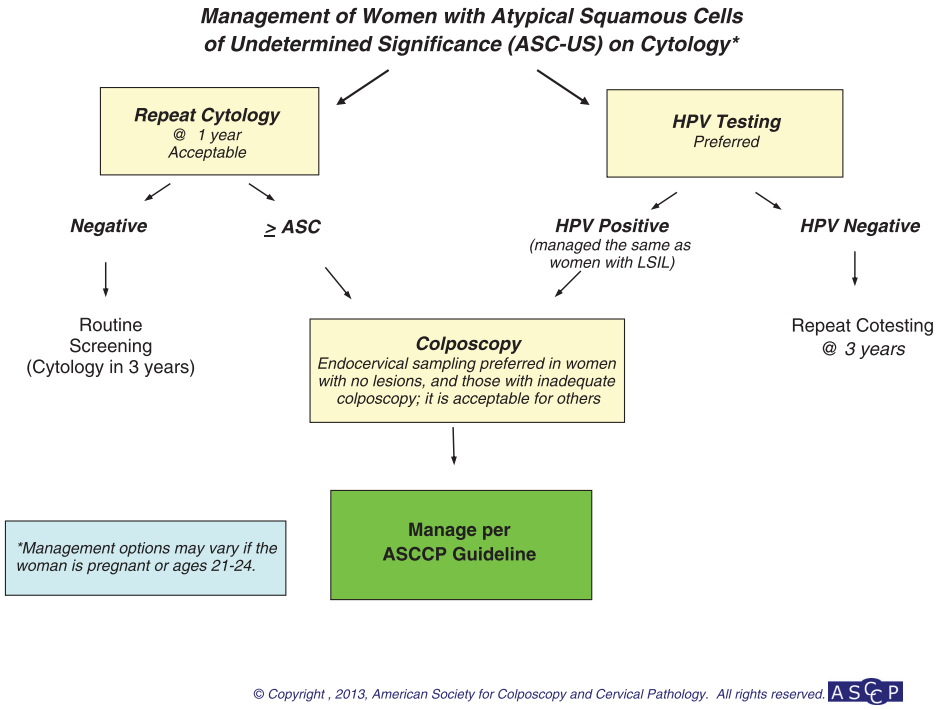


Figure 4.

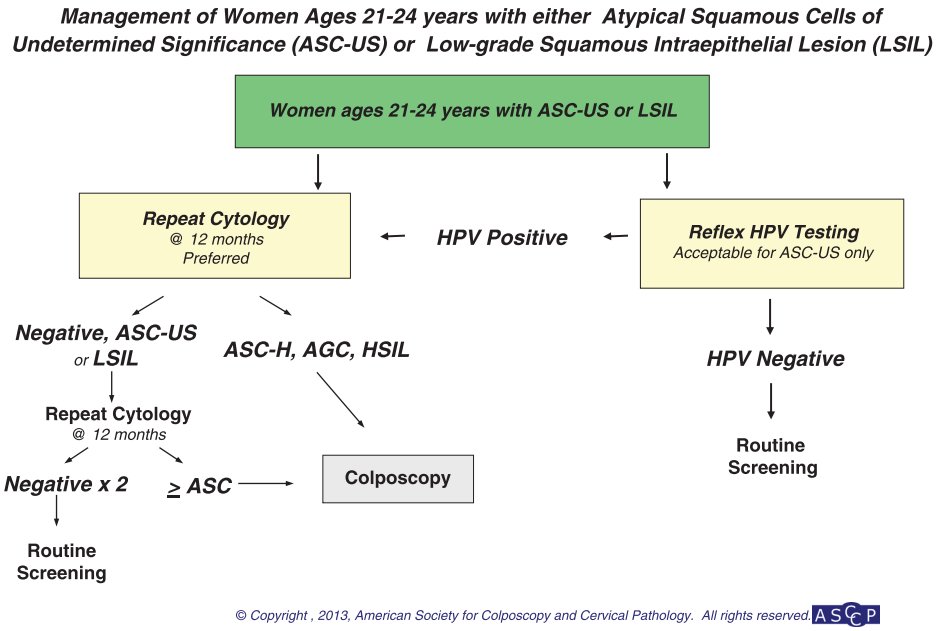


Figure 5.

inadequate colposcopy (AII) but is acceptable for women with an adequate colposcopy and a lesion identified in the transformation zone (CII).

Because of the potential for overtreatment, the routine use of diagnostic excisional procedures such as loop electrosurgical excision for women with an initial ASC-US in the absence of CIN 2+ is unacceptable (EII).

ASC-US in Special Populations

Women Aged 21–24 years (Fig. 5)

Initial Management

For women aged 21–24 years with ASC-US, cytology alone at 12-month intervals is preferred, but reflex HPV testing is acceptable (BII). If reflex HPV testing is performed with ASC-US and the HPV result is positive, repeat cytology in 12 months is recommended (BII). Immediate colposcopy or repeat HPV testing is not recommended. If reflex HPV testing is performed and is negative, return for routine screening with cytology alone in 3 years is recommended (BII).

Follow-Up

For women with ASC-US who are aged 21–24 years, follow-up with cytology at 12-month intervals is recommended. Colposcopy is not recommended. (BII) For women with ASC-H or HSIL+ (HSIL, atypical glandular cells [AGC], or cancer) at the 12-month follow up, colposcopy is recommended. For women with ASC-US or worse at the 24-month follow-up, colposcopy is recommended. For women with two consecutive negative results, return to routine screening is recommended. (BII)

Women Aged 65 Years and Older. Postmenopausal women with ASC-US should be managed in the same manner as women in the general population, except when considering exit from screening for women aged 65 years and older. For those women, HPV-negative ASC-US results should be considered abnormal (AII). Additional surveillance is recommended with repeat screening in 1 year; co-testing is preferred but cytology is acceptable (BII).

Pregnant Women. Management options for pregnant women with ASC-US are identical to those described for nonpregnant women, with the exception that deferring colposcopy until 6 weeks postpartum is acceptable (CIII). Endocervical curettage in pregnant women is unacceptable (EIII). For pregnant women who have no cytologic, histologic, or colposcopically suspected CIN 2+ at the initial colposcopy, postpartum follow-up is recommended (BIII).

Postmenopausal Women. Postmenopausal women with ASC-US should be managed in the same manner as women in the general population (BII).

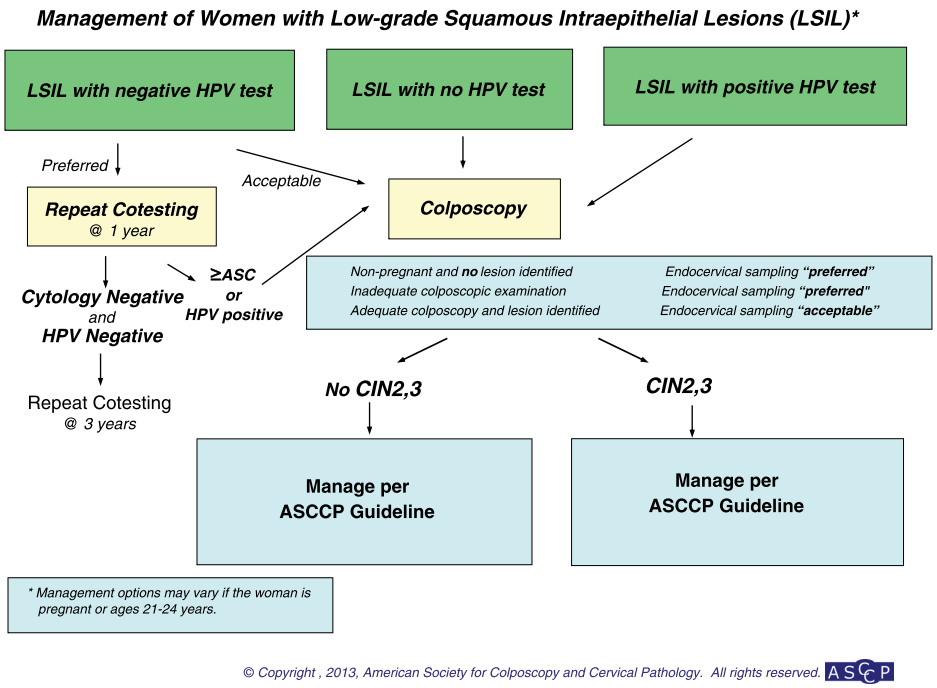


Figure 6.

Low-Grade Squamous Intraepithelial Lesion

The ASCUS-LSIL Triage Study showed that the natural history of LSIL approximates that of HPV-positive ASC-US (64), suggesting that women with either should be managed similarly. Analysis of the KPNC dataset confirmed that women with LSIL at ages 21–24 years carry a lower risk of CIN 3+ than older women (33, 65). Low-grade squamous intraepithelial lesions are highly associated with HPV infection, with a pooled estimate of HPV positivity of 77% (66). This rate appears too high to allow reflex HPV testing to select women for colposcopy efficiently. However, when co-testing is performed in women 30 years of age and older, some women have HPV-negative LSIL. In the KPNC cohort, the risk of CIN 3+ in HPV-negative women with LSIL was low, similar to that of ASC-US alone (67).

Management of Women with LSIL (Fig. 6)

For women with LSIL cytology and no HPV test or a positive HPV test, colposcopy is recommended (AI). If co-testing shows HPV-negative LSIL, repeat co-testing at 1 year is preferred, but colposcopy is acceptable. If repeat co-testing at 1 year is elected, and if the cytology is ASC-US or worse or the HPV test is positive (ie, if the co-testing result is other than HPV negative, cytology negative), colposcopy is recommended. If the co-testing result at 1 year is HPV negative and cytology negative, repeat co-testing after an additional 3 years is recommended. If all tests are negative at that time, routine screening is recommended (BIII).

LSIL in Special Populations

Women Aged 21–24 Years (Fig. 5). For women with LSIL who are aged 21-24 years, follow-up with cytology at 12-month intervals is recommended (BII). Colposcopy is not recommended (DII). For women with ASC-H or HSIL+ at the 12-month follow up, colposcopy is recommended. For women with ASC-US or worse at the 24-month follow up, colposcopy is recommended. For women with two consecutive negative results, return to routine screening is recommended (BII).

Pregnant Women (Fig. 7). For pregnant women with LSIL, colposcopy is preferred (BII). Endocervical curettage in pregnant women is unacceptable (EIII). For pregnant women aged 21–24 years, follow-up according to the guidelines for management of LSIL in women aged 21–24 years is recommended (discussed in previous paragraph). Deferring colposcopy until 6 weeks postpartum is acceptable (CIII). For pregnant women who have no cytologic, histologic, or colposcopically suspected CIN 2+ at the initial colposcopy, postpartum follow-up is recommended (BIII). Additional colposcopic and cytologic

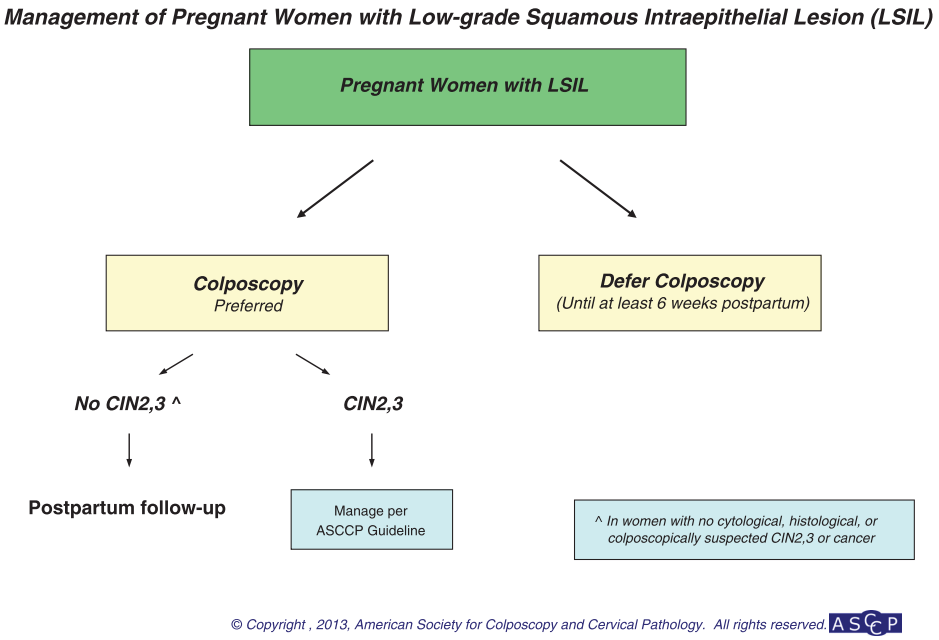


Figure 7.

examinations during pregnancy are unacceptable for these women (DIII).

Postmenopausal Women. Acceptable options for the management of postmenopausal women with LSIL and no HPV test include obtaining HPV testing, repeat cytologic testing at 6 months and 12 months, and colposcopy (CIII). If the HPV test is negative or if CIN is not identified at colposcopy, repeat cytology in 12 months is recommended. If either the HPV test is positive or repeat cytology is ASC-US or greater, colposcopy is recommended (AII). If two consecutive repeat cytology tests are negative, return to routine screening is recommended. (BII)

Atypical Squamous Cells, Cannot Exclude High-Grade Squamous Intraepithelial Lesion (ASC-H)

Data from KPNC confirmed that a report of ASC-H confers higher risk for CIN 3+ over time than ASC-US or

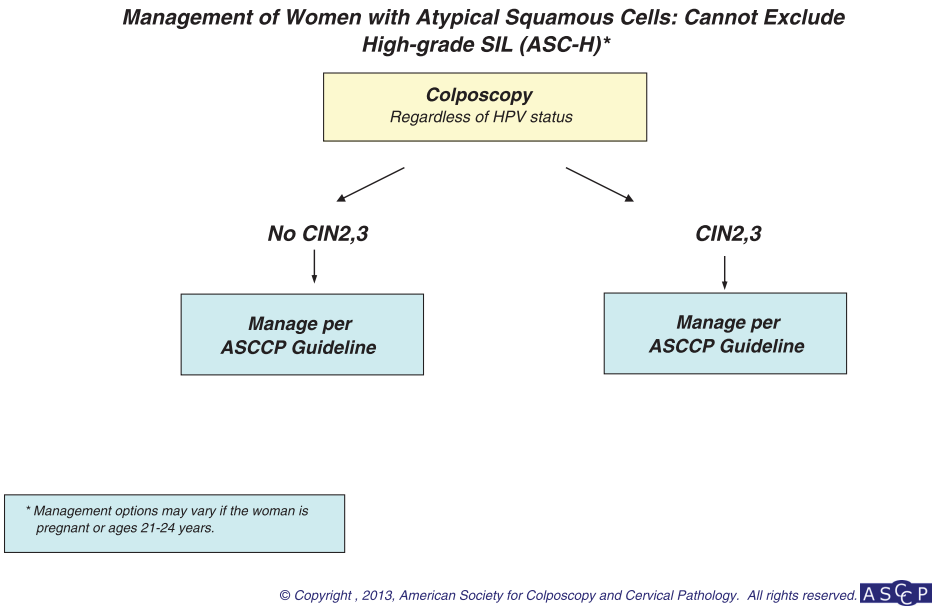


Figure 8.

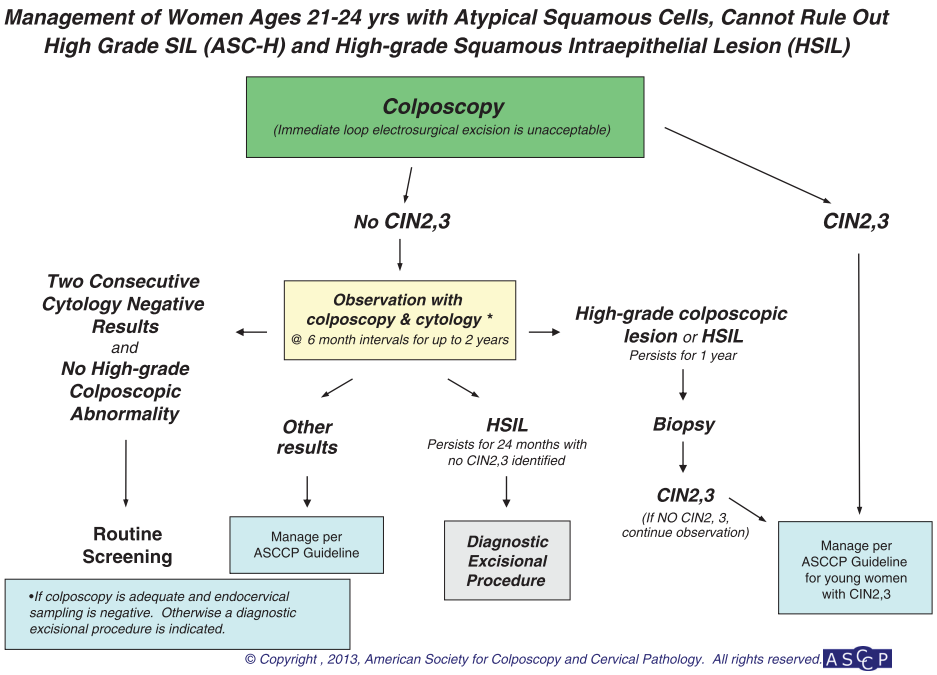


Figure 9.

LSIL (68, 69), although risk is lower than that following HSIL. This is also true for women aged 21–24 years, although their risk of CIN 3+ is lower than that for older women with ASC-H (33). The high rate of HPV detection in women with ASC-H makes reflex HPV testing unsuitable (3). In addition, the 5-year cancer risk among women with HPV-negative ASC-H is 2%, which is too high to justify observation (68).

Management of Women With ASC-H (Fig. 8). For women with ASC-H cytology, colposcopy is recommended regardless of HPV result. Reflex HPV testing is not recommended (DII).

ASC-H in Special Populations

Women Aged 21–24 Years (Fig. 9)

Colposcopy is recommended (AII). Further management should follow guidelines for women aged 21–24 years with HSIL.

High-Grade Squamous Intraepithelial Lesion (HSIL)

HSIL cytology results identify women at substantial risk. CIN 2+ is found at colposcopy in some 60% of women with HSIL (69–71). This justifies immediate excision of the transformation zone for many women, especially those who are at risk for loss to follow-up or who have completed childbearing. Cervical cancer is found at colposcopy in some 2% of women with HSIL, although risk rises with age and is low among women aged 21–24 years, even with follow-up (33). Five-year cervical cancer risk is 8% among women 30 years of age and older (72). Risks are modified by HPV test results: HPV-negative HSIL co-test results, although uncommon, still carry a 5-year risk for CIN 3+ of 29%, while 7% will develop cancer (72). This precludes reflex HPV triage for HSIL. In the KPNC cohort, among women 30 years of age and older with HPV-positive HSIL, the 5-year risk of CIN 3+ was 50%, while the 5-year cancer risk was 7% (72). When HPV results are known from co-testing for women with HSIL, these risks may inform the choice between immediate diagnostic excision and colposcopy and between diagnostic excision and cytologic and colposcopic surveillance when CIN 2+ is not identified. The sensitivity of colposcopy for detecting CIN 2+ is lower than previously appreciated (73–75), and multiple biopsies should be considered at colposcopy when large confluent or multiple discrete lesions are seen.

Management of Women With HSIL (Fig. 10). For women with HSIL cytology, immediate loop electrosurgical excision or colposcopy is acceptable, except in special populations (BII). Triage using either a program of repeat cytology alone or reflex HPV testing is unacceptable (EII). For women not managed with immediate excision, colposcopy is recommended regardless of HPV

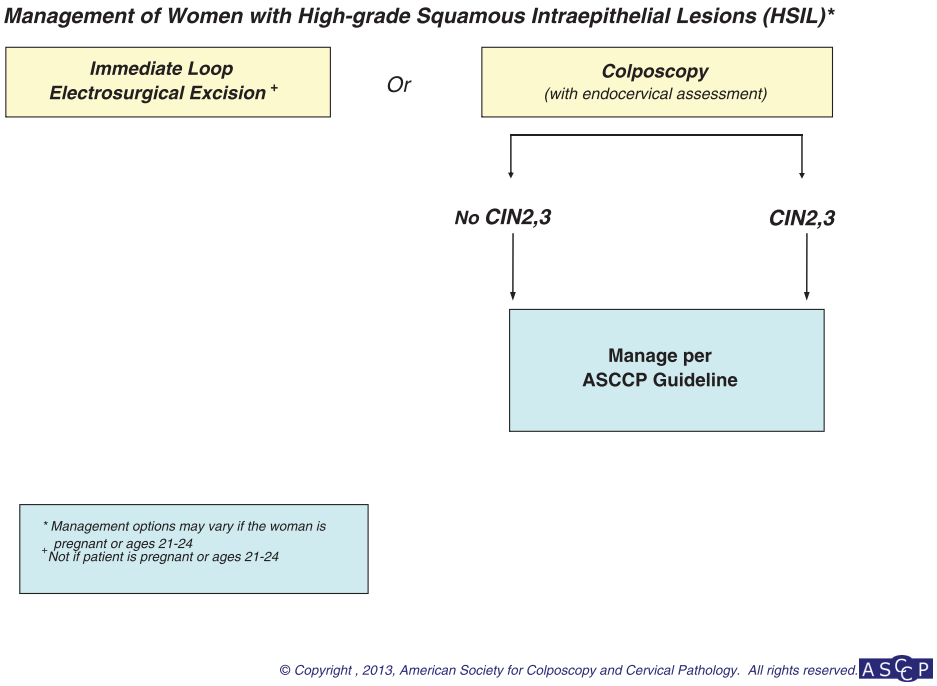


Figure 10.

result obtained at co-testing (BII). Accordingly, reflex HPV testing is not recommended (BII).

A diagnostic excisional procedure is recommended for women with HSIL when the colposcopic examination is inadequate, except during pregnancy (BII). Women with CIN 2, CIN 3, and CIN 2,3 should be managed according to the appropriate 2012 consensus guideline (see "Management of Women With CIN 2, CIN 3, and CIN 2,3"). Ablation is unacceptable in the following circumstances: when colposcopy has not been performed, when CIN 2,3 is not identified histologically, and when the endocervical assessment identifies CIN 2, CIN 3, CIN 2,3 or ungraded CIN (EII).

HSIL in Special Populations

Women Aged 21–24 Years (Fig. 9). For women aged 21–24 years with HSIL, colposcopy is recommended. Immediate treatment (ie, see-and-treat) is unacceptable. (AII) When CIN 2+ is not identified histologically, observation for up to 24 months using both colposcopy and cytology at 6-month intervals is recommended, provided the colposcopic examination is adequate and endocervical assessment is negative or CIN 1 (BIII). If CIN 2, CIN 3, or CIN 2,3 is identified histologically, management according to the 2012 consensus guideline for the management of young women with CIN 2, CIN 3, or CIN 2,3 is recommended (see "Management of Women With CIN 2, CIN 3, and CIN 2,3"). (BIII) If during follow-up a high-grade colposcopic lesion is identified or HSIL cytology persists for 1 year, biopsy is recommended. (BIII) If HSIL persists for 24 months without identification of CIN 2+, a diagnostic excisional procedure is recommended. (BIII) A diagnostic excisional procedure is recommended for women aged 21–24 years with HSIL when colposcopy is unsatisfactory or CIN 2, CIN 3, CIN 2,3, or ungraded CIN is identified on endocervical sampling. (BII) After two consecutive negative cytology results and no evidence of high-grade colposcopic abnormality, return to routine screening is recommended (BIII).

Atypical Glandular Cells, Cytologic Adenocarcinoma In Situ, and Benign Glandular Changes

An AGC interpretation is poorly reproducible (76) and uncommon (77). AGC has been associated with polyps and metaplasia but also with neoplasias, including adenocarcinomas of the endometrium, cervix, ovary, fallopian tube, and other sites (78). Neoplasia risk is higher when reported as AGC favor neoplasia or frank AIS. Although the cancer risk is lower in women younger than 35 years of age with AGC, the risk of CIN 2+ is higher, and intensive assessment is warranted at all ages (78). In the KPNC cohort, CIN 3+ was found in 9% of women aged 30 years and older with AGC cytology, with cancer in 3% (72, 77). Despite its

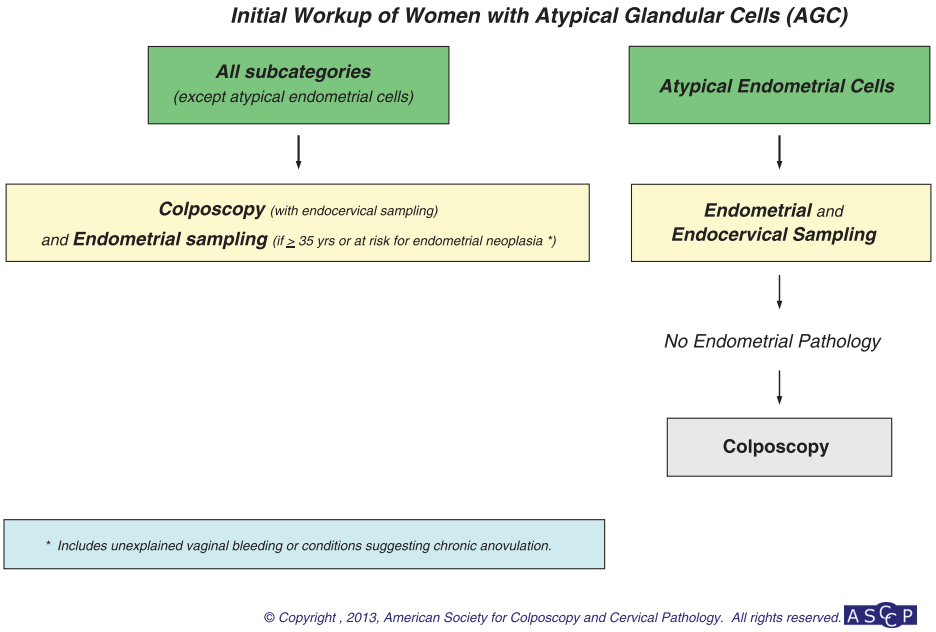


Figure 11.

appellation, AGC cytology is most commonly associated with squamous lesions including CIN 1. However, glandular and squamous lesions often coexist, with CIN found in approximately half of women with AIS (79–81), so identification of CIN does not preclude AIS or adenocarcinoma. Although cervical adenocarcinoma is HPV associated and can be detected with HPV testing, endometrial cancer is not, so reflex HPV testing does not identify a subgroup of women who need less invasive assessment. A negative HPV test can be useful in identifying women at greater risk for endometrial rather than cervical disease (80). Endometrial cancer risk is low in young women without endometrial cancer risk factors but is substantially greater in older women and young women with risk factors.

Benign-appearing endometrial cells and stromal cells or histiocytes are rarely associated with premalignant lesions or cancer in young women. However, in postmenopausal women, these changes can be associated with an approximately 5% risk of clinically important pathology including endometrial adenocarcinoma (81).

Management of Women With AGC or Cytologic AIS

Initial Workup (Fig. 11)

For women with all subcategories of AGC and AIS except atypical endometrial cells, colposcopy with endocervical sampling is recommended regardless of HPV result (AII). Accordingly, triage by reflex HPV testing is not recommended, and triage using repeat cervical cytology is unacceptable (DII). Endometrial sampling is recommended in conjunction with colposcopy and endocervical sampling in women 35 years of age and older with all subcategories of AGC and AIS (BII). Endometrial sampling is also recommended for women younger than 35 years with clinical indications suggesting they may be at risk for endometrial neoplasia (BII). These include unexplained vaginal bleeding or conditions suggesting chronic anovulation. For women with atypical endometrial cells, initial evaluation limited to endometrial and endocervical sampling is preferred, with colposcopy acceptable either at the initial evaluation or deferred until the results of endometrial and endocervical sampling are known; if colposcopy is deferred and no endometrial pathology is identified, colposcopy is then recommended (AII).

Subsequent Management (Fig. 12)

For women with AGC not otherwise specified cytology in whom CIN 2+ is not identified, co-testing at 12 months and 24 months is recommended. If both co-tests are negative, return for repeat co-testing in 3 years is recommended. If any test is abnormal, colposcopy is recommended. (BII)

If CIN 2+ but no glandular neoplasia is identified histologically during the initial workup of a woman with atypical endocervical, endometrial, or glandular cells not

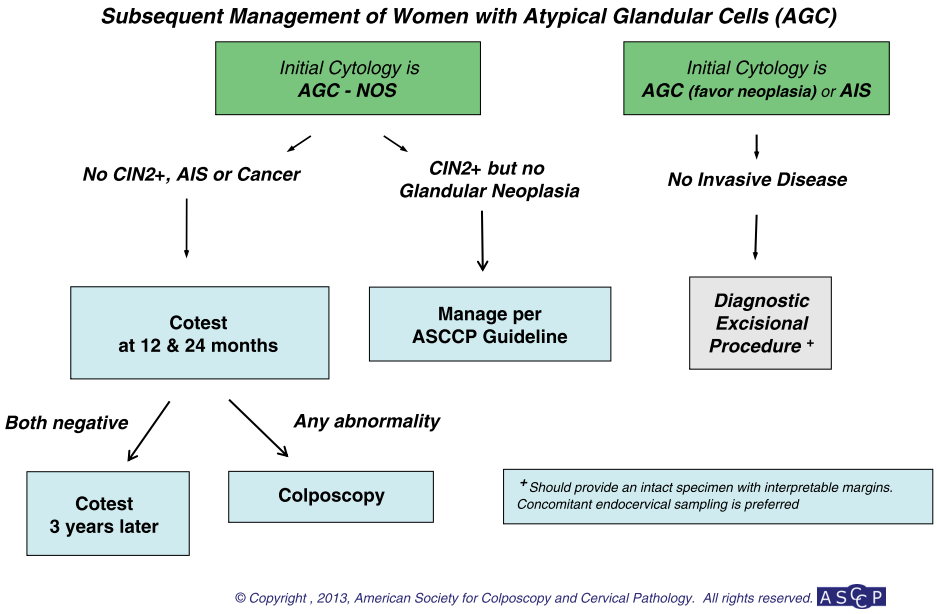


Figure 12.

otherwise specified, management should be according to the 2012 consensus guidelines for the lesion found (CII).

For women with AGC "favor neoplasia" or endocervical AIS cytology, if invasive disease is not identified during the initial colposcopic workup, a diagnostic excisional procedure is recommended (AII).

It is recommended that the type of diagnostic excisional procedure used in this setting provide an intact specimen with interpretable margins (BII). Endocervical sampling after excision is preferred (BII).

AGC or Cytologic AIS in Special Populations

Pregnant Women

The initial evaluation of AGC in pregnant women should be identical to that of nonpregnant women (BII), except that endocervical curettage and endometrial biopsy are unacceptable (EIII).

Women Aged 21–24 Years

It is recommended that ASCCP guidelines for management of AGC be followed for all women, including those aged 21–24 years (BII).

Management of Benign Glandular Changes. For asymptomatic premenopausal women with benign endometrial cells, endometrial stromal cells, or histiocytes, no further evaluation is recommended (BII). For postmenopausal women with benign endometrial cells, endometrial assessment is recommended (BII). For posthysterectomy patients with a cytologic report of benign glandular cells, no further evaluation is recommended (BII).

MANAGEMENT OF CIN AND HISTOLOGIC AIS

CIN 1 and No CIN Found at Colposcopy After Abnormal Cytology

CIN 1 is the histologic manifestation of HPV infection. Although most CIN 1 lesions are associated with oncogenic HPV, HPV-16 is less common in CIN 1 than in CIN 3, and nononcogenic HPV types are also commonly found in CIN 1 lesions (82, 83). The natural history of CIN 1 is similar to that of HPV-positive ASC-US and LSIL in the absence of CIN, suggesting similar management. Regression rates are high, especially in younger women (32, 64), and progression to CIN 2+ is uncommon (64, 84).

The risk of occult CIN 3+ among women with CIN 1 at colposcopic biopsy is linked to the risk conveyed by prior cytology. KPNC data showed similar, relatively low 5-year risk of CIN 3+ when CIN 1 or no lesion was diagnosed after ASC-US or LSIL, but a substantially higher risk after HSIL, ASC-H, and AGC. For example, women with CIN 1 after LSIL or HPV-positive ASC-US had a 5-year risk of CIN 3+ of 3.8%, while those with CIN 1 after HSIL had a 5-year risk of CIN 3+ of 15% (68).

Failure to detect CIN 2+ at colposcopy in women with HSIL does not mean that a CIN 2+ lesion has been excluded, although occult carcinoma is unlikely. As a result, women with HSIL who do not have immediate diagnostic excision require close follow-up. Few studies

of the natural history of HSIL managed without treatment have been reported, and follow-up in those is limited (68); management relies on expert opinion.

Women with minor cytologic abnormalities have similar risk for CIN 3+ whether colposcopy shows CIN 1 or no lesion (64, 68). Since CIN 3+ risk is elevated for women with either HPV-16 or HPV-18 or persistent oncogenic HPV infection of any type even when cytology is negative, guidelines must provide for follow-up for women with these "lesser abnormalities" even when no CIN is found. These "lesser abnormalities" include HPV-16 or HPV-18 positivity, persistent untyped oncogenic HPV, ASC-US, and LSIL.

The management of CIN 1 in endocervical samples merits special attention. Traditional management strategies prescribed excisional therapy for women with CIN on endocervical sampling. However, these strategies preceded full understanding of the high spontaneous regression rates of CIN 1. Endocervical samples are often contaminated by ectocervical lesions. Women with CIN 1 on endocervical sampling have a low risk for CIN 2+ (85, 86) (Fukuchi E, Fetterman B, Poitras N, Kinney W, Lorey T, Little RD. Risk of cervical precancer and cancer in women with cervical intraepithelial neoplasia grade 1 on endocervical curettage. J Low Genit Tract Dis [in press]). Current guidelines on management of CIN 1 on endocervical sampling do not apply when CIN 2, CIN 3, or CIN 2,3 is specified or when the lesion seen cannot be graded, as an associated invasive cancer cannot be excluded without a diagnostic excision procedure.

Management of Women With CIN 1 or No Lesion Preceded by "Lesser Abnormalities" (Fig. 13). Co-testing at 1 year is recommended (BII). If both the HPV test and cytology are negative, then age-appropriate retesting 3 years later is recommended (cytology if age is younger than 30 years, co-testing if 30 years of age or older). If all tests are negative, then return to routine screening is recommended (BII). If any test is abnormal, then colposcopy is recommended (CIII).

If CIN 1 persists for at least 2 years, either continued follow-up or treatment is acceptable (CII). If treatment is selected and the colposcopic examination is adequate, either excision or ablation is acceptable (AI). A diagnostic excisional procedure is recommended if the colposcopic examination is inadequate; the endocervical sampling contains CIN 2,CIN 3, CIN 2,3 or ungraded CIN; or the patient has been previously treated (AIII). Treatment modality should be determined by the judgment of the clinician and should be guided by experience, resources, and clinical value for the specific patient (A1II). In patients with CIN 1 and an inadequate colposcopic examination, ablative procedures are unacceptable (EI). Podophyllin or podophyllin-related products are unacceptable for use in the vagina

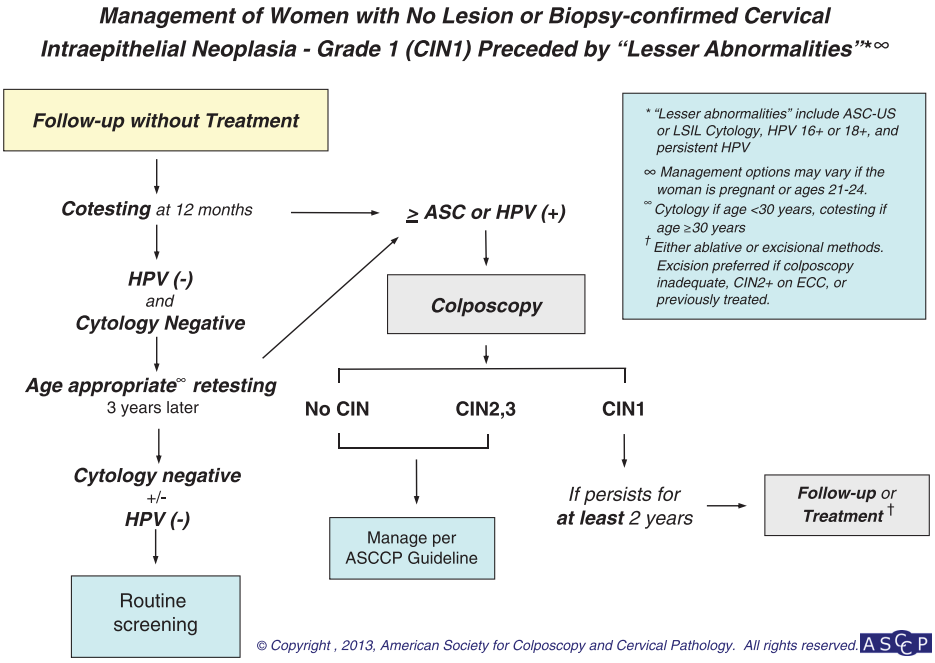


Figure 13.

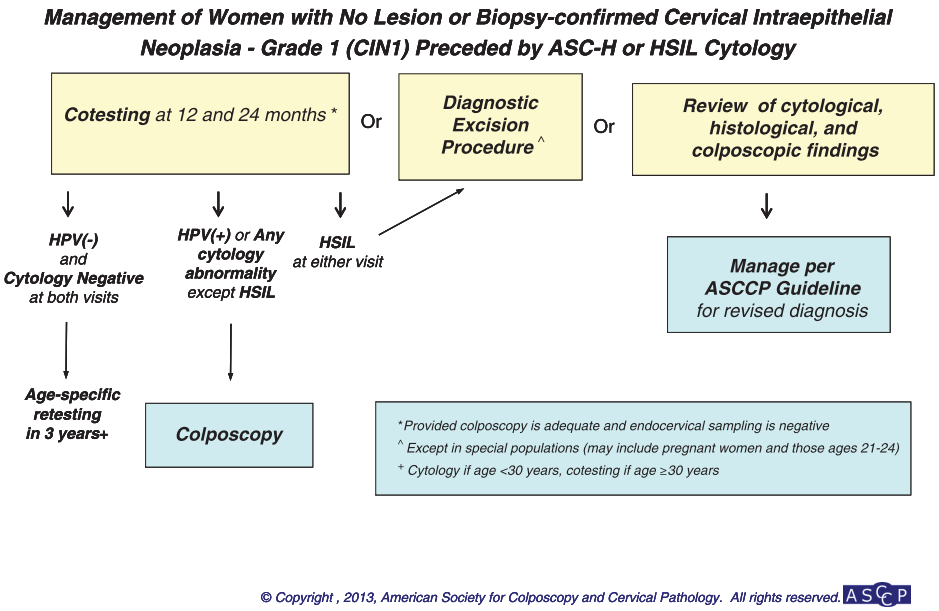


Figure 14.

or on the cervix (EII). Hysterectomy as the primary and principal treatment for histologically diagnosed CIN 1 is unacceptable (EII).

Management of Women With CIN 1 or No Lesion Preceded by ASC-H or HSIL (**Fig. 14**). When CIN 2+ is not identified histologically, either a diagnostic excisional procedure or observation with co-testing at 12 months and 24 months is recommended, provided in the latter case that the colposcopic examination is adequate and the endocervical sampling is negative. (BIII). In this circumstance, it is acceptable to review the cytologic, histologic, and colposcopic findings; if the review yields a revised interpretation, management should follow guidelines for the revised interpretation (BII). If observation with co-testing is elected and both co-tests are negative, return for retesting in 3 years is recommended. If any test is abnormal, repeat colposcopy is recommended. A diagnostic

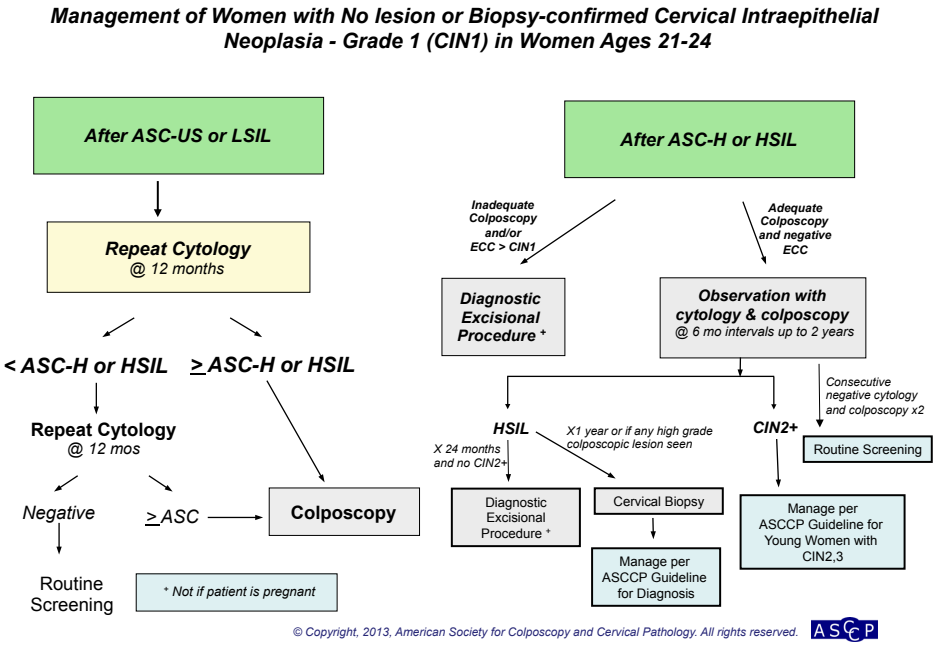


Figure 15.

excisional procedure is recommended for women with repeat HSIL cytologic results at either the 1-year or 2-year visit (CIII).

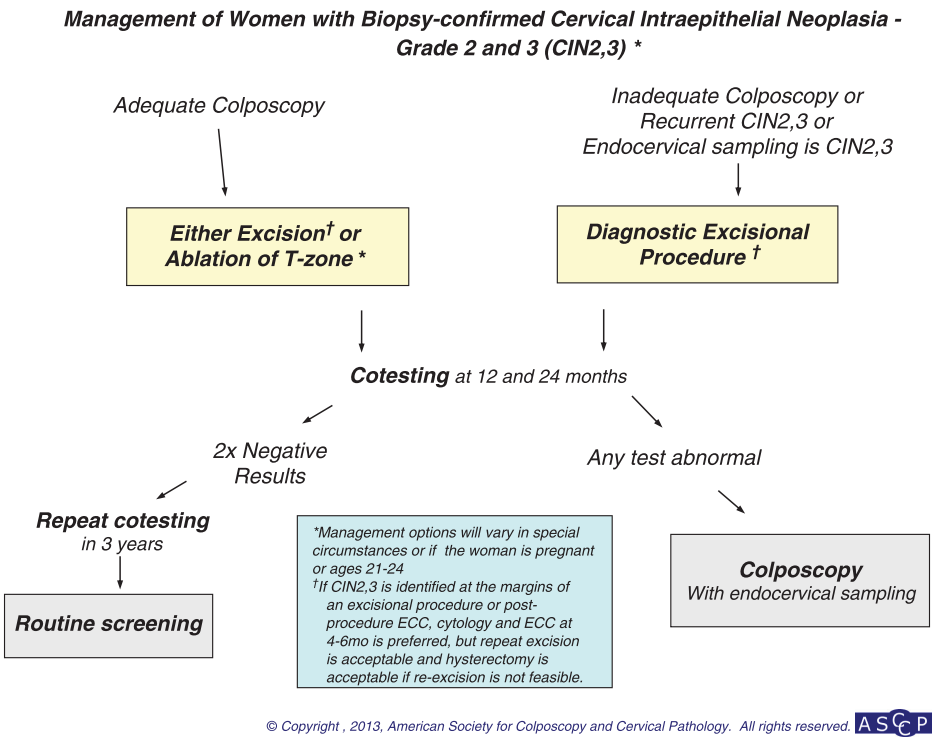
Management of Women With CIN 1 on Endocervical Sampling. When CIN 1 is detected on endocervical sampling after lesser abnormalities but no CIN 2+ is detected in colposcopic biopsies, management should follow ASCCP management guidelines for CIN 1, with the addition of repeat endocervical sampling in 12 months (BII). For women with CIN 1 on endocervical sampling and cytology reported as ASC-H, HSIL, or AGC, or with a colposcopic biopsy reported as CIN 2+, management according to the ASCCP management guidelines for the specific abnormality is recommended (BII). For women not treated, repeat endocervical sampling at the time of evaluation for the other abnormality is recommended (BII).

CIN 1 in Special Populations

Women Aged 21–24 Years (Fig. 15). For women aged 21–24 years with CIN 1 after ASC-US or LSIL cytology, repeat cytology at 12-month intervals is recommended. Follow-up with HPV testing is unacceptable (EII). For women with ASC-H or HSIL+ at the 12-month follow up, colposcopy is recommended. For women with ASC-US or worse at the 24 month follow up, colposcopy is recommended. After two consecutive negative tests, routine screening is recommended. (BII)

For women aged 21–24 years with CIN 1 after ASC-H or HSIL cytology, observation for up to 24 months using both colposcopy and cytology at 6-month intervals is recommended, provided the colposcopic examination is adequate and endocervical assessment is negative (BIII). If CIN 2, CIN 3, or CIN 2,3 is identified histologically, management should follow the guideline for the management of young women with CIN 2, CIN 3, or CIN 2,3 (BIII, see "Management of Women With CIN 2, CIN 3, and CIN 2,3"). If during follow-up a high-grade colposcopic lesion is identified or HSIL cytology persists for 1 year, biopsy is recommended (BIII). If HSIL persists for 24 months without identification of CIN 2+, a diagnostic excisional procedure is recommended (BIII). When colposcopy is inadequate or CIN 2, CIN 3, CIN 2,3 or ungraded CIN is identified on endocervical sampling, a diagnostic excision procedure is recommended (BII).

Regardless of antecedent cytology, treatment of CIN 1 in women aged 21–24 years is not recommended (BII).



© Copyright , 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

Figure 16.

Pregnant Women. For pregnant women with a histologic diagnosis of CIN 1, follow-up without treatment is recommended (BII). Treatment of pregnant women for CIN 1 is unacceptable.

CIN 2, CIN 3, and CIN 2,3

While distinction between CIN 2 and CIN 3 is difficult in individual cases, regression rates are lower and progression to cancer more common for women with CIN 3 than for those with CIN 2 (87, 88). Cervical intraepithelial neoplasia 2 remains the consensus threshold for treatment in the United States, except in special circumstances. Women with unambiguous CIN 3 have the immediate precursor to invasive cancer and should not be observed, regardless of age or concern about future fertility.

After treatment for CIN 2+, recurrence risk remains well above that of women with negative co-test results throughout observation periods that have been reported to date (89). After two negative co-tests in the first 2 years after treatment, risk is similar to that of women with a negative Pap test, suggesting a 3-year interval between surveillance examinations (89). Whether routine screening may be appropriate after three or more negative co-tests is unclear.

The objective of screening during pregnancy is to identify cervical cancer. Cervical intraepithelial neoplasia 3 does not pose a risk to the pregnancy and poses no immediate risk to the mother. Treatment during pregnancy carries substantial risk for hemorrhage and pregnancy loss.

Management of Women With CIN 2, CIN 3, and CIN 2,3 (Fig. 16)

Initial Management. For women with a histologic diagnosis of CIN 2, CIN 3, or CIN 2,3 and adequate colposcopy, both excision and ablation are acceptable treatment modalities, except in pregnant women and young women (AI). A diagnostic excisional procedure is recommended for women with recurrent CIN 2, CIN 3, or CIN 2,3 (AII). Ablation is unacceptable and a diagnostic excisional procedure is recommended for women with a histologic diagnosis of CIN 2, CIN 3, or CIN 2,3 and inadequate colposcopy or endocervical sampling showing CIN 2, CIN 3, CIN 2,3, or CIN not graded (AII). Observation of CIN 2, CIN 3, or CIN 2,3 with sequential cytology and colposcopy is unacceptable, except in pregnant women and young women (EII). Hysterectomy is unacceptable as primary therapy for CIN 2, CIN 3, or CIN 2,3 (EII).

Follow-Up After Treatment. For women treated for CIN 2, CIN 3, or CIN 2,3, co-testing at 12 months and 24 months is recommended (BII). If both co-tests are

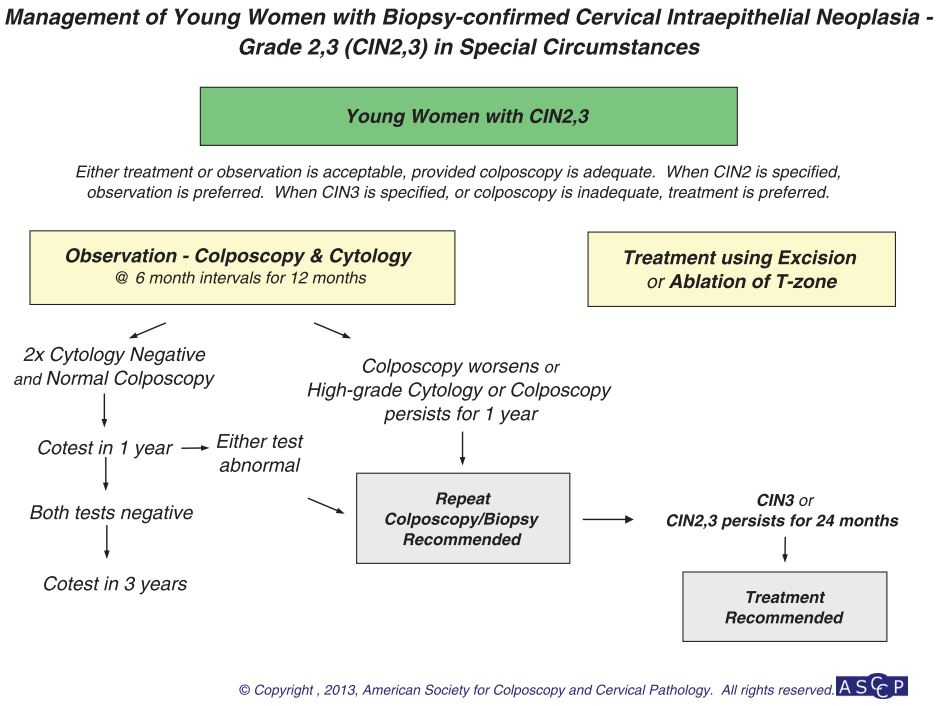


Figure 17.

negative, retesting in 3 years is recommended (BII). If any test is abnormal, colposcopy with endocervical sampling is recommended (BII). If all tests are negative, routine screening is recommended for at least 20 years, even if this extends screening beyond 65 years of age (CIII). Repeat treatment or hysterectomy based on a positive HPV test is unacceptable (EII).

If CIN 2, CIN 3, or CIN 2,3 is identified at the margins of a diagnostic excisional procedure or in an endocervical sample obtained immediately after the procedure, reassessment using cytology with endocervical sampling at 4–6 months after treatment is preferred (BII). Performing a repeat diagnostic excisional procedure is acceptable (CIII). Hysterectomy is acceptable if a repeat diagnostic procedure is not feasible (CIII).

A repeat diagnostic excisional procedure or hysterectomy is acceptable for women with a histologic diagnosis of recurrent or persistent CIN 2, CIN 3, or CIN 2,3 (BII).

CIN 2, CIN 3, or CIN 2,3 in Special Populations

Young Women (Fig. 17). For young women with a histologic diagnosis of CIN 2,3 not otherwise specified, either treatment or observation for up to 12 months using both colposcopy and cytology at 6-month intervals is acceptable, provided colposcopy is adequate. (BIII) When a histologic diagnosis of CIN 2 is specified for a young woman, observation is preferred but treatment is acceptable. If the colposcopic appearance of the lesion worsens or if HSIL cytology or a high-grade colposcopic lesion persists for 1 year, repeat biopsy is recommended (BIII).

After two consecutive negative cytology results, an additional co-test 1 year later is recommended (BIII). If the additional co-test is negative, then repeat co-testing in 3 years is recommended (BIII). Colposcopy is recommended if either the 2-year or 5-year co-test is abnormal (BIII).

Treatment is recommended if colposcopy is inadequate, if CIN 3 is specified, or if CIN 2 or CIN 2,3 persists for 24 months (BII). For women aged 21–24 years who are treated, follow-up according to ASCCP guidelines for treated CIN 2, CIN 3, or CIN 2,3 is recommended (BIII).

Treatment is recommended if CIN 3 is subsequently identified or if CIN 2, CIN 3, or CIN 2,3 persists for 24 months (BII).

Pregnant Women. In the absence of invasive disease or advanced pregnancy, additional colposcopic and cytologic examinations are acceptable in pregnant women with a histologic diagnosis of CIN 2, CIN 3, or CIN 2,3 at intervals no more frequent than every 12 weeks (BII). Repeat biopsy is recommended only if the appearance of the lesion worsens or if cytology suggests invasive cancer (BII). Deferring reevaluation until at least 6 weeks postpartum is acceptable (BII). A diagnostic excisional procedure is recommended only if invasion is suspected (BII). Unless invasive cancer is identified, treatment is unacceptable (EII). Reevaluation with cytology and colposcopy is recommended no sooner than 6 weeks postpartum (CIII).

ADENOCARCINOMA IN SITU (AIS)

The incidence of AIS is low but rising (90). Management of AIS is controversial, as many assumptions used to justify conservative management for women with CIN 2 and CIN 3 do not apply. For example, colposcopic changes associated with AIS can be minimal, so determining the limits of a lesion can be difficult. AIS frequently extends into the endocervical canal, complicating determination of the desired depth of excision. AIS can be multifocal and discontinuous, so negative margins on an excision specimen do not provide assurance that the disease has been completely excised. Invasive cancer cannot be excluded without a diagnostic excisional procedure.

For these reasons, total hysterectomy remains the treatment of choice in women who have completed childbearing. For women who wish to maintain fertility, observation is an option, although it carries a less than 10% risk of persistent AIS and a small risk of cancer even when excision margins are negative (91–3). Like margin status, endocervical sampling at the time of an excisional procedure also predicts residual disease (94). Moreover, a negative HPV test after treatment identifies women at low risk for persistent or recurrent AIS (94). In 2001, knife conization was favored over loop excision because margin status and the interpretability of margins are critical to future treatment planning. In 2006, wording was changed to allow diagnostic excision using any modality, but care must be taken to keep the specimen intact and margins interpretable, avoiding fragmentation of the specimen, including "top-hat" serial endocervical excisions. This may require use of larger loops than those employed to excise visible squamous lesions.

Management of Women With AIS (Fig. 18)

Hysterectomy is preferred for women who have completed childbearing and have a histologic diagnosis of AIS on a specimen from a diagnostic excisional procedure

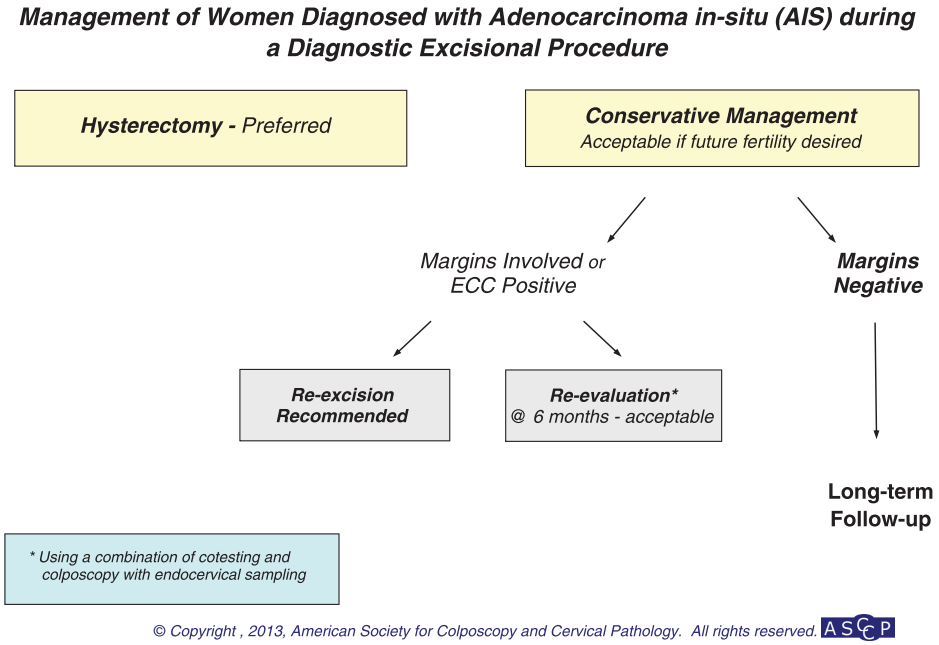


Figure 18.

(BIII). Conservative management is acceptable if future fertility is desired (AII). If conservative management is planned and the margins of the specimen are involved or endocervical sampling obtained at the time of excision contains CIN or AIS, reexcision to increase the likelihood of complete excision is preferred. Reevaluation at 6 months using a combination of co-testing and colposcopy with endocervical sampling is acceptable in this circumstance. Long-term follow-up is recommended for women who do not undergo hysterectomy (CIII).

RECOMMENDATIONS FOR FUTURE RESEARCH

Literature review for the 2012 ASCCP Consensus Guidelines Conference identified several issues important to patient management that lack high-level evidence.

Follow-up is insufficient to determine posttreatment outcomes or optimal long-term follow-up intervals for women with treated CIN 2 and CIN 3 managed with serial co-testing. Evidence to guide management of women with negative colposcopy after abnormal cytology or with CIN 1 is also scanty. The path to routine screening for these women is based on consensus expert opinion and should be modified as evidence becomes available.

Follow-up studies of women managed using HPV genotyping, p16 and other immunostains, cytogenetics, and other markers are needed to guide their incorporation into management of cervical abnormalities. The effect of HPV vaccination on large cohorts over long periods of follow-up remains to be studied, and whether prior HPV vaccination alters natural history or management of cytologic or histologic abnormalities remains unknown. Prospective study of the negative consequences of screening, diagnosis, and treatment are needed to allow balancing of risks and benefits.

Outcomes analyses using the LAST Project's two-tier squamous intraepithelial lesions (SIL) terminology are needed to direct how translation of three-tier CIN terminology to the two-tier terminology can be made and to define how specific management recommendations for histologic diagnoses in the two-tier system can be created (See Box 2). In particular, studies of the safety of observation for young women with histologic HSIL are needed, as reports to date have included diagnostic excision as a study endpoint. Estimates of regression and progression rates and the proportion of women who eventually require excision are needed. Long-term outcomes after apparent regression without treatment are unknown.

As the number and sophistication of tools applied to cervical cancer prevention continue to increase, the complexity of management promises to grow. Electronic medical records and bedside and pocket computers hold great promise for assisting clinicians and patients in negotiating this complexity. Development of risk scoring that incorporates past screening and treatment history into management decisions may help to balance risks and

benefits on a more individualized level than consensus guidelines. Future consensus conferences will be needed to integrate new approaches.

REFERENCES

1. Solomon D, Davey D, Kurman R, Moriarty A, O'Connor D, Prey M, et al. The 2001 Bethesda System: terminology for reporting results of cervical cytology. JAMA 2002; 287:2114–9.

2. ASC-US-LSIL Triage Study (ALTS) Group. Results of a randomized trial on the management of cytology interpretations of atypical squamous cells of undetermined significance. Am J Obstet Gynecol 2003;188:1383–92.

3. ASC-US-LSIL Triage Study (ALTS) Group. A randomized trial on the management of low-grade squamous intraepithelial lesion cytology interpretations. Am J Obstet Gynecol 2003;188:1393–400.

4. Wright TC, Cox JT, Massad LS, Twiggs LB, Wilkinston EJ. 2001 Consensus guidelines for the management of women with cervical cytological abnormalities and cervical cancer precursors: Part 1: Cytological abnormalities. JAMA 2002; 287: 2120–9.

5. Wright TC Jr, Cox JT, Massad LS, Carlson J, Twiggs LB, Wilkinson EJ; 2001 ASCCP-sponsored Consensus Workshop. 2001 consensus guidelines for the management of women with cervical intraepithelial neoplasia. J Low Genit Tract Dis. 2003 Jul;7(3):154–67.

6. Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D; 2006 ASCCP-Sponsored Consensus Conference. 2006 consensus guidelines for the management of women with abnormal cervical screening tests. J Low Genit Tract Dis 2007;11:201–22.

7. Wright TC, Massad LS, Dunton CJ, Spitzer M, Wilkiinson EJ, Solomon D for the 2006 ASCCP-sponsored consensus conference. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in-situ. Am J Obstet Gynecol. 2007;197:340–5.

8. Davey DD, Austin RM, Birdsong G, Buck HW, Cox JT, Darragh TM, et al. ASCCP patient management guidelines: Pap test specimen adequacy and quality indicators. J Low Genit Tract Dis 2002;6:195–9.

9. Davey DD, Cox JT, Austin RM, Birdsong G, Colgan TJ, Howell LP, et al. Cervical cytology specimen adequacy: Updated patient management guidelines. J Low Genit Tract Dis 2008;12:71–81.

10. Saslow D, Solomon D, Lawson HW, Killackey M, Kulasingam SL, Cain J et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. CA Cancer J Clin 2012;62:147–72.

11. Moyer VA, LeFevre ML, Siu AL, Bibbins-Domingo K, Curry SJ, Flores G, et al for the U.S. Preventive Services Task Force. Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;156:880–91.

12. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Thomas Lorey T, et al. Benchmarking CIN3+ risk as the basis for incorporating HPV and Pap cotesting into cervical screening and management guidelines. J Lower Genit Tract Dis 2013;17:S28–S35.

13. Castle PE, Sideri M, Jeronimo J, Solomon D, Schiffman M. Risk assessment to guide the prevention of cervical cancer. J Low Genit Tract Dis 2008;12:1–7

14. Darragh TM, Colgan TJ, Cox JT, Heller DS, Henry MR, Luff RD, et al; Members of LAST Project Work Groups. The Lower Anogenital Squamous Terminology Standardization Project for HPV-associated lesions: background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology. J Low Genit Tract Dis 2012;16:205–42.

15. Mogensen ST, Bak M, Dueholm M, Frost L, Knolblaugh NO, Praest J, et al. Cytobrush and endocervical curettage in the diagnosis of dysplasia and malignancy of the uterine cervix. Acta Obstet Gynecol Scand 1997;76:69–73.

16. Goksedef BP, Api M, Kaya O, Gorgen H, Tarlaci A, Cetin A. Diagnostic accuracy of two endocervical sampling method: randomized controlled trial. Arch Gynecol Obstet 2013;287:117–22.

17. Martin-Hirsch PPL, Paraskevaidis E, Bryant A, Dickinson HO, Keep SL. Surgery for cervical intraepithelial neoplasia. Cochrane Database of Systematic Reviews 2010, Issue 6. Art. No.: CD001318. DOI: 10.1002/14651858.CD001318.pub2.

18. Kyrgiou M, Tsoumpou I, Vrekoussis T, Martin-Hirsch P, Arbyn M, Prendiville W, et al. The up-to-date evidence on colposcopy practice and treatment of cervical intraepithelial neoplasia: the Cochrane colposcopy and cervical cytopathology collaborative group (C5 group) approach. Cancer Treat Rev 2006;32:516–23.

19. Nuovo J, Melnikow J, Willan AR, Chan BK. Treatment outcomes for squamous intraepithelial lesions. Int J Gynaecol Obstet 2000;68:25–33.

20. Kalliala I, Nieminen P, Dyba T, Pukkala E, Anttilla A. Cancer free survival after CIN treatment: comparisons of treatment methods and histology. Gynecol Oncol 2007;105: 228–33.

21. Paraskevaidis E, Arbyn M, Sotiriadis A, Diakomanolis E, Martin-Hirsch P, Koliopoulos G, et al. The role of HPV DNA testing in the follow-up period after treatment for CIN: a systematic review of the literature. Cancer Treat Rev 2004; 30:205–11.

22. Jakobsson M, Gissler M, Paavonen J, Tapper AM. Long-term mortality in women treated for cervical intraepithelial neoplasia. BJOG 2009;116:838–44.

23. Kalogirou D, Antoniou G, Karakitsos P, Potsis D, Kalogirou O, Giannikos L. Predictive factors used to justify

hysterectomy after loop conization: increasing age and severity of disease. Eur J Gynaecol Oncol 1997;18:113–6.

24. Ghaem-Maghami S, Sagi S, Majeed G, Soutter WP. Incomplete excision of cervical intraepithelial neoplasia and risk of treatment failure: a meta-analysis. Lancet Oncol 2007; 8:985–93.

25. Kocken M, Uijterwaal MH, de Vries AL, Berkhof J, Ket JC, Helmerhorst TJ, et al. High-risk human papillomavirus testing versus cytology in predicting post-treatment disease in women treated for high-grade cervical disease: a systematic review and meta-analysis. Gynecol Oncol 2012;125:500–7.

26. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-Year Risk of CIN 3+ and Cervical Cancer Among Women With HPV Testing of ASC-US Pap Results. J Low Genit Tract Dis 2013;17:S36–S42.

27. Jakobsson M, Gissler M, Paavonen J, Tapper AM. Loop electrosurgical excision procedure and the risk for preterm birth. Obstet Gynecol 2009;114:504–10.

28. Sadler L, Saftlas A, Wang W, Exeter M, Whittaker J, McCowan L. Treatment for cervical intraepithelial neoplasia and risk of preterm delivery. JAMA 2004;29:2100–6.

29. Bruinsma FJ, Quinn MA. The risk of preterm birth following treatment for precancerous changes in the cervix: a systematic review and meta-analysis. BJOG 2011;118:1031–41.

30. Khalid S, Dimitriou E, Conroy R, Paraskevaidis E, Kyrgiou M, Harrity C, et al. The thickness and volume of LLETZ specimens can predict the relative risk of pregnancy-related morbidity. BJOG 2012;119;685–91.

31. Moscicki AB, Ma Y, Wibblesman C, Darragh TM, Powers A, Farhat S, et al. Rate of and risks for regression of cervical intraepithelial neoplasia 2 in adolescents and young women. Obstet Gynecol 2010;116:1373–80.

32. Moscicki AB, Shiboski S, Hills NK, Powell KJ, Jay N, Hanson EN, et al. Regression of low-grade squamous intraepithelial lesions in young women. Lancet. 2004;364:1678–83.

33. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-Year Risk of CIN 3+ to Guide the Management of Women Aged 21 to 24 Years. J Low Genit Tract Dis 2013;17:S64–S68.

34. Moscicki AB, Cox JT. Practice improvement in cervical screening and management (PICSM): symposium on management of cervical abnormalities in adolescents and young women. J Low Genit Tract Dis. 2010 Jan;14:73–80.

35. Benard VB, Watson M, Castle PE, Saraiya M. Cervical Cancer Rates Among Young Females in the United States. Obstet Gynecol 2012;120:1117–23.

36. Winer RL, Lee SK, Hughes JP, Adam DE, Kiviat NB, Koutsky LA. Genital human papillomavirus infection: incidence and risk factors in a cohort of female university students. Am J Epidemiol. 2003;157:218–26.

37. Moscicki AB, Hills N, Shiboski S, Powell K, Jay N, Hanson E, et al. Risks for incident human papillomavirus infection and low-grade squamous intraepithelial lesion development in young females. JAMA. 2001;285:2995–3002.

38. Sharp L, Cotton S, Carsin AE, Gray N, Thornton A, Cruickshank M, et al on behalf of the TOMBOLA Group. Factors associated with psychological distress following colposcopy among women with low-grade abnormal cervical cytology: a prospective study within the Trial Of Management of Borderline and Other Low-grade Abnormal smears (TOMBOLA). Psychooncology. 2011 Dec 12. doi: 10.1002/pon.2097. [Epub ahead of print]

39. Kahn J, Slap G, Bernstein D, Kollar L, Tissot A, Hillard P, et al. Psychological, behavioral, and interpersonal impact of human papillomavirus and Pap test results. J Womens Health 2005;14:650–9.

40. Kahn J, Slap G, Bernstein D, Tissot A, Kollar L, Hillard P, et al. Personal Meaning of Human Papillomavirus and Pap Test Results in Adolescent and Young Adult Women. Health Psychol 2007;26:192–200.

41. Lerner D, Parsons SK, Justicia-Linde F, Chelmow D, Chang H, Rogers WH, et al. The impact of pre-cancerous cervical lesions on functioning at work and work productivity. J Occup Environ Med. 2010;52:926–33.

42. Moriarty AT, Clayton AC, Zaleski S, Henry MR, Schwartz MR, Eversole GM, et al. Unsatisfactory reporting rates: 2006 practices of participants in the College of American Pathologists interlaboratory comparison program in gynecologic cytology. Arch Pathol Lab Med. 2009;133:1912–6.

43. Hoda RS, Loukeris K, Abdul-Karim FW. Gynecologic cytology on conventional and liquid-based preparations: A comprehensive review of similarities and differences. Diagn Cytopathol. 2012 Apr 17. doi: 10.1002/dc.22842. [Epub ahead of print].

44. Hock YL, Ramaiah S, Wall ES, Harris AM, Marston L, Marshall J, et al. Outcome of women with inadequate cervical smears followed up for five years. J Clin Pathol 2003; 56:592–5

45. Ransdell JS, Davey DD, Zaleski S. Clinicopathologic correlation of the unsatisfactory Papanicolaou smear. Cancer (Cancer Cytopathol) 1997;81:139–43.

46. Siebers AG, Klinkhamer PJJM, Vedder JEM, Arbyn M, Bulten J. Causes and relevance of unsatisfactory and satisfactory but limited smears of liquid-based compared with conventional cervical cytology. Arch Pathol Lab Med 2012;136:76–83

47. Zhao C, Austin RM. High-risk human papillomavirus DNA test results are useful for disease risk stratification in women with unsatisfactory liquid-based cytology Pap test results. J Lower Genit Tract Dis 2009;13:79–84.

48. Holton T, Smith D, Terry M, Madgwick A, Levine T. The effect of lubricant contamination on ThinPrep liquid-based preparations. Cytopathology 2008;19:236–43.

49. Buntinx F, Brouwers M. Relation between sampling device and detection of abnormality in cervical smears: a meta-analysis of randomized and quasi-randomised studies. BMJ 1996;313:1285–90.

50. Martin-Hirsch P, Jarvis G, Kitchener H, Lilford R. Collection devices for obtaining cervical cytology samples. Cochrane Database Syst Rev 2000;CD001036.

51. Huang A, Quinn M, Tan J. Outcome in women with no endocervical component on cervical cytology after treatment for high-grade cervical dysplasia. Aust N Z J Obstet Gynaec 2009;49:426–8.

52. Mitchell H, Hocking J, Saville M. Cervical cytology screening history of women diagnosed with adenocarcinoma in situ of the cervix. A case-control study. Acta Cytol 2004; 48:595–600

53. Mitchell HS. Longitudinal analysis of histologic high-grade disease after negative cervical cytology according to endocervical status. Cancer 2001;93:237–40

54. Elumir-Tanner L, Doraty M. Management of Papanicolaou test results that lack endocervical cells. CMAJ 2011; 183:563–8.

55. Zhao C, Austin RM. Human papillomavirus DNA detection in ThinPrep Pap test vials is independent of cytologic sampling of the transformation zone. Gynecol Oncol 2007; 107:231–5.

56. Huang A, Quinn M, Tan J. Outcome in women with no endocervical component on cervical cytology after treatment for high-grade cervical dysplasia. Aust NZ J Obstet Gynaecol 2009;49:426–8.

57. Katki HA, Kinney WK, Fetterman B, Lorey T, Poitras NE, Cheung L, et al. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. Lancet Oncol. 2011;12:663–72

58. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-Year Risks of CIN 3+ and Cervical Cancer Among Women Who Test Pap-Negative But Are HPV-Positive. J Low Genit Tract Dis 2013;17:S56–S63.

59. Castle PE, Rodríguez AC, Burk RD, Herrero R, Wacholder S, Alfaro M, et al for the Proyecto Epidemiológico Guanacaste (PEG) Group. Short term persistence of human papillomavirus and risk of cervical precancer and cancer: population based cohort study. BMJ. 2009;339:b2569. doi: 10.1136/bmj.b2569.

60. Rodriguez AC, Schiffman M, Herrero R, Wacholder S, Hildesheim A, Castle PE, et al for the Proyecto Epidemiológico Guanacaste Group. Rapid clearance of human papillomavirus and implications for clinical focus on persistent infections. J Natl Cancer Inst 2008;100:513–7.

61. Stoler MH, Wright TC, Sharma A, Apple R, Gutekunst K, Wright TL. High-risk human papillomavirus testing in women with ASC-US cytology: results from the ATHENA HPV study. Am J Clin Pathol 2011;135:466–75.

62. Einstein MH, Martens MG, Garcia FA, Ferris DG, Mitchell AL, Day SP, et al. Clinical validation of the Cervista HPV HR and 16/18 genotyping tests for use in women with ASC-US cytology. Gynecol Oncol 2010;118:116–22.

63. Gage JC, Schiffman M, Solomon D, Wheeler CM, Castle PE. Comparison of measurements of human papillomavirus persistence for postcolposcopic surveillance for cervical precancerous lesions. Cancer Epidemiol Biomarkers Prev. 2010;19:1668–74.

64. Cox JT, Schiffman M, Solomon D. Prospective follow-up suggests similar risk of subsequent cervical intraepithelial neoplasia grade 2 or 3 among women with cervical intraepithelial neoplasia grade 1 or negative colposcopy and directed biopsy. Am J Obstet Gynecol 2003;188:1406–12.

65. Moore G, Fetterman B, Cox JT, Poitras N, Lorey T, Kinney W, et al. Lessons from practice: risk of CIN3 or cancer associated with an LSIL or HPV-positive ASC-US screening result in women aged 21–24. J Lower Genit Tract Dis 2010; 14:97–102.

66. Arbyn M, Sasieni P, Meijer CJ, Clavel C, Koliopoulos G, Dillner J. Chapter 9: clinical applications of HPV testing : a summary of meta-analyses. Vaccine 2006;24 (suppl 3):S78–S89.

67. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-Year Risks of CIN 2+ and CIN 3+ Among Women With HPV-Positive and HPV-Negative LSIL Pap Results. J Low Genit Tract Dis 2013;17:S43–S49.

68. Katki HA, Gage JC, Schiffman M, Castle PE, Fetterman B, Poitras NE, et al. Follow-up Testing After Colposcopy: Five-Year Risk of CIN 2+ After a Colposcopic Diagnosis of CIN 1 or Less. J Low Genit Tract Dis 2013;5:S69–S77.

69. Massad LS, Collins YC, Meyer PM. Biopsy correlates of abnormal cervical cytology classified using the Bethesda system. Gynecol Oncol 2001;82:516–22.

70. Alvarez RD, Wright TC. Effective cervical neoplasia detection with a novel optical detection system: a randomized trial. Gynecol Oncol 2007;104:281–9.

71. Dunn TS, Burke M, Shwayder J. A "see and treat" management for high grade squamous intraepithelial lesion Pap smears. J Lower Gen Tract Dis 2003;7:104–6.

72. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-year risk of cervical cancer and CIN3 for HPV-positive and HPV-negative high-grade Pap results. J Low Genit Tract Dis 2013;17:S50–S55.

73. Pretorius RG, Zhange WH, Belinson JL, Huang MN, Wu LY, Zhange X, et al. Colposcopically directed biopsy, random cervical biopsy, and endocervical curettage in the diagnosis of Cervical intraepithelial neoplasia II or worse. Am J Obstet Gynecol 2004;191:430–4.

74. Gage JC, Hanson VW, Abbey K, Dipery S, Gardner S, Kubota J, et al. Number of cervical biopsies and sensitivity of colposcopy. Obstet Gynecol 2006;108:264–72.

75. Guido R, Schiffman M, Solomon D, Burke L for the ASCUS/LSIL Triage Study (ALTS) Group. Post-colposcopy management strategies for women referred with low-grade squamous intraepithelial lesions of human papillomavirus DNA-positive atypical squamous cells of undetermined significance: a two-year prospective trial. Am J Obstet Gynecol 2003;188:1401–5.

76. Lee KR, Darragh TM, Joste NE, Krane JF, Sherman ME, Hurley LB, et al. Atypical glandular cells of undetermined significance (AGUS): interobserver reproducibility in cervical smears and corresponding thin-layer preparations. Am J Clin Pathol 2002;117:96–102.

77. Davey DD, Neal MH, Wilbur DC, Colgan TJ, Styer PE, Mody DR. Bethesda 2001 implementation and reporting rates: 2003 practices of participants in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology. Arch Pathol Lab Med 2004;128: 1224–9.

78. Zhao C, Florea A, Onisko A, Austin RM. Histologic follow-up results in 662 patients with Pap test findings of atypical glandular cells: results from a large academic womens hospital laboratory employing sensitive screening methods. Gynecol Oncol 2009;114:383–9.

79. Sharpless KE, Schnatz PF, Mandavilli S, Greene JF, Sorosky JI. Dysplasia associated with atypical glandular cells on cervical cytology. Obstet Gynecol 2005;105:494–500.

80. Castle PE, Fetterman M, Poitras N, Lorey T, Shaber R, Kinney W. Relationship of atypical glandular cell cytology, age and human papillomavirus detection to cervical and endometrial cancer risks. Obstet Gynecol 2010;115:243–8.

81. Simsir A, Carter W, Elgert P, Cangiarella J. Reporting endometrial cells in women 70 years and older: assessing the clinical usefulness of Bethesda 2001. Am J Clin Pathol 2005; 123:571–5.

82. Schlecht NF, Platt RW, Duarte-Franco E, Costa MC, Sobrinho JP, Prado JC, et al. Human papillomavirus infection and time to progression and regression of cervical intraepithelial neoplasia. J Natl Cancer Inst 2003;95:1336–43.

83. Sideri M, Iqidbashian S, Boveri S, Radice D, Casadio C, Spolti N, et al. Age distribution of HPV genotypes in cervical intraepithelial neoplasia. Gynecol Oncol 2011;212:510–3.

84. Trimble CL, Piantadosi S, Gravitt P, Ronnett B, Pizer E, Elko A, et al. Spontaneous regression of high-grade cervical dysplasia: effects of human papillomavirus type and HLA phenotype. Clin Cancer Res. 2005;11:4717–23.

85. Petersen S, Belnap C, Larsen WI, Farley J. Grading of squamous dysplasia in endocervical curettage specimens: The case for conservative management of mild endocervical dysplasia. J Reprod Med. 2007;52:917–21.

86. Gage JC, Duggan MA, Nation JG, Gao S, Castle PE. Comparative risk of high-grade histopathology diagnosis following a CIN1 finding in endocervical curettage vs. cervical biopsy. J Lower Genit Tract Dis 2012;17:137–41.

87. Ostor AG. Natural history of cervical intraepithelial neoplasia: A critical review. Intern J Gynecol Pathol 1993; 12:186–92.

88. Holowaty P, Miller AB, Rohan T, To T. Natural history of dysplasia of the uterine cervix. J Natl Cancer Inst 1999; 91:252–8.

89. Katki HA, Schiffman M, Castle PE, Fetterman B, Poitras NE, Lorey T, et al. Five-Year Risk of Recurrence After Treatment of CIN 2, CIN 3, or AIS: Performance of HPV and Pap Cotesting in Posttreatment Management. J Low Genit Tract Dis 2013;17:S78–S84.

90. Sherman ME, Wang SS, Carreon J, Devesa SS. Mortality trends for cervical squamous and adenocarcinoma in the United States. Relation to incidence and survival. Cancer. 2005;103:1258–64.

91. Bull-Phelps SL, Garner EI, Walsh CS, Gehrig PA, Miller DS, Schorge JO. Fertility-sparing surgery in 101 women with adenocarcinoma in situ of the cervix. Gynecol Oncol 2007; 107:316–9.

92. Costa S, Venturoli S, Negri G, Sideri M, Preti M, Pesaresi M, et al. Factors predicting the outcome of conservatively treated adenocarcinoma in situ of the uterine cervix: an analysis of 166 cases. Gynecol Oncol 2012;124:490–5.

93. van Hanegem N, Barroilhet LM, Nucci MR, Bernstein M, Feldman S. Fertility-sparing treatment in younger women with adenocarcinoma in situ of the cervix. Gynecol Oncol 2012;124:72–7.

94. Lea JS, Shin CH, Sheets EE, Coleman RL, Gehrig PA, Duska LR, et al. Endocervical curettage at conization to predict residual cervical adenocarcinoma in situ. Gynecol Oncol 2002;87:129–32.

APPENDIX A: ADDITIONAL COAUTHOR PARTICIPANTS, ACKNOWLEDGED NONAUTHOR DELEGATES, AND PARTICIPATING ORGANIZATIONS

See Appendix 2, available online at http://links.lww.com/LGT/A10, for financial disclosure information from the coauthor delegates.

Coauthor Delegates: Deborah Arrindell; James R. Bentley, MD; Monique A. Bertrand, MD; Lori A. Boardman, MD; Philip E. Castle, PhD, MPH; David Chelmow, MD; Janie Daddario, MSN, WHNP-BC; Diane D. Davey, MD; Linda Dominguez, CNP, RN; Levi S. Downs, Jr., MD; Patricia Fontaine, MD, MS; Julia C. Gage, PhD, MPH; Francisco A.R. Garcia, MD, MPH; Mohiedean Ghofrani, MD, MBA; Richard S. Guido, MD; Eric C. Huang, MD, PhD; Versie Johnson-Mallard, PhD, ARNP; Elizabeth A. Kostas-Polston, PhD, APRN, WHNP-BC; Robert Kurman, MD; Susan M. McFaul, MD; Deborah L. Nucatola, MD; R. Patricia P. Power, MD; Walter Prendiville, MD; Debbie Saslow, PhD; Karen Shea, MSN, WHNP-BC; Mary K. Sidawy, MD; Mario Sideri, MD; Kate Simon, PhD; Silvio Tatti, MD; Jeffrey Waldman, MD; Jason D. Wright, MD; Fred Wyand; and Laurie C. Zephyrin, MD, MPH, MBA

Nonauthor Delegates Whose Contribution is Acknowledged: Vicki B. Benard, PhD; Natalia Comella, PhD; MariBeth Gagnon, MS CT(ASCP) HTL; Ann Laros, MD; Mona Saraiya, MD, MPH; Elizabeth R. Unger, PhD, MD; and Rose H. Xu, PharmD, MSc.

Participating Organizations: American Academy of Family Physicians; American Board of Pathology; American Cancer Society; American College Health

Association; American College of Obstetricians and Gynecologists; American Social Health Association; American Society for Colposcopy and Cervical Pathology; American Society for Cytopathology; Association of Reproductive Health Professionals; CDC - Division of Cancer Prevention and Control; CDC - Division of High-Consequence Pathogens and Pathology; CDC - Division of Laboratory Science & Standards; College of American Pathologists; Food & Drug Administration; International Federation for Cervical Pathology and Colposcopy; International Gynecologic Cancer Society; National Cancer Institute; Nurse Practitioners in Women's Health; Planned Parenthood Federation of America; Society of Canadian Colposcopists; Society of Gynecologic Oncologists; Society of Obstetricians and Gynaecologists of Canada; and Women Veterans Health Strategic Healthcare Group.

APPENDIX B: DEFINITION OF TERMS

Colposcopy is the examination of the cervix, vagina, and, in some instances the vulva, with a colposcope after the application of a 3% to 5% acetic acid solution coupled with obtaining colposcopically directed biopsies of all lesions suspected of representing neoplasia.

Adequate colposcopy indicates that the entire squamocolumnar junction and the margins of any visible lesion can be visualized with the colposcope.

Co-testing is assessment for cervical disease using a combination of cytology and HPV testing at the same time, regardless of the cytology result.

Reflex HPV testing is the performance of HPV testing only in response to an abnormality to stratify risk and guide further management.

Endometrial sampling includes obtaining a specimen for histologic evaluation using an endometrial biopsy, dilation and curettage, or hysteroscopy.

Endocervical sampling includes obtaining a specimen for either histologic evaluation using an endocervical curette or a cytobrush or for cytologic evaluation using a cytobrush.

Endocervical assessment is the process of evaluating the endocervical canal for the presence of neoplasia using either a colposcope or endocervical sampling.

Diagnostic excisional procedure is the process of obtaining a specimen from the transformation zone and endocervical canal for histologic evaluation and includes laser conization, cold-knife conization, loop or needle electrosurgical excision, and loop electrosurgical conization.

Lesser abnormalities are those that carry lower risk of CIN 3+ than other results. These include negative cytology with either HPV-16 or HPV-18 or persistent untyped oncogenic HPV, ASC-US, and LSIL.

HPV, human papillomavirus; CIN, cervical intraepithelial neoplasia; ASC-US, atypical squamous cells of undetermined significance; LSIL, low-grade squamous intraepithelial lesions.

ASCCP

The society for lower genital tract disorders since 1964.

Algorithms

Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors

American Society for Colposcopy and Cervical Pathology

Introduction

Cytology

Since the publication of the 2006 consensus guidelines, new cervical cancer screening guidelines have been published and new information has become available which includes key cervical cancer screening and follow up, and cervical precancer management data over a nine year period among more than 1 million women cared for at Kaiser Permanente Northern California. Moreover, women under age 21 are no longer receiving cervical cancer screening and cotesting with high-risk HPV type assays, and cervical cytology is being used to screen women 30 years of age and older.

Therefore, in 2012 the American Society for Colposcopy and Cervical Pathology (ASCCP), together with its 24 partner professional societies, Federal agencies, and international organizations, began the process of revising the 2006 management guidelines. This culminated in the consensus conference held at the National Institutes of Health in September 2012. This report provides updated recommendations for managing women with cytological abnormalities. A more comprehensive discussion of these recommendations and their supporting evidence was published in the *Journal of Lower Genital Tract Disease* and *Obstetrics and Gynecology* and is made available on the ASCCP website at www.asccp.org.

Histopathology

Appropriate management of women with histo-pathologically diagnosed cervical precancer is an important component of cervical cancer prevention programs. Although the precise number of women diagnosed with cervical precancer each year in the U.S. is not known, it appears to be a relatively common occurence. In 2001 and 2006, the American Society for Colposcopy and Cervical Pathology and 28 partner professional societies, federal agencies, and international organizations, convened processes to develop and update consensus guidelines for the management of women with cervical precancer. Since then, considerable new information has emerged about management of young women, and the impact of treatment for precursor disease on pregnancy outcomes. Progress has also been made in our understanding of the management of women with adenocarcinoma in-situ, also a human papillomavirus (HPV)—associated precursor lesion to invasive cervical adenocarcinoma. Therefore, in 2012 the ASCCP, together with its partner organizations, reconvened the consensus process of revising the guidelines. This culminated in the September 2012 Consensus Conference held at the National Institutes of Health. This report provides the recommendations developed for managing women with cervical precancer. A summary of the guidelines themselves–including the recommendations for managing women with cervical cytological abnormalities — are published in JLGTD and Obstetrics & Gynecology.

© Copyright, 2002, 2006, 2013 American Society for Colposcopy and Cervical Pathology. All rights reserved

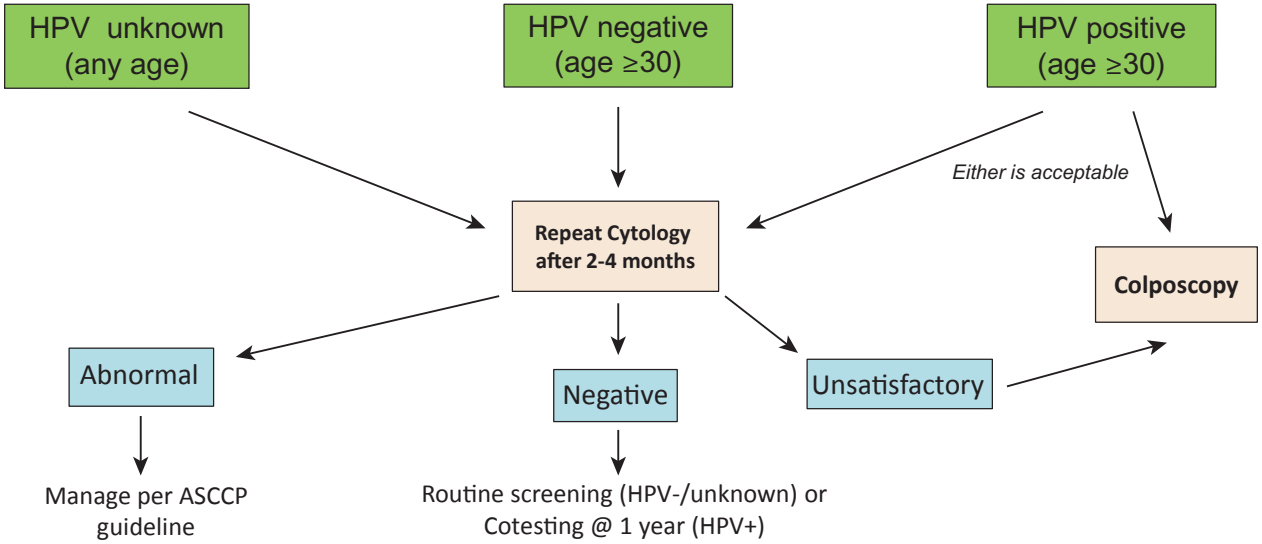
General Comments

Although the guidelines are based on evidence whenever possible, for certain clinical situations limited high-quality evidence exists. In these situations the guidelines are based on consensus expert opinion. Guidelines should never be a substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient since guidelines may not apply to all patient-related situations. Finally, both clinicians and patients need to recognize that while most cases of cervical cancer can be prevented through a program of screening and management of cervical precancer, no screening or treatment modality is 100% effective and invasive cervical cancer can develop in women participating in such programs.

The 2001 Bethesda System terminology is used for cytological classification. This terminology utilizes the terms low-grade squamous intraepithelial lesion (LSIL) and high-grade squamous intraepithelial lesion (HSIL) to refer to low-grade lesions and high-grade cervical cancer precursors respectively. For managing cervical precancer, the histopathological classification is two-tiered applying the terms cervical intraepithelial neoplasia grade 1 (CIN 1) to low-grade lesions and CIN2,3 to high-grade lesions. If using the 2012 Lower Anogenital Squamous Terminology (LAST), CIN1 is equivalent to histopathological LSIL and CIN2,3 is equivalent to histopathological HSIL. Please note that cytological LSIL is not equivalent to histopathological CIN 1 and cytological HSIL is not equivalent to histopathological CIN2,3. The current guidelines expand clinical indications for HPV testing based on studies using FDA-approved, validated HPV assays. Management decisions based on results using HPV tests not similarly validated may not result in outcomes intended by these guidelines. HPV testing should be restricted to high-risk (oncogenic) HPV types. Testing for low-risk (non-oncogenic) HPV types has no role in evaluating women with abnormal cervical cytological results. Therefore, whenever "HPV testing" is mentioned in the guidelines, it refers to testing for high-risk (oncogenic) HPV types only.

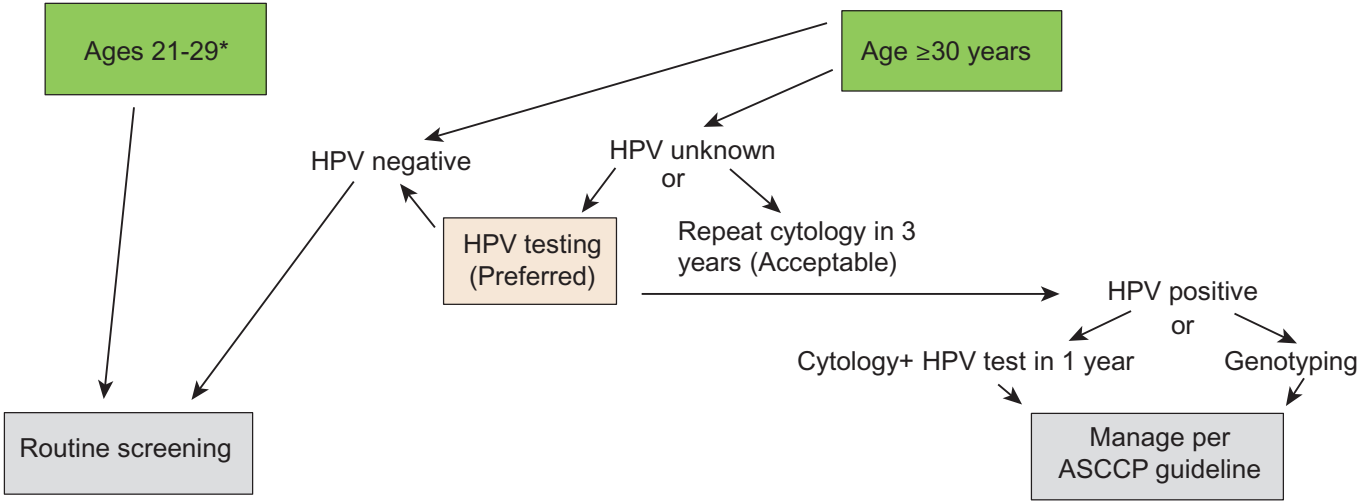
© Copyright, 2002, 2006, 2013 American Society for Colposcopy and Cervical Pathology. All rights reserved

Unsatisfactory Cytology



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

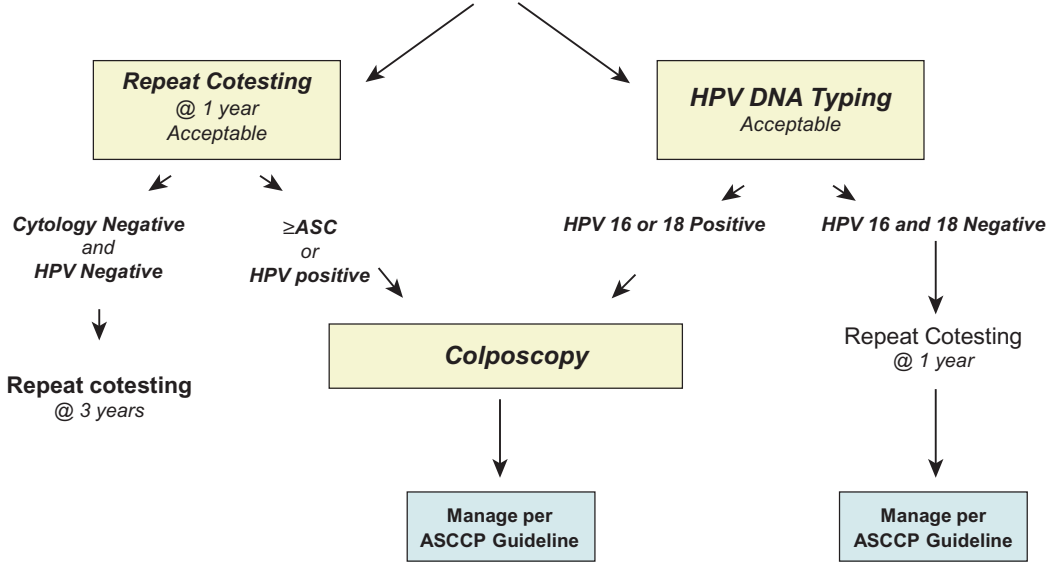
Cytology NILM but EC/TZ Absent/Insufficient



*HPV testing is unacceptable for managing women ages 21-29 years

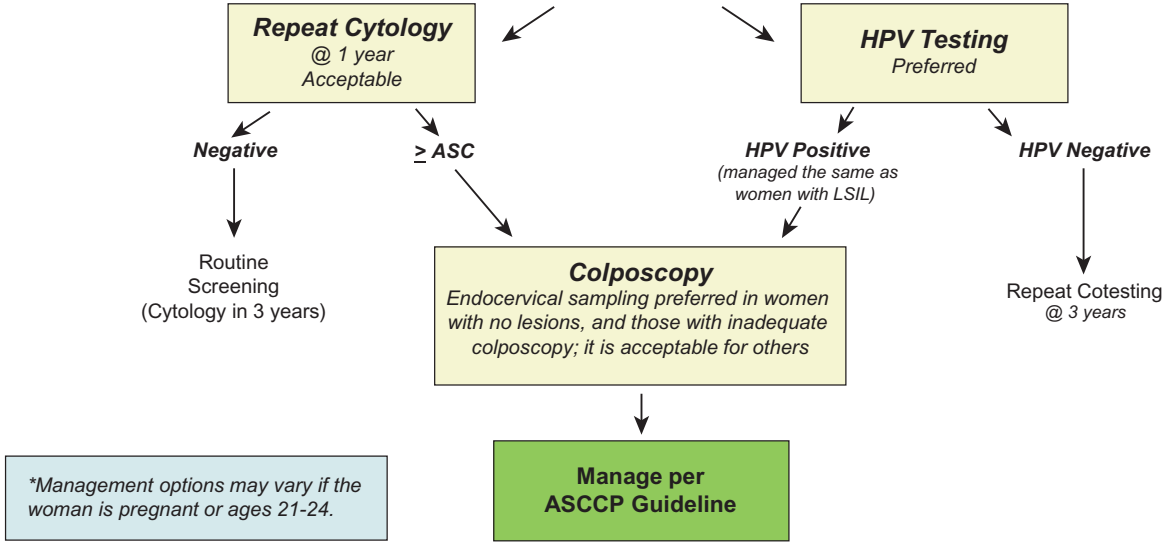
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women ≥ Age 30, who are Cytology Negative, but HPV Positive



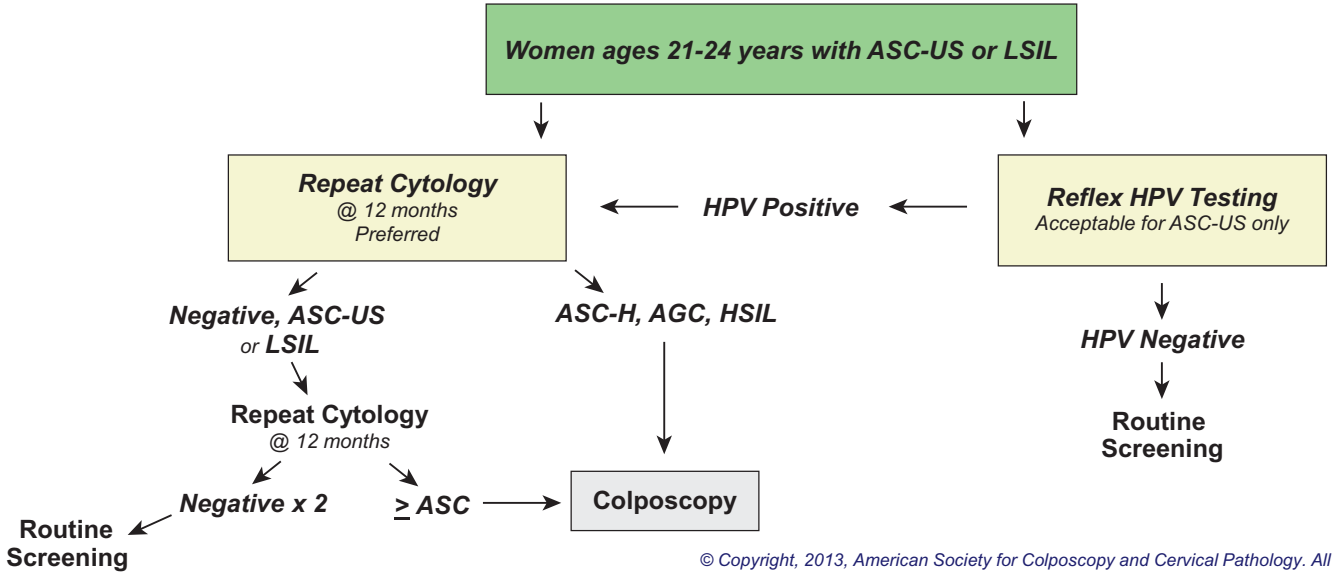
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US) on Cytology*



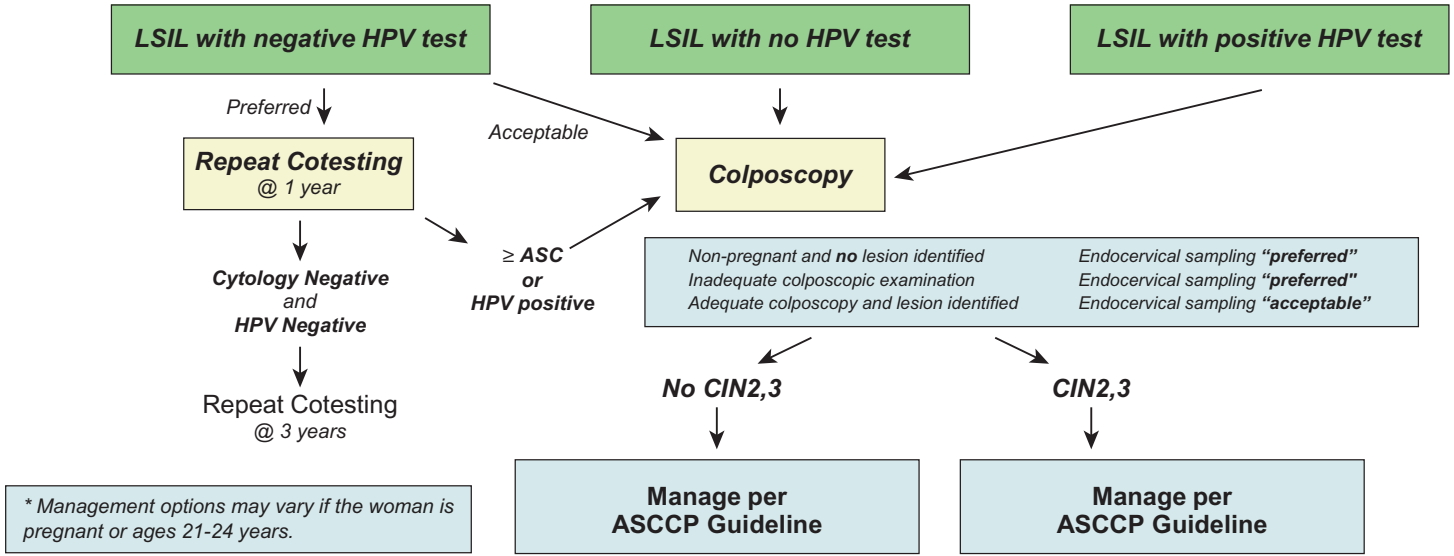
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women Ages 21-24 years with either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

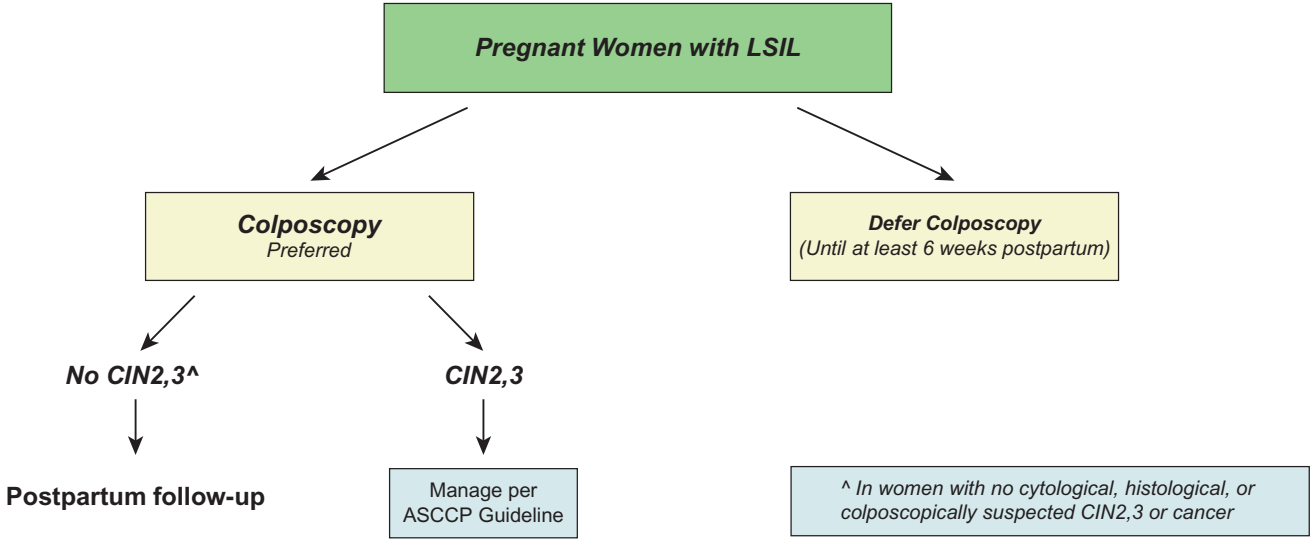
Management of Women with Low-grade Squamous Intraepithelial Lesions (LSIL)*



* Management options may vary if the woman is pregnant or ages 21-24 years.

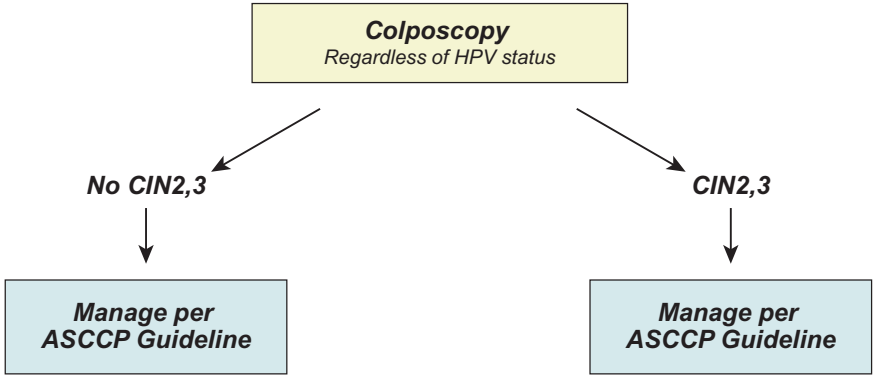
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

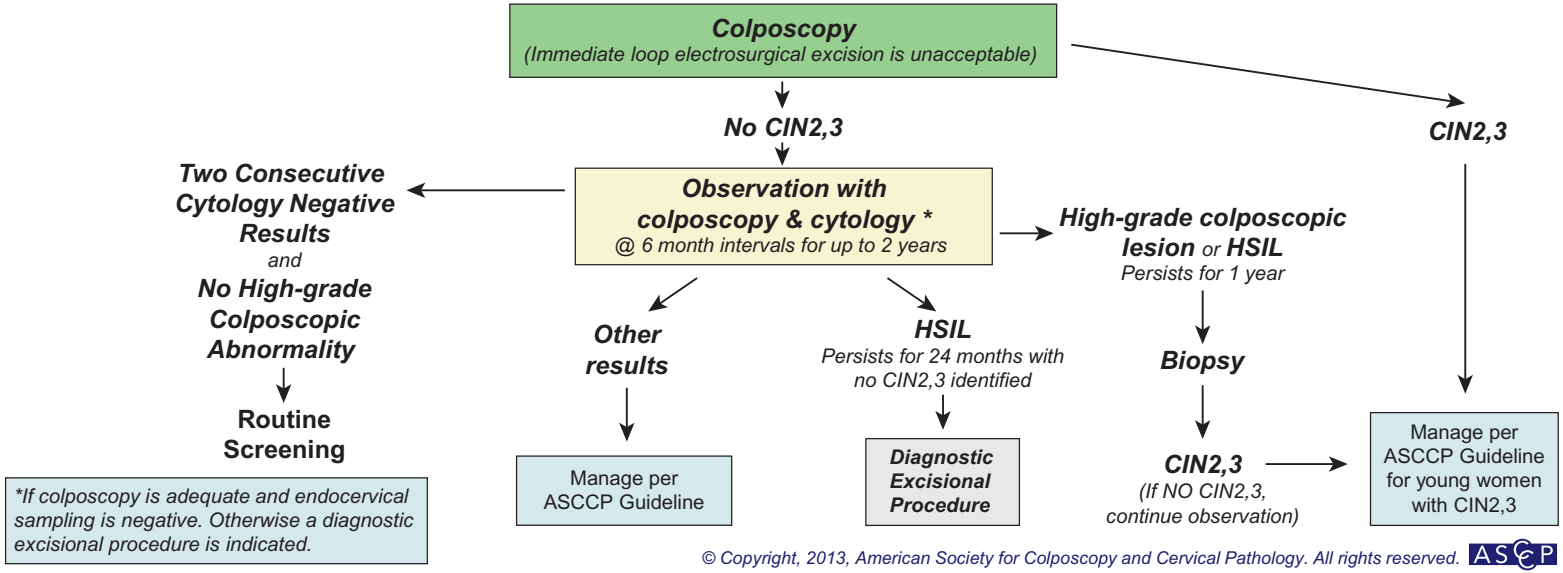
*Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)**



** Management options may vary if the woman is pregnant or ages 21-24 years.*

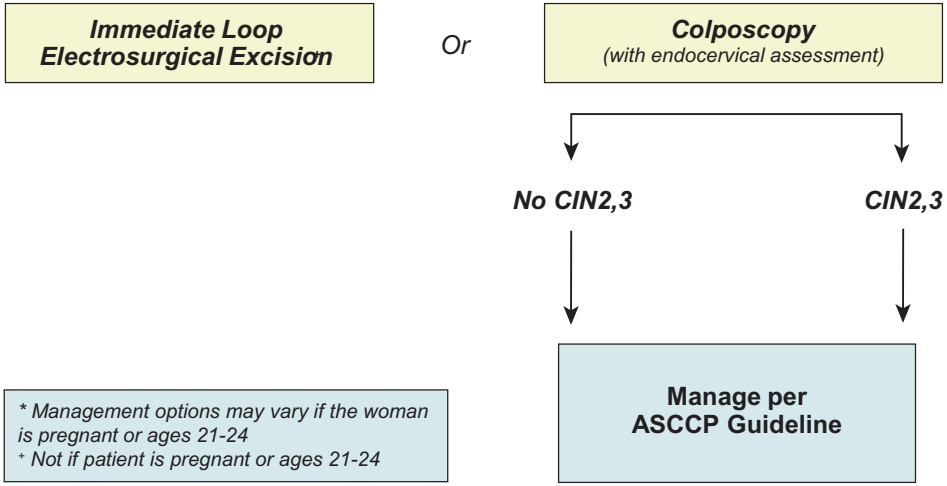
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women Ages 21-24 yrs with Atypical Squamous Cells, Cannot Rule Out High Grade SIL (ASC-H) and High-grade Squamous Intraepithelial Lesion (HSIL)



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

Management of Women with High-grade Squamous Intraepithelial Lesions (HSIL)*



* Management options may vary if the woman is pregnant or ages 21-24
+ Not if patient is pregnant or ages 21-24

© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Initial Workup of Women with Atypical Glandular Cells (AGC)

All subcategories
(except atypical endometrial cells)

↓

Colposcopy *(with endocervical sampling)*
and ***Endometrial sampling*** *(if ≥ 35 yrs or at risk for endometrial neoplasia*)*

Atypical Endometrial Cells

↓

Endometrial *and*
Endocervical Sampling

↓

No Endometrial Pathology

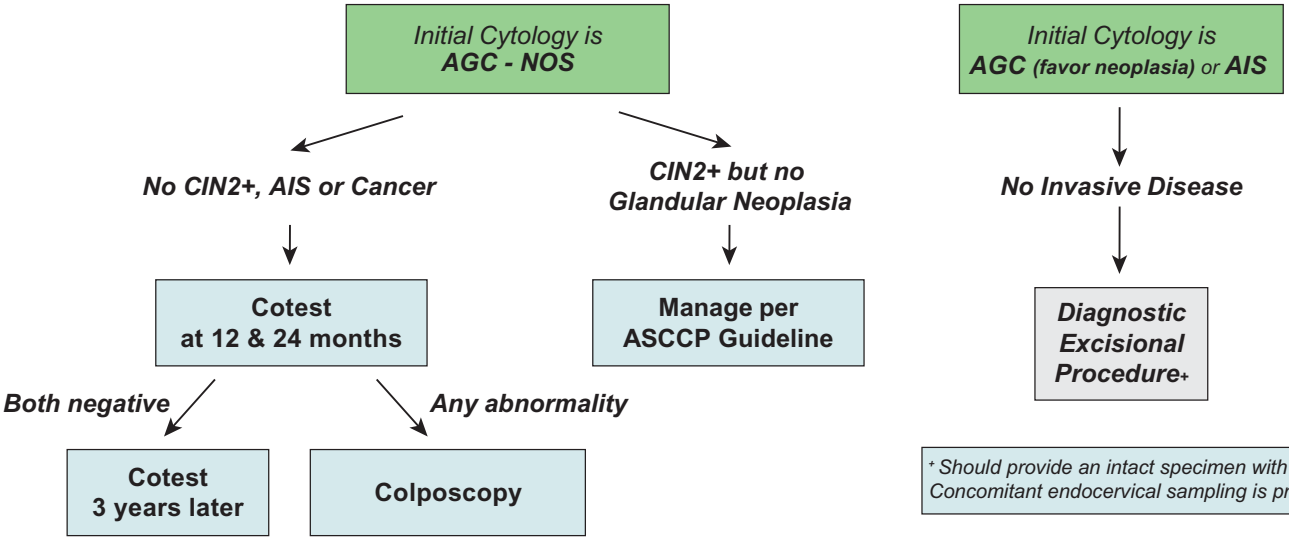
↓

Colposcopy

* *Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.*

© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

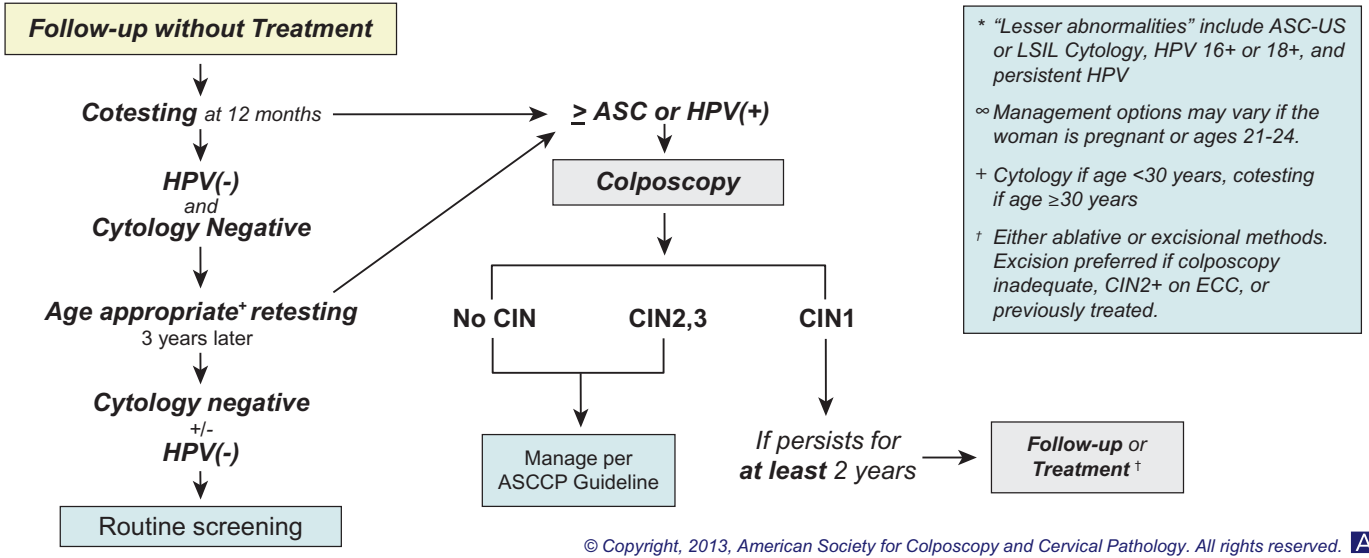
Subsequent Management of Women with Atypical Glandular Cells (AGC)



+ Should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred

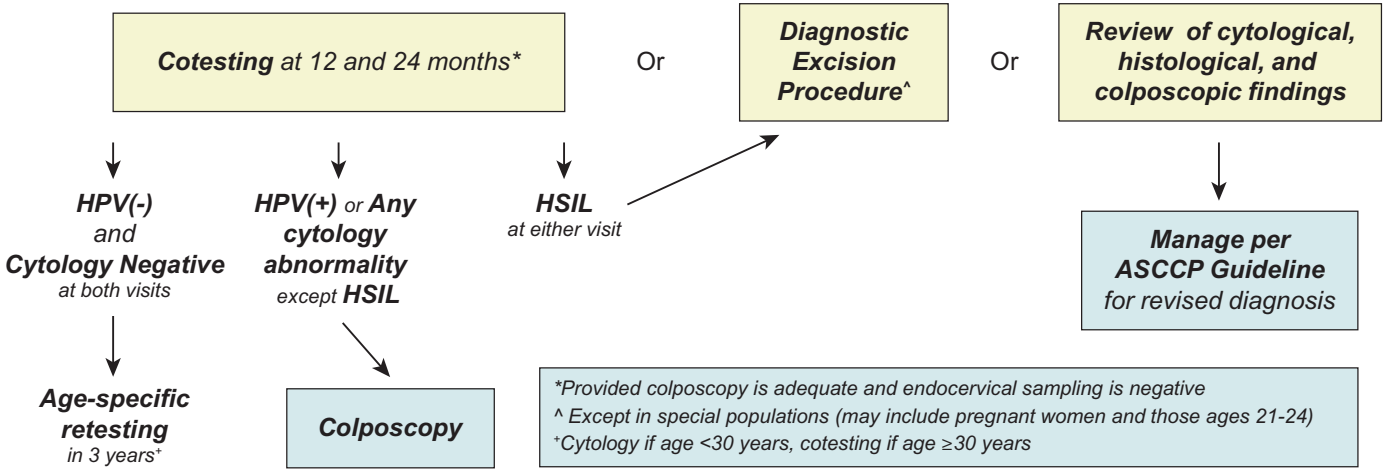
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by "Lesser Abnormalities"*∞



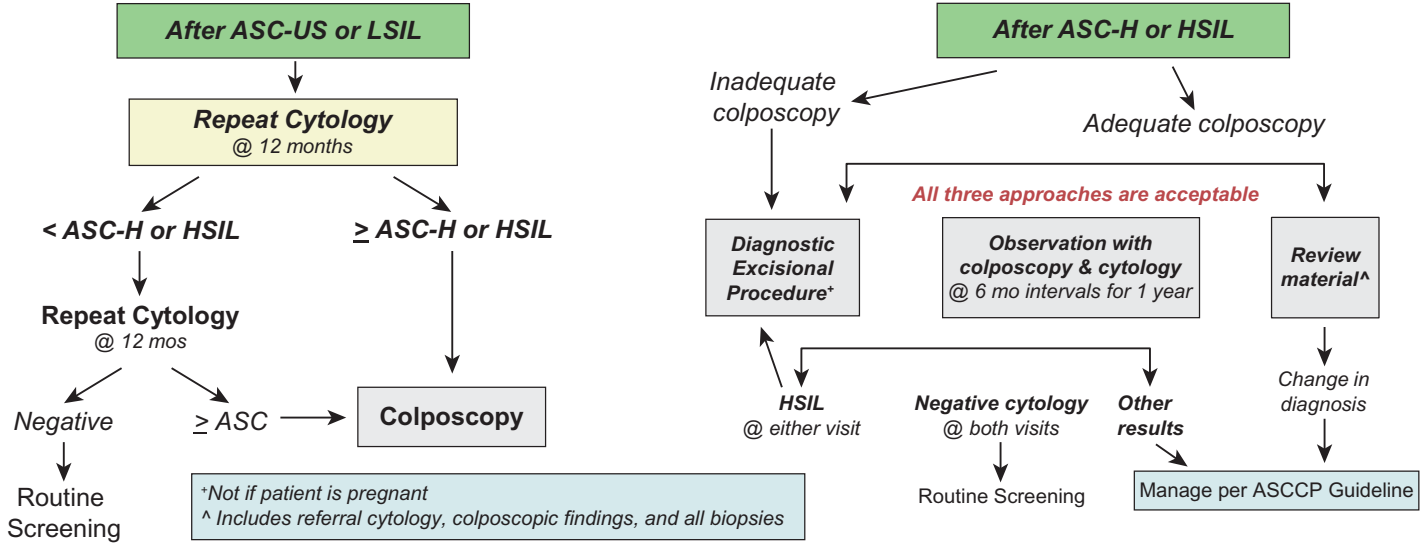
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved. ASCCP

Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by ASC-H or HSIL Cytology



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women with No lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) in Women Ages 21-24

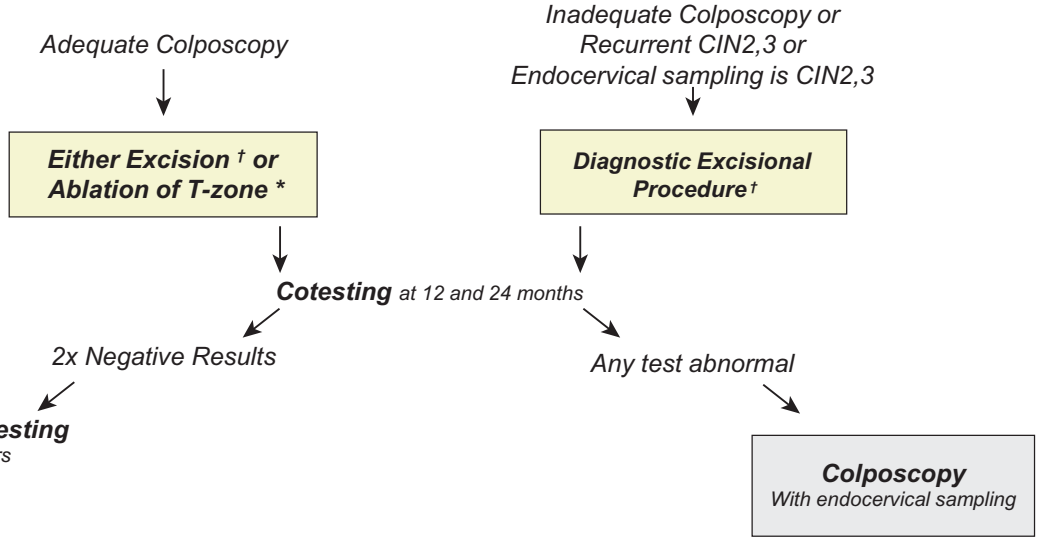


© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2 and 3 (CIN2,3)*

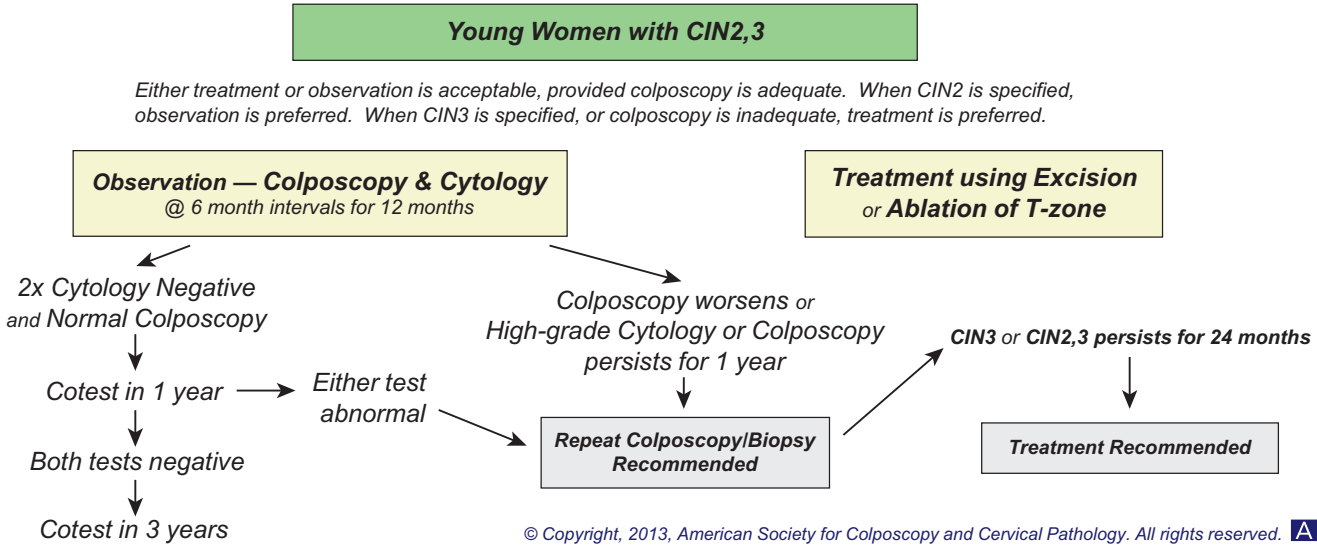
*Management options will vary in special circumstances or if the woman is pregnant or ages 21-24

†If CIN2,3 is identified at the margins of an excisional procedure or post-procedure ECC, cytology and ECC at 4-6mo is preferred, but repeat excision is acceptable and hysterectomy is acceptable if re-excision is not feasible.



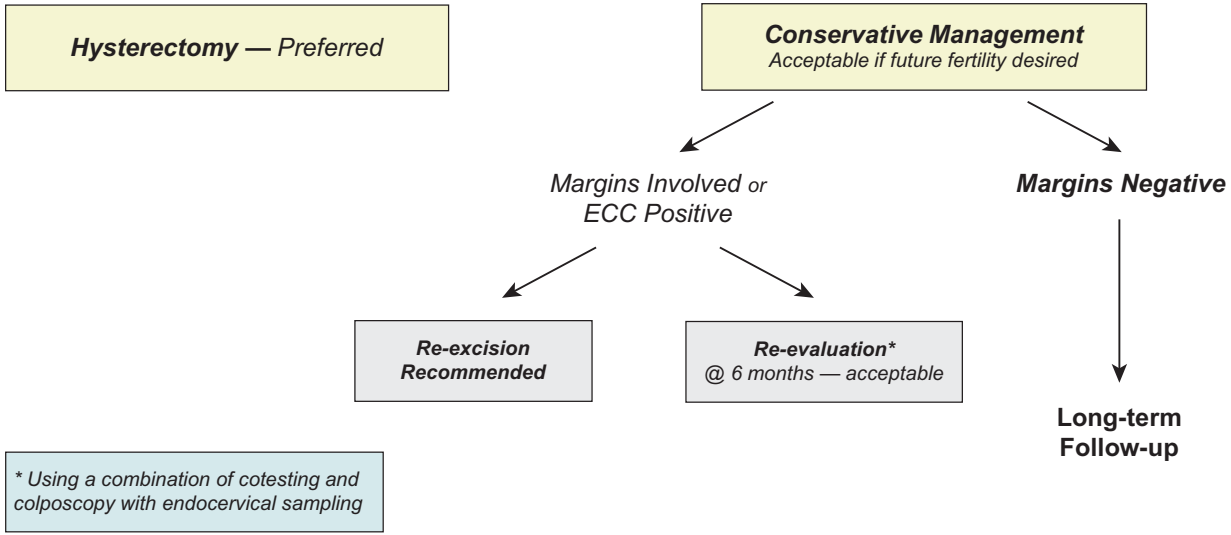
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Young Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2,3 (CIN2,3) in Special Circumstances



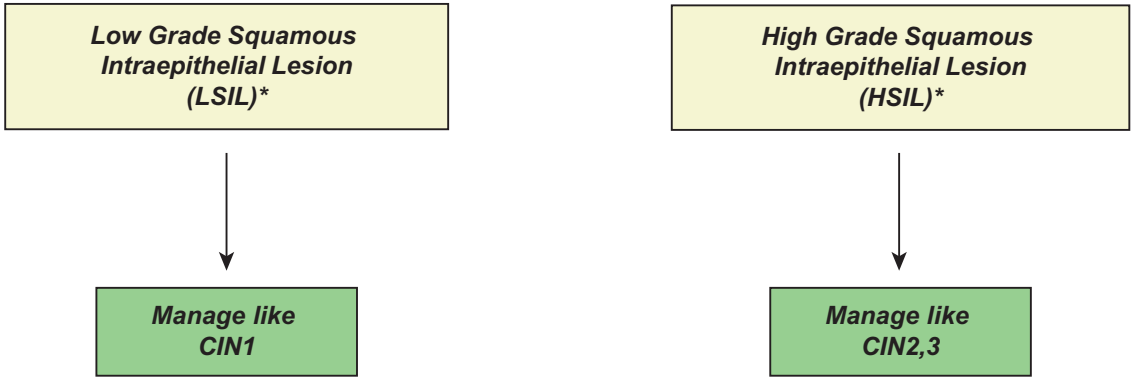
© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Management of Women Diagnosed with Adenocarcinoma in-situ (AIS) during a Diagnostic Excisional Procedure



© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Interim Guidance for Managing Reports using the Lower Anogenital Squamous Terminology (LAST) Histopathology Diagnoses



*Histopathology Results only.

© Copyright, 2013, American Society for Colposcopy and Cervical Pathology. All rights reserved.

Definitions

Terms Utilized in the Consensus Guidelines

- **Colposcopy** is the examination of the cervix, vagina, and, in some instances the vulva, with the colposcope after the application of a 3-5% acetic acid solution coupled with obtaining colposcopically-directed biopsies of all lesions suspected of representing neoplasia.
- **Endocervical sampling** includes obtaining a specimen for either histopathological evaluation using an endocervical curette or a cytobrush or for cytological evaluation using a cytobrush.
- **Endocervical assessment** is the process of evaluating the endocervical canal for the presence of neoplasia using either a colposcope or endocervical sampling.
- **Diagnostic excisional procedure** is the process of obtaining a specimen from the transformation zone and endocervical canal for histopathological evaluation and includes laser conization, cold-knife conization, loop electrosurgical excision procedure (LEEP), and loop electrosurgical conization.
- **Adequate colposcopy** indicates that the entire squamocolumnar junction and the margin of any visible lesion can be visualized with the colposcope.
- **Endometrial sampling** includes obtaining a specimen for histopathological evaluation using an endometrial aspiration or biopsy device, a "dilatation and curettage" or hysteroscopy.

© Copyright, 2002, 2006, 2013 American Society for Colposcopy and Cervical Pathology. All rights reserved

Acknowledgments

These guidelines were developed with funding from the American Society for Colposcopy and Cervical Pathology (ASCCP). The contents are solely the responsibility of the authors and the ASCCP.

L. Stewart Massad, M.D., Washington University School of Medicine, St. Louis, MO; Mark H. Einstein, M.D., Albert Einstein College of Medicine, Bronx, NY; Warner K. Huh, M.D., University of Alabama School of Medicine, Birmingham, AL; Hormuzd A. Katki, Ph.D., Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD; Walter K. Kinney, M.D., The Permanente Medical Group, Sacramento, CA; Mark Schiffman, M.D., Diane Solomon, M.D., Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; Nicolas Wentzensen, M.D., Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD; Herschel W. Lawson, M.D., Emory University School of Medicine, Atlanta, GA, on behalf of the 2012 ASCCP Consensus Guidelines Conference

All copyright permission requests should be sent to the ASCCP National Office, 1530 Tilco Dr., Ste. C, Frederick, MD 21704

ASCCP
1530 Tilco Drive, Suite C
Frederick, MD 21704
(301) 733-3640 (telephone)
(800) 787-7227 (toll free)
(240) 575-9880 (fax)

For more information, or to order additional copies, please email:
administrator@asccp.org

ASCCP The society for lower genital tract disorders since 1964.

www.asccp.org/Consensus2012

Cervical Cancer Screening Guidelines for Average-Risk Women[1]

	American Cancer Society (ACS), American Society for Colposcopy and Cervical Pathology (ASCCP), and American Society for Clinical Pathology (ASCP)[2] 2012	U.S. Preventive Services Task Force (USPSTF)[3] 2012	American College of Obstetricians and Gynecologists (ACOG)[4] 2009
When to start screening[5]	Age 21. Women aged <21 years should not be screened regardless of the age of sexual initiation or other risk factors. *(Strong recommendation)*	Age 21. *(A recommendation)* Recommend against screening women aged <21 years. *(D recommendation)*	Age 21 regardless of the age of onset of sexual activity. Should be avoided <21 years. *(Level A evidence)*
Statement about annual screening	Women of any age should not be screened annually by any screening method. *(Strong recommendation)*	Individuals and clinicians can use the annual Pap test screening visit as an opportunity to discuss other health problems and preventive measures. Individuals, clinicians, and health systems should seek effective ways to facilitate the receipt of recommended preventive services at intervals that are beneficial to the patient. Efforts also should be made to ensure that individuals are able to seek care for additional health concerns as they present.	Physicians should inform their patients that annual gynecologic examinations may be appropriate. *(Level C evidence)*[6]
Screening method and intervals[7]			
Cytology (conventional or liquid based) — 21–29 years of age	Every 3 years.[8] *(Strong recommendation)*	Every 3 years. *(A recommendation)*	Every 2 years. *(Level A evidence)*
Cytology (conventional or liquid based) — 30–65 years of age	Every 3 years.[8] *(Strong recommendation)*	Every 3 years. *(A recommendation)*	May screen every 3 years with a history of 3 negative cytology tests. *(Level A evidence)*
HPV co-test (cytology + HPV test administered together) — 21–29 years of age	HPV co-testing should not be used for women aged <30 years.	Recommend against HPV co-testing women aged <30 years. *(D recommendation)*	Not recommended for women aged <30 years.
HPV co-test (cytology + HPV test administered together) — 30–65 years of age	Every 5 years *(Strong recommendation)* ; this is the preferred method *(Weak recommendation)* .	For women who want to extend their screening interval, HPV co-testing every 5 years is an option. *(A recommendation)*	Every 3 years if cytology normal, HPV test negative. *(Level A evidence)*
Primary HPV testing[9]	For women aged 30–65 years, screening by HPV testing alone is not recommended in most clinical settings. *(Weak recommendation)*[10]	Recommends against screening for cervical cancer with HPV testing (alone or in combination with cytology) in women aged <30 years. *(D recommendation)*	Not addressed.
When to stop screening	Women aged >65 years with adequate screening history should not be screened.[10] Women aged >65 years with a history of CIN2, CIN3, or AIS should continue screening for at least 20 years after spontaneous regression or appropriate management. *(Weak recommendation)*	Women aged >65 years with adequate recent screening with normal Pap tests, who are not otherwise at high risk for cervical cancer. *(D recommendation)*[11]	Between 65–70 years of age with 3 consecutive normal cytology tests and no abnormal tests in the past 10 years *(Level B evidence).* An older woman who is sexually active and has multiple partners should continue to have routine screening.
Screening post-total hysterectomy	Women who have had a total hysterectomy (removal of the uterus and cervix) should stop screening, unless the hysterectomy was done as a treatment for cervical pre-cancer or cancer. Women who have had a hysterectomy without removal of the cervix (supra-cervical hysterectomy) should continue screening according to guidelines. *(Strong recommendation)*	Recommend against screening in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (CIN2 or CIN3) or cervical cancer. *(D recommendation)*	If removal for benign disease and no history of high-grade CIN or worse, may discontinue screening. *(Level A evidence)* Women for whom a negative history cannot be documented should continue to be screened. *(Level B evidence)*
The need for a bimanual pelvic exam	Not addressed in 2012 guidelines but was addressed in 2002 ACS guidelines.[12]	Addressed in USPSTF ovarian cancer screening recommendations (draft).[13]	Physicians should inform their patients that annual gynecologic examinations may be appropriate. *(Level C evidence)*[6]
Screening among those immunized against HPV 16/18	Women at any age with a history of HPV vaccination should be screened according to the age-specific recommendations for the general population.	The possibility that vaccination might reduce the need for screening with cytology alone or in combination with HPV testing is not established. Given these uncertainties, women who have been vaccinated should continue to be screened.	Recommendations remain the same regardless of vaccination status. *(Level C evidence)*

HPV = human papillomavirus; CIN = cervical intraepithelial neoplasia

[1]These recommendations do not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion (CIN 2 or 3) or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised, or are HIV positive.

[2]Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin.* 2012 Mar 14. Available at http://www.cancer.org/Cancer/CervicalCancer/DetailedGuide/cervical-cancer-prevention

[3]USPSTF. Screening for Cervical Cancer. 2012. Available at http://www.uspreventiveservicestaskforce.org/uspstf11/cervcancer/cervcancerrs.htm. These recommendations apply to women who have a cervix, regardless of sexual history.

[4]ACOG Practice Bulletin No. 109: Cervical cytology screening. ACOG Committee on Practice Bulletins-Gynecology. *Obstet Gynecol.* 2009 Dec;114(6):1409-20.

[5]Since cervical cancer is believed to be caused by sexually transmissible human papillomavirus infections, women who have not had sexual exposures (e.g., virgins) are likely at low risk. Women aged >21 years who have not engaged in sexual intercourse may not need a Pap test depending on circumstances. The decision should be made at the discretion of the women and her physician. Women who have had sex with women are still at risk of cervical cancer. 10%–15% of women aged 21–24 years in the United States report no vaginal intercourse (Saraiya M, Martinez G, Glaser K, et al *Obstet Gynecol* 2009. 114 (6)). Providers should also be aware of instances of non-consensual sex among their patients.

[6]More specific guidance from 2003 states an annual pelvic examination is a routine part of preventive care for all women aged ≥21 years even if they do not need cervical cytology screening. *(Level C evidence)*

[7]Conventional cytology and liquid-based cytology are equivalent regarding screening guidelines, and no distinction should be made by test when recommending next screening.

[8] There is insufficient evidence to support longer intervals in women aged 30-65 years, even with a screening history of consecutive negative cytology tests.

[9]Primary HPV testing (HPV testing alone) is defined as conducting the HPV test as the first screening test. It may be followed by other tests (like a Pap) for triage.

[10]No further explanation of which clinical settings HPV testing should be used to screen women aged 30–65 years as a standalone test.

[11]Current guidelines define adequate screening as three consecutive negative cytology results or two consecutive negative co-tests within 10 years before cessation of screening, with the most recent test performed within 5 years, and are the same for ACS and USPSTF.

[12]2002 guidelines statement: The ACS and others should educate women, particularly teens and young women, that a pelvic exam does not equate to a cytology test and that women who may not need a cytology test still need regular health care visits including gynecologic care. Women should discuss the need for pelvic exams with their providers. Saslow D, Runowicz CD, Solomon D, et al. American Cancer Society Guideline for the Early Detection of Cervical Neoplasia and Cancer. *CA Cancer J Clin* 2002;52:342–362.

[13]The bimanual pelvic examination is often conducted (usually annually) in part to screen for ovarian cancer, although its effectiveness and harms are not well known and were not a focus of this review. No randomized trial has assessed the role of the bimanual pelvic examination for cancer screening. In the PLCO Trial, bimanual examination was discontinued as a screening strategy in the intervention arm because no cases of ovarian cancer were detected solely by this method and a high proportion of women underwent bimanual examination with ovarian palpation in the usual care arm.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 3
July 29, 2016

U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONTENTS

Introduction 1
Methods 2
How to Use This Document 3
Keeping Guidance Up to Date 5
References 8
Abbreviations and Acronyms 9
Appendix A: Summary of Changes from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* 10
Appendix B: Classifications for Intrauterine Devices 18
Appendix C: Classifications for Progestin-Only Contraceptives 35
Appendix D: Classifications for Combined Hormonal Contraceptives 55
Appendix E: Classifications for Barrier Methods 81
Appendix F: Classifications for Fertility Awareness–Based Methods 88
Appendix G: Lactational Amenorrhea Method 90
Appendix H: Coitus Interruptus (Withdrawal) 91
Appendix I: Female and Male Sterilization 92
Appendix J: Classifications for Emergency Contraception 93
Appendix K: Summary of Classifications for Hormonal Contraceptive Methods and Intrauterine Devices 96

Disclosure of Relationship

CDC, our planners, and our content experts wish to disclose they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Title]. MMWR Recomm Rep 2016;65(No. RR-#):[inclusive page numbers].

Centers for Disease Control and Prevention

Thomas R. Frieden, MD, MPH, *Director*
Harold W. Jaffe, MD, MA, *Associate Director for Science*
Joanne Cono, MD, ScM, *Director, Office of Science Quality*
Chesley L. Richards, MD, MPH, *Deputy Director for Public Health Scientific Services*
Michael F. Iademarco, MD, MPH, *Director, Center for Surveillance, Epidemiology, and Laboratory Services*

***MMWR* Editorial and Production Staff (Serials)**

Sonja A. Rasmussen, MD, MS, *Editor-in-Chief*
Charlotte K. Kent, PhD, MPH, *Executive Editor*
Christine G. Casey, MD, *Editor*
Teresa F. Rutledge, *Managing Editor*
David C. Johnson, *Lead Technical Writer-Editor*
Catherine B. Lansdowne, MS, *Project Editor*

Martha F. Boyd, *Lead Visual Information Specialist*
Maureen A. Leahy, Julia C. Martinroe,
Stephen R. Spriggs, Moua Yang, Tong Yang,
Visual Information Specialists
Quang M. Doan, MBA, Phyllis H. King, Terraye M. Starr,
Information Technology Specialists

***MMWR* Editorial Board**

Timothy F. Jones, MD, *Chairman*
Matthew L. Boulton, MD, MPH
Virginia A. Caine, MD
Katherine Lyon Daniel, PhD
Jonathan E. Fielding, MD, MPH, MBA
David W. Fleming, MD

William E. Halperin, MD, DrPH, MPH
King K. Holmes, MD, PhD
Robin Ikeda, MD, MPH
Rima F. Khabbaz, MD
Phyllis Meadows, PhD, MSN, RN
Jewel Mullen, MD, MPH, MPA

Jeff Niederdeppe, PhD
Patricia Quinlisk, MD, MPH
Patrick L. Remington, MD, MPH
Carlos Roig, MS, MA
William L. Roper, MD, MPH
William Schaffner, MD

U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

Kathryn M. Curtis, PhD[1]
Naomi K. Tepper, MD[1]
Tara C. Jatlaoui, MD[1]
Erin Berry-Bibee, MD[1,2]
Leah G. Horton, MSPH[1]
Lauren B. Zapata, PhD[1]
Katharine B. Simmons, MD[1,2]
H. Pamela Pagano, MPH[1]
Denise J. Jamieson, MD[1]
Maura K. Whiteman, PhD[1]

[1]*Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia*
[2]*Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, North Carolina*

Summary

The 2016 U.S. Medical Eligibility Criteria for Contraceptive Use *(U.S. MEC) comprises recommendations for the use of specific contraceptive methods by women and men who have certain characteristics or medical conditions. These recommendations for health care providers were updated by CDC after review of the scientific evidence and consultation with national experts who met in Atlanta, Georgia, during August 26–28, 2015. The information in this report updates the 2010 U.S. MEC* (CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010:59 [No. RR-4]). *Notable updates include the addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort; revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate; and revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases, and human immunodeficiency virus; and women who are receiving antiretroviral therapy. The recommendations in this report are intended to assist health care providers when they counsel women, men, and couples about contraceptive method choice. Although these recommendations are meant to serve as a source of clinical guidance, health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients. Persons should seek advice from their health care providers when considering family planning options.*

Introduction

Approximately 45% of all pregnancies that occur in the United States are unintended (*1*), with associated increased risks for adverse maternal and infant health outcomes (*2*) and increased health care costs (*3*). Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including long-acting reversible contraception methods such as intrauterine devices (IUDs) and implants, to reduce the risk for an unintended pregnancy. However, with these expanded options comes the need for evidence-based guidance to help health care providers offer quality family planning care to their patients, including choosing the most appropriate contraceptive method for individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness.

Corresponding author: Kathryn M. Curtis, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Telephone: 770-488-5200; E-mail: kmc6@cdc.gov.

In 2010, CDC published the first *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC), which provided recommendations on safe use of contraceptive methods for women with various medical conditions and other characteristics (and was adapted from global guidance developed by the World Health Organization [WHO MEC]) (*4*,*5*). U.S. MEC is a companion document to the *U.S. Selected Practice Recommendations for Contraceptive Use* (U.S. SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate (*6*). WHO intended for the global guidance to be used by local or national policy makers, family planning program managers, and the scientific community as a reference when they develop family planning guidance at the country or program level. During 2008–2010, CDC participated in a formal process to adapt the global guidance for appropriateness

for use in the United States, which included rigorous identification and critical appraisal of the scientific evidence through systematic reviews, and input from national experts on how to translate that evidence into recommendations for U.S. health care providers (*5*). At that time, CDC committed to keeping this guidance up to date and based on the best available evidence, with full review every few years (*5*).

This document updates CDC's U.S. MEC 2010 (*5*), based on new evidence and input from experts. A summary of changes from U.S. MEC 2010 is provided (Appendix A). Notable updates include the following:

- addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort
- revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate
- revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases (STDs), and human immunodeficiency virus (HIV); and women who are receiving antiretroviral therapy

The goal of these recommendations is to remove unnecessary medical barriers to accessing and using contraception, thereby decreasing the number of unintended pregnancies. These recommendations are meant to serve as a source of clinical guidance for health care providers; health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients, who should seek advice from their health care providers when considering family planning options.

Methods

Since publication of U.S. MEC 2010, CDC has monitored the literature for new evidence relevant to the recommendations through the WHO/CDC continuous identification of research evidence (CIRE) system. This system identifies new evidence as it is published and allows WHO and CDC to update systematic reviews and facilitate updates to recommendations as new evidence warrants. Automated searches are run in PubMed weekly, and the results are reviewed. Abstracts that meet specific criteria are added to the web-based CIRE system, which facilitates coordination and peer review of systematic reviews for both WHO and CDC (*7*). In 2014, CDC reviewed all of the existing recommendations in U.S. MEC 2010 for new evidence identified by CIRE that had the potential to lead to a changed recommendation. During August 27–28, 2014, CDC held a meeting in Atlanta, Georgia, of 11 family planning experts and representatives from partner organizations to solicit their input on the scope of and process for updating both U.S. MEC 2010 and U.S. SPR 2013. The participants were experts in family planning and represented various types of health care providers, as well as health care provider organizations. A list of participants is provided at the end of this report. Meeting participants discussed topics to be addressed in the update of U.S. MEC based on new evidence published since 2010 (identified through the CIRE system), topics addressed at a 2014 WHO meeting to update global guidance, and suggestions CDC received from health care providers for the addition of recommendations for women with medical conditions not yet included in U.S. MEC (e.g., from provider feedback through e-mail, public inquiry, and questions received at conferences). CDC identified several topics to consider when updating the guidance, including revision of existing recommendations for certain medical conditions or characteristics (breastfeeding, postpartum, HIV, receiving antiretroviral therapy, obesity, dyslipidemia, increased risk for STDs, superficial venous thrombosis, gestational trophoblastic disease, and migraine headaches), addition of recommendations for new medical conditions (cystic fibrosis, multiple sclerosis, use of certain psychotropic drugs, and St. John's wort), and addition of recommendations for new contraceptive methods (ulipristal acetate for emergency contraception). CDC determined that all other recommendations in U.S. MEC 2010 were up to date and consistent with the existing body of evidence for that recommendation.

In preparation for a subsequent expert meeting held during August 26–28, 2015, to review the scientific evidence for potential recommendations, CDC staff members and other invited authors listed at the end of this report conducted independent systematic reviews for each of the topics being considered. The purpose of these systematic reviews was to identify direct evidence about the safety of contraceptive method use by women with selected conditions (e.g., risk for disease progression or other adverse health effects in women with multiple sclerosis who use combined hormonal contraceptives [CHCs]). Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews (*8*,*9*), and strength and quality of the evidence were assigned using the system of the U.S. Preventive Services Task Force (*10*). When direct evidence was limited or not available, indirect evidence (e.g., evidence on surrogate outcomes or among healthy women) and theoretical issues were considered and either added to direct evidence within a systematic review or separately compiled for presentation to the meeting participants. Completed systematic

reviews were peer reviewed by two or three experts and then provided to participants before the expert meeting. Reviews are referenced and cited throughout this document; the full reviews appear in the published literature and contain the details of each review, including the systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessments. CDC staff continued to monitor new evidence identified through the CIRE system during the preparation for the August 2015 meeting.

During August 26–28, 2015, in Atlanta, Georgia, CDC held a meeting with 44 participants who were invited to provide their individual perspectives on the scientific evidence presented and potential recommendations. Twenty-nine of the participants represented a wide range of expertise in family planning provision and research, and included obstetricians/gynecologists, pediatricians, family physicians, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management; these individuals participated in the entire meeting. Fifteen participants with expertise relevant to specific topics on the meeting agenda provided information and participated in the discussion (e.g., an expert in cystic fibrosis was asked to provide general information about the condition and to assist in interpreting the evidence and any theoretical concerns on the use of contraceptive methods in women with the condition); these participants provided input only during the session for which their topics were discussed. Lists of participants and any potential conflicts of interest are provided at the end of this report. During the meeting, the evidence from the systematic review for each topic was presented, including direct evidence and any indirect evidence or theoretical concerns. Participants provided their perspectives on using the evidence to develop recommendations that would meet the needs of U.S. health care providers. After the meeting, CDC determined the recommendations in this report, taking into consideration the perspectives provided by the meeting participants. Feedback also was received from three external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These reviewers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. Areas of research that need additional investigation also were considered during the meeting (*11*).

How to Use This Document

These recommendations are intended to help health care providers determine the safe use of contraceptive methods among women and men with various characteristics and medical conditions. Providers also can use the information in these recommendations when consulting with women, men, and couples about their selection of contraceptive methods. The tables in this document include recommendations for the use of contraceptive methods by women and men with particular characteristics or medical conditions. Each condition is defined as representing either an individual's characteristics (e.g., age or history of pregnancy) or a known preexisting medical or pathologic condition (e.g., diabetes or hypertension). The recommendations refer to contraceptive methods being used for contraceptive purposes; the recommendations do not consider the use of contraceptive methods for treatment of medical conditions because the eligibility criteria in these situations might differ. The conditions affecting eligibility for the use of each contraceptive method are classified into one of four categories (Box 1).

Using the Categories in Practice

Health care providers can use the eligibility categories when assessing the safety of contraceptive method use for women and men with specific medical conditions or characteristics. Category 1 comprises conditions for which no restrictions exist for use of the contraceptive method. Classification of a method/condition as category 2 indicates the method generally can be used, although careful follow-up might be required. For a method/condition classified as category 3, use of that method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be considered, and careful follow-up is required. Hence, provision of a contraceptive method to a woman with a condition classified as category 3 requires careful clinical judgement and access to clinical services. Category 4 comprises conditions that represent an unacceptable health risk if the method is used. For example, a smoker aged <35 years generally can use combined oral contraceptives (COCs) (category 2). However, for a woman

BOX 1. Categories of medical eligibility criteria for contraceptive use

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

aged ≥35 years who smokes <15 cigarettes per day, the use of COCs usually is not recommended unless other methods are not available or acceptable to her (category 3). A woman aged ≥35 years who smokes ≥15 cigarettes per day should not use COCs because of unacceptable health risks, primarily the risk for myocardial infarction and stroke (category 4). The programmatic implications of these categories might depend on the circumstances of particular professional or service organizations. For example, in some settings, a category 3 might mean that a special consultation is warranted.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a medical condition develops or worsens during use of a contraceptive method. When the categories differ for initiation and continuation, these differences are noted in the Initiation and Continuation columns. When initiation and continuation are not indicated, the category is the same for initiation and continuation of use.

On the basis of this classification system, the eligibility criteria for initiating and continuing use of a specific contraceptive method are presented in tables (Appendices A–K). In these tables, the first column indicates the condition. Several conditions are divided into subconditions to differentiate between varying types or severity of the condition. The second column classifies the condition for initiation or continuation (or both) into category 1, 2, 3, or 4. For certain conditions, the numeric classification does not adequately capture the recommendation; in these cases, the third column clarifies the numeric category. These clarifications were determined during the discussions of the scientific evidence and are considered a necessary element of the recommendation. The third column also summarizes the evidence for the recommendation if evidence exists. The recommendations for which no evidence is cited are based on expert opinion from either the WHO or U.S. expert meeting in which these recommendations were developed, and might be based on evidence from sources other than systematic reviews. For certain recommendations, additional comments appear in the third column and generally come from the WHO meeting or the U.S. meeting.

Recommendations for Use of Contraceptive Methods

The classifications for whether women with certain medical conditions or characteristics can use specific contraceptive methods are provided for intrauterine contraception, including the copper-containing IUD and levonorgestrel-releasing IUDs (Appendix B); progestin-only contraceptives (POCs), including etonogestrel implants, depot medroxyprogesterone acetate injections, and progestin-only pills (Appendix C); CHCs, including low-dose (containing ≤35 μg ethinyl estradiol) COCs, combined hormonal patch, and combined vaginal ring (Appendix D); barrier contraceptive methods, including male and female condoms, spermicides, diaphragm with spermicide, and cervical cap (Appendix E); fertility awareness–based methods (Appendix F); lactational amenorrhea method (Appendix G); coitus interruptus (Appendix H); female and male sterilization (Appendix I); and emergency contraception, including emergency use of the copper-containing IUD and emergency contraceptive pills (Appendix J). A table at the end of this report summarizes the classifications for the hormonal and intrauterine methods (Appendix K).

Contraceptive Method Choice

Many elements need to be considered by women, men, or couples at any given point in their lifetimes when choosing the most appropriate contraceptive method. These elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability. The guidance in this report focuses primarily on the safety of a given contraceptive method for a person with a particular characteristic or medical condition. Therefore, the classification of category 1 means that the method can be used in that circumstance with no restrictions with regard to safety but does not necessarily imply that the method is the best choice for that person; other factors, such as effectiveness, availability, and acceptability, might play an important role in determining the most appropriate choice. Voluntary informed choice of contraceptive methods is an essential guiding principle, and contraceptive counseling, when applicable, might be an important contributor to the successful use of contraceptive methods.

In choosing a method of contraception, dual protection from the simultaneous risk for HIV and other STDs also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs, including HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonococcal infection, and trichomoniasis (*12*). Although evidence is limited, use of female condoms can provide protection from acquisition and transmission of STDs (*12*). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (*12*). Additional information about prevention and treatment of STDs is available from the CDC *Sexually Transmitted Diseases Treatment Guidelines* (http://www.cdc.gov/std/treatment) (*12*).

Contraceptive Method Effectiveness

Contraceptive method effectiveness is critical for minimizing the risk for an unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (Figure). Methods that depend on consistent and correct use have a wide range of effectiveness. IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method.

Unintended Pregnancy and Increased Health Risk

For women with conditions that might make pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods might be the best choice to avoid unintended pregnancy (Figure). Women with these conditions should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure (Figure). Conditions included in U.S. MEC that are associated with increased risk for adverse health events as a result of pregnancy are identified throughout the document (Box 2). Some of the medical conditions included in U.S. MEC recommendations are treated with teratogenic drugs. While the woman's medical condition may not affect her eligibility to use certain contraceptive methods, women using teratogenic drugs are at increased risk for poor pregnancy outcomes; long-acting, highly effective contraceptive methods might be the best option to avoid unintended pregnancy or delay pregnancy until teratogenic drugs are no longer needed.

BOX 2. Conditions associated with increased risk for adverse health events as a result of pregnancy*

- Breast cancer
- Complicated valvular heart disease
- Cystic fibrosis
- Diabetes: insulin dependent; with nephropathy, retinopathy, or neuropathy or other vascular disease; or of >20 years' duration
- Endometrial or ovarian cancer
- Epilepsy
- Hypertension (systolic ≥160 mm Hg or diastolic ≥100 mm Hg)
- History of bariatric surgery within the past 2 years
- HIV: not clinically well or not receiving antiretroviral therapy
- Ischemic heart disease
- Gestational trophoblastic disease
- Hepatocellular adenoma and malignant liver tumors (hepatoma)
- Peripartum cardiomyopathy
- Schistosomiasis with fibrosis of the liver
- Severe (decompensated) cirrhosis
- Sickle cell disease
- Solid organ transplantation within the past 2 years
- Stroke
- Systemic lupus erythematosus
- Thrombogenic mutations
- Tuberculosis

* Long-acting, highly effective contraceptive methods might be the best choice for women with conditions that are associated with increased risk for adverse health events as a result of pregnancy. These women should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure.

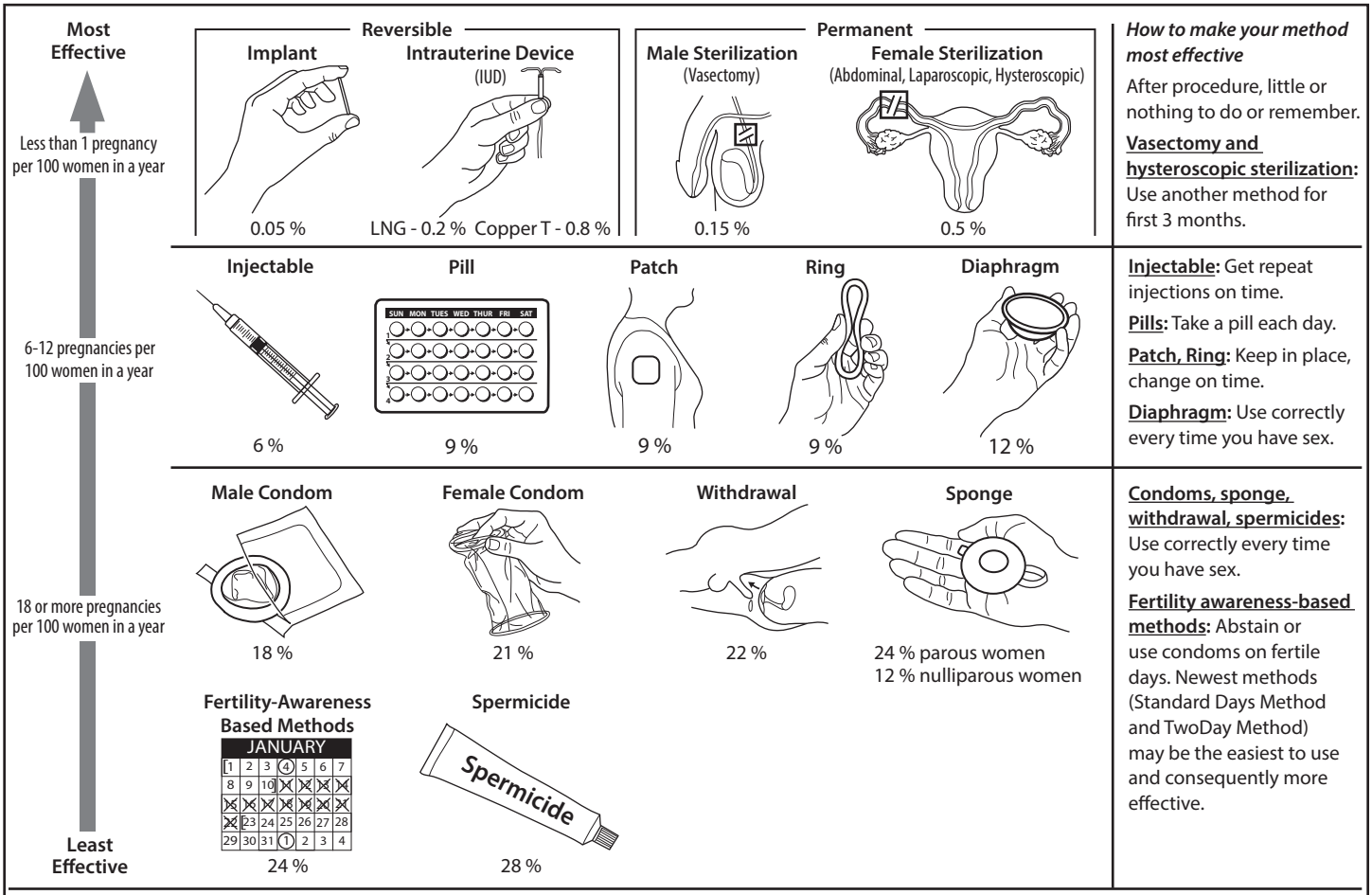
Keeping Guidance Up to Date

Updating the evidence-based recommendations as new scientific evidence becomes available is a challenge. CDC will continue to work with WHO to identify and assess new relevant evidence as it becomes available and to determine whether changes in the recommendations are warranted (*7*). In most cases, U.S. MEC follows the WHO guidance updates, which typically occur every 5 years (or sooner if warranted by new data). However, CDC will review all WHO updates for their application in the United States. CDC also will identify and assess any new literature for the recommendations and medical conditions that are not included in the WHO guidance. CDC will completely review U.S. MEC every 5 years as well. Updates to the guidance will appear on the CDC U.S. MEC website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm).

Acknowledgments

This report is based, in part, on the work of the Promoting Family Planning Team, Department of Reproductive Health and Research, World Health Organization, and its development of *Medical Eligibility Criteria for Contraceptive Use, 5th edition*.

FIGURE. Effectiveness of family planning methods*



Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/ Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

U.S. Medical Eligibility Criteria for Contraceptive Use Participants

CDC Guideline Development Group for *U.S. Medical Eligibility Criteria for Contraceptive Use* and *U.S. Selected Practice Recommendations for Contraceptive Use*

Kathryn M. Curtis, PhD (Chair), Erin Berry-Bibee, MD, Suzanne G. Folger, PhD, Leah G. Horton, MSPH, Denise J. Jamieson, MD, Tara C. Jatlaoui, MD, Polly A. Marchbanks, PhD, H. Pamela Pagano, MPH, Halley E.M. Riley, MPH, Mirelys Rodriguez, Katharine B. Simmons, MD, Naomi K. Tepper, MD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia.

Invited Meeting Participants, August 27–28, 2014, Atlanta, Georgia

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Gale Burstein, MD, Erie County Department of Health, Buffalo, New York; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, Washington; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360 and American College of Obstetricians and Gynecologists, Durham, North Carolina; Deborah Nucatola, MD, Planned Parenthood Federation of America, New York, New York; Michael Policar, MD, University of California, San Francisco, California; Carolyn Westhoff, MD, Columbia University, New York, New York.

Systematic Review Presenters and Authors, Meeting, August 26–28, 2015, Atlanta, Georgia

Erin Berry-Bibee, MD, Kathryn M. Curtis, PhD, Leah G. Horton, MSPH, Denise J. Jamieson, MD, Tara C. Jatlaoui, MD, Polly A. Marchbanks PhD, Titilope Oduyebo, MD, Pamela Pagano, MPH, Halley E.M. Riley, MPH, Katharine B. Simmons, MD, Naomi K. Tepper, MD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia; Monica Dragoman, MD, Mary E. Gaffield, PhD, Sharon J. Phillips, MD, Marleen Temmerman, MD, World Health Organization, Geneva, Switzerland; Andra James, MD, Duke University Medical Center, Durham, North Carolina; Nathalie Kapp, MD, HRA Pharma, Paris, France; Kavita Nanda, MD, FHI360, Durham, North Carolina; Seth Walker, MD, Emory University, Atlanta, Georgia.

Invited Meeting Participants, August 26–28, 2015, Atlanta, Georgia

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Rebecca Allen, MD, American Society for Reproductive Medicine and Women and Infants Hospital, Providence, Rhode Island; Jean Anderson, MD, Johns Hopkins University, Baltimore, Maryland; Abbey Berenson, MD, University of Texas Medical Branch, Galveston, Texas; Amanda Black, MD, University of Ottawa, Ontario, Canada; Cora Collette Breuner, MD, American Academy of Pediatrics and Seattle Children's Hospital, Seattle, Washington; Gale Burstein MD, Erie County Department of Health, Buffalo, New York; Anne Calhoun, MD, University of North Carolina, Chapel Hill, North Carolina; Nahida Chakhtoura, MD, National Institutes of Health, Rockville, Maryland; Alicia Christy, MD, National Institutes of Health, Rockville, Maryland; Mitchell D. Creinin, MD, University of California, Davis, California; Linda Dominguez, Southwest Women's Health, Albuquerque, New Mexico; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, Washington; Marji Gold, MD, Albert Einstein College of Medicine, Bronx, New York; Donald Goldstein, MD, Harvard Medical School, Boston, Massachusetts; Robert Hatcher, MD, Emory University, Atlanta, Georgia; Mark Hathaway, MD, JHPIEGO and Unity Healthcare, Washington, DC; Stephen Heartwell, MD, Susan Thompson Buffett Foundation, Omaha, Nebraska; Paula Hillard, MD, Stanford University, Palo Alto, California; Maria Houtchens, MD, Harvard Medical School, Boston, Massachusetts; Andra James, MD, Duke University Medical Center, Durham, North Carolina; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Myong-Jin Kim, Pharm-D, Food and Drug Administration, Rockville, Maryland; Barbara Konkle, MD, Bloodworks Northwest, Seattle, Washington; Tobias Kurth, MD, INSERM, Bordeaux, France; Miriam Labbok, MD, Academy of Breastfeeding Medicine and University of North Carolina, Chapel Hill, North Carolina; Reagan McDonald-Mosley, MD, Planned Parenthood Federation of America, New York, New York; Joan Meek, MD, American Academy of Pediatrics and Florida State University College of Medicine, Orlando, Florida; Mark Mirochnick, MD, Boston University, Boston, Massachusetts; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360, Durham, North Carolina; Jeffrey Peipert, MD, Washington University, St. Louis, Missouri; Michael Policar, MD, University of California, San Francisco, California; Sarah Prager, MD, University of Washington, Seattle Washington; David Soper, MD, Medical University of South Carolina, Charleston, South Carolina; Lisa Soule, MD, Food and Drug Administration, Rockville, Maryland; Alison Stuebe, MD, American College of Obstetricians and Gynecologist and University of North Carolina, Chapel Hill, North Carolina; James Trussell, PhD, Princeton University, Princeton, New Jersey; Seth Walker, MD, Emory University, Atlanta, Georgia; Nanette Wenger, MD, Emory University, Atlanta, Georgia; Carolyn Westhoff, MD, Columbia University, New York, New York; Christopher Zahn, MD, American College of Obstetricians and Gynecologists, Washington, DC.

CDC Attendees

Wanda D. Barfield, MD, Peter Briss, MD, W. Craig Hooper, PhD, Jill Huppert, MD, Caroline King, PhD, Michele Mandel, Titilope Oduyebo, MD, Cria Perrine, MD, Sam Posner, PhD.

External Reviewers

Abigail R.A. Aiken, PhD, Princeton University, Princeton, New Jersey; Linda Burdette, PA-C, Premier Women's Health of Yakima, Yakima, Washington; Mimi Zieman, MD, Planned Parenthood Southeast, Atlanta, Georgia.

Conflicts of Interest for Invited Meeting Participants, August 26–28, 2015, Atlanta, Georgia

Rebecca Allen, Nexplanon trainer for Merck and Liletta trainer for Actavis, consultant, advisory board and education grant from Bayer; Mitchell D. Creinin, Nexplanon trainer for Merck, litigation consultant for Bayer, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Lemonaid – PolkaDoc app, research support to University of California, Davis from Medicines360, Contramed, Merck, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and Society of Family Planning; Linda Dominguez, speaker for Bayer, Merck, and Actavis; Alison Edelman, royalties from Up to Date, Inc., consultant for Genzyme, grant support from the National Institutes of Health and the Gates Foundation, travel funds from the World Health Organization, grant support and honorarium from Society of Family Planning, honorarium and travel funds from Contemporary Forum, trainer for Merck, consultant for Gynuity Health Projects, honorarium from CDC, Projects In Knowledge, and American Congress of Obstetricians and Gynecologists, advisory board for Agile Therapeutics; Eve Espey, travel funds from the American Congress of Obstetricians and Gynecologists, Society for Family Planning, and U.S. Food and Drug Administration, Reproductive and Drug Advisory Committee for U.S. Food and Drug Administration, travel funds and honoraria from Wayne State University, Telluride Conference, New Mexico Department of Health Clinician Conference, Planned Parenthood National Medical Conference and Society of Family Planning, British Columbia Contraception Access Research Team Conference, and American Congress of Obstetricians and Gynecologists annual meeting; Emily Godfrey, research funding from Bayer Women's Health, Prima-Temp, and Teva Pharmaceutical Industries, Ltd., trainer for Merck and Upstream USA, grant reviewer for Fellowship of Family Planning and Society of Family Planning Research Fund; Mark Hathaway, Liletta trainer and speaker for Actavis and Medicines360, Nexplanon trainer for Merck, advisory board for Contramed and Afaxys Pharmaceuticals; Paula Hillard, consultant for American Civil Liberties Union, Advanced Health Media, CMEology, National Sleep Foundation, and Planned Parenthood Federation of America, honoraria from National Sleep Foundation, Dignity Health, CMEology, Advance Health Media, and Medscape, editorial board for Advanstar–Contemporary OB/GYN, board examiner for the American Board of Obstetrics and Gynecology, contract reviewer for the U.S. Department of Health and Human Services, editorial board for EBSCO–PEMSoft, Nexplanon trainer for Merck, scientific advisor to Proctor and Gamble, publication royalties from Wiley Blackwell Publishing; Andrew Kaunitz, advisory board participant of Allergan, Bayer, Merck, and Pfizer, clinical trial funding to University of Florida from Agile Therapeutics, Bayer, Merck; Mark Mirochnick, data and safety monitoring board for Merck and ViiV Healthcare, advisory board for Merck; Jeffrey Peipert, research funding from Bayer and Teva Pharmaceutical Industries, Ltd., advisory board for Perrigo; Michael Policar, litigation consultant for Bayer; James Trussell, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Bayer; Nanette Wenger, research grants from Alnylam Pharmaceuticals, Gilead Sciences, National Heart, Lung, and Blood Institute, Pfizer, and Society for Women's Health Research, consultant for Amgen, AstraZeneca, Gilead Sciences and Merck; Carolyn Westhoff, data and safety monitoring board for Merck and Bayer, advisory board for Agile Therapeutics, MicroChips Biotech, and Actavis, research support to Columbia University from Medicines360, León Farma, and ContraMed.

Handling Conflicts of Interest

To promote transparency, all participants were asked to disclose any potential conflicts of interest to CDC prior to the expert meeting and to report any potential conflicts of interest during the introductory portion of the expert meeting. All potential conflicts of interest are listed above. No participants were excluded from discussion based on potential conflicts of interest. CDC staff who ultimately decided and developed these recommendations have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters relevant to these recommendations.

References

1. Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008–2011. N Engl J Med 2016;374:843–52.http://dx.doi.org/10.1056/NEJMsa1506575
2. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. Stud Fam Plann 2008;39:18–38. http://dx.doi.org/10.1111/j.1728-4465.2008.00148.x
3. Sonfield A, Kost K. Public costs from unintended pregnancies and the role of public insurance programs in paying for pregnancy-related care: national and state estimates for 2010. New York: Guttmacher Institute; 2015.
4. World Health Organization. Medical eligibility criteria for contraceptive use. 4th ed. Geneva, Switzerland: World Health Organization; 2009.
5. CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR Recomm Rep 2010;59(No. RR-4).
6. Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-4).
7. Mohllajee AP, Curtis KM, Flanagan RG, Rinehart W, Gaffield ML, Peterson HB. Keeping up with evidence a new system for WHO's evidence-based family planning guidance. Am J Prev Med 2005;28:483–90.http://dx.doi.org/10.1016/j.amepre.2005.02.008
8. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. J Clin Epidemiol 2009;62:e1–34. http://dx.doi.org/10.1016/j.jclinepi.2009.06.006
9. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg 2010;8:336–41. http://dx.doi.org/10.1016/j.ijsu.2010.02.007
10. Harris RP, Helfand M, Woolf SH, et al; Methods Work Group, Third US Preventive Services Task Force. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med 2001;20(Suppl):21–35. http://dx.doi.org/10.1016/S0749-3797(01)00261-6
11. Horton L, Folger SG, Berry-Bibee E, Jatlaoui TC, Tepper NK, Curtis KM. Research gaps from evidence-based contraception guidance: the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, and the U.S. Selected Practice Recommendations for Contraceptive Use, 2016. Contraception. In press 2016.
12. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-3).

Abbreviations and Acronyms

ARV = antiretroviral [therapy]
BMD = bone mineral density
BMI = body mass index
CHC = combined hormonal contraceptive
COC = combined oral contraceptive
Cu-IUD = copper-containing intrauterine device
DMPA = depot medroxyprogesterone acetate
DVT = deep venous thrombosis
ECP = emergency contraceptive pills
FAB = fertility awareness–based [methods]
hCG = human chorionic gonadotropin
HDL = high-density lipoprotein
HIV = human immunodeficiency virus
IBD = inflammatory bowel disease
IUD = intrauterine device
LARC = long-acting reversible contraception
LDL = low-density lipoprotein
LNG = levonorgestrel
LNG-IUD = levonorgestrel-releasing intrauterine device
NET-EN = norethisterone enantate
NNRTI = nonnucleoside reverse transcriptase inhibitor
NRTI = nucleoside reverse transcriptase inhibitor
PE = pulmonary embolism
PID = pelvic inflammatory disease
POC = progestin-only contraceptive
POP = progestin-only pill
SLE = systemic lupus erythematosus
SSRI = selective serotonin reuptake inhibitors
STD = sexually transmitted disease
UPA = ulipristal acetate
U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use
U.S. SPR = U.S. Selected Practice Recommendations for Contraceptive Use
VTE = venous thromboembolism

Appendix A

Summary of Changes from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

The classification additions, deletions, and modifications from the 2010 *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) are summarized in the following tables (Box A1) (Tables A1 and A2). For conditions for which classifications changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics (Tables A1 and A2). Conditions that do not appear in this table remain unchanged from the 2010 U.S. MEC.

BOX A1. Categories for classifying intrauterine devices and hormonal contraceptives

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE A1. Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Breastfeeding							
a. <21 days postpartum	—	—	2	2	2	***4***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*).
b. 21 to <30 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	***2***	***2***	***2***	***3***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*). ***CHCs: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.***
ii. Without other risk factors for VTE	—	—	***2***	***2***	***2***	***3***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*).
c. 30–42 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	***1***	***1***	***1***	***3***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*). ***CHCs: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.***
ii. Without other risk factors for VTE	—	—	***1***	***1***	***1***	***2***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*).
d. >42 days postpartum	—	—	***1***	***1***	***1***	***2***	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*1*).

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Postpartum (nonbreastfeeding women)							
a. <21 days postpartum	—	—	1	1	1	***4***	—
b. 21–42 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	***1***	***1***	***1***	***3***	***CHCs: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.***
ii. Without other risk factors for VTE	—	—	***1***	***1***	***1***	***2***	—
c. >42 days postpartum	—	—	***1***	***1***	***1***	***1***	—
Postpartum (including cesarean delivery)							
a. <10 minutes after delivery of the placenta							***IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.*** ***Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).***
i. Breastfeeding	***1***	***2***	—	—	—	—	
ii. Nonbreastfeeding	***1***	***1***	—	—	—	—	
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2	2	—	—	—	—	***IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.*** ***Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).***
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1	1	—	—	—	—	***IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.*** ***Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).***
d. Postpartum sepsis	4	4	—	—	—	—	—

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	2	2	3	2	3/4	**Implants, DMPA, POP:** When multiple major risk factors exist, risk for cardiovascular disease might increase substantially. Certain POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs. The effects of DMPA might persist for some time after discontinuation. **CHCs:** When a woman has multiple major risk factors, any of which alone would substantially increase her risk for cardiovascular disease, use of CHCs might increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two category 2 risk factors might not necessarily warrant a higher category. **Implants, DMPA, POP, CHCs:** The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the *U.S. Selected Practice Recommendations for Contraceptive Use* (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm)
Superficial venous disorders							
a. Varicose veins	1	1	1	1	1	1	—
b. Superficial venous thrombosis (acute or history)	1	1	1	1	1	***3***	***CHCs: Superficial venous thrombosis might be associated with an increased risk for VTE. If a woman has risk factors for concurrent DVT (e.g., known thrombophilia or cancer) or has current or history of DVT, see recommendations for DVT/PE. Superficial venous thrombosis associated with a peripheral intravenous catheter is less likely to be associated with additional thrombosis and use of CHCs may be considered.***
Headaches							
a. Nonmigraine (mild or severe)	1	1	1	1	1	***1***	**CHCs:** Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see *The International Headache Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
b. Migraine							**CHCs:** Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated. **CHCs:** Classification is for women without any other risk factors for stroke (e.g., age, hypertension, and smoking).
i. Without aura (This category of migraine includes menstrual migraine.)	1	***1***	***1***	***1***	***1***	***2***	
ii. With aura	1	***1***	***1***	***1***	***1***	4	
Multiple sclerosis							
a. With prolonged immobility	***1***	***1***	***1***	***2***	***1***	***3***	—
b. Without prolonged immobility	***1***	***1***	***1***	***2***	***1***	***1***	—
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).							***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.***
a. Suspected gestational trophoblastic disease (immediate postevacuation)							***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.***
i. Uterine size first trimester	***1***	***1***	***1***	***1***	***1***	***1***	
ii. Uterine size second trimester	***2***	***2***	***1***	***1***	***1***	***1***	

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs	Clarification
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation	Continuation	Initiation	Continuation					
i. Undetectable/nonpregnant β-hCG levels	***1***	***1***	***1***	***1***	***1***	***1***	***1***	***1***	***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.***
ii. Decreasing β-hCG levels	***2***	***1***	***2***	***1***	***1***	***1***	***1***	***1***	***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.*** ***IUD: For women at higher risk for disease progression, the benefits of effective contraception must be weighed against the potential need for early IUD removal.***
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	***2***	***1***	***2***	***1***	***1***	***1***	***1***	***1***	***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.***
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	***4***	***2***	***4***	***2***	***1***	***1***	***1***	***1***	***For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.***
Sexually transmitted diseases	Initiation	Continuation	Initiation	Continuation					
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2	4	2	1	1	1	1	**IUD continuation:** Treat the STD using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID.
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	2	2	2	2	1	1	1	1	—
c. Other factors related to STDs	***2***	***2***	***2***	***2***	1	1	1	1	***IUD initiation: Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC STD treatment guidelines (2), screening may be performed at the time of IUD insertion and insertion should not be delayed.***
High risk for HIV	Initiation	Continuation	Initiation	Continuation					
	2	2	2	2	1	1	1	1	***DMPA: Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms (male or female) and take other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection are essential. These recommendations will be continually reviewed in light of new evidence.***
HIV infection ***For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).***	—	—	—	—	1	1	1	1	**Implants, DMPA, POP, CHCs:** Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section.
a. Clinically well receiving ARV therapy	***1***	***1***	***1***	***1***	—	—	—	—	—
b. Not clinically well or not receiving ARV therapy	***2***	***1***	***2***	***1***	—	—	—	—	—

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs	Clarification
Cystic fibrosis *This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).*	*1*		*1*		*1*	*2*	*1*	*1*	***Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.*** ***Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.***
Antiretroviral therapy	Initiation	Continuation	Initiation	Continuation					**IUD:** No known interaction exists between ARV therapy and IUD use. However, IUD insertion is classified as category 2 if the woman is not clinically well or not receiving ARV therapy. Otherwise, both insertion and continuation are classified as category 1 (see HIV Infection section).
a. Nucleoside reverse transcriptase inhibitors (NRTIs)									
i. Abacavir (ABC)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
ii. Tenofovir (TDF)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
iii. Zidovudine (AZT)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
iv. Lamivudine (3TC)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
v. Didanosine (DDI)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
vi. Emtricitabine (FTC)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
vii. Stavudine (D4T)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)									
i. Efavirenz (EFV)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	***Implants, DMPA, POP, CHCs: Evidence suggests drug interactions between efavirenz and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.***
ii. Etravirine (ETR)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
iii. Nevirapine (NVP)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
iv. Rilpivirine (RPV)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
c. Ritonavir-boosted protease inhibitors									
i. Ritonavir-boosted atazanavir (ATV/r)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	***Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.*** ***CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.***
ii. Ritonavir-boosted darunavir (DRV/r)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	***Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.*** ***CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.***

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs	Clarification
iii. Ritonavir-boosted fosamprenavir (FPV/r)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	*Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.* *CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.*
iv. Ritonavir-boosted lopinavir (LPV/r)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
v. Ritonavir-boosted saquinavir (SQV/r)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	*Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.* *CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.*
vi. Ritonavir-boosted tipranavir (TPV/r)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	*Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.* *CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.*
d. Protease inhibitors without ritonavir									
i. Atazanavir (ATV)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*2*	*CHCs: Theoretical concern exists that increased levels of ethinyl estradiol because of interactions with ATV might increase the risk for adverse events.*
ii. Fosamprenavir (FPV)	*1/2*	*1*	*1/2*	*1*	*2*	*2*	*2*	*3*	*Implants, DMPA, POP: Theoretical concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the antiretroviral drug. The drug interaction likely involves CYP3A4 pathways; POCs have less effect on CYP3A4 enzymes than CHCs.* *CHCs: Concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the antiretroviral drug.*
iii. Indinavir (IDV)	*1/2*	*1*	*1/2*	*1*	*1*	*1*	*1*	*1*	—
iv. Nelfinavir (NFV)	*1/2*	*1*	*1/2*	*1*	*2*	*1*	*2*	*2*	*Implants, DMPA, POP: Theoretically, drug interactions might occur between certain protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA. Concern exists that interactions between NFV and POCs might decrease NFV levels.* *CHCs: Evidence suggests drug interactions between certain protease inhibitors and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.*

See table footnotes on page 16.

TABLE A1. (*Continued*) Summary of changes in classifications from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs	Clarification
e. CCR5 co-receptor antagonists									
i. Maraviroc (MVC)	***1/2***	***1***	***1/2***	***1***	***1***	***1***	***1***	***1***	—
f. HIV integrase strand transfer inhibitors									
i. Raltegravir (RAL)	***1/2***	***1***	***1/2***	***1***	***1***	***1***	***1***	***1***	—
ii. Dolutegravir (DTG)	***1/2***	***1***	***1/2***	***1***	***1***	***1***	***1***	***1***	—
iii. Elvitegravir (EVG)	***1/2***	***1***	***1/2***	***1***	***1***	***1***	***1***	***1***	—
g. Fusion inhibitors									
i. Enfuvirtide	***1/2***	***1***	***1/2***	***1***	***1***	***1***	***1***	***1***	—
Psychotropic medications									
a. SSRIs		***1***		***1***	***1***	***1***	***1***	***1***	—
St. John's wort		***1***		***1***	***2***	***1***	***2***	***2***	—

Abbreviations: ARV = antiretroviral; BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; LNG-IUD = levonorgestrel-releasing intrauterine device; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; POP = progestin-only pill; SSRI = selective serotonin uptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

* For conditions for which classification changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics.

TABLE A2. Summary of changes for emergency contraception from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

	Category				
Condition	**Cu-IUD**	**UPA**	**LNG**	**COC**	**Clarification**
Pregnancy	4	***NA***	NA	NA	***IUD: The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion.*** ***ECPs: Although this method is not indicated for a woman with a known or suspected pregnancy, no harm to the woman, the course of her pregnancy, or the fetus if ECPs are inadvertently used is known to exist.***
Breastfeeding	***1***	***1***	1	1	***UPA: Breastfeeding is not recommended for 24 hours after taking UPA because it is excreted in breast milk with highest concentrations in the first 24 hours, and maximum maternal serum levels are reached 1-3 hours after administration. Mean UPA concentrations in breast milk decrease markedly from 0 to 24–48 hours and then slowly decrease over 5 days (3). Breast milk should be expressed and discarded for 24 hours after taking UPA.***
Past ectopic pregnancy	***1***	***1***	1	1	—
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	***1***	***1***	1	1	—
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	***1***	***1***	1	1	—
History of severe cardiovascular disease (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	***1***	***2***	2	2	—
Rheumatoid arthritis					
a. Receiving immunosuppressive therapy	***2***	***1***	1	1	—
b. Not receiving immunosuppressive therapy	***1***	***1***	1	1	—
Migraine	***1***	***1***	***1***	2	—
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	***1***	***1***	1	1	—
Severe liver disease (including jaundice) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	***1***	***2***	2	2	—

See table footnotes on page 17.

TABLE A2. (*Continued*) Summary of changes for emergency contraception from *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010**

Condition	Category				Clarification
	Cu-IUD	UPA	LNG	COC	
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	***3***	***1***	1	1	—
b. Uncomplicated	***2***	***1***	1	1	—
Repeated ECP use	***1***	***1***	1	1	**ECPs:** Recurrent ECP use is an indication that the woman requires further counseling about other contraceptive options. Frequently repeated ECP use might be harmful for women with conditions classified as 2, 3, or 4 for CHC or POC use.
Sexual assault	***2***	***1***	1	1	***IUD: Women who have experienced sexual assault are at increased risk for STDs. According to CDC STD treatment guidelines, routine presumptive treatment of chlamydia, gonorrhea, and trichomonas is recommended after sexual assault (2). Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (category 4).***
Obesity (BMI ≥30 kg/m²)	***1***	***2***	***2***	***2***	***ECPs: ECPs might be less effective among women with BMI ≥30 kg/m² than among women with BMI <25 kg/m². Despite this, no safety concerns exist.***
CYP3A4 inducers (e.g., bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate, efavirenz, and lumacaftor)	***1***	***2***	***2***	***2***	***ECPs: Strong CYP3A4 inducers might reduce the effectiveness of ECPs.***

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; ECP = emergency contraceptive pill; IUD = intrauterine device; LNG = levonorgestrel; NA = not applicable; POC = progestin-only contraceptive; STD = sexually transmitted disease; UPA = ulipristal acetate.
* For conditions for which classification changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics.

References

1. US Department of Health and Human Services. Healthy people 2020: maternal, infant, and child health objectives. Washington, DC: US Department of Health and Human Services; 2015. http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives
2. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-03).
3. Watson Pharmaceuticals. Ella [Prescribing information]. Morristown, NJ; 2010. https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf

Appendix B

Classifications for Intrauterine Devices

Classifications for intrauterine devices (IUDs) are for the copper-containing IUD and levonorgestrel-releasing IUD (containing a total of either 13.5 mg or 52 mg levonorgestrel) (Box B1) (Table B1). IUDs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX B1. Categories for classifying intrauterine devices

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE B1. Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD	Category: LNG-IUD	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History			
Pregnancy	4	4	**Clarification:** The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion.
Age			
a. Menarche to <20 years	2	2	**Comment:** Concern exists both about the risk for expulsion from nulliparity and for STDs from sexual behavior in younger age groups.
b. ≥20 years	1	1	—
Parity			
a. Nulliparous	2	2	**Evidence:** Data conflict about whether IUD use is associated with infertility among nulliparous women, although well-conducted studies suggest no increased risk (*1–9*).
b. Parous	1	1	—
Postpartum (including cesarean delivery)			
a. <10 minutes after delivery of the placenta			**Clarification:** Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.
i. Breastfeeding	1	2	**Clarification (breastfeeding):** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*10*).
ii. Nonbreastfeeding	1	1	**Evidence:** Studies suggest that immediate postplacental (<10 minutes) and early postpartum (10 minutes up until 72 hours) placement of Cu-IUDs and LNG-IUDs is associated with increased risk for expulsion compared with interval placement (i.e., not related to pregnancy). Early postpartum placement has similar or increased risk for expulsion compared with immediate postplacental placement. Although immediate postplacental placement at the time of cesarean delivery might have increased risk for expulsion compared with interval placement, risk appears lower than that for placement at the time of vaginal delivery. Evidence for infection, perforation, and removals for pain or bleeding are limited; however, these events are rare (*11–62*).
			Evidence (breastfeeding): Two randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum. Initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development (*63*,*64*). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (*11–62*,*65*).
			Comment (breastfeeding): Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category		Clarifications/Evidence/Comments
	Cu-IUD	LNG-IUD	
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2	2	**Clarification:** Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower. **Clarification (breastfeeding):** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*10*). **Evidence:** Studies suggest that immediate postplacental (<10 minutes) and early postpartum (10 minutes up until 72 hours) placement of Cu-IUDs and LNG-IUDs is associated with increased risk for expulsion compared with interval placement (i.e., not related to pregnancy). Early postpartum placement has similar or increased risk for expulsion compared with immediate postplacental placement. Although immediate postplacental placement at the time of cesarean delivery might have increased risk for expulsion compared with interval placement, risk appears lower than that for placement at the time of vaginal delivery. Evidence for infection, perforation, and removals for pain or bleeding are limited; however, these events are rare (*11–62*). **Evidence (breastfeeding):** Two randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum. Initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development (*63*,*64*). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (*11–62*,*65*). **Comment (breastfeeding):** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1	1	**Clarification:** Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower. **Clarification (breastfeeding):** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*10*). **Evidence (breastfeeding):** Initiation of LNG-IUDs at 4 weeks postpartum or later demonstrated no detrimental effect on breastfeeding outcomes and no harmful effect on infant health, growth, or development (*63*,*64*). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (*11–62*,*65*). **Comment (breastfeeding):** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
d. Postpartum sepsis	4	4	**Comment:** Theoretical concern exists that postpartum insertion of an IUD in a women with recent chorioamnionitis or current endometritis might be associated with increased complications.

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD	Category: LNG-IUD	Clarifications/Evidence/Comments
Postabortion			
a. First trimester	1	1	**Clarification:** IUDs can be inserted immediately after spontaneous or induced abortion. **Evidence:** Risk for complications from immediate versus delayed insertion of an IUD after abortion did not differ. Expulsion was greater when an IUD was inserted after a second trimester abortion than when inserted after a first trimester abortion. Safety or expulsion for postabortion insertion of an LNG-IUD did not differ from that of a Cu-IUD (*66*).
b. Second trimester	2	2	
c. Immediate postseptic abortion	4	4	**Comment:** Insertion of an IUD might substantially worsen the condition.
Past ectopic pregnancy	1	1	**Comment:** The absolute risk for ectopic pregnancy is extremely low because of the high effectiveness of IUDs. However, when a woman becomes pregnant during IUD use, the relative likelihood of ectopic pregnancy increases substantially.
History of pelvic surgery (see Postpartum [Including Cesarean Delivery] section)	1	1	—
Smoking			
a. Age <35 years	1	1	—
b. Age ≥35 years			
i. <15 cigarettes per day	1	1	—
ii. ≥15 cigarettes per day	1	1	—
Obesity			
a. BMI ≥30 kg/m^2	1	1	—
b. Menarche to <18 years and BMI ≥30 kg/m^2	1	1	—
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).			
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	—
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	—
Cardiovascular Disease			
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	2	—
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).			
a. Adequately controlled hypertension	1	1	**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
b. Elevated blood pressure levels (properly taken measurements)			**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Comment:** Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1	1	
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1	2	

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category		Clarifications/Evidence/Comments
	Cu-IUD	LNG-IUD	
c. Vascular disease	1	2	**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Comment:** Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	1	1	—
Deep venous thrombosis/ Pulmonary embolism			
a. History of DVT/PE, not receiving anticoagulant therapy			
i. Higher risk for recurrent DVT/PE (one or more risk factors) • History of estrogen-associated DVT/PE • Pregnancy-associated DVT/PE • Idiopathic DVT/PE • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	1	2	—
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	2	—
b. Acute DVT/PE	2	2	**Evidence:** No direct evidence exists on the use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with the use of POCs in otherwise healthy women are inconsistent, any small increased risk is substantially less than that with COCs (*67–69*).
c. DVT/PE and established anticoagulant therapy for at least 3 months			**Evidence:** No direct evidence exists on the use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with the use of POCs in otherwise healthy women are inconsistent, any small increased risk is substantially less than that with COCs (*67–69*). **Evidence:** Limited evidence indicates that insertion of the LNG-IUD does not pose major bleeding risks in women receiving chronic anticoagulant therapy (*70–73*). **Comment:** The LNG-IUD might be a useful treatment for menorrhagia in women receiving long-term anticoagulation therapy.
i. Higher risk for recurrent DVT/PE (one or more risk factors) • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	2	2	—
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	—
d. Family history (first-degree relatives)	1	1	—
e. Major surgery			
i. With prolonged immobilization	1	2	—
ii. Without prolonged immobilization	1	1	—
f. Minor surgery without immobilization	1	1	

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD	Category: LNG-IUD		Clarifications/Evidence/Comments
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2		**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
Superficial venous disorders				
a. Varicose veins	1	1		—
b. Superficial venous thrombosis (acute or history)	1	1		—
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	Initiation 2	Continuation 3	**Comment:** Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2		**Comment:** Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.
Valvular heart disease Complicated valvular heart disease is a condition associated with increased risk for adverse health events as a result of pregnancy (Box 2).				**Comment**: According to the American Heart Association, administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for patients who undergo genitourinary tract procedures, including insertion or removal of IUDs (*74*).
a. Uncomplicated	1	1		
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1	1		
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				**Evidence:** No direct evidence exists on the safety of IUDs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies did not demonstrate any cases of arrhythmia or infective endocarditis in women with cardiac disease who used IUDs (*75*).
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (*76*)				**Comment:** IUD insertion might induce cardiac arrhythmias in healthy women; women with peripartum cardiomyopathy have a high incidence of cardiac arrhythmias.
i. <6 months	2	2		
ii. ≥6 months	2	2		
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (*76*)	2	2		
Rheumatic Diseases				
Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation		
a. Positive (or unknown) antiphospholipid antibodies	1	1	3	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*73,77–94*).
				Evidence: Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (*95,96*)

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD		LNG-IUD		Clarifications/Evidence/Comments
b. Severe thrombocytopenia	3	2	2		**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*73*,*77–94*). **Clarification:** Severe thrombocytopenia increases the risk for bleeding. The category should be assessed according to the severity of thrombocytopenia and its clinical manifestations. In women with very severe thrombocytopenia who are at risk for spontaneous bleeding, consultation with a specialist and certain pretreatments might be warranted. **Evidence:** The LNG-IUD might be a useful treatment for menorrhagia in women with severe thrombocytopenia (*73*).
c. Immunosuppressive therapy	2	1	2		**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*73*,*77–94*).
d. None of the above	1	1	2		**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*73*,*77–94*).
Rheumatoid arthritis	Initiation	Continuation	Initiation	Continuation	
a. Receiving immunosuppressive therapy	2	1	2	1	—
b. Not receiving immunosuppressive therapy	1		1		—
Neurologic Conditions					
Headaches					
a. Nonmigraine (mild or severe)	1		1		—
b. Migraine					
i. Without aura (This category of migraine includes menstrual migraine.)	1		1		**Evidence:** No studies directly examined the risk for stroke among women with migraine using LNG-IUDs (*97*). Limited evidence demonstrated that women using LNG-IUDs do not have an increased risk for ischemic stroke compared with women not using hormonal contraceptives (*98*). **Comment:** Menstrual migraine is a subtype of migraine without aura. For more information see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
ii. With aura	1		1		
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		—
Multiple sclerosis					
a. With prolonged immobility	1		1		—
b. Without prolonged immobility	1		1		—
Depressive Disorders					
Depressive disorders	1		1		**Clarification**: If a woman is receiving psychotropic medications or St. John's wort, see Drug Interactions section. **Evidence:** The frequency of psychiatric hospitalizations for women with bipolar disorder or depression did not significantly differ among women using DMPA, LNG-IUD, Cu-IUD, or sterilization (*99*).

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD		LNG-IUD		Clarifications/Evidence/Comments
Reproductive Tract Infections and Disorders					
Vaginal bleeding patterns			Initiation	Continuation	
a. Irregular pattern without heavy bleeding	1		1	1	—
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2		1	2	**Clarification:** Unusually heavy bleeding should raise suspicion of a serious underlying condition. **Evidence:** Evidence from studies examining the treatment effects of the LNG-IUD among women with heavy or prolonged bleeding reported no increase in adverse effects and found the LNG-IUD to be beneficial in treating menorrhagia (*100–107*).
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	Initiation 4	Continuation 2	Initiation 4	Continuation 2	**Clarification:** If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation. The IUD does not need to be removed before evaluation.
Endometriosis	2		1		**Evidence:** LNG-IUD use among women with endometriosis decreased dysmenorrhea, pelvic pain, and dyspareunia (*108–112*).
Benign ovarian tumors (including cysts)	1		1		—
Severe dysmenorrhea	2		1		**Comment:** Dysmenorrhea might intensify with Cu-IUD use. LNG-IUD use has been associated with reduction of dysmenorrhea.
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Suspected gestational trophoblastic disease (immediate postevacuation)					**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.
i. Uterine size first trimester	1		1		
ii. Uterine size second trimester	2		2		**Evidence:** Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (*113*). **Comment:** The risk for expulsion immediately postevacuation for gestational trophoblastic disease is unknown. Expulsion is greater after IUD insertion immediately postevacuation for a spontaneous or induced abortion in the second trimester compared with IUD insertion after a first trimester abortion.
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation	Continuation	Initiation	Continuation	
i. Undetectable/nonpregnant β-hCG levels	1	1	1	1	**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance. **Evidence:** Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (*113*). **Comment:** Once β-hCG levels have decreased to nonpregnant levels, the risk for disease progression is likely to be very low.
ii. Decreasing β-hCG levels	2	1	2	1	**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance. **Clarification:** For women at higher risk for disease progression, the benefits of effective contraception must be weighed against the potential need for early IUD removal. **Evidence:** Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (*113*).

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD		LNG-IUD		Clarifications/Evidence/Comments
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2	1	2	1	**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance. **Evidence:** Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (*113*).
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4	2	4	2	**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance. **Evidence:** Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (*113*). **Comment:** For women with suspected or confirmed intrauterine disease, an IUD should not be inserted because of theoretical risk for perforation, infection, and hemorrhage. For women who already have an IUD in place, individual circumstance along with the benefits of effective contraception must be weighed against theoretical risks of either removal or continuation of the IUD.
Cervical ectropion	1		1		—
Cervical intraepithelial neoplasia	1		2		**Comment:** Theoretical concern exists that LNG-IUDs might enhance progression of cervical intraepithelial neoplasia.
Cervical cancer (awaiting treatment)	Initiation 4	Continuation 2	Initiation 4	Continuation 2	**Comment:** Concern exists about the increased risk for infection and bleeding at insertion. The IUD most likely will need to be removed at the time of treatment but until then, the woman is at risk for pregnancy.
Breast disease Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Undiagnosed mass	1		2		—
b. Benign breast disease	1		1		—
c. Family history of cancer	1		1		—
d. Breast cancer					**Comment:** Breast cancer is a hormonally sensitive tumor. Concerns about progression of the disease might be less with LNG-IUDs than with COCs or higher-dose POCs.
i. Current	1		4		
ii. Past and no evidence of current disease for 5 years	1		3		
Endometrial hyperplasia	1		1		**Evidence:** Among women with endometrial hyperplasia, no adverse health events occurred with LNG-IUD use; most women experienced disease regression (*114*).
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation 4	Continuation 2	Initiation 4	Continuation 2	**Comment:** Concern exists about the increased risk for infection, perforation, and bleeding at insertion. The IUD most likely will need to be removed at the time of treatment, but until then, the woman is at risk for pregnancy.
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		**Comment:** Women with ovarian cancer who undergo fertility-sparing treatment and need contraception may use an IUD.
Uterine fibroids	2		2		**Evidence:** Among women with uterine fibroids using an LNG-IUD, most experienced improvements in serum levels of hemoglobin, hematocrit, and ferritin and in menstrual blood loss (*115*). Rates of LNG-IUD expulsion were higher in women with uterine fibroids (11%) than in women without fibroids (0%–3%); these findings were either not statistically significant or significance testing was not conducted (*115*). Rates of expulsion found in noncomparative studies ranged from 0%–20% (*115*). **Comment:** Women with heavy or prolonged bleeding should be assigned the category for that condition.

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD		Category: LNG-IUD		Clarifications/Evidence/Comments
Anatomical abnormalities					
a. Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion)	4		4		**Comment:** An anatomical abnormality that distorts the uterine cavity might preclude proper IUD placement.
b. Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion	2		2		—
Pelvic inflammatory disease	Initiation	Continuation	Initiation	Continuation	
a. Past PID					**Comment:** IUDs do not protect against STDs, including HIV, or PID. In women at low risk for STDs, IUD insertion poses little risk for PID.
i. With subsequent pregnancy	1	1	1	1	
ii. Without subsequent pregnancy	2	2	2	2	
b. Current PID	4	2	4	2	**Clarification (continuation):** Treat the PID using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID. **Evidence:** Among IUD users treated for PID, clinical course did not differ regardless of whether the IUD was removed or left in place (*116*).
Sexually transmitted diseases	Initiation	Continuation	Initiation	Continuation	
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2	4	2	**Clarification (continuation):** Treat the STD using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID. **Evidence:** Among women who had an IUD inserted, the absolute risk for subsequent PID was low among women with STD at the time of insertion but greater than among women with no STD at the time of IUD insertion (*117–123*).
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	2	2	2	2	—
c. Other factors related to STDs	2	2	2	2	**Clarification (initiation):** Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC STD treatment guidelines (*124*), screening may be performed at the time of IUD insertion and insertion should not be delayed. **Evidence:** Women who undergo same-day STD screening and IUD insertion have low incidence rates of PID. Algorithms for predicting PID among women with risk factors for STDs have poor predictive value. Risk for PID among women with risk factors for STDs is low (*125*).
HIV					
High risk for HIV	Initiation	Continuation	Initiation	Continuation	**Evidence:** Among women at risk for HIV, Cu-IUD use did not increase risk for HIV acquisition (*126–136*).
	2	2	2	2	
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					**Evidence:** Among IUD users, limited evidence shows a low risk for PID among HIV-infected women using IUDs and no higher risk for pelvic infectious complications in HIV-infected than in HIV-noninfected women or among women with varying degrees of HIV severity. IUD use did not adversely affect progression of HIV during 6–45 months of follow-up or when compared with hormonal contraceptive use among HIV-infected women. Furthermore, IUD use among HIV-infected women was not associated with increased risk for transmission to sex partners or with increased genital viral shedding (*137*).
a. Clinically well receiving ARV therapy	1	1	1	1	
b. Not clinically well or not receiving ARV therapy	2	1	2	1	

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category: Cu-IUD		LNG-IUD		Clarifications/Evidence/Comments
Other Infections					
Schistosomiasis					
Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Uncomplicated	1		1		—
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1		1		—
Tuberculosis	Initiation	Continuation	Initiation	Continuation	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Nonpelvic	1	1	1	1	—
b. Pelvic	4	3	4	3	**Comment:** Insertion of an IUD might substantially worsen the condition.
Malaria	1		1		—
Endocrine Conditions					
Diabetes					
Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. History of gestational disease	1		1		—
b. Nonvascular disease					**Evidence:** Limited evidence on the use of the LNG-IUD among women with insulin-dependent or non–insulin-dependent diabetes suggests that these methods have little effect on short-term or long-term diabetes control (e.g., glycosylated hemoglobin levels), hemostatic markers, or lipid profile (*138*,*139*).
i. Non-insulin dependent	1		2		
ii. Insulin dependent	1		2		
c. Nephropathy, retinopathy, or neuropathy	1		2		—
d. Other vascular disease or diabetes of >20 years' duration	1		2		—
Thyroid disorders					
a. Simple goiter	1		1		—
b. Hyperthyroid	1		1		—
c. Hypothyroid	1		1		—
Gastrointestinal Conditions					
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1		1		**Evidence:** Although two case reports described three women with IBD who experienced exacerbation of disease 5 days–25 months after LNG-IUD insertion, no comparative studies have examined the safety of IUD use among women with IBD (*140*).
Gallbladder disease					
a. Symptomatic					
i. Treated by cholecystectomy	1		2		—
ii. Medically treated	1		2		—
iii. Current	1		2		—
b. Asymptomatic	1		2		—
History of cholestasis					
a. Pregnancy related	1		1		—
b. Past COC related	1		2		**Comment:** Concern exists that history of COC related cholestasis might predict subsequent cholestasis with LNG use. Whether risk exists with use of LNG-IUD is unclear.
Viral hepatitis					
a. Acute or flare	1		1		—
b. Carrier	1		1		—
c. Chronic	1		1		—
Cirrhosis					
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Mild (compensated)	1		1		—
b. Severe (decompensated)	1		3		—

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category				Clarifications/Evidence/Comments
	Cu-IUD		LNG-IUD		
Liver tumors Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Benign					
i. Focal nodular hyperplasia	1		2		—
ii. Hepatocellular adenoma	1		3		**Comment:** No evidence is available about hormonal contraceptive use in women with hepatocellular adenoma. COC use in healthy women is associated with development and growth of hepatocellular adenoma; whether other hormonal contraceptives have similar effects is not known.
b. Malignant (hepatoma)	1		3		—
Respiratory Conditions					
Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		**Clarification:** Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.
Anemias					
Thalassemia	2		1		**Comment:** Concern exists about an increased risk for blood loss with Cu-IUDs.
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	2		1		**Comment:** Concern exists about an increased risk for blood loss with Cu-IUDs.
Iron deficiency anemia	2		1		**Comment:** Concern exists about an increased risk for blood loss with Cu-IUDs.
Solid Organ Transplantation					
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation	Initiation	Continuation	**Evidence:** No comparative studies have examined IUD use among transplant patients. Four case reports of transplant patients using IUDs provided inconsistent results, including beneficial effects and contraceptive failures (*141*).
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	2	3	2	
b. Uncomplicated	2	2	2	2	
Drug Interactions					
Antiretroviral therapy	Initiation	Continuation	Initiation	Continuation	**Clarification:** No known interaction exists between ARV therapy and IUD use. However, IUD insertion is classified as category 2 if the woman is not clinically well or not receiving ARV therapy. Otherwise, both insertion and continuation are classified as category 1 (see HIV Infection section).
a. Nucleoside reverse transcriptase inhibitors (NRTIs)					
i. Abacavir (ABC)	1/2	1	1/2	1	—
ii. Tenofovir (TDF)	1/2	1	1/2	1	—
iii. Zidovudine (AZT)	1/2	1	1/2	1	—
iv. Lamivudine (3TC)	1/2	1	1/2	1	—
v. Didanosine (DDI)	1/2	1	1/2	1	—
vi. Emtricitabine (FTC)	1/2	1	1/2	1	—
vii. Stavudine (D4T)	1/2	1	1/2	1	—
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)					
i. Efavirenz (EFV)	1/2	1	1/2	1	—
ii. Etravirine (ETR)	1/2	1	1/2	1	—
iii. Nevirapine (NVP)	1/2	1	1/2	1	—
iv. Rilpivirine (RPV)	1/2	1	1/2	1	—
c. Ritonavir-boosted protease inhibitors					
i. Ritonavir-boosted atazanavir (ATV/r)	1/2	1	1/2	1	—
ii. Ritonavir-boosted darunavir (DRV/r)	1/2	1	1/2	1	—

See table footnotes on page 30.

TABLE B1. (*Continued*) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition	Category				Clarifications/Evidence/Comments
	Cu-IUD		LNG-IUD		
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1/2	1	1/2	1	—
iv. Ritonavir-boosted lopinavir (LPV/r)	1/2	1	1/2	1	—
v. Ritonavir-boosted saquinavir (SQV/r)	1/2	1	1/2	1	—
vi. Ritonavir-boosted tipranavir (TPV/r)	1/2	1	1/2	1	—
d. Protease inhibitors without ritonavir					
i. Atazanavir (ATV)	1/2	1	1/2	1	—
ii. Fosamprenavir (FPV)	1/2	1	1/2	1	—
iii. Indinavir (IDV)	1/2	1	1/2	1	—
iv. Nelfinavir (NFV)	1/2	1	1/2	1	—
e. CCR5 co-receptor antagonists					
i. Maraviroc (MVC)	1/2	1	1/2	1	—
f. HIV integrase strand transfer inhibitors					
i. Raltegravir (RAL)	1/2	1	1/2	1	—
ii. Dolutegravir (DTG)	1/2	1	1/2	1	—
iii. Elvitegravir (EVG)	1/2	1	1/2	1	—
g. Fusion inhibitors					
i. Enfuvirtide	1/2	1	1/2	1	—
Anticonvulsant therapy					
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	1		1		**Evidence:** Limited evidence suggests use of certain anticonvulsants does not interfere with the contraceptive effectiveness of the LNG-IUD (*142*).
b. Lamotrigine	1		1		**Evidence:** No drug interactions have been reported among women with epilepsy who are receiving lamotrigine and using the LNG-IUD (*143*).
Antimicrobial therapy					
a. Broad-spectrum antibiotics	1		1		—
b. Antifungals	1		1		—
c. Antiparasitics	1		1		—
d. Rifampin or rifabutin therapy	1		1		**Evidence:** One cross-sectional survey found that rifabutin had no impact on the effectiveness of the LNG-IUD (*142*).
Psychotropic medications					**Comment:** For many common psychotropic agents, limited or no theoretical concern exists for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications.
a. SSRIs	1		1		—
St. John's wort	1		1		—

Abbreviations: ARV = antiretroviral; BMI = body mass index; COC = combined oral contraceptive; Cu-IUD = copper-containing IUD; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; IUD = intrauterine device; LDL = low-density lipoprotein; LNG = levonorgestrel; LNG-IUD = levonorgestrel-releasing IUD; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; SLE = systemic lupus erythematosus; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

References

1. Cramer DW, Schiff I, Schoenbaum SC, et al. Tubal infertility and the intrauterine device. N Engl J Med 1985;312:941–7. http://dx.doi.org/10.1056/NEJM198504113121502
2. Daling JR, Weiss NS, Metch BJ, et al. Primary tubal infertility in relation to the use of an intrauterine device. N Engl J Med 1985;312:937–41. http://dx.doi.org/10.1056/NEJM198504113121501
3. Daling JR, Weiss NS, Voigt LF, McKnight B, Moore DE. The intrauterine device and primary tubal infertility. N Engl J Med 1992;326:203–4. http://dx.doi.org/10.1056/NEJM199201163260314
4. Delbarge W, Bátár I, Bafort M, et al. Return to fertility in nulliparous and parous women after removal of the GyneFix intrauterine contraceptive system. Eur J Contracept Reprod Health Care 2002;7:24–30. http://dx.doi.org/10.1080/ejc.7.1.24.30
5. Doll H, Vessey M, Painter R. Return of fertility in nulliparous women after discontinuation of the intrauterine device: comparison with women discontinuing other methods of contraception. BJOG 2001;108:304–14. http://dx.doi.org/10.1111/j.1471-0528.2001.00075.x
6. Hubacher D, Lara-Ricalde R, Taylor DJ, Guerra-Infante F, Guzmán-Rodríguez R. Use of copper intrauterine devices and the risk of tubal infertility among nulligravid women. N Engl J Med 2001;345:561–7. http://dx.doi.org/10.1056/NEJMoa010438
7. Skjeldestad FE, Bratt H. Return of fertility after use of IUDs (Nova-T, MLCu250 and MLCu375). Adv Contracept 1987;3:139–45. http://dx.doi.org/10.1007/BF01890702
8. Urbach DR, Marrett LD, Kung R, Cohen MM. Association of perforation of the appendix with female tubal infertility. Am J Epidemiol 2001;153:566–71. http://dx.doi.org/10.1093/aje/153.6.566
9. Wilson JC. A prospective New Zealand study of fertility after removal of copper intrauterine contraceptive devices for conception and because of complications: a four-year study. Am J Obstet Gynecol 1989;160:391–6. http://dx.doi.org/10.1016/0002-9378(89)90455-9
10. US Department of Health and Human Services. Healthy people 2020: Maternal, infant, and child health objectives. Washington, DC: US Department of Health and Human Services; 2015. http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives

11. Annus J, Brat T, Diethelm MP, et al.; World Health Organization Special. Comparative multicentre trial of three IUDs inserted immediately following delivery of the placenta. Contraception 1980;22:9–18.http://dx.doi.org/10.1016/0010-7824(80)90112-2
12. Apelo RA, Waszak CS. Postpartum IUD insertions in Manila, Philippines. Adv Contracept 1985;1:319–28.
13. Baldwin MK, Edelman AB, Lim JY, Nichols MD, Bednarek PH, Jensen JT. Intrauterine device placement at 3 versus 6weeks postpartum: a randomized trial. Contraception 2016;93:356–63.http://dx.doi.org/10.1016/j.contraception.2015.12.006
14. Bonilla Rosales F, Aguilar Zamudio ME, Cázares Montero ML, Hernández Ortiz ME, Luna Ruiz MA. [Factors for expulsion of intrauterine device Tcu380A applied immediately postpartum and after a delayed period]. Rev Med Inst Mex Seguro Soc 2005;43:5–10.
15. Braniff K, Gomez E, Muller R. A randomised clinical trial to assess satisfaction with the levonorgestrel- releasing intrauterine system inserted at caesarean section compared to postpartum placement. Aust N Z J Obstet Gynaecol 2015;55:279–83.http://dx.doi.org/10.1111/ajo.12335
16. Bryant AG, Kamanga G, Stuart GS, Haddad LB, Meguid T, Mhango C. Immediate postpartum versus 6-week postpartum intrauterine device insertion: a feasibility study of a randomized controlled trial. Afr J Reprod Health 2013;17:72–9.
17. Caliskan E, Ozturk N, Dilbaz BO, Dilbaz S. Analysis of risk factors associated with uterine perforation by intrauterine devices. Eur J Contracep Reprod 2003;8:150–5.
18. Çelen S, Möröy P, Sucak A, Aktulay A, Danişman N. Clinical outcomes of early postplacental insertion of intrauterine contraceptive devices. Contraception 2004;69:279–82.http://dx.doi.org/10.1016/j.contraception.2003.12.004
19. Çelen Ş, Sucak A, Yıldız Y, Danışman N. Immediate postplacental insertion of an intrauterine contraceptive device during cesarean section. Contraception 2011;84:240–3.http://dx.doi.org/10.1016/j.contraception.2011.01.006
20. Chen BA, Reeves MF, Hayes JL, Hohmann HL, Perriera LK, Creinin MD. Postplacental or delayed insertion of the levonorgestrel intrauterine device after vaginal delivery: a randomized controlled trial. Obstet Gynecol 2010;116:1079–87.http://dx.doi.org/10.1097/AOG.0b013e3181f73fac
21. Chen JH, Wu SC, Shao WQ, et al. The comparative trial of TCu 380A IUD and progesterone-releasing vaginal ring used by lactating women. Contraception 1998;57:371–9.http://dx.doi.org/10.1016/S0010-7824(98)00043-2
22. Cohen R, Sheeder J, Arango N, Teal SB, Tocce K. Twelve-month contraceptive continuation and repeat pregnancy among young mothers choosing postdelivery contraceptive implants or postplacental intrauterine devices. Contraception 2016;93:178–83.http://dx.doi.org/10.1016/j.contraception.2015.10.001
23. Dahlke JD, Terpstra ER, Ramseyer AM, Busch JM, Rieg T, Magann EF. Postpartum insertion of levonorgestrel—intrauterine system at three time periods: a prospective randomized pilot study. Contraception 2011;84:244–8.http://dx.doi.org/10.1016/j.contraception.2011.01.007
24. Dias T, Abeykoon S, Kumarasiri S, Gunawardena C, Padeniya T, D'Antonio F. Use of ultrasound in predicting success of intrauterine contraceptive device insertion immediately after delivery. Ultrasound Obstet Gynecol 2015;46:104–8.
25. Elsedeek MS. Puerperal and menstrual bleeding patterns with different types of contraceptive device fitted during elective cesarean delivery. Int J Gynaecol Obstet 2012;116:31–4.http://dx.doi.org/10.1016/j.ijgo.2011.07.036
26. Elsedeek MS. Five-year follow-up of two types of contraceptive device fitted during elective cesarean delivery. Int J Gynaecol Obstet 2015;130:179–82.http://dx.doi.org/10.1016/j.ijgo.2015.02.031
27. El-Shafei MM, Mashali A, Hassan EO, El-Boghdad L, El-Lakkany N. Postpartum and postabortion intrauterine device insertion unmet needs of safe reproductive health: three years experience of Mansoura University Hospital. J Egypt Soc Obstet Gynecol 2000;26:253–62.
28. Eroğlu K, Akkuzu G, Vural G, et al. Comparison of efficacy and complications of IUD insertion in immediate postplacental/early postpartum period with interval period: 1 year follow-up. Contraception 2006;74:376–81.http://dx.doi.org/10.1016/j.contraception.2006.07.003
29. Gueye M, Gaye YF, Diouf AA, et al. Trancesarean intra-uterine device. Pilot study performed at Dakar teaching hospital. [French]. J Gynecol Obstet Biol Reprod (Paris) 2013;42:585–90.http://dx.doi.org/10.1016/j.jgyn.2013.06.003
30. Gupta S, Malik S, Sinha R, Shyamsunder S, Mittal MK. Association of the Position of the Copper T 380A as Determined by the Ultrasonography Following its Insertion in the Immediate Postpartum Period with the Subsequent Complications: An Observational Study. J Obstet Gynaecol India 2014;64:349–53.http://dx.doi.org/10.1007/s13224-014-0532-5
31. Hagbard L, Ingemanson CA, Sorbe B. Early postpartum insertion of copper IUD. Contraception 1978;17:355–63.http://dx.doi.org/10.1016/0010-7824(78)90081-1
32. Hayes JL, Cwiak C, Goedken P, Zieman M. A pilot clinical trial of ultrasound-guided postplacental insertion of a levonorgestrel intrauterine device. Contraception 2007;76:292–6.http://dx.doi.org/10.1016/j.contraception.2007.06.003
33. Jatlaoui TC, Marcus M, Jamieson DJ, Goedken P, Cwiak C. Postplacental intrauterine device insertion at a teaching hospital. Contraception 2014;89:528–33.http://dx.doi.org/10.1016/j.contraception.2013.10.008
34. Kumar S, Sethi R, Balasubramaniam S, et al. Women's experience with postpartum intrauterine contraceptive device use in India. Reprod Health 2014;11:32.http://dx.doi.org/10.1186/1742-4755-11-32
35. Laes E, Lehtovirta P, Weintraub D, Pyörälä T, Luukkainen T. Early puerperal insertions of copper-T-200. Contraception 1975;11:289–95.http://dx.doi.org/10.1016/0010-7824(75)90037-2
36. Lara Ricalde R, Menocal Tobías G, Ramos Pérez C, Velázquez Ramírez N. [Random comparative study between intrauterine device Multiload Cu375 and TCu 380a inserted in the postpartum period]. Ginecol Obstet Mex 2006;74:306–11.
37. Lavin P, Bravo C, Waszak C. Comparison of T Cu 200 and Progestasert IUDs. Contracept Deliv Syst 1983;4:143–7.
38. Lavin P, Waszak C, Bravo C. Preliminary report on a postpartum CuT 200 study, Santiago, Chile. Int J Gynaecol Obstet 1983;21:71–5.http://dx.doi.org/10.1016/0020-7292(83)90073-5
39. Lester F, Kakaire O, Byamugisha J, et al. Intracesarean insertion of the Copper T380A versus 6 weeks postcesarean: a randomized clinical trial. Contraception 2015;91:198–203.http://dx.doi.org/10.1016/j.contraception.2014.12.002
40. Letti Müller AL, Lopes Ramos JG, Martins-Costa SH, et al. Transvaginal ultrasonographic assessment of the expulsion rate of intrauterine devices inserted in the immediate postpartum period: a pilot study. Contraception 2005;72:192–5.http://dx.doi.org/10.1016/j.contraception.2005.03.014
41. Levi E, Cantillo E, Ades V, Banks E, Murthy A. Immediate postplacental IUD insertion at cesarean delivery: a prospective cohort study. Contraception 2012;86:102–5.http://dx.doi.org/10.1016/j.contraception.2011.11.019
42. Levi EE, Stuart GS, Zerden ML, Garrett JM, Bryant AG. Intrauterine device placement during cesarean delivery and continued use 6 months postpartum: a randomized controlled trial. Obstet Gynecol 2015;126:5–11.http://dx.doi.org/10.1097/AOG.0000000000000882
43. Mishra S. Evaluation of Safety, Efficacy, and Expulsion of Post-Placental and Intra-Cesarean Insertion of Intrauterine Contraceptive Devices (PPIUCD). J Obstet Gynaecol India 2014;64:337–43.http://dx.doi.org/10.1007/s13224-014-0550-3
44. Morrison C, Waszak C, Katz K, Diabaté F, Mate EM. Clinical outcomes of two early postpartum IUD insertion programs in Africa. Contraception 1996;53:17–21.http://dx.doi.org/10.1016/0010-7824(95)00254-5
45. Nelson AL, Chen S, Eden R. Intraoperative placement of the Copper T-380 intrauterine devices in women undergoing elective cesarean delivery: a pilot study. Contraception 2009;80:81–3.http://dx.doi.org/10.1016/j.contraception.2009.01.014

46. Newton J, Harper M, Chan KK. Immediate post-placental insertion of intrauterine contraceptive devices. Lancet 1977;310:272–4.http://dx.doi.org/10.1016/S0140-6736(77)90955-2
47. Prema K, Gayathri TL, Philips FS. Comparative study of early postpartum, postabortal and interval insertion of Cu T 200 mm2 device. J Obstet Gynaecol India 1978;28:946–8.
48. Puzey M. Mirena at caesarean section. Eur J Contracep Reprod 2005;10:164–7.
49. Ragab A, Hamed HO, Alsammani MA, et al. Expulsion of Nova-T380, Multiload 375, and Copper-T380A contraceptive devices inserted during cesarean delivery. Int J Gynaecol Obstet 2015;130:174–8.http://dx.doi.org/10.1016/j.ijgo.2015.03.025
50. Shukla M, Qureshi S; Chandrawati. Post-placental intrauterine device insertion—a five year experience at a tertiary care centre in north India. Indian J Med Res 2012;136:432–5.
51. Singal S, Bharti R, Dewan R, et al. Clinical Outcome of Postplacental Copper T 380A Insertion in Women Delivering by Caesarean Section. J Clin Diagn Res 2014;8:OC01–04.
52. Stuart GS, Bryant AG, O'Neill E, Doherty IA. Feasibility of postpartum placement of the levonorgestrel intrauterine system more than 6 h after vaginal birth. Contraception 2012;85:359–62.http://dx.doi.org/10.1016/j.contraception.2011.08.005
53. Stuart GS, Lesko CR, Stuebe AM, Bryant AG, Levi EE, Danvers AI. A randomized trial of levonorgestrel intrauterine system insertion 6 to 48 h compared to 6 weeks after vaginal delivery; lessons learned. Contraception 2015;91:284–8.http://dx.doi.org/10.1016/j.contraception.2014.12.009
54. Thiery M, Van Kets H, Van der Pas H. Immediate post-placental IUD insertion: the expulsion problem. Contraception 1985;31:331–49.http://dx.doi.org/10.1016/0010-7824(85)90002-2
55. Van Der Pas MT, Delbeke L, Van Dets H. Comparative performance of two copper-wired IUDs (ML Cu 250 and T Cu 200: immediate postpartum and interval insertion. Contracept Deliv Syst 1980;1:27–35.
56. Welkovic S, Costa LO, Faúndes A, de Alencar Ximenes R, Costa CF. Post-partum bleeding and infection after post-placental IUD insertion. Contraception 2001;63:155–8.http://dx.doi.org/10.1016/S0010-7824(01)00180-9
57. Whitaker AK, Endres LK, Mistretta SQ, Gilliam ML. Postplacental insertion of the levonorgestrel intrauterine device after cesarean delivery vs. delayed insertion: a randomized controlled trial. Contraception 2014;89:534–9.http://dx.doi.org/10.1016/j.contraception.2013.12.007
58. Woo CJ, Alamgir H, Potter JE. Women's experiences after Planned Parenthood's exclusion from a family planning program in Texas. Contraception 2016;93:298–302.http://dx.doi.org/10.1016/j.contraception.2015.12.004
59. Wu SC; Research Group on Failure Causes and Prevention Measures of Intrauterine Device. [Efficacy of intrauterine device TCu380A when inserted in four different periods]. Zhonghua Fu Chan Ke Za Zhi 2009;44:431–5.
60. Xu J, Yang X, Gu X, et al. Comparison between two techniques used in immediate postplacental insertion of TCu 380A intrauterine device: 36-month follow-up. Reprod Contracept 1999;10:156–62.
61. Xu J, Zhuang L, Yu G. [Comparison of two techniques used in immediate postplacental insertion of TCu 380A intrauterine device: 12 month follow-up of 910 cases]. Zhonghua Fu Chan Ke Za Zhi 1997;32:354–7.
62. Xu JX, Rivera R, Dunson TR, et al. A comparative study of two techniques used in immediate postplacental insertion (IPPI) of the Copper T-380A IUD in Shanghai, People's Republic of China. Contraception 1996;54:33–8.http://dx.doi.org/10.1016/0010-7824(96)00117-5
63. Braniff K, Gomez E, Muller R. A randomised clinical trial to assess satisfaction with the levonorgestrel- releasing intrauterine system inserted at caesarean section compared to postpartum placement. Aust N Z J Obstet Gynaecol 2015;55:279–83. http://dx.doi.org/10.1111/ajo.12335
64. Phillips SJ, Tepper NK, Kapp N, Nanda K, Temmerman M, Curtis KM. Progestogen-only contraceptive use among breastfeeding women: a systematic review. Contraception 2015;S0010-7824(15)00585-5.
65. Berry-Bibee E, Tepper N, Jatlaoui T, Whiteman M, Jamieson D, Curtis K. The safety of intrauterine devices in breastfeeding women: a systematic review. Contraception. In press 2016.
66. Steenland MW, Tepper NK, Curtis KM, Kapp N. Intrauterine contraceptive insertion postabortion: a systematic review. Contraception 2011;84:447–64. http://dx.doi.org/10.1016/j.contraception.2011.03.007
67. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Cardiovascular disease and use of oral and injectable progestogen-only contraceptives and combined injectable contraceptives. Results of an international, multicenter, case-control study. Contraception 1998;57:315–24. http://dx.doi.org/10.1016/S0010-7824(98)00041-9.
68. Heinemann LA, Assmann A, DoMinh T, Garbe E. Oral progestogen-only contraceptives and cardiovascular risk: results from the Transnational Study on Oral Contraceptives and the Health of Young Women. Eur J Contracept Reprod Health Care 1999;4:67–73. http://dx.doi.org/10.3109/13625189909064007
69. Vasilakis C, Jick H, del Mar Melero-Montes M. Risk of idiopathic venous thromboembolism in users of progestagens alone. Lancet 1999;354:1610–1. http://dx.doi.org/10.1016/S0140-6736(99)04394-9
70. Kingman CE, Kadir RA, Lee CA, Economides DL. The use of levonorgestrel-releasing intrauterine system for treatment of menorrhagia in women with inherited bleeding disorders. BJOG 2004;111:1425–8. http://dx.doi.org/10.1111/j.1471-0528.2004.00305.x
71. Lukes AS, Reardon B, Arepally G. Use of the levonorgestrel-releasing intrauterine system in women with hemostatic disorders. Fertil Steril 2008;90:673–7. http://dx.doi.org/10.1016/j.fertnstert.2007.07.1315
72. Pisoni CN, Cuadrado MJ, Khamashta MA, Hunt BJ. Treatment of menorrhagia associated with oral anticoagulation: efficacy and safety of the levonorgestrel releasing intrauterine device (Mirena coil). Lupus 2006;15:877–80. http://dx.doi.org/10.1177/0961203306071706
73. Schaedel ZE, Dolan G, Powell MC. The use of the levonorgestrel-releasing intrauterine system in the management of menorrhagia in women with hemostatic disorders. Am J Obstet Gynecol 2005;193:1361–3. http://dx.doi.org/10.1016/j.ajog.2005.05.002
74. Wilson W, Taubert KA, Gewitz M, et al; American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee; American Heart Association Council on Cardiovascular Disease in the Young; American Heart Association Council on Clinical Cardiology; American Heart Association Council on Cardiovascular Surgery and Anesthesia; Quality of Care and Outcomes Research Interdisciplinary Working Group. Prevention of infective endocarditis: guidelines from the American Heart Association: a guideline from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation 2007;116:1736–54. http://dx.doi.org/10.1161/CIRCULATIONAHA.106.183095
75. Tepper NK, Paulen ME, Marchbanks PA, Curtis KM. Safety of contraceptive use among women with peripartum cardiomyopathy: a systematic review. Contraception 2010;82:95–101. http://dx.doi.org/10.1016/j.contraception.2010.02.004
76. The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown and Co; 1994.
77. Bernatsky S, Clarke A, Ramsey-Goldman R, et al. Hormonal exposures and breast cancer in a sample of women with systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1178–81. http://dx.doi.org/10.1093/rheumatology/keh282
78. Bernatsky S, Ramsey-Goldman R, Gordon C, et al. Factors associated with abnormal Pap results in systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1386–9. http://dx.doi.org/10.1093/rheumatology/keh331
79. Chopra N, Koren S, Greer WL, et al. Factor V Leiden, prothrombin gene mutation, and thrombosis risk in patients with antiphospholipid antibodies. J Rheumatol 2002;29:1683–8.

80. Esdaile JM, Abrahamowicz M, Grodzicky T, et al. Traditional Framingham risk factors fail to fully account for accelerated atherosclerosis in systemic lupus erythematosus. Arthritis Rheum 2001;44:2331–7. http://dx.doi.org/10.1002/1529-0131(200110)44:10<2331::AID-ART395≥3.0.CO;2-I
81. Julkunen HA, Kaaja R, Friman C. Contraceptive practice in women with systemic lupus erythematosus. Br J Rheumatol 1993;32:227–30. http://dx.doi.org/10.1093/rheumatology/32.3.227
82. Manzi S, Meilahn EN, Rairie JE, et al. Age-specific incidence rates of myocardial infarction and angina in women with systemic lupus erythematosus: comparison with the Framingham Study. Am J Epidemiol 1997;145:408–15. http://dx.doi.org/10.1093/oxfordjournals.aje.a009122
83. McAlindon T, Giannotta L, Taub N, D'Cruz D, Hughes G. Environmental factors predicting nephritis in systemic lupus erythematosus. Ann Rheum Dis 1993;52:720–4. http://dx.doi.org/10.1136/ard.52.10.720
84. McDonald J, Stewart J, Urowitz MB, Gladman DD. Peripheral vascular disease in patients with systemic lupus erythematosus. Ann Rheum Dis 1992;51:56–60. http://dx.doi.org/10.1136/ard.51.1.56
85. Mintz G, Gutiérrez G, Delezé M, Rodríguez E. Contraception with progestagens in systemic lupus erythematosus. Contraception 1984;30:29–38. http://dx.doi.org/10.1016/0010-7824(84)90076-3
86. Petri M. Musculoskeletal complications of systemic lupus erythematosus in the Hopkins Lupus Cohort: an update. Arthritis Care Res 1995;8:137–45. http://dx.doi.org/10.1002/art.1790080305
87. Petri M. Lupus in Baltimore: evidence-based 'clinical pearls' from the Hopkins Lupus Cohort. Lupus 2005;14:970–3. http://dx.doi.org/10.1191/0961203305lu2230xx
88. Sánchez-Guerrero J, Uribe AG, Jiménez-Santana L, et al. A trial of contraceptive methods in women with systemic lupus erythematosus. N Engl J Med 2005;353:2539–49. http://dx.doi.org/10.1056/NEJMoa050817
89. Sarabi ZS, Chang E, Bobba R, et al. Incidence rates of arterial and venous thrombosis after diagnosis of systemic lupus erythematosus. Arthritis Rheum 2005;53:609–12. http://dx.doi.org/10.1002/art.21314
90. Somers E, Magder LS, Petri M. Antiphospholipid antibodies and incidence of venous thrombosis in a cohort of patients with systemic lupus erythematosus. J Rheumatol 2002;29:2531–6.
91. Urowitz MB, Bookman AA, Koehler BE, Gordon DA, Smythe HA, Ogryzlo MA. The bimodal mortality pattern of systemic lupus erythematosus. Am J Med 1976;60:221–5. http://dx.doi.org/10.1016/0002-9343(76)90431-9
92. Julkunen HA. Oral contraceptives in systemic lupus erythematosus: side-effects and influence on the activity of SLE. Scand J Rheumatol 1991;20:427–33. http://dx.doi.org/10.3109/03009749109096822
93. Jungers P, Dougados M, Pélissier C, et al. Influence of oral contraceptive therapy on the activity of systemic lupus erythematosus. Arthritis Rheum 1982;25:618–23. http://dx.doi.org/10.1002/art.1780250603
94. Petri M, Kim MY, Kalunian KC, et al; OC-SELENA Trial. Combined oral contraceptives in women with systemic lupus erythematosus. N Engl J Med 2005;353:2550–8. http://dx.doi.org/10.1056/NEJMoa051135
95. Choojitarom K, Verasertniyom O, Totemchokchyakarn K, Nantiruj K, Sumethkul V, Janwityanujit S. Lupus nephritis and Raynaud's phenomenon are significant risk factors for vascular thrombosis in SLE patients with positive antiphospholipid antibodies. Clin Rheumatol 2008;27:345–51. http://dx.doi.org/10.1007/s10067-007-0721-z
96. Wahl DG, Guillemin F, de Maistre E, Perret C, Lecompte T, Thibaut G. Risk for venous thrombosis related to antiphospholipid antibodies in systemic lupus erythematosus—a meta-analysis. Lupus 1997;6:467–73. http://dx.doi.org/10.1177/096120339700600510
97. Tepper NK, Whiteman MK, Zapata LB, Marchbanks PA, Curtis KM. Safety of hormonal contraceptives among women with migraine: a systematic review. Contraception 2016. Epub May 3, 2016. http:// dx.doi.org/10.1016/j.contraception.2016.04.016
98. Tepper NK, Whiteman MK, Marchbanks PA, James AH, Curtis KM. Progestin-only contraception and thromboembolism: a systematic review. Contraception 2016. Epub May 3, 2016. http://dx.doi.org/10.1016/j.contraception.2016.04.014
99. Pagano HP, Zapata LB, Berry-Bibee EN, Nanda K, Curtis KM. Safety of hormonal contraception and intrauterine devices among women with depressive and bipolar disorders: a systematic review. Contraception 2016. Epub June 27, 2016. http://dx.doi.org/10.1016/j.contraception.2016.06.012
100. Barrington JW, Arunkalaivanan AS, Abdel-Fattah M. Comparison between the levonorgestrel intrauterine system (LNG-IUS) and thermal balloon ablation in the treatment of menorrhagia. Eur J Obstet Gynecol Reprod Biol 2003;108:72–4. http://dx.doi.org/10.1016/S0301-2115(02)00408-6
101. Gupta B, Mittal S, Misra R, Deka D, Dadhwal V. Levonorgestrel-releasing intrauterine system vs. transcervical endometrial resection for dysfunctional uterine bleeding. Int J Gynaecol Obstet 2006;95:261–6. http://dx.doi.org/10.1016/j.ijgo.2006.07.004
102. Hurskainen R, Teperi J, Rissanen P, et al. Quality of life and cost-effectiveness of levonorgestrel-releasing intrauterine system versus hysterectomy for treatment of menorrhagia: a randomised trial.[see comment]. Lancet 2001;357:273–7. http://dx.doi.org/10.1016/S0140-6736(00)03615-1
103. Istre O, Trolle B. Treatment of menorrhagia with the levonorgestrel intrauterine system versus endometrial resection. Fertil Steril 2001;76:304–9. http://dx.doi.org/10.1016/S0015-0282(01)01909-4
104. Koh SC, Singh K. The effect of levonorgestrel-releasing intrauterine system use on menstrual blood loss and the hemostatic, fibrinolytic/inhibitor systems in women with menorrhagia. J Thromb Haemost 2007;5:133–8. http://dx.doi.org/10.1111/j.1538-7836.2006.02243.x
105. Lethaby AE, Cooke I, Rees M. Progesterone/progestogen releasing intrauterine systems versus either placebo or any other medication for heavy menstrual bleeding. Cochrane Database Syst Rev 2000;(2):CD002126.
106. Magalhães J, Aldrighi JM, de Lima GR. Uterine volume and menstrual patterns in users of the levonorgestrel-releasing intrauterine system with idiopathic menorrhagia or menorrhagia due to leiomyomas. Contraception 2007;75:193–8. http://dx.doi.org/10.1016/j.contraception.2006.11.004
107. Stewart A, Cummins C, Gold L, Jordan R, Phillips W. The effectiveness of the levonorgestrel-releasing intrauterine system in menorrhagia: a systematic review. BJOG 2001;108:74–86. http://dx.doi.org/10.1111/j.1471-0528.2001.00020.x
108. Fedele L, Bianchi S, Zanconato G, Portuese A, Raffaelli R. Use of a levonorgestrel-releasing intrauterine device in the treatment of rectovaginal endometriosis. Fertil Steril 2001;75:485–8. http://dx.doi.org/10.1016/S0015-0282(00)01759-3
109. Lockhat FBE, Emembolu J, Konje JC. The effect of a levonorgestrel intrauterine system (LNG-IUS) on symptomatic endometriosis. Fertil Steril 2002;77(Suppl 1):S24. http://dx.doi.org/10.1016/S0015-0282(01)03086-2
110. Petta CA, Ferriani RA, Abrao MS, et al. Randomized clinical trial of a levonorgestrel-releasing intrauterine system and a depot GnRH analogue for the treatment of chronic pelvic pain in women with endometriosis. Hum Reprod 2005;20:1993–8. http://dx.doi.org/10.1093/humrep/deh869
111. Vercellini P, Aimi G, Panazza S, De Giorgi O, Pesole A, Crosignani PG. A levonorgestrel-releasing intrauterine system for the treatment of dysmenorrhea associated with endometriosis: a pilot study. Fertil Steril 1999;72:505–8. http://dx.doi.org/10.1016/S0015-0282(99)00291-5
112. Vercellini P, Frontino G, De Giorgi O, Aimi G, Zaina B, Crosignani PG. Comparison of a levonorgestrel-releasing intrauterine device versus expectant management after conservative surgery for symptomatic endometriosis: a pilot study. Fertil Steril 2003;80:305–9. http://dx.doi.org/10.1016/S0015-0282(03)00608-3
113. Gaffield ME, Kapp N, Curtis KM. Combined oral contraceptive and intrauterine device use among women with gestational trophoblastic disease. Contraception 2009;80:363–71. http://dx.doi.org/10.1016/j.contraception.2009.03.022

114. Whiteman MK, Zapata LB, Tepper NK, Marchbanks PA, Curtis KM. Use of contraceptive methods among women with endometrial hyperplasia: a systematic review. Contraception 2010;82:56–63. http://dx.doi.org/10.1016/j.contraception.2010.02.005
115. Zapata LB, Whiteman MK, Tepper NK, Jamieson DJ, Marchbanks PA, Curtis KM. Intrauterine device use among women with uterine fibroids: a systematic review. Contraception 2010;82:41–55. http://dx.doi.org/10.1016/j.contraception.2010.02.011
116. Tepper NK, Steenland MW, Gaffield ME, Marchbanks PA, Curtis KM. Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review. Contraception 2013;87:655–60. http://dx.doi.org/10.1016/j.contraception.2012.08.011
117. Faúndes A, Telles E, Cristofoletti ML, Faúndes D, Castro S, Hardy E. The risk of inadvertent intrauterine device insertion in women carriers of endocervical Chlamydia trachomatis. Contraception 1998;58:105–9. http://dx.doi.org/10.1016/S0010-7824(98)00064-X
118. Ferraz do Lago R, Simões JA, Bahamondes L, Camargo RP, Perrotti M, Monteiro I. Follow-up of users of intrauterine device with and without bacterial vaginosis and other cervicovaginal infections. Contraception 2003;68:105–9. http://dx.doi.org/10.1016/S0010-7824(03)00109-4
119. Morrison CS, Sekadde-Kigondu C, Miller WC, Weiner DH, Sinei SK. Use of sexually transmitted disease risk assessment algorithms for selection of intrauterine device candidates. Contraception 1999;59:97–106. http://dx.doi.org/10.1016/S0010-7824(99)00006-2
120. Pap-Akeson M, Solheim F, Thorbert G, Akerlund M. Genital tract infections associated with the intrauterine contraceptive device can be reduced by inserting the threads into the uterine cavity. Br J Obstet Gynaecol 1992;99:676–9. http://dx.doi.org/10.1111/j.1471-0528.1992.tb13854.x
121. Sinei SK, Schulz KFLP, Lamptey PR, et al. Preventing IUCD-related pelvic infection: the efficacy of prophylactic doxycycline at insertion. Br J Obstet Gynaecol 1990;97:412–9. http://dx.doi.org/10.1111/j.1471-0528.1990.tb01828.x
122. Skjeldestad FE, Halvorsen LE, Kahn H, Nordbø SA, Saake K. IUD users in Norway are at low risk for genital C. trachomatis infection. Contraception 1996;54:209–12. http://dx.doi.org/10.1016/S0010-7824(96)00190-4
123. Walsh TL, Bernstein GS, Grimes DA, Frezieres R, Bernstein L, Coulson AH; IUD Study Group. Effect of prophylactic antibiotics on morbidity associated with IUD insertion: results of a pilot randomized controlled trial. Contraception 1994;50:319–27. http://dx.doi.org/10.1016/0010-7824(94)90019-1
124. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-03).
125. Jatlaoui TC, Simmons KB, Curtis KM. The safety of intrauterine contraception initiation among women with current asymptomatic cervical infections or at increased risk of sexually transmitted infections. Contraception 2016. Epub June 1, 2016. http://dx.doi.org/10.1016/j.contraception.2016.05.013
126. Carael M, Van de Perre PH, Lepage PH, et al. Human immunodeficiency virus transmission among heterosexual couples in Central Africa. AIDS 1988;2:201–5.
127. European Study Group on Heterosexual Transmission of HIV. Comparison of female to male and male to female transmission of HIV in 563 stable couples. BMJ 1992;304:809–13. http://dx.doi.org/10.1136/bmj.304.6830.809
128. Kapiga SH, Lyamuya EF, Lwihula GK, Hunter DJ. The incidence of HIV infection among women using family planning methods in Dar es Salaam, Tanzania. AIDS 1998;12:75–84. http://dx.doi.org/10.1097/00002030-199801000-00009.
129. Kapiga SH, Shao JF, Lwihula GK, Hunter DJ. Risk factors for HIV infection among women in Dar-es-Salaam, Tanzania. J Acquir Immune Defic Syndr 1994;7:301–9.
130. Mann JM, Nzilambi N, Piot P, et al. HIV infection and associated risk factors in female prostitutes in Kinshasa, Zaire. AIDS 1988;2:249–54. http://dx.doi.org/10.1097/00002030-198808000-00002
131. Martin HL Jr, Nyange PM, Richardson BA, et al. Hormonal contraception, sexually transmitted diseases, and risk of heterosexual transmission of human immunodeficiency virus type 1. J Infect Dis 1998;178:1053–9. http://dx.doi.org/10.1086/515654
132. Mali JK, Hunter DJ, Maggwa BN, Tukei PM. Contraceptive use and the risk of HIV infection in Nairobi, Kenya. Int J Gynaecol Obstet 1995;48:61–7. http://dx.doi.org/10.1016/0020-7292(94)02214-3
133. Nicolosi A, Corrêa Leite ML, Musicco M, Arici C, Gavazzeni G, Lazzarin A; Italian Study Group on HIV Heterosexual Transmission. The efficiency of male-to-female and female-to-male sexual transmission of the human immunodeficiency virus: a study of 730 stable couples. [comment]. Epidemiology 1994;5:570–5. http://dx.doi.org/10.1097/00001648-199411000-00003
134. Plourde PJ, Plummer FA, Pepin J, et al. Human immunodeficiency virus type 1 infection in women attending a sexually transmitted diseases clinic in Kenya.[comment]. J Infect Dis 1992;166:86–92. http://dx.doi.org/10.1093/infdis/166.1.86
135. Sinei SK, Fortney JA, Kigondu CS, et al. Contraceptive use and HIV infection in Kenyan family planning clinic attenders. Int J STD AIDS 1996;7:65–70. http://dx.doi.org/10.1258/0956462961917104
136. Spence MR, Robbins SM, Polansky M, Schable CA. Seroprevalence of human immunodeficiency virus type I (HIV-1) antibodies in a family-planning population. Sex Transm Dis 1991;18:143–5. http://dx.doi.org/10.1097/00007435-199107000-00003
137. Tepper NK, Curtis KM, Nanda K, Jamieson DJ. Safety of intrauterine devices among women with HIV: a systematic review. Contraception 2016. Epub June 22, 2016. http://dx.doi.org/0.1016/j.contraception.2016.06.011
138. Grigoryan OR, Grodnitskaya EE, Andreeva EN, Shestakova MV, Melnichenko GA, Dedov II. Contraception in perimenopausal women with diabetes mellitus. Gynecol Endocrinol 2006;22:198–206. http://dx.doi.org/10.1080/09513590600624317
139. Rogovskaya S, Rivera R, Grimes DA, et al. Effect of a levonorgestrel intrauterine system on women with type 1 diabetes: a randomized trial. Obstet Gynecol 2005;105:811–5. http://dx.doi.org/10.1097/01.AOG.0000156301.11939.56
140. Zapata LB, Paulen ME, Cansino C, Marchbanks PA, Curtis KM. Contraceptive use among women with inflammatory bowel disease: a systematic review. Contraception 2010;82:72–85. http://dx.doi.org/10.1016/j.contraception.2010.02.012
141. Paulen ME, Folger SG, Curtis KM, Jamieson DJ. Contraceptive use among solid organ transplant patients: a systematic review. Contraception 2010;82:102–12. http://dx.doi.org/10.1016/j.contraception.2010.02.007
142. Bounds W, Guillebaud J. Observational series on women using the contraceptive Mirena concurrently with anti-epileptic and other enzyme-inducing drugs. J Fam Plann Reprod Health Care 2002;28:78–80. http://dx.doi.org/10.1783/147118902101195992
143. Reimers A, Helde G, Brodtkorb E. Ethinyl estradiol, not progestogens, reduces lamotrigine serum concentrations. Epilepsia 2005;46:1414–7. http://dx.doi.org/10.1111/j.1528-1167.2005.10105.x

Appendix C

Classifications for Progestin-Only Contraceptives

Classifications for progestin-only contraceptives (POCs) include those for progestin-only implants, depot medroxyprogesterone acetate (DMPA; 150 mg intramuscularly or 104 mg subcutaneously), and progestin-only pills (POPs) (Box C1) (Table C1). POCs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX C1. Categories for classifying progestin-only contraceptives

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE C1. Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category: Implants	Category: DMPA	Category: POPs	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History				
Pregnancy	NA	NA	NA	**Clarification:** Use of POCs is not required. No known harm to the woman, the course of her pregnancy, or the fetus occurs if POCs are inadvertently used during pregnancy. However, the relation between DMPA use during pregnancy and its effects on the fetus remains unclear.
Age				**Evidence:** Most studies have found that women lose BMD during DMPA use but recover BMD after discontinuation. Limited evidence shows a weak association with fracture. However, one large study suggests that women who choose DMPA might be at higher risk for fracture before initiation (*1*). It is unclear whether adult women with long durations of DMPA use can regain BMD to baseline levels before entering menopause and whether adolescents can reach peak bone mass after discontinuation of DMPA. The relationship between these changes in BMD during the reproductive years and future fracture risk is unknown. Studies generally find no effect of POCs other than DMPA on BMD *(1–48)*.
a. Menarche to <18 years	1	2	1	
b. 18–45 years	1	1	1	
c. >45 years	1	2	1	
Parity				
a. Nulliparous	1	1	1	—
b. Parous	1	1	1	—
Breastfeeding				
a. <21 days postpartum	2	2	2	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*49*). **Evidence:** Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (*50*,*51*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
b. 21 to <30 days postpartum				
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	2	2	2	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*49*). **Evidence:** Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (*50*,*51*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
ii. Without other risk factors for VTE	2	2	2	
c. 30–42 days postpartum				
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	1	1	1	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*49*). **Evidence:** Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (*50*,*51*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
ii. Without other risk factors for VTE	1	1	1	
d. >42 days postpartum	1	1	1	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*49*). **Evidence:** Overall, studies found that initiation of POPs, injectables, and implants at >6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (*51*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Postpartum (nonbreastfeeding women)				
a. <21 days postpartum	1	1	1	—
b. 21–42 days postpartum				
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	1	1	1	—
ii. Without other risk factors for VTE	1	1	1	—
c. >42 days postpartum	1	1	1	—
Postabortion				
a. First trimester	1	1	1	**Clarification:** POCs may be started immediately postabortion. **Evidence:** Limited evidence suggests that no adverse side effects occur when implants (Norplant) or progestin-only injectables (NET-EN) are initiated after first trimester abortion (*52–55*).
b. Second trimester	1	1	1	**Clarification:** POCs may be started immediately postabortion.
c. Immediate postseptic abortion	1	1	1	**Clarification:** POCs may be started immediately postabortion.
Past ectopic pregnancy	1	1	2	**Comment:** POP users have a higher absolute rate of ectopic pregnancy than do users of other POCs but still lower than women using no method.
History of pelvic surgery	1	1	1	—
Smoking				
a. Age <35 years	1	1	1	—
b. Age ≥35 years				
i. <15 cigarettes per day	1	1	1	—
ii. ≥15 cigarettes per day	1	1	1	—
Obesity				—
a. BMI ≥30 kg/m^2	1	1	1	—
b. Menarche to <18 years and BMI ≥30 kg/m^2	1	2	1	**Evidence:** Among adult women, generally no association has been found between baseline weight and weight gain among DMPA users compared with nonusers. Evidence is mixed for adolescent DMPA users, with some studies observing greater weight gain among obese compared with normal weight users but other studies showing no association; methodologic differences across studies might account for the differences in findings. Data on other POC methods and other adverse outcomes including weight gain are limited (*56–73*).
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent laparoscopic placement of an adjustable gastric band (*74*).
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	3	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent a biliopancreatic diversion; however, evidence from pharmacokinetic studies suggested conflicting results regarding oral contraceptive effectiveness among women who underwent a jejunoileal bypass (*74*). **Comment:** Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhea, vomiting, or both.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Cardiovascular Disease				
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	2	3	2	**Clarification:** When multiple major risk factors exist, risk for cardiovascular disease might increase substantially. Certain POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs. The effects of DMPA might persist for some time after discontinuation. **Clarification:** The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the *U.S. Selected Practice Recommendations for Contraceptive Use* (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm).
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Adequately controlled hypertension	1	2	1	**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Clarification:** Women adequately treated for hypertension are at lower risk for acute myocardial infarction and stroke than are untreated women. Although no data exist, POC users with adequately controlled and monitored hypertension should be at lower risk for acute myocardial infarction and stroke than are untreated hypertensive POC users.
b. Elevated blood pressure levels (properly taken measurements)				**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Evidence:** Limited evidence suggests that among women with hypertension, those who used POPs or progestin-only injectables had a small increased risk for cardiovascular events compared with women who did not use these methods (*75*).
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1	2	1	
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	2	3	2	
c. Vascular disease	2	3	2	**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Comment:** Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	1	1	1	—
Deep venous thrombosis/Pulmonary embolism				
a. History of DVT/PE, not receiving anticoagulant therapy				

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category: Implants	Category: DMPA	Category: POPs	Clarifications/Evidence/Comments
i. Higher risk for recurrent DVT/PE (one or more risk factors) • History of estrogen-associated DVT/PE • Pregnancy-associated DVT/PE • Idiopathic DVT/PE • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	2	2	2	—
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	—
b. Acute DVT/PE	2	2	2	**Evidence:** No direct evidence exists on use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with use of POCs in otherwise healthy women is inconsistent, any small increased risk is substantially less than that with COCs (*75–77*).
c. DVT/PE and established anticoagulant therapy for at least 3 months				**Evidence:** No direct evidence exists on use of POCs among women with DVT/PE receiving anticoagulant therapy. Although findings on the risk for venous thrombosis with use of POCs is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COCs (*75–77*). Limited evidence indicates that intramuscular injections of DMPA in women receiving chronic anticoagulation therapy does not pose a significant risk for hematoma at the injection site or increase the risk for heavy or irregular vaginal bleeding (*78*).
i. Higher risk for recurrent DVT/PE (one or more risk factors) • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	2	2	2	
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	
d. Family history (first-degree relatives)	1	1	1	—
e. Major surgery				
i. With prolonged immobilization	2	2	2	—
ii. Without prolonged immobilization	1	1	1	—
f. Minor surgery without immobilization	1	1	1	—
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	2	2	2	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
Superficial venous disorders				
a. Varicose veins	1	1	1	—
b. Superficial venous thrombosis (acute or history)	1	1	1	—
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation 2 Continuation 3	3	Initiation 2 Continuation 3	**Comment:** Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation 2 Continuation 3	3	Initiation 2 Continuation 3	**Comment:** Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category				Clarifications/Evidence/Comments
	Implants	DMPA		POPs	
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1	1		1	—
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					**Evidence:** No direct evidence exists on the safety of POCs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies of women with cardiac disease demonstrated few cases of hypertension, thromboembolism, and heart failure in women with cardiac disease using POPs and DMPA (*79*). **Comment:** Progestin-only implants might induce cardiac arrhythmias in healthy women; women with peripartum cardiomyopathy have a high incidence of cardiac arrhythmias.
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (*80*)					
i. <6 months	1	1		1	
ii. ≥6 months	1	1		1	
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (*80*)	2	2		2	
Rheumatic Diseases					
Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		Initiation	Continuation		
a. Positive (or unknown) antiphospholipid antibodies	3	3	3	3	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*81–99*). **Evidence:** Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (*100*,*101*).
b. Severe thrombocytopenia	2	3	2	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*81–99*). **Comment:** Severe thrombocytopenia increases the risk for bleeding. POCs might be useful in treating menorrhagia in women with severe thrombocytopenia. However, given the increased or erratic bleeding that might be seen on initiation of DMPA and its irreversibility for 11–13 weeks after administration, initiation of this method in women with severe thrombocytopenia should be done with caution.
c. Immunosuppressive therapy	2	2	2	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*81–99*).

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category: Implants	DMPA: Initiation	DMPA: Continuation	POPs	Clarifications/Evidence/Comments
d. None of the above	2	2	2	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*81–99*).
Rheumatoid arthritis					
a. Receiving immunosuppressive therapy	1	2/3		1	**Clarification (DMPA):** DMPA use among women receiving long-term corticosteroid therapy with a history of, or with risk factors for, nontraumatic fractures is classified as category 3. Otherwise, DMPA use for women with rheumatoid arthritis is classified as category 2. **Evidence:** Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (*102*).
b. Not receiving immunosuppressive therapy	1	2		1	**Evidence:** Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (*102*).
Neurologic Conditions					
Headaches					
a. Nonmigraine (mild or severe)	1	1		1	—
b. Migraine					**Evidence:** No studies directly examined the risk for stroke among women with migraine using POCs (*103*). Limited evidence demonstrated that women using POPs, DMPA, or implants do not have an increased risk for ischemic stroke compared with nonusers (*104*).
i. Without aura (This category of migraine includes menstrual migraine.)	1	1		1	
ii. With aura	1	1		1	**Comment:** Menstrual migraine is a subtype of migraine without aura. For more information, see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1		1	**Clarification:** If a woman is taking anticonvulsants, see Drug Interactions section. Certain anticonvulsants lower POC effectiveness.
Multiple sclerosis					**Evidence:** Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with multiple sclerosis does not worsen the clinical course of disease (*105*).
a. With prolonged immobility	1	2		1	
b. Without prolonged immobility	1	2		1	**Comment:** Women with multiple sclerosis might have compromised bone health from disease-related disability, immobility, and use of corticosteroids. Use of DMPA, which has been associated with small changes in BMD, might be of concern.
Depressive Disorders					
Depressive disorders	1	1		1	**Clarification:** If a woman is taking psychotropic medications or St. John's wort, see Drug Interactions section. **Evidence:** The frequency of psychiatric hospitalizations for women with bipolar disorder or depression did not significantly differ among women using DMPA, LNG-IUD, Cu-IUD, or sterilization (*106*).
Reproductive Tract Infections and Disorders					
Vaginal bleeding patterns					
a. Irregular pattern without heavy bleeding	2	2		2	**Comment:** Irregular menstrual bleeding patterns are common among healthy women. POC use frequently induces an irregular bleeding pattern. Implant use might induce irregular bleeding patterns, especially during the first 3–6 months, although these patterns might persist longer.
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2	2		2	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	3	3	2	**Clarification:** If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation. **Comment:** POCs might cause irregular bleeding patterns, which might mask symptoms of underlying pathologic conditions. The effects of DMPA might persist for some time after discontinuation.
Endometriosis	1	1	1	—
Benign ovarian tumors (including cysts)	1	1	1	—
Severe dysmenorrhea	1	1	1	—
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.
a. Suspected gestational trophoblastic disease (immediate postevacuation)				
i. Uterine size first trimester	1	1	1	
ii. Uterine size second trimester	1	1	1	
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)				
i. Undetectable/nonpregnant β–hCG levels	1	1	1	
ii. Decreasing β–hCG levels	1	1	1	
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	1	1	1	
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	1	1	1	
Cervical ectropion	1	1	1	—
Cervical intraepithelial neoplasia	2	2	1	**Evidence:** Among women with persistent human papillomavirus infection, long-term DMPA use (≥5 years) might increase the risk for carcinoma in situ and invasive carcinoma (*107*).
Cervical cancer (awaiting treatment)	2	2	1	**Comment:** Theoretical concern exists that POC use might affect prognosis of the existing disease. While awaiting treatment, women may use POCs. In general, treatment of this condition can render a woman sterile.
Breast disease Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Undiagnosed mass	2	2	2	**Clarification:** Evaluation should be pursued as early as possible.
b. Benign breast disease	1	1	1	—
c. Family history of cancer	1	1	1	—
d. Breast cancer				**Comment:** Breast cancer is a hormonally sensitive tumor, and the prognosis for women with current or recent breast cancer might worsen with POC use.
i. Current	4	4	4	
ii. Past and no evidence of current disease for 5 years	3	3	3	
Endometrial hyperplasia	1	1	1	—
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	**Comment:** While awaiting treatment, women may use POCs. In general, treatment of this condition renders a woman sterile.
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	**Comment:** While awaiting treatment, women may use POCs. In general, treatment of this condition can render a woman sterile.
Uterine fibroids	1	1	1	**Comment:** POCs do not appear to cause growth of uterine fibroids.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Pelvic inflammatory disease				**Comment:** Whether POCs, like COCs, reduce the risk for PID among women with STDs is unknown; however, they do not protect against HIV or lower genital tract STDs.
a. Past PID				
i. With subsequent pregnancy	1	1	1	
ii. Without subsequent pregnancy	1	1	1	
b. Current PID	1	1	1	
Sexually transmitted diseases				
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	1	1	1	—
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	1	1	1	—
c. Other factors related to STDs	1	1	1	—
HIV				
High risk for HIV	1	1	1	**Clarification (DMPA):** Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms (male or female) and take other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection are essential. These recommendations will be continually reviewed in light of new evidence. **Evidence:** Overall, evidence does not support an association between oral contraceptives and risk for HIV acquisition, evidence is inconsistent regarding an association between DMPA and increased risk for HIV acquisition, and no studies have suggested an increased risk for HIV acquisition with etonogestrel implants although data are limited (*108*).
HIV infection For women with HIV infection who are not clinically well or not using ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	**Clarification:** Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section. **Evidence:** Overall, evidence does not support an association between POC use and progression of HIV. Limited direct evidence on an association between POC use and transmission of HIV to noninfected partners, as well as studies measuring genital viral shedding as a proxy for infectivity, have had mixed results. Studies measuring whether hormonal contraceptive methods affect plasma HIV viral load generally have found no effect (*109–111*).
Other Infections				
Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	**Evidence:** Among women with uncomplicated schistosomiasis, limited evidence showed that DMPA use had no adverse effects on liver function (*112*).
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1	1	1	—
Tuberculosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				**Clarification:** If a woman is taking rifampin, see Drug Interactions section. Rifampin is likely to decrease the effectiveness of some POCs.
a. Nonpelvic	1	1	1	
b. Pelvic	1	1	1	
Malaria	1	1	1	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category: Implants	Category: DMPA	Category: POPs	Clarifications/Evidence/Comments
Endocrine Conditions				
Diabetes				
Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. History of gestational disease	1	1	1	**Evidence:** POCs had no adverse effects on serum lipid levels in women with a history of gestational diabetes in two small studies (*113*,*114*). Limited evidence is inconsistent about the development of noninsulin-dependent diabetes among users of POCs with a history of gestational diabetes (*115*–*118*).
b. Nonvascular disease				**Evidence:** Among women with insulin-dependent or non–insulin-dependent diabetes, limited evidence on use of POCs (POPs, DMPA, and LNG implant) suggests that these methods have little effect on short-term or long-term diabetes control (e.g., glycosylated hemoglobin levels), hemostatic markers, or lipid profile (*119*–*122*).
i. Non-insulin dependent	2	2	2	
ii. Insulin dependent	2	2	2	
c. Nephropathy, retinopathy, or neuropathy	2	3	2	**Comment:** Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. The effects of DMPA might persist for some time after discontinuation. Some POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs.
d. Other vascular disease or diabetes of >20 years' duration	2	3	2	**Comment:** Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. The effects of DMPA might persist for some time after discontinuation. Some POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs.
Thyroid disorders				
a. Simple goiter	1	1	1	—
b. Hyperthyroid	1	1	1	—
c. Hypothyroid	1	1	1	—
Gastrointestinal Conditions				
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	2	2	**Evidence:** Risk for disease relapse among women with IBD using oral contraceptives (most studies did not specify formulation) did not increase significantly from that for nonusers (*123*). **Comment:** Absorption of POPs among women with IBD might be reduced if the woman has substantial malabsorption caused by severe disease or small bowel surgery. Women with IBD have a higher prevalence of osteoporosis and osteopenia than the general population. Use of DMPA, which has been associated with small changes in BMD, might be of concern.
Gallbladder disease				
a. Symptomatic				
i. Treated by cholecystectomy	2	2	2	—
ii. Medically treated	2	2	2	—
iii. Current	2	2	2	—
b. Asymptomatic	2	2	2	—
History of cholestasis				
a. Pregnancy related	1	1	1	—
b. Past COC related	2	2	2	**Comment:** Theoretical concern exists that a history of COC-related cholestasis might predict subsequent cholestasis with POC use. However, this has not been documented.
Viral hepatitis				
a. Acute or flare	1	1	1	—
b. Carrier	1	1	1	—
c. Chronic	1	1	1	—
Cirrhosis				
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Mild (compensated)	1	1	1	—
b. Severe (decompensated)	3	3	3	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Liver tumors Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Benign				
i. Focal nodular hyperplasia	2	2	2	**Evidence:** Limited direct evidence suggests that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia (*124*).
ii. Hepatocellular adenoma	3	3	3	**Comment:** No evidence is available about hormonal contraceptive use among women with hepatocellular adenoma. COC use in healthy women is associated with development and growth of hepatocellular adenoma; whether other hormonal contraceptives have similar effects is not known.
b. Malignant (hepatoma)	3	3	3	—
Respiratory Conditions				
Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	1	**Clarification:** Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions. **Clarification:** Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives. **Evidence:** Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with cystic fibrosis is not associated with worsening of disease severity. Very limited evidence suggests that cystic fibrosis does not impair the effectiveness of hormonal contraception (*125*). **Comment:** Women with cystic fibrosis have a higher prevalence of osteopenia, osteoporosis, and fragility fractures than the general population. Use of DMPA, which has been associated with small changes in BMD, might be of concern.
Anemias				
Thalassemia	1	1	1	—
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	**Evidence:** Among women with sickle cell disease, POC use did not have adverse effects on hematologic parameters and, in some studies, was beneficial with respect to clinical symptoms (*126–133*).
Iron deficiency anemia	1	1	1	**Comment:** Changes in the menstrual pattern associated with POC use have little effect on hemoglobin levels.
Solid Organ Transplantation				
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	2	2	2	—
b. Uncomplicated	2	2	2	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Drug Interactions				
Antiretroviral therapy				**Comment:** These recommendations generally are for ARV agents used alone. However, most women receiving ARV therapy are using multiple drugs in combination. In general, whether interactions between ARVs and hormonal contraceptives differ when ARVs are given alone or in combination is unknown.
a. Nucleoside reverse transcriptase inhibitors (NRTIs)				
i. Abacavir (ABC)	1	1	1	**Evidence:** NRTIs do not appear to have significant risk for interactions with hormonal contraceptive methods (*134–139*).
ii. Tenofovir (TDF)	1	1	1	
iii. Zidovudine (AZT)	1	1	1	
iv. Lamivudine (3TC)	1	1	1	
v. Didanosine (DDI)	1	1	1	
vi. Emtricitabine (FTC)	1	1	1	
vii. Stavudine (D4T)	1	1	1	
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)				
i. Efavirenz (EFV)	2	1	2	**Clarification:** Evidence suggests drug interactions between EFV and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive. **Evidence:** One study found that women using etonogestrel implants with EFV had a higher pregnancy rate than women not using ARVs, although confidence intervals overlapped and absolute pregnancy rates were still lower than for other hormonal methods; another study found that etonogestrel levels were decreased and 5% of women had presumptive ovulation while using etonogestrel implants with EFV (*140*,*141*). Three studies of women using LNG implants showed increased pregnancy rates for women using EFV-containing ARV therapy compared with no ARV use, although absolute pregnancy rates were still lower than for other hormonal methods in one study (*141–143*); another study of LNG implant users found no difference in pregnancy rates with EFV compared with no EFV (*144*).No significant effects were found on pregnancy rates, DMPA levels, EFV levels, or HIV disease progression in women using DMPA and EFV compared with DMPA alone (*141*,*144–148*). No significant effects were found on HIV disease progression in women using LNG implants and EFV compared with no ARVs (*143*). No data have assessed effectiveness of contraceptive implants during later years of use when progestin concentrations are lower and risk for failure from drug interactions might be greater.
ii. Etravirine (ETR)	1	1	1	—
iii. Nevirapine (NVP)	1	1	1	**Evidence:** Five studies found no significant increase in pregnancy rates among women using implants and NVP compared with implants alone (*141–144*,*149*). Four studies found no significant increase in pregnancy rates among women using DMPA or other contraceptive injectables and NVP compared with DMPA or other contraceptive injectables alone (*141*,*144*,*147*,*150*). One study found no ovulations or changes in DMPA concentrations (*145*). No effect was found on HIV disease progression with use of NVP and DMPA or LNG implants (*143*,*145*,*147–149*,*151*). No data have assessed effectiveness of contraceptive implants during later years of use when progestin concentrations are lower and risk for failure from drug interactions might be greater.
iv. Rilpivirine (RPV)	1	1	1	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
c. Ritonavir-boosted protease inhibitors				
i. Ritonavir-boosted atazanavir (ATV/r)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA. **Evidence:** One pharmacokinetic study demonstrated increased progestin concentrations with use of POPs and ATV/r compared with POPs alone (*152*).
ii. Ritonavir-boosted darunavir (DRV/r)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
iii. Ritonavir-boosted fosamprenavir (FPV/r)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
iv. Ritonavir-boosted lopinavir (LPV/r)	1	1	1	**Evidence:** One study demonstrated no pregnancies, no ovulations, no change in LPV/r level, and no change in HIV disease progression in women using DMPA (*153*); another study found a small increase in pregnancy rate in women using DMPA with LPV/r compared with no ARV therapy, however confidence intervals overlapped (*141*). Two studies found no increased risk for pregnancy in women using implants (*141*,*142*). Two studies found contraceptive hormones increased in women using LPV/r with DMPA or etonogestrel implants (*140*,*153*).
v. Ritonavir-boosted saquinavir (SQV/r)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
vi. Ritonavir-boosted tipranavir (TPV/r)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
d. Protease inhibitors without ritonavir				
i. Atazanavir (ATV)	1	1	1	**Comment:** When ATV is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels might vary when combined with other ARVs.
ii. Fosamprenavir (FPV)	2	2	2	**Clarification:** Theoretical concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the ARV drug. The drug interaction likely involves CYP3A4 pathways; POCs have less effect on CYP3A4 enzymes than CHCs.
iii. Indinavir (IDV)	1	1	1	—

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
iv. Nelfinavir (NFV)	2	1	2	**Clarification:** Theoretically, drug interactions might occur between certain protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA. Concern exists that interactions between NFV and POCs might decrease NFV levels. **Evidence:** One study found no pregnancies, no ovulations, no change in DMPA concentrations and no change in HIV disease progression with use of DMPA and NFV compared with DMPA alone; NFV concentrations were decreased with concomitant DMPA use (*145,147*).
e. CCR5 co-receptor antagonists				
i. Maraviroc (MVC)	1	1	1	
f. HIV integrase strand transfer inhibitors				
i. Raltegravir (RAL)	1	1	1	—
ii. Dolutegravir (DTG)	1	1	1	—
iii. Elvitegravir (EVG)	1	1	1	**Comment:** When EVG is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
g. Fusion inhibitors				
i. Enfuvirtide	1	1	1	—
Anticonvulsant therapy				—
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	2	1	3	**Clarification:** Although the interaction of certain anticonvulsants with POPs and etonogestrel implants is not harmful to women, it is likely to reduce the effectiveness of POPs and etonogestrel implants. Whether increasing the hormone dose of POPs alleviates this concern remains unclear. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is a category 1 because its effectiveness is not decreased by use of certain anticonvulsants. **Evidence:** Use of certain anticonvulsants might decrease the effectiveness of POCs (*154–156*).
b. Lamotrigine	1	1	1	**Evidence:** No drug interactions have been reported among women with epilepsy receiving lamotrigine and POCs (*157*).
Antimicrobial therapy				
a. Broad-spectrum antibiotics	1	1	1	—
b. Antifungals	1	1	1	—
c. Antiparasitics	1	1	1	—
d. Rifampin or rifabutin therapy	2	1	3	**Clarification:** Although the interaction of rifampin or rifabutin with POPs and etonogestrel implants is not harmful to women, it is likely to reduce the effectiveness of POPs and etonogestrel implants. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is a category 1 because its effectiveness is not decreased by use of rifampin or rifabutin. Whether increasing the hormone dose of POPs alleviates this concern remains unclear.

See table footnotes on page 49.

TABLE C1. (*Continued*) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

Condition	Category			Clarifications/Evidence/Comments
	Implants	DMPA	POPs	
Psychotropic medications				**Comment:** For many common psychotropic agents, limited or no theoretical concern exits for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications.
a. SSRIs	1	1	1	**Evidence:** No evidence specifically examined the use of POCs with SSRIs. Limited clinical and pharmacokinetic data do not demonstrate concern for SSRIs decreasing the effectiveness of oral contraceptives. Limited evidence suggests that for women taking SSRIs, the use of hormonal contraceptives was not associated with differences in effectiveness of the SSRI for treatment or in adverse events when compared with women not taking hormonal contraceptives (*158*). **Comment:** Drugs that are inhibitors of CYP3A4 or CYP2C9 theoretically have the potential to increase levels of contraceptive steroid, which might increase adverse events. Fluvoxamine is an SSRI known to be a moderate inhibitor of both 3A4 and 2C9; however, no clinical or pharmacokinetic studies were identified to explore potential drug-drug interactions.
St. John's wort	2	1	2	**Evidence:** No evidence specifically examined the use of POCs with St John's wort. Although clinical data are limited, studies with pharmacokinetic and pharmacodynamics outcomes raise concern that St. John's wort might decrease effectiveness of hormonal contraceptives, including increased risk for breakthrough bleeding and ovulation and increased metabolism of estrogen and progestin. Any interactions might be dependent on the dose of St John's wort, and the concentration of active ingredients across types of St. John's wort preparations may vary (*159*). **Comment:** Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.

Abbreviations: ARV = antiretroviral; BMD = bone mineral density; BMI = body mass index; COC = combined oral contraceptive; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; LDL = low-density lipoprotein; LNG = levonorgestrel; NA = not applicable; NET-EN = norethisterone enantate; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; POP = progestin-only pill; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

References

1. Lanza LL, McQuay LJ, Rothman KJ, et al. Use of depot medroxyprogesterone acetate contraception and incidence of bone fracture. Obstet Gynecol 2013;121:593–600. http://dx.doi.org/10.1097/AOG.0b013e318283d1a1
2. Harel Z, Riggs S, Vaz R, Flanagan P, Harel D, Machan JT. Bone accretion in adolescents using the combined estrogen and progestin transdermal contraceptive method Ortho Evra: a pilot study. J Pediatr Adolesc Gynecol 2010;23:23–31. http://dx.doi.org/10.1016/j.jpag.2009.04.008
3. Kaunitz AM, Miller PD, Rice VM, Ross D, McClung MR. Bone mineral density in women aged 25–35 years receiving depot medroxyprogesterone acetate: recovery following discontinuation. Contraception 2006;74:90–9. http://dx.doi.org/10.1016/j.contraception.2006.03.010
4. Kaunitz AM, Arias R, McClung M. Bone density recovery after depot medroxyprogesterone acetate injectable contraception use. Contraception 2008;77:67–76. http://dx.doi.org/10.1016/j.contraception.2007.10.005
5. Kaunitz AM, Darney PD, Ross D, Wolter KD, Speroff L. Subcutaneous DMPA vs. intramuscular DMPA: a 2-year randomized study of contraceptive efficacy and bone mineral density. Contraception 2009;80:7–17. http://dx.doi.org/10.1016/j.contraception.2009.02.005
6. Lappe JM, Stegman MR, Recker RR. The impact of lifestyle factors on stress fractures in female Army recruits. Osteoporos Int 2001;12:35–42. http://dx.doi.org/10.1007/s001980170155
7. Lara-Torre E, Edwards CP, Perlman S, Hertweck SP. Bone mineral density in adolescent females using depot medroxyprogesterone acetate. J Pediatr Adolesc Gynecol 2004;17:17–21. http://dx.doi.org/10.1016/j.jpag.2003.11.017
8. Lopez LM, Chen M, Mullins S, Curtis KM, Helmerhorst FM. Steroidal contraceptives and bone fractures in women: evidence from observational studies. Cochrane Database Syst Rev 2012;8:CD009849.
9. Lopez LM, Grimes DA, Schulz KF, Curtis KM. Steroidal contraceptives: effect on bone fractures in women. Cochrane Database Syst Rev 2011;(7):CD006033.
10. Meier C, Brauchli YB, Jick SS, Kraenzlin ME, Meier CR. Use of depot medroxyprogesterone acetate and fracture risk. J Clin Endocrinol Metab 2010;95:4909–16. http://dx.doi.org/10.1210/jc.2010-0032
11. Merki-Feld GS, Neff M, Keller PJ. A 2-year prospective study on the effects of depot medroxyprogesterone acetate on bone mass-response to estrogen and calcium therapy in individual users. Contraception 2003;67:79–86. http://dx.doi.org/10.1016/S0010-7824(02)00460-2
12. Monteiro-Dantas C, Espejo-Arce X, Lui-Filho JF, Fernandes AM, Monteiro I, Bahamondes L. A three-year longitudinal evaluation of the forearm bone density of users of etonogestrel- and levonorgestrel-releasing contraceptive implants. Reprod Health 2007;4:11. http://dx.doi.org/10.1186/1742-4755-4-11
13. Naessen T, Olsson SE, Gudmundson J. Differential effects on bone density of progestogen-only methods for contraception in premenopausal women. Contraception 1995;52:35–9. http://dx.doi.org/10.1016/0010-7824(95)00121-P
14. Sanches L, Marchi NM, Castro S, Juliato CT, Villarroel M, Bahamondes L. Forearm bone mineral density in postmenopausal former users of depot medroxyprogesterone acetate. Contraception 2008;78:365–9. http://dx.doi.org/10.1016/j.contraception.2008.07.013
15. Scholes D, LaCroix AZ, Ichikawa LE, Barlow WE, Ott SM. Injectable hormone contraception and bone density: results from a prospective study. Epidemiology 2002;13:581–7. http://dx.doi.org/10.1097/00001648-200209000-00015

16. Scholes D, LaCroix AZ, Ichikawa LE, Barlow WE, Ott SM. Change in bone mineral density among adolescent women using and discontinuing depot medroxyprogesterone acetate contraception. Arch Pediatr Adolesc Med 2005;159:139–44. http://dx.doi.org/10.1001/archpedi.159.2.139
17. Segall-Gutierrez P, Agarwal R, Ge M, Lopez C, Hernandez G, Stanczyk FZ. A pilot study examining short-term changes in bone mineral density among class 3 obese users of depot-medroxyprogesterone acetate. Eur J Contracept Reprod Health Care 2013;18:199–205. http://dx.doi.org/10.3109/13625187.2013.774358
18. Tang OS, Tang G, Yip PS, Li B. Further evaluation on long-term depot-medroxyprogesterone acetate use and bone mineral density: a longitudinal cohort study. Contraception 2000;62:161–4. http://dx.doi.org/10.1016/S0010-7824(00)00168-2
19. Vestergaard P, Rejnmark L, Mosekilde L. The effects of depot medroxyprogesterone acetate and intrauterine device use on fracture risk in Danish women. Contraception 2008;78:459–64. http://dx.doi.org/10.1016/j.contraception.2008.07.014
20. Viola AS, Castro S, Marchi NM, Bahamondes MV, Viola CF, Bahamondes L. Long-term assessment of forearm bone mineral density in postmenopausal former users of depot medroxyprogesterone acetate. Contraception 2011;84:122–7. http://dx.doi.org/10.1016/j.contraception.2010.11.007
21. Walsh JS, Eastell R, Peel NF. Depot medroxyprogesterone acetate use after peak bone mass is associated with increased bone turnover but no decrease in bone mineral density. Fertil Steril 2010;93:697–701. http://dx.doi.org/10.1016/j.fertnstert.2008.10.004
22. Wetmore CM, Ichikawa L, LaCroix AZ, Ott SM, Scholes D. Association between caffeine intake and bone mass among young women: potential effect modification by depot medroxyprogesterone acetate use. Osteoporos Int 2008;19:519–27. http://dx.doi.org/10.1007/s00198-007-0473-2
23. Wong AY, Tang LC, Chin RK. Levonorgestrel-releasing intrauterine system (Mirena) and depot medroxyprogesterone acetate (Depoprovera) as long-term maintenance therapy for patients with moderate and severe endometriosis: a randomised controlled trial. Aust N Z J Obstet Gynaecol 2010;50:273–9. http://dx.doi.org/10.1111/j.1479-828X.2010.01152.x
24. Yang KY, Kim YS, Ji YI, Jung MH. Changes in bone mineral density of users of the levonorgestrel-releasing intrauterine system. J Nippon Med Sch 2012;79:190–4. http://dx.doi.org/10.1272/jnms.79.190
25. Zhang MH, Zhang W, Zhang AD, Yang Y, Gai L. Effect of depot medroxyprogesterone acetate on bone mineral density in adolescent women. Chin Med J (Engl) 2013;126:4043–7.
26. Bahamondes MV, Monteiro I, Castro S, Espejo-Arce X, Bahamondes L. Prospective study of the forearm bone mineral density of long-term users of the levonorgestrel-releasing intrauterine system. Hum Reprod 2010;25:1158–64. http://dx.doi.org/10.1093/humrep/deq043
27. Banks E, Berrington A, Casabonne D. Overview of the relationship between use of progestogen-only contraceptives and bone mineral density. BJOG 2001;108:1214–21. http://dx.doi.org/10.1111/j.1471-0528.2001.00296.x
28. Beerthuizen R, van Beek A, Massai R, Mäkäräinen L, Hout J, Bennink HC. Bone mineral density during long-term use of the progestagen contraceptive implant Implanon compared to a non-hormonal method of contraception. Hum Reprod 2000;15:118–22. http://dx.doi.org/10.1093/humrep/15.1.118
29. Beksinska ME, Kleinschmidt I, Smit JA, Farley TM. Bone mineral density in adolescents using norethisterone enanthate, depot-medroxyprogesterone acetate or combined oral contraceptives for contraception. Contraception 2007;75:438–43. http://dx.doi.org/10.1016/j.contraception.2007.02.001
30. Beksinska ME, Kleinschmidt I, Smit JA, Farley TM. Bone mineral density in a cohort of adolescents during use of norethisterone enanthate, depot-medroxyprogesterone acetate or combined oral contraceptives and after discontinuation of norethisterone enanthate. Contraception 2009;79:345–9. http://dx.doi.org/10.1016/j.contraception.2008.11.009
31. Berenson AB, Breitkopf CR, Grady JJ, Rickert VI, Thomas A. Effects of hormonal contraception on bone mineral density after 24 months of use. Obstet Gynecol 2004;103:899–906. http://dx.doi.org/10.1097/01.AOG.0000117082.49490.d5
32. Berenson AB, Rahman M, Breitkopf CR, Bi LX. Effects of depot medroxyprogesterone acetate and 20-microgram oral contraceptives on bone mineral density. Obstet Gynecol 2008;112:788–99. http://dx.doi.org/10.1097/AOG.0b013e3181875b78
33. Busen NH, Britt RB, Rianon N. Bone mineral density in a cohort of adolescent women using depot medroxyprogesterone acetate for one to two years. J Adolesc Health 2003;32:257–9. http://dx.doi.org/10.1016/S1054-139X(02)00567-0
34. Caird LE, Reid-Thomas V, Hannan WJ, Gow S, Glasier AF. Oral progestogen-only contraception may protect against loss of bone mass in breast-feeding women. Clin Endocrinol (Oxf) 1994;41:739–45. http://dx.doi.org/10.1111/j.1365-2265.1994.tb02788.x
35. Clark MK, Sowers M, Levy B, Nichols S. Bone mineral density loss and recovery during 48 months in first-time users of depot medroxyprogesterone acetate. Fertil Steril 2006;86:1466–74. http://dx.doi.org/10.1016/j.fertnstert.2006.05.024
36. Cromer BA, Lazebnik R, Rome E, et al. Double-blinded randomized controlled trial of estrogen supplementation in adolescent girls who receive depot medroxyprogesterone acetate for contraception. Am J Obstet Gynecol 2005;192:42–7. http://dx.doi.org/10.1016/j.ajog.2004.07.041
37. Cromer BA, Blair JM, Mahan JD, Zibners L, Naumovski Z. A prospective comparison of bone density in adolescent girls receiving depot medroxyprogesterone acetate (Depo-Provera), levonorgestrel (Norplant), or oral contraceptives. J Pediatr 1996;129:671–6. http://dx.doi.org/10.1016/S0022-3476(96)70148-8
38. Cromer BA, Bonny AE, Stager M, et al. Bone mineral density in adolescent females using injectable or oral contraceptives: a 24-month prospective study. Fertil Steril 2008;90:2060–7. http://dx.doi.org/10.1016/j.fertnstert.2007.10.070
39. Cromer BA, Stager M, Bonny A, et al. Depot medroxyprogesterone acetate, oral contraceptives and bone mineral density in a cohort of adolescent girls. J Adolesc Health 2004;35:434–41. http://dx.doi.org/10.1016/j.jadohealth.2004.07.005
40. Cundy T, Ames R, Horne A, et al. A randomized controlled trial of estrogen replacement therapy in long-term users of depot medroxyprogesterone acetate. J Clin Endocrinol Metab 2003;88:78–81. http://dx.doi.org/10.1210/jc.2002-020874
41. Cundy T, Cornish J, Evans MC, Roberts H, Reid IR. Recovery of bone density in women who stop using medroxyprogesterone acetate. BMJ 1994;308:247–8. http://dx.doi.org/10.1136/bmj.308.6923.247
42. Cundy T, Cornish J, Roberts H, Reid IR. Menopausal bone loss in long-term users of depot medroxyprogesterone acetate contraception. Am J Obstet Gynecol 2002;186:978–83. http://dx.doi.org/10.1067/mob.2002.122420
43. Di X, Li Y, Zhang C, Jiang J, Gu S. Effects of levonorgestrel-releasing subdermal contraceptive implants on bone density and bone metabolism. Contraception 1999;60:161–6. http://dx.doi.org/10.1016/S0010-7824(99)00080-3
44. Díaz S, Reyes MV, Zepeda A, et al. Norplant® implants and progesterone vaginal rings do not affect maternal bone turnover and density during lactation and after weaning. Hum Reprod 1999;14:2499–505. http://dx.doi.org/10.1093/humrep/14.10.2499
45. Gai L, Zhang J, Zhang H, Gai P, Zhou L, Liu Y. The effect of depot medroxyprogesterone acetate (DMPA) on bone mineral density (BMD) and evaluating changes in BMD after discontinuation of DMPA in Chinese women of reproductive age. Contraception 2011;83:218–22. http://dx.doi.org/10.1016/j.contraception.2010.07.027
46. Bahamondes L, Espejo-Arce X, Hidalgo MM, Hidalgo-Regina C, Teatin-Juliato C, Petta CA. A cross-sectional study of the forearm bone density of long-term users of levonorgestrel-releasing intrauterine system. Hum Reprod 2006;21:1316–9. http://dx.doi.org/10.1093/humrep/dei457
47. Bahamondes L, Monteiro-Dantas C, Espejo-Arce X, et al. A prospective study of the forearm bone density of users of etonorgestrel- and levonorgestrel-releasing contraceptive implants. Hum Reprod 2006;21:466–70. http://dx.doi.org/10.1093/humrep/dei358

48. Pitts SA, Feldman HA, Dorale A, Gordon CM. Bone mineral density, fracture, and vitamin D in adolescents and young women using depot medroxyprogesterone acetate. J Pediatr Adolesc Gynecol 2012;25:23–6. http://dx.doi.org/10.1016/j.jpag.2011.07.014
49. US Department of Health and Human Services. Healthy people 2020: maternal, infant, and child health objectives. Washington, DC: US Department of Health and Human Services; 2015. http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives
50. Braga GC, Ferriolli E, Quintana SM, Ferriani RA, Pfrimer K, Vieira CS. Immediate postpartum initiation of etonogestrel-releasing implant: a randomized controlled trial on breastfeeding impact. Contraception 2015;92:536–42. http://dx.doi.org/10.1016/j.contraception.2015.07.009
51. Phillips SJ, Tepper NK, Kapp N, Nanda K, Temmerman M, Curtis KM. Progestogen-only contraceptive use among breastfeeding women: a systematic review. Contraception 2015;S0010-7824(15)00585-5.
52. Kurunmäki H. Contraception with levonorgestrel-releasing subdermal capsules, Norplant, after pregnancy termination. Contraception 1983;27:473–82. http://dx.doi.org/10.1016/0010-7824(83)90044-6
53. Kurunmäki H, Toivonen J, Lähteenmäki PL, Luukkainen T. Immediate postabortal contraception with Norplant: levonorgestrel, gonadotropin, estradiol, and progesterone levels over two postabortal months and return of fertility after removal of Norplant capsules. Contraception 1984;30:431–42. http://dx.doi.org/10.1016/0010-7824(84)90035-0.
54. Lähteenmäki P, Toivonen J, Lähteenmäki PL. Postabortal contraception with norethisterone enanthate injections. Contraception 1983;27:553–62 http://dx.doi.org/10.1016/0010-7824(83)90020-3
55. Ortayli N, Bulut A, Sahin T, Sivin I. Immediate postabortal contraception with the levonorgestrel intrauterine device, Norplant, and traditional methods. Contraception 2001;63:309–14. http://dx.doi.org/10.1016/S0010-7824(01)00212-8
56. Beksinska ME, Smit JA, Kleinschmidt I, Milford C, Farley TM. Prospective study of weight change in new adolescent users of DMPA, NET-EN, COCs, nonusers and discontinuers of hormonal contraception. Contraception 2010;81:30–4. http://dx.doi.org/10.1016/j.contraception.2009.07.007
57. Bender NM, Segall-Gutierrez P, Najera SO, Stanczyk FZ, Montoro M, Mishell DR Jr. Effects of progestin-only long-acting contraception on metabolic markers in obese women. Contraception 2013;88:418–25. http://dx.doi.org/10.1016/j.contraception.2012.12.007
58. Berenson AB, Rahman M. Changes in weight, total fat, percent body fat, and central-to-peripheral fat ratio associated with injectable and oral contraceptive use. Am J Obstet Gynecol 2009;200:329.e1–8. http://dx.doi.org/10.1016/j.ajog.2008.12.052
59. Bonny AE, Secic M, Cromer B. Early weight gain related to later weight gain in adolescents on depot medroxyprogesterone acetate. Obstet Gynecol 2011;117:793–7. http://dx.doi.org/10.1097/AOG.0b013e31820f387c.
60. Bonny AE, Ziegler J, Harvey R, Debanne SM, Secic M, Cromer BA. Weight gain in obese and nonobese adolescent girls initiating depot medroxyprogesterone, oral contraceptive pills, or no hormonal contraceptive method. Arch Pediatr Adolesc Med 2006;160:40–5 http://dx.doi.org/10.1001/archpedi.160.1.40
61. Clark MK, Dillon JS, Sowers M, Nichols S. Weight, fat mass, and central distribution of fat increase when women use depot-medroxyprogesterone acetate for contraception. Int J Obes 2005;29:1252–8. http://dx.doi.org/10.1038/sj.ijo.0803023
62. Gerlach LS, Saldaña SN, Wang Y, Nick TG, Spigarelli MG. Retrospective review of the relationship between weight change and demographic factors following initial depot medroxyprogesterone acetate injection in adolescents. Clin Ther 2011;33:182–7. http://dx.doi.org/10.1016/j.clinthera.2011.02.008
63. Jain J, Jakimiuk AJ, Bode FR, Ross D, Kaunitz AM. Contraceptive efficacy and safety of DMPA-SC. Contraception 2004;70:269–75. http://dx.doi.org/10.1016/j.contraception.2004.06.011
64. Kozlowski KJ, Rickert VI, Hendon A, Davis P. Adolescents and Norplant: preliminary findings of side effects. J Adolesc Health 1995;16:373–8. http://dx.doi.org/10.1016/S1054-139X(94)00029-E
65. Le YC, Rahman M, Berenson AB. Early weight gain predicting later weight gain among depot medroxyprogesterone acetate users. Obstet Gynecol 2009;114:279–84. http://dx.doi.org/10.1097/AOG.0b013e3181af68b2
66. Leiman G. Depo-medroxyprogesterone acetate as a contraceptive agent: its effect on weight and blood pressure. Am J Obstet Gynecol 1972;114:97–102. http://dx.doi.org/10.1016/0002-9378(72)90296-7.
67. Lopez LM, Grimes DA, Chen M, et al. Hormonal contraceptives for contraception in overweight or obese women. Cochrane Database Syst Rev 2013;4:CD008452.
68. Mangan SA, Larsen PG, Hudson S. Overweight teens at increased risk for weight gain while using depot medroxyprogesterone acetate. J Pediatr Adolesc Gynecol 2002;15:79–82. http://dx.doi.org/10.1016/S1083-3188(01)00147-4
69. Nyirati CM, Habash DL, Shaffer LE. Weight and body fat changes in postpartum depot-medroxyprogesterone acetate users. Contraception 2013;88:169–76. http://dx.doi.org/10.1016/j.contraception.2012.10.016
70. Pantoja M, Medeiros T, Baccarin MC, Morais SS, Bahamondes L, Fernandes AM. Variations in body mass index of users of depot-medroxyprogesterone acetate as a contraceptive. Contraception 2010;81:107–11. http://dx.doi.org/10.1016/j.contraception.2009.07.008
71. Risser WL, Gefter LR, Barratt MS, Risser JM. Weight change in adolescents who used hormonal contraception. J Adolesc Health 1999;24:433–6. http://dx.doi.org/10.1016/S1054-139X(98)00151-7
72. Segall-Gutierrez P, Xiang AH, Watanabe RM, et al. Deterioration in cardiometabolic risk markers in obese women during depot medroxyprogesterone acetate use. Contraception 2012;85:36–41. http://dx.doi.org/10.1016/j.contraception.2011.04.016
73. Westhoff C, Jain JK, Milsom I, Ray A. Changes in weight with depot medroxyprogesterone acetate subcutaneous injection 104 mg/0.65 mL. Contraception 2007;75:261–7. http://dx.doi.org/10.1016/j.contraception.2006.12.009
74. Paulen ME, Zapata LB, Cansino C, Curtis KM, Jamieson DJ. Contraceptive use among women with a history of bariatric surgery: a systematic review. Contraception 2010;82:86–94. http://dx.doi.org/10.1016/j.contraception.2010.02.008
75. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Cardiovascular disease and use of oral and injectable progestogen-only contraceptives and combined injectable contraceptives. Results of an international, multicenter, case-control study. Contraception 1998;57:315–24 http://dx.doi.org/10.1016/S0010-7824(98)00041-9
76. Heinemann LA, Assmann A, DoMinh T, Garbe E. Oral progestogen-only contraceptives and cardiovascular risk: results from the Transnational Study on Oral Contraceptives and the Health of Young Women. Eur J Contracept Reprod Health Care 1999;4:67–73. http://dx.doi.org/10.3109/13625189909064007
77. Vasilakis C, Jick H, del Mar Melero-Montes M. Risk of idiopathic venous thromboembolism in users of progestagens alone. Lancet 1999;354:1610–1. http://dx.doi.org/10.1016/S0140-6736(99)04394-9
78. Sönmezer M, Atabekoğlu C, Cengiz B, Dökmeci F, Cengiz SD. Depot-medroxyprogesterone acetate in anticoagulated patients with previous hemorrhagic corpus luteum. Eur J Contracept Reprod Health Care 2005;10:9–14. http://dx.doi.org/10.1080/13625180400020952
79. Tepper NK, Paulen ME, Marchbanks PA, Curtis KM. Safety of contraceptive use among women with peripartum cardiomyopathy: a systematic review. Contraception 2010;82:95–101. http://dx.doi.org/10.1016/j.contraception.2010.02.004
80. The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown and Co; 1994.
81. Bernatsky S, Clarke A, Ramsey-Goldman R, et al. Hormonal exposures and breast cancer in a sample of women with systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1178–81. http://dx.doi.org/10.1093/rheumatology/keh282

82. Bernatsky S, Ramsey-Goldman R, Gordon C, et al. Factors associated with abnormal Pap results in systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1386–9. http://dx.doi.org/10.1093/rheumatology/keh331
83. Chopra N, Koren S, Greer WL, et al. Factor V Leiden, prothrombin gene mutation, and thrombosis risk in patients with antiphospholipid antibodies. J Rheumatol 2002;29:1683–8.
84. Esdaile JM, Abrahamowicz M, Grodzicky T, et al. Traditional Framingham risk factors fail to fully account for accelerated atherosclerosis in systemic lupus erythematosus. Arthritis Rheum 2001;44:2331–7. http://dx.doi.org/10.1002/1529-0131(200110)44:10<2331::AID-ART395≥3.0.CO;2-I
85. Julkunen HA. Oral contraceptives in systemic lupus erythematosus: side-effects and influence on the activity of SLE. Scand J Rheumatol 1991;20:427–33. http://dx.doi.org/10.3109/03009749109096822
86. Julkunen HA, Kaaja R, Friman C. Contraceptive practice in women with systemic lupus erythematosus. Br J Rheumatol 1993;32:227–30. http://dx.doi.org/10.1093/rheumatology/32.3.227
87. Jungers P, Dougados M, Pélissier C, et al. Influence of oral contraceptive therapy on the activity of systemic lupus erythematosus. Arthritis Rheum 1982;25:618–23. http://dx.doi.org/10.1002/art.1780250603
88. Manzi S, Meilahn EN, Rairie JE, et al. Age-specific incidence rates of myocardial infarction and angina in women with systemic lupus erythematosus: comparison with the Framingham Study. Am J Epidemiol 1997;145:408–15. http://dx.doi.org/10.1093/oxfordjournals.aje.a009122
89. McAlindon T, Giannotta L, Taub N, D'Cruz D, Hughes G. Environmental factors predicting nephritis in systemic lupus erythematosus. Ann Rheum Dis 1993;52:720–4. http://dx.doi.org/10.1136/ard.52.10.720
90. McDonald J, Stewart J, Urowitz MB, Gladman DD. Peripheral vascular disease in patients with systemic lupus erythematosus. Ann Rheum Dis 1992;51:56–60. http://dx.doi.org/10.1136/ard.51.1.56
91. Mintz G, Gutiérrez G, Delezé M, Rodríguez E. Contraception with progestagens in systemic lupus erythematosus. Contraception 1984;30:29–38. http://dx.doi.org/10.1016/0010-7824(84)90076-3
92. Petri M. Musculoskeletal complications of systemic lupus erythematosus in the Hopkins Lupus Cohort: an update. Arthritis Care Res 1995;8:137–45. http://dx.doi.org/10.1002/art.1790080305
93. Petri M. Lupus in Baltimore: evidence-based 'clinical pearls' from the Hopkins Lupus Cohort. Lupus 2005;14:970–3. http://dx.doi.org/10.1191/0961203305lu2230xx
94. Petri M, Kim MY, Kalunian KC, et al; OC-SELENA Trial. Combined oral contraceptives in women with systemic lupus erythematosus. N Engl J Med 2005;353:2550–8. http://dx.doi.org/10.1056/NEJMoa051135
95. Sánchez-Guerrero J, Uribe AG, Jiménez-Santana L, et al. A trial of contraceptive methods in women with systemic lupus erythematosus. N Engl J Med 2005;353:2539–49. http://dx.doi.org/10.1056/NEJMoa050817
96. Sarabi ZS, Chang E, Bobba R, et al. Incidence rates of arterial and venous thrombosis after diagnosis of systemic lupus erythematosus. Arthritis Rheum 2005;53:609–12. http://dx.doi.org/10.1002/art.21314
97. Schaedel ZE, Dolan G, Powell MC. The use of the levonorgestrel-releasing intrauterine system in the management of menorrhagia in women with hemostatic disorders. Am J Obstet Gynecol 2005;193:1361–3. http://dx.doi.org/10.1016/j.ajog.2005.05.002
98. Somers E, Magder LS, Petri M. Antiphospholipid antibodies and incidence of venous thrombosis in a cohort of patients with systemic lupus erythematosus. J Rheumatol 2002;29:2531–6.
99. Urowitz MB, Bookman AA, Koehler BE, Gordon DA, Smythe HA, Ogryzlo MA. The bimodal mortality pattern of systemic lupus erythematosus. Am J Med 1976;60:221–5. http://dx.doi.org/10.1016/0002-9343(76)90431-9
100. Choojitarom K, Verasertniyom O, Totemchokchyakarn K, Nantiruj K, Sumethkul V, Janwityanujit S. Lupus nephritis and Raynaud's phenomenon are significant risk factors for vascular thrombosis in SLE patients with positive antiphospholipid antibodies. Clin Rheumatol 2008;27:345–51. http://dx.doi.org/10.1007/s10067-007-0721-z
101. Wahl DG, Guillemin F, de Maistre E, Perret C, Lecompte T, Thibaut G. Risk for venous thrombosis related to antiphospholipid antibodies in systemic lupus erythematosus—a meta-analysis. Lupus 1997;6:467–73. http://dx.doi.org/10.1177/096120339700600510
102. Farr SL, Folger SG, Paulen ME, Curtis KM. Safety of contraceptive methods for women with rheumatoid arthritis: a systematic review. Contraception 2010;82:64–71. http://dx.doi.org/10.1016/j.contraception.2010.02.003
103. Tepper NK, Whiteman MK, Zapata LB, Marchbanks PA, Curtis KM. Safety of hormonal contraceptives among women with migraine: a systematic review. Contraception 2016. Epub May 3, 2016. http://dx.doi.org/10.1016/j.contraception.2016.04.016
104. Tepper NK, Whiteman MK, Marchbanks PA, James AH, Curtis KM. Progestin-only contraception and thromboembolism: a systematic review. Contraception 2016. Epub May 3, 2016. http://dx.doi.org/10.1016/j.contraception.2016.04.014
105. Zapata LB, Oduyebo T, Whiteman MK, Marchbanks PA, Curtis KM. Contraceptive use among women with multiple sclerosis: a systematic review. Contraception. In press 2016.
106. Pagano HP, Zapata LB, Berry-Bibee EN, Nanda K, Curtis KM. Safety of hormonal contraception and intrauterine devices among women with depressive and bipolar disorders: a systematic review. Contraception 2016. Epub June 27, 2016. http://dx.doi.org/10.1016/j.contraception.2016.06.012
107. Smith JS, Green J, Berrington de Gonzalez A, et al. Cervical cancer and use of hormonal contraceptives: a systematic review. Lancet 2003;361:1159–67. http://dx.doi.org/10.1016/S0140-6736(03)12949-2.
108. Polis CB, Phillips SJ, Curtis KM, et al. Hormonal contraceptive methods and risk of HIV acquisition in women: a systematic review of epidemiological evidence. Contraception 2014;90:360–90 http://dx.doi.org/10.1016/j.contraception.2014.07.009
109. Phillips SJ, Curtis KM, Polis CB. Effect of hormonal contraceptive methods on HIV disease progression: a systematic review. AIDS 2013;27:787–94. http://dx.doi.org/10.1097/QAD.0b013e32835bb672
110. Polis CB, Phillips SJ, Curtis KM. Hormonal contraceptive use and female-to-male HIV transmission: a systematic review of the epidemiologic evidence. AIDS 2013;27:493–505. http://dx.doi.org/10.1097/QAD.0b013e32835ad539
111. Phillips SJ, Polis CB, Curtis KM. The safety of hormonal contraceptives for women living with HIV and their sexual partners. Contraception 2016;93:11–6 http://dx.doi.org/10.1016/j.contraception.2015.10.002.
112. Tagy AH, Saker ME, Moussa AA, Kolgah A. The effect of low-dose combined oral contraceptive pills versus injectable contraceptive (Depot Provera) on liver function tests of women with compensated bilharzial liver fibrosis. Contraception 2001;64:173–6. http://dx.doi.org/10.1016/S0010-7824(01)00248-7
113. Pyörälä T, Vähäpassi J, Huhtala M. The effect of lynestrenol and norethindrone on the carbohydrate and lipid metabolism in subjects with gestational diabetes. Ann Chir Gynaecol 1979;68:69–74.
114. Rådberg T, Gustafson A, Skryten A, Karlsson K. Metabolic studies in gestational diabetic women during contraceptive treatment: effects on glucose tolerance and fatty acid composition of serum lipids. Gynecol Obstet Invest 1982;13:17–29. http://dx.doi.org/10.1159/000299480

115. Kjos SL, Peters RK, Xiang A, Thomas D, Schaefer U, Buchanan TA. Contraception and the risk of type 2 diabetes mellitus in Latina women with prior gestational diabetes mellitus. JAMA 1998;280:533–8. http://dx.doi.org/10.1001/jama.280.6.533
116. Nelson AL, Le MH, Musherraf Z, Vanberckelaer A. Intermediate-term glucose tolerance in women with a history of gestational diabetes: natural history and potential associations with breastfeeding and contraception. Am J Obstet Gynecol 2008;198:699.e1–8.
117. Xiang AH, Kawakubo M, Buchanan TA, Kjos SL. A longitudinal study of lipids and blood pressure in relation to method of contraception in Latino women with prior gestational diabetes mellitus. Diabetes Care 2007;30:1952–8. http://dx.doi.org/10.2337/dc07-0180
118. Xiang AH, Kawakubo M, Kjos SL, Buchanan TA. Long-acting injectable progestin contraception and risk of type 2 diabetes in Latino women with prior gestational diabetes mellitus. Diabetes Care 2006;29:613–7. http://dx.doi.org/10.2337/diacare.29.03.06.dc05-1940
119. Diab KM, Zaki MM. Contraception in diabetic women: comparative metabolic study of Norplant, depot medroxyprogesterone acetate, low dose oral contraceptive pill and CuT380A. J Obstet Gynaecol Res 2000;26:17–26. http://dx.doi.org/10.1111/j.1447-0756.2000.tb01195.x
120. Lunt H, Brown LJ. Self-reported changes in capillary glucose and insulin requirements during the menstrual cycle. Diabet Med 1996;13:525–30. http://dx.doi.org/10.1002/(SICI)1096-9136(199606)13:6<525::AID-DIA123≥3.0.CO;2-D
121. Rådberg T, Gustafson A, Skryten A, Karlsson K. Oral contraception in diabetic women. A cross-over study on serum and high density lipoprotein (HDL) lipids and diabetes control during progestogen and combined estrogen/progestogen contraception. Horm Metab Res 1982;14:61–5.
122. Skouby SO, Mølsted-Pedersen L, Kühl C, Bennet P. Oral contraceptives in diabetic women: metabolic effects of four compounds with different estrogen/progestogen profiles. Fertil Steril 1986;46:858–64 http://dx.doi.org/10.1016/S0015-0282(16)49825-0.
123. Zapata LB, Paulen ME, Cansino C, Marchbanks PA, Curtis KM. Contraceptive use among women with inflammatory bowel disease: a systematic review. Contraception 2010;82:72–85. http://dx.doi.org/10.1016/j.contraception.2010.02.012
124. Kapp N, Curtis KM. Hormonal contraceptive use among women with liver tumors: a systematic review. Contraception 2009;80:387–90. http://dx.doi.org/10.1016/j.contraception.2009.01.021
125. Whiteman MK, Oduyebo T, Zapata LB, Walker S, Curtis KM. Contraceptive safety among women with cystic fibrosis: a systematic review. Contraception 2016. Epub June 7, 2016. http://dx.doi.org/10.1016/j.contraception.2016.05.016
126. Adadevoh BK, Isaacs WA. The effect of megestrol acetate on sickling. Am J Med Sci 1973;265:367–70. http://dx.doi.org/10.1097/00000441-197305000-00002
127. Barbosa IC, Ladipo OA, Nascimento ML, et al. Carbohydrate metabolism in sickle cell patients using a subdermal implant containing nomegestrol acetate (Uniplant). Contraception 2001;63:263–5. http://dx.doi.org/10.1016/S0010-7824(01)00202-5
128. de Abood M, de Castillo Z, Guerrero F, Espino M, Austin KL. Effect of Depo-Provera or Microgynon on the painful crises of sickle cell anemia patients. Contraception 1997;56:313–6. http://dx.doi.org/10.1016/S0010-7824(97)00156-X
129. De Ceulaer K, Hayes R, Gruber C, Serjeant GR. Medroxyprogesterone acetate and homozygous sickle-cell disease. Lancet 1982;320:229–31. http://dx.doi.org/10.1016/S0140-6736(82)90320-8
130. Howard RJ, Lillis C, Tuck SM. Contraceptives, counselling, and pregnancy in women with sickle cell disease. BMJ 1993;306:1735–7. http://dx.doi.org/10.1136/bmj.306.6894.1735
131. Ladipo OA, Falusi AG, Feldblum PJ, Osotimehin BO, Otolorin EO, Ojengbede OA. Norplant use by women with sickle cell disease. Int J Gynaecol Obstet 1993;41:85–7. http://dx.doi.org/10.1016/0020-7292(93)90159-T
132. Nascimento ML, Ladipo OA, Coutinho EM. Nomegestrol acetate contraceptive implant use by women with sickle cell disease. Clin Pharmacol Ther 1998;64:433–8. http://dx.doi.org/10.1016/S0009-9236(98)90074-1
133. Yoong WC, Tuck SM, Yardumian A. Red cell deformability in oral contraceptive pill users with sickle cell anaemia. Br J Haematol 1999;104:868–70. http://dx.doi.org/10.1046/j.1365-2141.1999.01255.x
134. Aweeka FT, Rosenkranz SL, Segal Y, et al; NIAID AIDS Clinical Trials Group. The impact of sex and contraceptive therapy on the plasma and intracellular pharmacokinetics of zidovudine. AIDS 2006;20:1833–41. http://dx.doi.org/10.1097/01.aids.0000244202.18629.36
135. Kearney BP, Mathias A. Lack of effect of tenofovir disoproxil fumarate on pharmacokinetics of hormonal contraceptives. Pharmacotherapy 2009;29:924–9. http://dx.doi.org/10.1592/phco.29.8.924
136. Todd CS, Deese J, Wang M, et al; FEM-PrEP Study Group. Sino-implant (II)® continuation and effect of concomitant tenofovir disoproxil fumarate-emtricitabine use on plasma levonorgestrel concentrations among women in Bondo, Kenya. Contraception 2015;91:248–52. http://dx.doi.org/10.1016/j.contraception.2014.10.008
137. Murnane PM, Heffron R, Ronald A, et al; Partners PrEP Study Team. Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception. AIDS 2014;28:1825–30. http://dx.doi.org/10.1097/QAD.0000000000000290
138. Kasonde M, Niska RW, Rose C, et al. Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir-emtricitabine or placebo in Botswana. PLoS One 2014;9:e90111. http://dx.doi.org/10.1371/journal.pone.0090111
139. Callahan R, Nanda K, Kapiga S, et al; FEM-PrEP Study Group. Pregnancy and contraceptive use among women participating in the FEM-PrEP trial. J Acquir Immune Defic Syndr 2015;68:196–203. http://dx.doi.org/10.1097/QAI.0000000000000413
140. Vieira CS, Bahamondes MV, de Souza RM, et al. Effect of antiretroviral therapy including lopinavir/ritonavir or efavirenz on etonogestrel-releasing implant pharmacokinetics in HIV-positive women. J Acquir Immune Defic Syndr 2014;66:378–85. http://dx.doi.org/10.1097/QAI.0000000000000189
141. Patel RC, Onono M, Gandhi M, et al. Pregnancy rates in HIV-positive women using contraceptives and efavirenz-based or nevirapine-based antiretroviral therapy in Kenya: a retrospective cohort study. Lancet HIV 2015;2:e474–82. http://dx.doi.org/10.1016/S2352-3018(15)00184-8
142. Perry SH, Swamy P, Preidis GA, Mwanyumba A, Motsa N, Sarero HN. Implementing the Jadelle implant for women living with HIV in a resource-limited setting: concerns for drug interactions leading to unintended pregnancies. AIDS 2014;28:791–3. http://dx.doi.org/10.1097/QAD.0000000000000177
143. Scarsi KK, Darin KM, Nakalema S, et al. Unintended pregnancies observed with combined use of the levonorgestrel contraceptive implant and efavirenz-based antiretroviral therapy: a three-arm pharmacokinetic evaluation over 48 weeks. Clin Infect Dis 2015;62:675–82. http://dx.doi.org/10.1093/cid/civ1001

144. Pyra M, Heffron R, Mugo NR, et al; Partners in Prevention HSVHIV Transmission Study and Partners PrEP Study Teams. Effectiveness of hormonal contraception in HIV-infected women using antiretroviral therapy. AIDS 2015;29:2353–9. http://dx.doi.org/10.1097/QAD.0000000000000827
145. Cohn SE, Park JG, Watts DH, et al; ACTG A5093 Protocol Team. Depo-medroxyprogesterone in women on antiretroviral therapy: effective contraception and lack of clinically significant interactions. Clin Pharmacol Ther 2007;81:222–7. http://dx.doi.org/10.1038/sj.clpt.6100040
146. Nanda K, Amaral E, Hays M, Viscola MA, Mehta N, Bahamondes L. Pharmacokinetic interactions between depot medroxyprogesterone acetate and combination antiretroviral therapy. Fertil Steril 2008;90:965–71. http://dx.doi.org/10.1016/j.fertnstert.2007.07.1348
147. Watts DH, Park JG, Cohn SE, et al. Safety and tolerability of depot medroxyprogesterone acetate among HIV-infected women on antiretroviral therapy: ACTG A5093. Contraception 2008;77:84–90. http://dx.doi.org/10.1016/j.contraception.2007.10.002
148. Polis CB, Nakigozi G, Ssempijja V, et al. Effect of injectable contraceptive use on response to antiretroviral therapy among women in Rakai, Uganda. Contraception 2012;86:725–30. http://dx.doi.org/10.1016/j.contraception.2012.05.001
149. Hubacher D, Liku J, Kiarie J, et al. Effect of concurrent use of antiretroviral therapy and levonorgestrel sub-dermal implant for contraception on CD4 counts: a prospective cohort study in Kenya. J Int AIDS Soc 2013;16:18448. http://dx.doi.org/10.7448/IAS.16.1.18448
150. Myer L, Carter RJ, Katyal M, Toro P, El-Sadr WM, Abrams EJ. Impact of antiretroviral therapy on incidence of pregnancy among HIV-infected women in Sub-Saharan Africa: a cohort study. PLoS Med 2010;7:e1000229. http://dx.doi.org/10.1371/journal.pmed.1000229
151. Day S, Graham SM, Masese LN, et al. A prospective cohort study of the effect of depot medroxyprogesterone acetate on detection of plasma and cervical HIV-1 in women initiating and continuing antiretroviral therapy. J Acquir Immune Defic Syndr 2014;66:452–6. http://dx.doi.org/10.1097/QAI.0000000000000187
152. DuBois BN, Atrio J, Stanczyk FZ, Cherala G. Increased exposure of norethindrone in HIV+ women treated with ritonavir-boosted atazanavir therapy. Contraception 2015;91:71–5. http://dx.doi.org/10.1016/j.contraception.2014.08.009
153. Luque AE, Cohn SE, Park JG, et al. Depot medroxyprogesterone acetate in combination with a twice-daily lopinavir-ritonavir-based regimen in HIV-infected women showed effective contraception and a lack of clinically significant interactions, with good safety and tolerability: results of the ACTG 5283 study. Antimicrob Agents Chemother 2015;59:2094–101. http://dx.doi.org/10.1128/AAC.04701-14
154. Odlind V, Olsson SE. Enhanced metabolism of levonorgestrel during phenytoin treatment in a woman with Norplant implants. Contraception 1986;33:257–61. http://dx.doi.org/10.1016/0010-7824(86)90018-1
155. Schindlbeck C, Janni W, Friese K. Failure of Implanon contraception in a patient taking carbamazepin for epilepsia. Arch Gynecol Obstet 2006;273:255–6. http://dx.doi.org/10.1007/s00404-005-0064-4
156. Shane-McWhorter L, Cerveny JD, MacFarlane LL, Osborn C. Enhanced metabolism of levonorgestrel during phenobarbital treatment and resultant pregnancy. Pharmacotherapy 1998;18:1360–4.
157. Reimers A, Helde G, Brodtkorb E. Ethinyl estradiol, not progestogens, reduces lamotrigine serum concentrations. Epilepsia 2005;46:1414–7. http://dx.doi.org/10.1111/j.1528-1167.2005.10105.x
158. Berry-Bibee E, Kim MJ, Simmons K, Pagano P, Curtis K. Drug interactions between hormonal contraceptives and psychotropic drugs: a systematic review. Contraception. In press 2016.
159. Berry-Bibee E, Kim MJ, Tepper N, Riley H, Curtis K. The safety of St. John's wort and hormonal contraceptives: a systematic review. Contraception. In press 2016.

Appendix D

Classifications for Combined Hormonal Contraceptives

Combined hormonal contraceptives (CHCs) include low-dose (containing ≤35 μg ethinyl estradiol) combined oral contraceptives (COCs), the combined hormonal patch, and the combined vaginal ring (Box D1) (Table D1). Limited information is available about the safety of the combined hormonal patch and combined vaginal ring among women with specific medical conditions. Evidence indicates that the combined hormonal patch and the combined vaginal ring provide comparable safety and pharmacokinetic profiles to COCs with similar hormone formulations *(1–33)*. Pending further studies, the evidence available for recommendations about COCs applies to the recommendations for the combined hormonal patch and vaginal ring. Therefore, the patch and ring should have the same categories as COCs, except where noted. Therefore, the assigned categories should be considered a preliminary best judgement, which will be reevaluated as new data become available.

BOX D1. Categories for classifying combined hormonal contraceptives

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

COCs, the patch, and the ring do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited

TABLE D1. Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History		
Pregnancy	NA	**Clarification:** Use of CHCs is not required. No known harm to the woman, the course of her pregnancy, or the fetus occurs if CHCs are inadvertently used during pregnancy.
Age		**Evidence:** Evidence is inconsistent about whether CHC use affects fracture risk (*34*–*45*), although three recent studies show no effect (*34*,*35*,*45*). CHC use might decrease BMD in adolescents, especially in those choosing very low-dose formulations (COCs containing <30 μg ethinyl estradiol) (*46*–*59*). CHC use has little to no effect on BMD in premenopausal women (*60*–*74*) and might preserve bone mass in those who are perimenopausal (*75*–*83*). BMD is a surrogate marker for fracture risk that might not be valid for premenopausal women and therefore might not accurately predict current or future (postmenopausal) fracture risk (*84*–*86*). **Comment:** The risk for cardiovascular disease increases with age and might increase with CHC use. In the absence of other adverse clinical conditions, CHCs can be used until menopause.
a. Menarche to <40 years	1	
b. ≥40 years	2	
Parity		
a. Nulliparous	1	—
b. Parous	1	—
Breastfeeding		
a. <21 days postpartum	4	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90*–*94*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
b. 21 to <30 days postpartum		
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a category 4. **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90*–*94*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
ii. Without other risk factors for VTE	3	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
c. 30–42 days postpartum		
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a category 4. **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
ii. Without other risk factors for VTE	2	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
d. >42 days postpartum	2	**Clarification:** Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (*87*). **Evidence:** Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (*88*). **Comment:** Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
Postpartum (nonbreastfeeding women)		
a. <21 days postpartum	4	**Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*). Risk for pregnancy during the first 21 days postpartum is very low but increases after that point; ovulation before first menses is common (*95*).
b. 21–42 days postpartum		
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2 postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a category 4. **Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*).
ii. Without other risk factors for VTE	2	**Evidence:** One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (*89*). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (*90–94*).
c. >42 days postpartum	1	—

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Postabortion		**Clarification:** CHCs may be started immediately postabortion.
a. First trimester	1	**Evidence:** Women who started taking COCs immediately after first trimester medical or surgical abortion did not experience more side effects or adverse vaginal bleeding outcomes or clinically significant changes in coagulation parameters than did women who used a placebo, an IUD, a nonhormonal contraceptive method, or delayed COC initiation (*96–102*). Limited evidence on women using the ring immediately after first trimester medical or surgical abortion found no serious adverse events and no infection related to use of the combined vaginal ring during 3 cycles of follow-up postabortion (*103*).
b. Second trimester	1	
c. Immediate postseptic abortion	1	
Past ectopic pregnancy	1	**Comment:** The risk for future ectopic pregnancy is increased among women who have had an ectopic pregnancy in the past. CHCs protect against pregnancy in general, including ectopic gestation.
History of pelvic surgery	1	—
Smoking		**Evidence:** COC users who smoked were at increased risk for cardiovascular diseases, especially myocardial infarction, compared with those who did not smoke. Studies also showed an increased risk for myocardial infarction with increasing number of cigarettes smoked per day (*104–116*).
a. Age <35 years	2	
b. Age ≥35 years		
i. <15 cigarettes per day	3	
ii. ≥15 cigarettes per day	4	
Obesity		**Evidence:** Obese women who use COCs are more likely than obese women who do not use COCs to experience VTE. Research examining the interaction between COCs and BMI on VTE risk is limited, particularly for women in the highest BMI categories (BMI ≥35 kg/m^2). Although the absolute risk for VTE in otherwise healthy women of reproductive age is small, obese women are at 2–3 times higher risk for VTE than normal weight women regardless of COC use. Limited evidence suggests that obese women who use COCs do not have a higher risk for acute myocardial infarction or stroke than do obese nonusers (*117*). Limited evidence suggests that effectiveness of some COC formulations might decrease with increasing BMI, however the observed reductions in effectiveness are minimal and evidence is conflicting (*118–125*). Effectiveness of the patch might be reduced in women >90 kg (*126*). Limited evidence suggests obese women are no more likely to gain weight during COC or vaginal ring use than normal weight or overweight women (*117*,*127*).
a. BMI ≥30 kg/m^2	2	
b. Menarche to <18 years and BMI ≥30 kg/m^2	2	
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent laparoscopic placement of an adjustable gastric band (*128*).
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	COCs: 3 Patch and ring: 1	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent a biliopancreatic diversion; however, evidence from pharmacokinetic studies reported conflicting results of oral contraceptive effectiveness among women who underwent a jejunoileal bypass (*128*). **Comment:** Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications, such as long-term diarrhea or vomiting.
Cardiovascular Disease		
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4	**Clarification:** When a woman has multiple major risk factors, any of which alone would substantially increase her risk for cardiovascular disease, use of CHCs might increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two category 2 risk factors might not necessarily warrant a higher category. **Clarification:** The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the *U.S. Selected Practice Recommendations for Contraceptive Use* (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Adequately controlled hypertension	3	**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Clarification:** Women adequately treated for hypertension are at reduced risk for acute myocardial infarction and stroke compared with untreated women. Although no data exist, CHC users with adequately controlled and monitored hypertension should be at reduced risk for acute myocardial infarction and stroke compared with untreated hypertensive CHC users. **Evidence:** Among women with hypertension, COC users were at higher risk than nonusers for stroke, acute myocardial infarction, and peripheral arterial disease (*104*,*106*,*113–116*,*129–143*). Discontinuation of COCs in women with hypertension might improve blood pressure control (*144*).
b. Elevated blood pressure levels (properly taken measurements)		**Clarification:** For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive. **Evidence:** Among women with hypertension, COC users were at higher risk than nonusers for stroke, acute myocardial infarction, and peripheral arterial disease (*104*,*106*,*113–116*,*129–143*). Discontinuation of COCs in women with hypertension might improve blood pressure control (*144*).
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	3	
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	4	
c. Vascular disease	4	
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	2	**Evidence:** Women with a history of high blood pressure in pregnancy who also used COCs had a higher risk for myocardial infarction and VTE than did COC users who did not have a history of high blood pressure during pregnancy. The absolute risks for acute myocardial infarction and VTE in this population remained small (*115*,*130*,*142*,*143*,*145–151*).
Deep venous thrombosis/Pulmonary embolism		
a. History of DVT/PE, not receiving anticoagulant therapy		
i. Higher risk for recurrent DVT/PE (one or more risk factors) • History of estrogen-associated DVT/PE • Pregnancy-associated DVT/PE • Idiopathic DVT/PE • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	4	—
ii. Lower risk for recurrent DVT/PE (no risk factors)	3	—
b. Acute DVT/PE	4	—
c. DVT/PE and established anticoagulant therapy for at least 3 months		**Clarification:** Women using anticoagulant therapy are at risk for gynecologic complications of therapy, such as hemorrhagic ovarian cysts and severe menorrhagia. Hormonal contraceptive methods can be of benefit in preventing or treating these complications. When a contraceptive method is used as a therapy, rather than solely to prevent pregnancy, the risk/benefit ratio might differ and should be considered on a case-by-case basis.
i. Higher risk for recurrent DVT/PE (one or more risk factors) • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DTV/PE	4	
ii. Lower risk for recurrent DVT/PE (no risk factors)	3	
d. Family history (first-degree relatives)	2	**Comment:** Some conditions that increase the risk for DTV/PE are heritable.
e. Major surgery		
i. With prolonged immobilization	4	—
ii. Without prolonged immobilization	2	—
f. Minor surgery without immobilization	1	—
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	4	**Clarification**: Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening. **Evidence:** Among women with thrombogenic mutations, COC users had a twofold to twentyfold higher risk for thrombosis than did nonusers (*152–175*).
Superficial venous disorders		
a. Varicose veins	1	**Evidence:** One study suggested that among women with varicose veins, the rate of VTE and superficial venous thrombosis was higher in oral contraceptive users compared with nonusers; however, statistical significance was not reported and the number of events was small (*176*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
b. Superficial venous thrombosis (acute or history)	3	**Clarification:** Superficial venous thrombosis might be associated with an increased risk for VTE. If a woman has risk factors for concurrent DVT (e.g., known thrombophilia or cancer) or has current or history of DVT, see recommendations for DVT/PE. Superficial venous thrombosis associated with a peripheral intravenous catheter is less likely to be associated with additional thrombosis and use of CHCs may be considered. **Evidence:** One study demonstrated that among women with superficial venous thrombosis, the risk for VTE was higher in oral contraceptive users compared with nonusers (*176*).
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	4	—
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	4	—
Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Uncomplicated	2	—
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	4	**Comment:** Among women with valvular heart disease, CHC use may further increase the risk for arterial thrombosis; women with complicated valvular heart disease are at greatest risk.
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		**Evidence:** No direct evidence exists about the safety of CHCs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies of women with cardiac disease demonstrated few cases of hypertension and transient ischemic attack in women with cardiac disease using COCs. No cases of heart failure were reported (*177*).
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (*178*)		**Comment:** COCs might increase fluid retention in healthy women; fluid retention may worsen heart failure in women with peripartum cardiomyopathy. COCs might induce cardiac arrhythmias in healthy women; women with peripartum cardiomyopathy have a high incidence of cardiac arrhythmias.
i. <6 months	4	
ii. ≥6 months	3	
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (*178*)	4	
Rheumatic Diseases		
Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Positive (or unknown) antiphospholipid antibodies	4	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*179–197*). **Evidence:** Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (*198*,*199*).
b. Severe thrombocytopenia	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*179–197*).
c. Immunosuppressive therapy	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*179–197*).
d. None of the above	2	**Clarification:** Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (*179–197*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Rheumatoid arthritis		**Evidence:** Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (*200*).
a. Receiving immunosuppressive therapy	2	
b. Not receiving immunosuppressive therapy	2	
Neurologic Conditions		
Headaches		
a. Nonmigraine (mild or severe)	1	**Clarification:** Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
b. Migraine		**Clarification:** Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
i. Without aura (This category of migraine includes menstrual migraine.)	2	
ii. With aura	4	
		Clarification: Classification is for women without any other risk factors for stroke (e.g., age, hypertension, and smoking).
		Evidence: Among women with migraine, oral contraceptive use is associated with about a threefold increased risk for ischemic stroke compared with nonuse, although most studies did not specify migraine type or oral contraceptive formulation. The only study to examine migraine type found that the risk for ischemic stroke among women with migraine with aura was increased to a similar level among both oral contraceptive users and nonusers, compared with women without migraine (*201*). The risk for ischemic stroke is increased among women using COCs, compared with women not using COCs (*104*,*202*). The risk for ischemic stroke is also increased among women with migraine with aura, compared with women without migraine (*203*–*205*). One older meta-analysis found that migraine without aura was associated with an increased risk for ischemic stroke, while two more recent meta-analyses did not find such an association (*203*–*205*).
		Comment: Menstrual migraine is a subtype of migraine without aura. For more information, see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	**Clarification:** If a woman is taking anticonvulsants, see Drug Interactions section. Certain anticonvulsants lower COC effectiveness. The extent to which patch or ring use is similar to COC use in this regard remains unclear.
Multiple sclerosis		**Evidence:** Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with multiple sclerosis does not worsen the clinical course of disease (*206*).
a. With prolonged immobility	3	
b. Without prolonged immobility	1	
		Comment: No data exist that evaluate the increased risk for VTE among women with multiple sclerosis using CHCs. However, women with multiple sclerosis are at higher risk than unaffected women for VTE.
Depressive Disorders		
Depressive disorders	1	**Clarification**: If a woman is receiving psychotropic medications or St. John's wort, see Drug Interactions section.
		Evidence: COC use was not associated with increased depressive symptoms in women with depression or scoring above threshold levels on a validated depression screening instrument compared with baseline or with nonusers with depression. One small study of women with bipolar disorder found that oral contraceptives did not significantly change mood across the menstrual cycle (*207*).
Reproductive Tract Infections and Disorders		
Vaginal bleeding patterns		
a. Irregular pattern without heavy bleeding	1	**Comment:** Irregular menstrual bleeding patterns are common among healthy women.
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	1	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition.
		Evidence: A Cochrane Collaboration Review identified one randomized controlled trial evaluating the effectiveness of COC use compared with naproxen and danazol in treating menorrhagia. Women with menorrhagia did not report worsening of the condition or any adverse events related to COC use (*208*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	2	**Clarification:** If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
		Comment: No conditions that cause vaginal bleeding will be worsened in the short-term by use of CHCs.
Endometriosis	1	**Evidence:** A Cochrane Collaboration Review identified one randomized controlled trial evaluating the effectiveness of COC use compared with a gonadotropin-releasing hormone analog in treating the symptoms of endometriosis. Women with endometriosis did not report worsening of the condition or any adverse events related to COC use (*209*).
Benign ovarian tumors (including cysts)	1	
Severe dysmenorrhea	1	**Evidence:** Risk for side effects with COC use was not higher among women with dysmenorrhea than among women not using COCs. Some COC users had a reduction in pain and bleeding (*210*,*211*).
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		**Clarification:** For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.
a. Suspected gestational trophoblastic disease (immediate postevacuation)		**Evidence:** After molar pregnancy evacuation, the balance of evidence found COC use did not increase the risk for postmolar trophoblastic disease, and β–hCG levels regressed more rapidly in some COC users than in nonusers (*212*). Limited evidence suggests that use of COCs during chemotherapy does not significantly affect the regression or treatment of postmolar trophoblastic disease compared with women who used a nonhormonal contraceptive method or DMPA during chemotherapy (*212*).
i. Uterine size first trimester	1	
ii. Uterine size second trimester	1	
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)		
i. Undetectable/nonpregnant β-hCG levels	1	
ii. Decreasing β-hCG levels	1	
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	1	
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	1	
Cervical ectropion	1	**Comment:** Cervical ectropion is not a risk factor for cervical cancer, and restriction of CHC use is unnecessary.
Cervical intraepithelial neoplasia	2	**Evidence:** Among women with persistent human papillomavirus infection, long-term COC use (≥5 years) might increase the risk for carcinoma in situ and invasive carcinoma (*213*). Limited evidence on women with low-grade squamous intraepithelial lesions found use of the vaginal ring did not worsen the condition (*9*).
Cervical cancer (awaiting treatment)	2	**Comment:** Theoretical concern exists that CHC use might affect prognosis of the existing disease. While awaiting treatment, women may use CHCs. In general, treatment of this condition can render a woman sterile.
Breast disease Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Undiagnosed mass	2	**Clarification:** The woman should be evaluated as early as possible.
b. Benign breast disease	1	—
c. Family history of cancer	1	**Evidence:** Women with breast cancer susceptibility genes (e.g., *BRCA1* and *BRCA2*) have a higher baseline risk for breast cancer than women without these genes. The baseline risk for breast cancer is also higher among women with a family history of breast cancer than among those who do not have such a history. However, evidence does not suggest that the increased risk for breast cancer among women with either a family history of breast cancer or breast cancer susceptibility genes is modified by the use of COCs (*214*–*231*).
d. Breast cancer		**Comment:** Breast cancer is a hormonally sensitive tumor, and the prognosis for women with current or recent breast cancer might worsen with CHC use.
i. Current	4	
ii. Past and no evidence of current disease for 5 years	3	
Endometrial hyperplasia	1	—
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	**Comment:** COC use reduces the risk for endometrial cancer; whether patch or ring use reduces the risk for endometrial cancer is not known. While awaiting treatment, women may use CHCs. In general, treatment of this condition renders a woman sterile.
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	**Comment:** COC use reduces the risk for ovarian cancer; whether patch or ring use reduces the risk for ovarian cancer is not known. While awaiting treatment, women may use CHCs. In general, treatment of this condition can render a woman sterile.
Uterine fibroids	1	**Comment:** COCs do not appear to cause growth of uterine fibroids, and patch and ring also are not expected to cause growth.

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Pelvic inflammatory disease		**Comment:** COCs might reduce the risk for PID among women with STDs but do not protect against HIV or lower genital tract STDs. Whether use of patch or ring reduces the risk for PID among women with STDs is unknown; however, they do not protect against HIV or lower genital tract STDs.
a. Past PID		
i. With subsequent pregnancy	1	
ii. Without subsequent pregnancy	1	
b. Current PID	1	
Sexually transmitted diseases		
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	1	—
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	1	—
c. Other factors related to STDs	1	—
HIV		
High risk for HIV	1	**Evidence:** Overall, evidence does not support an association between oral contraceptives and risk for HIV acquisition (*232*).
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	**Clarification:** Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section. **Evidence:** Overall, evidence does not support an association between COC use and progression of HIV. Limited direct evidence does not support an association between COC use and transmission of HIV to noninfected partners; studies measuring genital viral shedding as a proxy for infectivity have had mixed results. Studies measuring whether hormonal contraceptive methods affect plasma HIV viral load generally have found no effect (*233–235*).
Other Infections		
Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Uncomplicated	1	**Evidence:** Among women with uncomplicated schistosomiasis, COC use had no adverse effects on liver function (*236–242*).
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1	—
Tuberculosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		**Clarification:** If a woman is taking rifampin, see Drug Interactions section. Rifampin is likely to decrease COC effectiveness. The extent to which patch or ring use is similar to COC use in this regard remains unclear.
a. Nonpelvic	1	
b. Pelvic	1	
Malaria	1	—
Endocrine Conditions		
Diabetes Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. History of gestational disease	1	**Evidence:** The development of non–insulin-dependent diabetes in women with a history of gestational diabetes is not increased by use of COCs (*243–250*). Likewise, lipid levels appear to be unaffected by COC use (*251–253*).
b. Nonvascular disease		**Evidence:** Among women with insulin-dependent or non–insulin-dependent diabetes, COC use had limited effect on daily insulin requirements and no effect on long-term diabetes control (e.g., glycosylated hemoglobin levels) or progression to retinopathy. Changes in lipid profile and hemostatic markers were limited, and most changes remained within normal values (*254–263*).
i. Non-insulin dependent	2	
ii. Insulin dependent	2	
c. Nephropathy, retinopathy, or neuropathy	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
d. Other vascular disease or diabetes of >20 years' duration	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
Thyroid disorders		
a. Simple goiter	1	—
b. Hyperthyroid	1	—
c. Hypothyroid	1	—
Gastrointestinal Conditions		
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	2/3	**Clarification:** For women with mild IBD and with no other risk factor for VTE, the benefits of CHC use generally outweigh the risks (category 2). However, for women with IBD who are at increased risk for VTE (e.g., those with active or extensive disease, surgery, immobilization, corticosteroid use, vitamin deficiencies, or fluid depletion), the risks of CHC use generally outweigh the benefits (category 3). **Evidence:** Risk for disease relapse was not significantly higher among women with IBD using oral contraceptives (most studies did not specify type) than among nonusers (*264*). Absorption of COCs among women with mild ulcerative colitis and no or small ileal resections was similar to the absorption among healthy women (*264*). Findings might not apply to women with Crohn's disease or more extensive bowel resections. No data exist that evaluate the increased risk for VTE among women with IBD using CHCs. However, women with IBD are at higher risk than unaffected women for VTE (*264*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs		Clarifications/Evidence/Comments
Gallbladder disease			**Comment:** CHCs might cause a small increased risk for gallbladder disease. CHCs might worsen existing gallbladder disease.
a. Symptomatic			
i. Treated by cholecystectomy	2		
ii. Medically treated	3		
iii. Current	3		
b. Asymptomatic	2		
History of cholestasis			
a. Pregnancy related	2		**Comment:** History of pregnancy-related cholestasis might predict an increased risk for COC-related cholestasis.
b. Past COC related	3		**Comment:** History of COC-related cholestasis predicts an increased risk with subsequent COC use.
Viral hepatitis	Initiation	Continuation	
a. Acute or flare	3/4	2	**Clarification (initiation):** The category should be assessed according to the severity of the condition. **Evidence:** Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (*265*).
b. Carrier	1	1	**Evidence:** Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (*265*).
c. Chronic	1	1	**Evidence:** Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (*265*).
Cirrhosis Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).			
a. Mild (compensated)	1		—
b. Severe (decompensated)	4		—
Liver tumors Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).			
a. Benign			
i. Focal nodular hyperplasia	2		**Evidence:** Limited direct evidence suggests that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia (*266*).
ii. Hepatocellular adenoma	4		—
b. Malignant (hepatoma)	4		—
Respiratory Conditions			
Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		**Clarification:** Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions. **Clarification:** Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives. **Evidence:** Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with cystic fibrosis is not associated with worsening of disease severity. Very limited evidence suggests that cystic fibrosis does not impair the effectiveness of hormonal contraception (*267*).
Anemias			
Thalassemia	1		**Comment:** Anecdotal evidence from countries where thalassemia is prevalent indicates that COC use does not worsen the condition.
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	2		—
Iron deficiency anemia	1		**Comment:** CHC use might decrease menstrual blood loss.
Solid Organ Transplantation			
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).			

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
a. Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	4	**Evidence:** Limited evidence of COC and patch users indicated no overall changes in biochemical measures. However, one study reported discontinuations of COC use in two (8%) of 26 women as a result of serious medical complications, and in one case report, a woman developed cholestasis associated with high-dose COC use (*268*).
b. Uncomplicated	2	**Clarification:** Women with Budd-Chiari syndrome should not use CHCs because of the increased risk for thrombosis. **Evidence:** Limited evidence of COC and patch users indicated no overall changes in biochemical measures. However, one study reported discontinuations of COC use in two (8%) of 26 women as a result of serious medical complications, and in one case report, a woman developed cholestasis associated with high-dose COC use (*268*).
Drug Interactions		
Antiretroviral therapy		**Comment:** These recommendations generally are for ARV agents used alone. However, most women receiving ARV therapy are using multiple drugs in combination. In general, whether interactions between ARVs and hormonal contraceptives differ when ARVs are given alone or in combination is unknown.
a. Nucleoside reverse transcriptase inhibitors (NRTIs)		
i. Abacavir (ABC)	1	**Evidence:** NRTIs do not appear to have significant risk for interactions with hormonal contraceptive methods (*269–274*).
ii. Tenofovir (TDF)	1	
iii. Zidovudine (AZT)	1	
iv. Lamivudine (3TC)	1	
v. Didanosine (DDI)	1	
vi. Emtricitabine (FTC)	1	
vii. Stavudine (D4T)	1	
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)		
i. Efavirenz (EFV)	2	**Clarification:** Evidence suggests drug interactions between EFV and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive. **Evidence:** Two studies suggested that pregnancy rates might be higher among women using COCs and EFV compared with COCs alone, although one study found no difference in pregnancy rates (*275–277*) Two studies found conflicting results on ovulations in women receiving COCs and EFV compared with EFV alone (*278*,*279*). Two pharmacokinetic studies demonstrated decreases in ethinyl estradiol and progestin concentrations in women receiving COCs and EFV compared with COCs alone (*279*,*280*). Pharmacokinetic studies demonstrated generally no changes in EFV concentrations with concomitant COC use (*279*,*280*).
ii. Etravirine (ETR)	1	**Evidence:** One study demonstrated no clinically relevant pharmacokinetic or pharmacodynamic changes in women using COCs and ETR compared with COCs alone (*281*).
iii. Nevirapine (NVP)	1	**Evidence:** Five studies found no significant differences in pregnancy rates among women using COCs and NVP compared with women using COCs alone (*275–277*,*282*,*283*). Three studies reported no ovulations among women receiving COCs and NVP (*278*,*283*,*284*). Two pharmacokinetic studies demonstrated decreased concentrations of ethinyl estradiol and progestin among women using COCs and NVP compared with COCs alone, and one study found no change in contraceptive hormone concentrations (*278*,*284*,*285*). Pharmacokinetic studies demonstrated generally no changes in NVP concentrations with concomitant COC use (*278*,*285*,*286*).
iv. Rilpivirine (RPV)	1	**Evidence:** One study demonstrated no clinical significant pharmacokinetic changes or adverse events in women using COCs and RPV compared with COCs alone (*287*).
c. Ritonavir-boosted protease inhibitors		
i. Ritonavir-boosted atazanavir (ATV/r)	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. **Evidence:** One pharmacokinetic study demonstrated decreased estrogen but increased progestin concentrations in women using COCs and ATV/r compared with COCs alone (*288*).
ii. Ritonavir-boosted darunavir (DRV/r)	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. **Evidence:** One pharmacokinetic study demonstrated no change in follicle-stimulating hormone or luteinizing hormone but decreases in ethinyl estradiol and norethindrone in women using COCs with DRV/r compared with COCs alone (*289*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
iii. Ritonavir-boosted fosamprenavir (FPV/r)	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. **Evidence:** Information from the package label states that both ethinyl estradiol and norethindrone concentrations decreased with concurrent administration of COCs and FPV/r (*290*).
iv. Ritonavir-boosted lopinavir (LPV/r)	1	**Evidence:** One study demonstrated a non-significant increase in pregnancy rates among women using COCs and LPV/r compared with COCs alone (*275*). One study demonstrated no ovulations in women using the combined hormonal patch and LPV/r compared with combined hormonal patch alone; ethinyl estradiol concentrations for COC and patch users decreased but norelgestromin concentrations increased with use of the patch (*291*).
v. Ritonavir-boosted saquinavir (SQV/r)	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. **Evidence:** One pharmacokinetic study demonstrated no change in SQV concentrations in women using COC and SQV compared with COCs alone (*292*).
iv. Ritonavir-boosted tipranavir (TPV/r)	2	**Clarification:** Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. **Evidence:** Information from the package label states that ethinyl estradiol concentrations decrease but norethindrone concentrations increased with concurrent administration of COCs and TPV/r (*293*).
d. Protease inhibitors without ritonavir		
i. Atazanavir (ATV)	2	**Clarification:** Theoretical concern exists that increased levels of ethinyl estradiol because of interactions with ATV might increase the risk for adverse events. **Evidence:** Information from the package label states that there are inconsistent changes in ethinyl estradiol concentrations and increases in progestin concentrations with concurrent administration of two different COCs and ATV (*294*). **Comment:** When ATV is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
ii. Fosamprenavir (FPV)	3	**Clarification:** Concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the ARV drug. **Evidence:** Information from the package label states that amprenavir concentrations decreased with concurrent administration of COCs and amprenavir. Norethindrone concentrations increased and ethinyl estradiol concentrations did not change (*290*).
iii. Indinavir (IDV)	1	**Evidence:** One small study found no pregnancies in women using COCs and IDV (*277*).
iv. Nelfinavir (NFV)	2	**Clarification:** Evidence suggests drug interactions between certain protease inhibitors and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive. **Evidence:** One small study suggested that women using COCs and NFV may have had higher pregnancy rates than those using COCs alone (*277*).
e. CCR5 co-receptor antagonists		
i. Maraviroc (MVC)	1	**Evidence:** COC concentrations were not altered by co-administration with MVC (*295*).
f. HIV integrase strand transfer inhibitors		
i. Raltegravir (RAL)	1	**Evidence:** One pharmacokinetic study demonstrated increased concentrations of norgestimate and no change in ethinyl estradiol among women using COCs and RAL compared with COCs alone (*296*).
ii. Dolutegravir (DTG)	1	**Evidence:** One study demonstrated no clinically relevant pharmacokinetic or pharmacodynamic changes in women using COCs and DTG compared with COCs alone (*297*).

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
iii. Elvitegravir (EVG)	1	**Evidence:** Information from the package label states that ethinyl estradiol concentrations decreased and norgestimate concentrations increased with concurrent administration of COCs and EVG (*298*). **Comment:** When ATV is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
g. Fusion inhibitors		
i. Enfuvirtide	1	—
Anticonvulsant therapy		
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	**Clarification:** Although the interaction of certain anticonvulsants with CHCs is not harmful to women, it is likely to reduce the effectiveness of CHCs. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. When a COC is chosen, a preparation containing a minimum of 30 μg ethinyl estradiol should be used. **Evidence:** Use of certain anticonvulsants might decrease the effectiveness of COCs (*299–302*).
b. Lamotrigine	3	**Clarification:** The recommendation for lamotrigine applies only for situations where lamotrigine monotherapy is taken concurrently with COCs. Anticonvulsant treatment regimens that combine lamotrigine and non–enzyme-inducing antiepileptic drugs (e.g., sodium valproate) do not interact with COCs. **Evidence:** Pharmacokinetic studies show levels of lamotrigine decrease significantly during COC use (*303–307*). Some women who used both COCs and lamotrigine experienced increased seizure activity in one trial (*303*).
Antimicrobial therapy		
a. Broad-spectrum antibiotics	1	**Evidence:** Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of COCs *(308–344)*, patch (*345*), or ring (*346*).
b. Antifungals	1	**Evidence:** Studies of antifungal agents have shown no clinically significant pharmacokinetic interactions with COCs (*347–356*), or ring (*357*).
c. Antiparasitics	1	**Evidence:** Studies of antiparasitic agents have shown no clinically significant pharmacokinetic interactions with COCs (*236*,*358–362*).
d. Rifampin or rifabutin therapy	3	**Clarification:** Although the interaction of rifampin or rifabutin therapy with CHCs is not harmful to women, it is likely to reduce the effectiveness of CHCs. Use of other contraceptives should be encouraged for women who are long-term users of either of these drugs. When a COC is chosen, a preparation containing a minimum of 30 μg ethinyl estradiol should be used. **Evidence:** The balance of the evidence suggests that rifampin reduces the effectiveness of COCs (*363–378*). Data on rifabutin are limited, but effects on metabolism of COCs are less than with rifampin, and small studies have not shown evidence of ovulation (*365*,*372*).
Psychotropic medications		**Comment:** For many common psychotropic agents, limited or no theoretical concern exists for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications. For psychotropic agents that are CYP1A2 substrates, such as duloxetine, mirtazapine, ziprasidone, olanzapine, clomipramine, imipramine, and amitriptyline, co-administration with CHCs could theoretically yield increased concentrations of the psychotropic drug. For agents with narrow therapeutic windows, such as tricyclic antidepressants, increased drug concentrations might pose safety concerns that could necessitate closer monitoring.
a. SSRIs	1	**Evidence:** Limited clinical and pharmacokinetic data do not demonstrate concern for SSRIs decreasing the effectiveness of oral contraceptives. Limited evidence suggests that for women taking SSRIs, the use of hormonal contraceptives was not associated with differences in effectiveness of the SSRI for treatment or in adverse events when compared with women not taking hormonal contraceptives (*379*). **Comment:** Drugs that are inhibitors of CYP3A4 or CYP2C9 theoretically have the potential to increase levels of contraceptive steroids which might increase adverse events. Fluvoxamine is an SSRI known to be a moderate inhibitor of both CYP3A4 and CYP2C9; however, no clinical or pharmacokinetic studies were identified to explore potential drug-drug interactions.

See table footnotes on page 69.

TABLE D1. (*Continued*) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
St. John's wort	2	**Evidence:** Although clinical data are limited, studies with pharmacokinetic and pharmacodynamics outcomes raise concern that St. John's wort might decrease effectiveness of hormonal contraceptives, including increased risk for breakthrough bleeding and ovulation and increased metabolism of estrogen and progestins. Any interactions might be dependent on the dose of St John's wort, and the concentration of active ingredients across types of St. John's wort preparations may vary (*380*).

Abbreviations: ARV = antiretroviral; BMD = bone mineral density; BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; LDL = low-density lipoprotein; PE = pulmonary embolism; PID = pelvic inflammatory disease; SLE = systemic lupus erythematosus; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted infection; VTE = venous thromboembolism.

References

1. Abrams LS, Skee DM, Natarajan J, Wong FA, Lasseter KC. Multiple-dose pharmacokinetics of a contraceptive patch in healthy women participants. Contraception 2001;64:287–94. http://dx.doi.org/10.1016/S0010-7824(01)00273-6
2. Ahrendt HJ, Nisand I, Bastianelli C, et al. Efficacy, acceptability and tolerability of the combined contraceptive ring, NuvaRing, compared with an oral contraceptive containing 30 microg of ethinyl estradiol and 3 mg of drospirenone. Contraception 2006;74:451–7. http://dx.doi.org/10.1016/j.contraception.2006.07.004
3. Audet M-C, Moreau M, Koltun WD, et al; ORTHO EVRA/EVRA 004 Study Group. Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs an oral contraceptive: a randomized controlled trial. JAMA 2001;285:2347–54. http://dx.doi.org/10.1001/jama.285.18.2347
4. Bjarnadóttir RI, Tuppurainen M, Killick SR. Comparison of cycle control with a combined contraceptive vaginal ring and oral levonorgestrel/ethinyl estradiol. Am J Obstet Gynecol 2002;186:389–95. http://dx.doi.org/10.1067/mob.2002.121103
5. Boonyarangkul A, Taneepanichskul S. Comparison of cycle control and side effects between transdermal contraceptive patch and an oral contraceptive in women older than 35 years. J Med Assoc Thai 2007;90:1715–9.
6. Burkman RT. The transdermal contraceptive patch: a new approach to hormonal contraception. Int J Fertil Womens Med 2002;47:69–76.
7. Cole JA, Norman H, Doherty M, Walker AM. Venous thromboembolism, myocardial infarction, and stroke among transdermal contraceptive system users. Obstet Gynecol 2007;109:339–46. http://dx.doi.org/10.1097/01.AOG.0000250968.82370.04
8. Devineni D, Skee D, Vaccaro N, et al. Pharmacokinetics and pharmacodynamics of a transdermal contraceptive patch and an oral contraceptive. J Clin Pharmacol 2007;47:497–509. http://dx.doi.org/10.1177/0091270006297919.
9. Dieben TO, Roumen FJ, Apter D. Efficacy, cycle control, and user acceptability of a novel combined contraceptive vaginal ring. Obstet Gynecol 2002;100:585–93.
10. Dittrich R, Parker L, Rosen JB, Shangold G, Creasy GW, Fisher AC; Ortho Evra/Evra 001 Study Group. Transdermal contraception: evaluation of three transdermal norelgestromin/ethinyl estradiol doses in a randomized, multicenter, dose-response study. Am J Obstet Gynecol 2002;186:15–20. http://dx.doi.org/10.1067/mob.2002.118844
11. Duijkers I, Killick S, Bigrigg A, Dieben TO. A comparative study on the effects of a contraceptive vaginal ring NuvaRing and an oral contraceptive on carbohydrate metabolism and adrenal and thyroid function. Eur J Contracept Reprod Health Care 2004;9:131–40. http://dx.doi.org/10.1080/13625180400007199
12. Duijkers IJ, Klipping C, Verhoeven CH, Dieben TO. Ovarian function with the contraceptive vaginal ring or an oral contraceptive: a randomized study. Hum Reprod 2004;19:2668–73. http://dx.doi.org/10.1093/humrep/deh493
13. Elkind-Hirsch KE, Darensbourg C, Ogden B, Ogden LF, Hindelang P. Contraceptive vaginal ring use for women has less adverse metabolic effects than an oral contraceptive. Contraception 2007;76:348–56. http://dx.doi.org/10.1016/j.contraception.2007.08.001
14. Hedon B, Helmerhorst FM, Cronje HS, Shangold GA, Fisher AC, Creasy GW. Comparison of efficacy, cycle control, compliance, and safety in users of a contraceptive patch versus an oral contraceptive. Int J Gynaecol Obstet 2000;70(Suppl 2):B78. http://dx.doi.org/10.1016/S0020-7292(00)85161-9
15. Jick S, Kaye JA, Li L, Jick H. Further results on the risk of nonfatal venous thromboembolism in users of the contraceptive transdermal patch compared to users of oral contraceptives containing norgestimate and 35 microg of ethinyl estradiol. Contraception 2007;76:4–7. http://dx.doi.org/10.1016/j.contraception.2007.03.003
16. Jick SS, Jick H. Cerebral venous sinus thrombosis in users of four hormonal contraceptives: levonorgestrel-containing oral contraceptives, norgestimate-containing oral contraceptives, desogestrel-containing oral contraceptives and the contraceptive patch. Contraception 2006;74:290–2. http://dx.doi.org/10.1016/j.contraception.2006.05.071
17. Jick SS, Jick H. The contraceptive patch in relation to ischemic stroke and acute myocardial infarction. Pharmacotherapy 2007;27:218–20. http://dx.doi.org/10.1592/phco.27.2.218
18. Jick SS, Kaye JA, Russmann S, Jick H. Risk of nonfatal venous thromboembolism in women using a contraceptive transdermal patch and oral contraceptives containing norgestimate and 35 microg of ethinyl estradiol. Contraception 2006;73:223–8. http://dx.doi.org/10.1016/j.contraception.2006.01.001
19. Magnusdóttir EM, Bjarnadóttir RI, Onundarson PT, et al. The contraceptive vaginal ring (NuvaRing) and hemostasis: a comparative study. Contraception 2004;69:461–7. http://dx.doi.org/10.1016/j.contraception.2003.12.010
20. Massai R, Mäkäräinen L, Kuukankorpi A, Klipping C, Duijkers I, Dieben T. The combined contraceptive vaginal ring and bone mineral density in healthy pre-menopausal women. Hum Reprod 2005;20:2764–8. http://dx.doi.org/10.1093/humrep/dei117
21. Milsom I, Lete I, Bjertnaes A, et al. Effects on cycle control and bodyweight of the combined contraceptive ring, NuvaRing, versus an oral contraceptive containing 30 μg ethinyl estradiol and 3 mg drospirenone. Hum Reprod 2006;21:2304–11. http://dx.doi.org/10.1093/humrep/del162
22. Oddsson K, Leifels-Fischer B, de Melo NR, et al. Efficacy and safety of a contraceptive vaginal ring (NuvaRing) compared with a combined oral contraceptive: a 1-year randomized trial. Contraception 2005;71:176–82. http://dx.doi.org/10.1016/j.contraception.2004.09.001
23. Pierson RA, Archer DF, Moreau M, Shangold GA, Fisher AC, Creasy GW. Ortho Evra/Evra versus oral contraceptives: follicular development and ovulation in normal cycles and after an intentional dosing error. Fertil Steril 2003;80:34–42. http://dx.doi.org/10.1016/S0015-0282(03)00556-9
24. Radowicki S, Skórzewska K, Szlendak K. Safety evaluation of a transdermal contraceptive system with an oral contraceptive [Polish]. Ginekol Pol 2005;76:884–9.

25. Sabatini R, Cagiano R. Comparison profiles of cycle control, side effects and sexual satisfaction of three hormonal contraceptives. Contraception 2006;74:220–3. http://dx.doi.org/10.1016/j.contraception.2006.03.022
26. Smallwood GH, Meador ML, Lenihan JP, Shangold GA, Fisher AC, Creasy GW; ORTHO EVRA/EVRA 002 Study Group. Efficacy and safety of a transdermal contraceptive system. Obstet Gynecol 2001;98:799–805.
27. Timmer CJ, Mulders TM. Pharmacokinetics of etonogestrel and ethinylestradiol released from a combined contraceptive vaginal ring. Clin Pharmacokinet 2000;39:233–42. http://dx.doi.org/10.2165/00003088-200039030-00005
28. Tuppurainen M, Klimscheffskij R, Venhola M, Dieben TO. The combined contraceptive vaginal ring (NuvaRing) and lipid metabolism: a comparative study. Contraception 2004;69:389–94. http://dx.doi.org/10.1016/j.contraception.2004.01.004
29. Urdl W, Apter D, Alperstein A, et al; ORTHO EVRA/EVRA 003 Study Group. Contraceptive efficacy, compliance and beyond: factors related to satisfaction with once-weekly transdermal compared with oral contraception. Eur J Obstet Gynecol Reprod Biol 2005;121:202–10. http://dx.doi.org/10.1016/j.ejogrb.2005.01.021
30. van den Heuvel MW, van Bragt AJM, Alnabawy AKM, Kaptein MCJ. Comparison of ethinylestradiol pharmacokinetics in three hormonal contraceptive formulations: the vaginal ring, the transdermal patch and an oral contraceptive. Contraception 2005;72:168–74. http://dx.doi.org/10.1016/j.contraception.2005.03.005
31. Veres S, Miller L, Burington B. A comparison between the vaginal ring and oral contraceptives. Obstet Gynecol 2004;104:555–63. http://dx.doi.org/10.1097/01.AOG.0000136082.59644.13
32. White T, Ozel B, Jain JK, Stanczyk FZ. Effects of transdermal and oral contraceptives on estrogen-sensitive hepatic proteins. Contraception 2006;74:293–6. http://dx.doi.org/10.1016/j.contraception.2006.04.005
33. Zieman M, Guillebaud J, Weisberg E, Shangold GA, Fisher AC, Creasy GW. Contraceptive efficacy and cycle control with the Ortho Evra/Evra transdermal system: the analysis of pooled data. Fertil Steril 2002;77(Suppl 2):S13–8. http://dx.doi.org/10.1016/S0015-0282(01)03275-7
34. Memon S, Iversen L, Hannaford PC. Is the oral contraceptive pill associated with fracture in later life? New evidence from the Royal College of General Practitioners Oral Contraception Study. Contraception 2011;84:40–7. http://dx.doi.org/10.1016/j.contraception.2010.11.019
35. Vestergaard P, Rejnmark L, Mosekilde L. Fracture risk in very young women using combined oral contraceptives. Contraception 2008;78:358–64. http://dx.doi.org/10.1016/j.contraception.2008.06.010
36. Vestergaard P, Rejnmark L, Mosekilde L. Oral contraceptive use and risk of fractures. Contraception 2006;73:571–6. http://dx.doi.org/10.1016/j.contraception.2006.01.006
37. Barad D, Kooperberg C, Wactawski-Wende J, Liu J, Hendrix SL, Watts NB. Prior oral contraception and postmenopausal fracture: a Women's Health Initiative observational cohort study. Fertil Steril 2005;84:374–83. http://dx.doi.org/10.1016/j.fertnstert.2005.01.132
38. Michaëlsson K, Baron JA, Farahmand BY, Ljunghall S. Influence of parity and lactation on hip fracture risk. Am J Epidemiol 2001;153:1166–72. http://dx.doi.org/10.1093/aje/153.12.1166
39. Michaëlsson K, Baron JA, Farahmand BY, Persson I, Ljunghall S. Oral-contraceptive use and risk of hip fracture: a case-control study. Lancet 1999;353:1481–4. http://dx.doi.org/10.1016/S0140-6736(98)09044-8
40. La Vecchia C, Tavani A, Gallus S. Oral contraceptives and risk of hip fractures. Lancet 1999;354:335–6. http://dx.doi.org/10.1016/S0140-6736(05)75239-9
41. Vessey M, Mant J, Painter R. Oral contraception and other factors in relation to hospital referral for fracture. Findings in a large cohort study. Contraception 1998;57:231–5. http://dx.doi.org/10.1016/S0010-7824(98)00026-2
42. O'Neill TW, Marsden D, Adams JE, Silman AJ. Risk factors, falls, and fracture of the distal forearm in Manchester, UK. J Epidemiol Community Health 1996;50:288–92. http://dx.doi.org/10.1136/jech.50.3.288
43. Mallmin H, Ljunghall S, Persson I, Bergström R. Risk factors for fractures of the distal forearm: a population-based case-control study. Osteoporos Int 1994;4:298–304. http://dx.doi.org/10.1007/BF01622186
44. Cooper C, Hannaford P, Croft P, Kay CR. Oral contraceptive pill use and fractures in women: a prospective study. Bone 1993;14:41–5. http://dx.doi.org/10.1016/8756-3282(93)90254-8
45. Meier C, Brauchli YB, Jick SS, Kraenzlin ME, Meier CR. Use of depot medroxyprogesterone acetate and fracture risk. J Clin Endocrinol Metab 2010;95:4909–16. http://dx.doi.org/10.1210/jc.2010-0032
46. Cibula D, Skrenkova J, Hill M, Stepan JJ. Low-dose estrogen combined oral contraceptives may negatively influence physiological bone mineral density acquisition during adolescence. Eur J Endocrinol 2012;166:1003–11. http://dx.doi.org/10.1530/EJE-11-1047
47. Gai L, Jia Y, Zhang M, et al. Effect of two kinds of different combined oral contraceptives use on bone mineral density in adolescent women. Contraception 2012;86:332–6. http://dx.doi.org/10.1016/j.contraception.2012.01.009
48. Scholes D, Hubbard RA, Ichikawa LE, et al. Oral contraceptive use and bone density change in adolescent and young adult women: a prospective study of age, hormone dose, and discontinuation. J Clin Endocrinol Metab 2011;96:E1380–7. http://dx.doi.org/10.1210/jc.2010-3027
49. Lattakova M, Borovsky M, Payer J, Killinger Z. Oral contraception usage in relation to bone mineral density and bone turnover in adolescent girls. Eur J Contracept Reprod Health Care 2009;14:207–14. http://dx.doi.org/10.1080/13625180902838828
50. Beksinska ME, Kleinschmidt I, Smit JA, Farley TM. Bone mineral density in a cohort of adolescents during use of norethisterone enanthate, depot-medroxyprogesterone acetate or combined oral contraceptives and after discontinuation of norethisterone enanthate. Contraception 2009;79:345–9. http://dx.doi.org/10.1016/j.contraception.2008.11.009
51. Pikkarainen E, Lehtonen-Veromaa M, Möttönen T, Kautiainen H, Viikari J. Estrogen-progestin contraceptive use during adolescence prevents bone mass acquisition: a 4-year follow-up study. Contraception 2008;78:226–31. http://dx.doi.org/10.1016/j.contraception.2008.05.002
52. Cromer BA, Bonny AE, Stager M, et al. Bone mineral density in adolescent females using injectable or oral contraceptives: a 24-month prospective study. Fertil Steril 2008;90:2060–7. http://dx.doi.org/10.1016/j.fertnstert.2007.10.070
53. Berenson AB, Rahman M, Breitkopf CR, Bi LX. Effects of depot medroxyprogesterone acetate and 20-μg oral contraceptives on bone mineral density. Obstet Gynecol 2008;112:788–99. http://dx.doi.org/10.1097/AOG.0b013e3181875b78
54. Harel Z, Riggs S, Vaz R, Flanagan P, Harel D, Machan JT. Bone accretion in adolescents using the combined estrogen and progestin transdermal contraceptive method Ortho Evra: a pilot study. J Pediatr Adolesc Gynecol 2010;23:23–31. http://dx.doi.org/10.1016/j.jpag.2009.04.008
55. Cobb KL, Bachrach LK, Sowers M, et al. The effect of oral contraceptives on bone mass and stress fractures in female runners. Med Sci Sports Exerc 2007;39:1464–73. http://dx.doi.org/10.1249/mss.0b013e318074e532
56. Beksinska ME, Kleinschmidt I, Smit JA, Farley TM. Bone mineral density in adolescents using norethisterone enanthate, depot-medroxyprogesterone acetate or combined oral contraceptives for contraception. Contraception 2007;75:438–43. http://dx.doi.org/10.1016/j.contraception.2007.02.001
57. Lara-Torre E, Edwards CP, Perlman S, Hertweck SP. Bone mineral density in adolescent females using depot medroxyprogesterone acetate. J Pediatr Adolesc Gynecol 2004;17:17–21. http://dx.doi.org/10.1016/j.jpag.2003.11.017
58. Cromer BA, Blair JM, Mahan JD, Zibners L, Naumovski Z. A prospective comparison of bone density in adolescent girls receiving depot medroxyprogesterone acetate (Depo-Provera), levonorgestrel (Norplant), or oral contraceptives. J Pediatr 1996;129:671–6. http://dx.doi.org/10.1016/S0022-3476(96)70148-8
59. Polatti F, Perotti F, Filippa N, Gallina D, Nappi RE. Bone mass and long-term monophasic oral contraceptive treatment in young women. Contraception 1995;51:221–4. http://dx.doi.org/10.1016/0010-7824(95)00036-A
60. Sørdal T, Grob P, Verhoeven C. Effects on bone mineral density of a monophasic combined oral contraceptive containing nomegestrol acetate/17ß-estradiol in comparison to levonorgestrel/ethinylestradiol. Acta Obstet Gynecol Scand 2012;91:1279–85. http://dx.doi.org/10.1111/j.1600-0412.2012.01498.x

61. Gargano V, Massaro M, Morra I, Formisano C, Di Carlo C, Nappi C. Effects of two low-dose combined oral contraceptives containing drospirenone on bone turnover and bone mineral density in young fertile women: a prospective controlled randomized study. Contraception 2008;78:10–5. http://dx.doi.org/10.1016/j.contraception.2008.01.016
62. Nappi C, Di Spiezio Sardo A, Greco E, Tommaselli GA, Giordano E, Guida M. Effects of an oral contraceptive containing drospirenone on bone turnover and bone mineral density. Obstet Gynecol 2005;105:53–60. http://dx.doi.org/10.1097/01.AOG.0000148344.26475.fc
63. Berenson AB, Radecki CM, Grady JJ, Rickert VI, Thomas A. A prospective, controlled study of the effects of hormonal contraception on bone mineral density. Obstet Gynecol 2001;98:576–82.
64. Berenson AB, Breitkopf CR, Grady JJ, Rickert VI, Thomas A. Effects of hormonal contraception on bone mineral density after 24 months of use. Obstet Gynecol 2004;103:899–906. http://dx.doi.org/10.1097/01.AOG.0000117082.49490.d5
65. Elgán C, Samsioe G, Dykes AK. Influence of smoking and oral contraceptives on bone mineral density and bone remodeling in young women: a 2-year study. Contraception 2003;67:439–47. http://dx.doi.org/10.1016/S0010-7824(03)00048-9
66. Elgán C, Dykes AK, Samsioe G. Bone mineral density changes in young women: a two year study. Gynecol Endocrinol 2004;19:169–77. http://dx.doi.org/10.1080/09513590400012119
67. Endrikat J, Mih E, Düsterberg B, et al. A 3-year double-blind, randomized, controlled study on the influence of two oral contraceptives containing either 20 μg or 30 μg ethinylestradiol in combination with levonorgestrel on bone mineral density. Contraception 2004;69:179–87. http://dx.doi.org/10.1016/j.contraception.2003.10.002
68. Paoletti AM, Orrù M, Lello S, et al. Short-term variations in bone remodeling markers of an oral contraception formulation containing 3 mg of drospirenone plus 30 microg of ethinyl estradiol: observational study in young postadolescent women. Contraception 2004;70:293–8. http://dx.doi.org/10.1016/j.contraception.2004.04.004
69. Nappi C, Di Spiezio Sardo A, Acunzo G, et al. Effects of a low-dose and ultra-low-dose combined oral contraceptive use on bone turnover and bone mineral density in young fertile women: a prospective controlled randomized study. Contraception 2003;67:355–9. http://dx.doi.org/10.1016/S0010-7824(03)00025-8
70. Reed SD, Scholes D, LaCroix AZ, Ichikawa LE, Barlow WE, Ott SM. Longitudinal changes in bone density in relation to oral contraceptive use. Contraception 2003;68:177–82. http://dx.doi.org/10.1016/S0010-7824(03)00147-1
71. Cobb KL, Kelsey JL, Sidney S, Ettinger B, Lewis CE. Oral contraceptives and bone mineral density in white and black women in CARDIA. Coronary Risk Development in Young Adults. Osteoporos Int 2002;13:893–900. http://dx.doi.org/10.1007/s001980200123
72. Burr DB, Yoshikawa T, Teegarden D, et al. Exercise and oral contraceptive use suppress the normal age-related increase in bone mass and strength of the femoral neck in women 18–31 years of age. Bone 2000;27:855–63. http://dx.doi.org/10.1016/S8756-3282(00)00403-8
73. Recker RR, Davies KM, Hinders SM, Heaney RP, Stegman MR, Kimmel DB. Bone gain in young adult women. JAMA 1992;268:2403–8. http://dx.doi.org/10.1001/jama.1992.03490170075028
74. Mazess RB, Barden HS. Bone density in premenopausal women: effects of age, dietary intake, physical activity, smoking, and birth-control pills. Am J Clin Nutr 1991;53:132–42.
75. Gambacciani M, Cappagli B, Lazzarini V, Ciaponi M, Fruzzetti F, Genazzani AR. Longitudinal evaluation of perimenopausal bone loss: effects of different low dose oral contraceptive preparations on bone mineral density. Maturitas 2006;54:176–80. http://dx.doi.org/10.1016/j.maturitas.2005.10.007
76. Gambacciani M, Spinetti A, Taponeco F, Cappagli B, Piaggesi L, Fioretti P. Longitudinal evaluation of perimenopausal vertebral bone loss: effects of a low-dose oral contraceptive preparation on bone mineral density and metabolism. Obstet Gynecol 1994;83:392–6.
77. Gambacciani M, Spinetti A, Cappagli B, et al. Hormone replacement therapy in perimenopausal women with a low dose oral contraceptive preparation: effects on bone mineral density and metabolism. Maturitas 1994;19:125–31. http://dx.doi.org/10.1016/0378-5122(94)90062-0
78. Gambacciani M, Cappagli B, Ciaponi M, Benussi C, Genazzani AR. Hormone replacement therapy in perimenopause: effect of a low dose oral contraceptive preparation on bone quantitative ultrasound characteristics. Menopause 1999;6:43–8. http://dx.doi.org/10.1097/00042192-199906010-00009
79. Volpe A, Malmusi S, Zanni AL, Landi S, Cagnacci A. Oral contraceptives and bone metabolism. Eur J Contracept Reprod Health Care 1997;2:225–8. http://dx.doi.org/10.3109/13625189709165298
80. Hansen MA, Overgaard K, Riis BJ, Christiansen C. Potential risk factors for development of postmenopausal osteoporosis—examined over a 12-year period. Osteoporos Int 1991;1:95–102. http://dx.doi.org/10.1007/BF01880450
81. Shargil AA. Hormone replacement therapy in perimenopausal women with a triphasic contraceptive compound: a three-year prospective study. Int J Fertil 1985;30:15, 18–28.
82. Taechakraichana N, Limpaphayom K, Ninlagarn T, Panyakhamlerd K, Chaikittisilpa S, Dusitsin N. A randomized trial of oral contraceptive and hormone replacement therapy on bone mineral density and coronary heart disease risk factors in postmenopausal women. Obstet Gynecol 2000;95:87–94.
83. Taechakraichana N, Jaisamrarn U, Panyakhamlerd K, Chaikittisilpa S, Limpaphayom K. Difference in bone acquisition among hormonally treated postmenopausal women with normal and low bone mass. J Med Assoc Thai 2001;84(Suppl 2):S586–92.
84. Grimes DA, Schulz KF. Surrogate end points in clinical research: hazardous to your health. Obstet Gynecol 2005;105:1114–8. http://dx.doi.org/10.1097/01.AOG.0000157445.67309.19
85. Schönau E. The peak bone mass concept: is it still relevant? Pediatr Nephrol 2004;19:825–31. http://dx.doi.org/10.1007/s00467-004-1465-5
86. Cohen A, Shane E. Treatment of premenopausal women with low bone mineral density. Curr Osteoporos Rep 2008;6:39–46. http://dx.doi.org/10.1007/s11914-008-0007-7
87. US Department of Health and Human Services. Healthy people 2020: maternal, infant, and child health objectives. Washington, DC: US Department of Health and Human Services; 2015. http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives.
88. Tepper NK, Phillips SJ, Kapp N, Gaffield ME, Curtis KM. Combined hormonal contraceptive use among breastfeeding women: an updated systematic review. Contraception 2015;S0010-7824(15)00218-8.
89. Petersen JF, Bergholt T, Nielsen AK, Paidas MJ, Løkkegaard EC. Combined hormonal contraception and risk of venous thromboembolism within the first year following pregnancy. Danish nationwide historical cohort 1995–2009. Thromb Haemost 2014;112:73–8. http://dx.doi.org/10.1160/TH13-09-0797
90. Jackson E, Curtis KM, Gaffield ME. Risk of venous thromboembolism during the postpartum period: a systematic review. Obstet Gynecol 2011;117:691–703. http://dx.doi.org/10.1097/AOG.0b013e31820ce2db
91. Kamel H, Navi BB, Sriram N, Hovsepian DA, Devereux RB, Elkind MS. Risk of a thrombotic event after the 6-week postpartum period. N Engl J Med 2014;370:1307–15. http://dx.doi.org/10.1056/NEJMoa1311485
92. Sultan AA, Tata LJ, West J, et al. Risk factors for first venous thromboembolism around pregnancy: a population-based cohort study from the United Kingdom. Blood 2013;121:3953–61. http://dx.doi.org/10.1182/blood-2012-11-469551
93. Sultan AA, West J, Tata LJ, Fleming KM, Nelson-Piercy C, Grainge MJ. Risk of first venous thromboembolism in and around pregnancy: a population-based cohort study. Br J Haematol 2012;156:366–73. http://dx.doi.org/10.1111/j.1365-2141.2011.08956.x

94. Tepper NK, Boulet SL, Whiteman MK, et al. Postpartum venous thromboembolism: incidence and risk factors. Obstet Gynecol 2014;123:987–96. http://dx.doi.org/10.1097/AOG.0000000000000230
95. Jackson E, Glasier A. Return of ovulation and menses in postpartum nonlactating women: a systematic review. Obstet Gynecol 2011;117:657–62. http://dx.doi.org/10.1097/AOG.0b013e31820ce18c
96. Lähteenmäki P. Influence of oral contraceptives on immediate postabortal pituitary-ovarian function. Acta Obstet Gynecol Scand Suppl 1978;76:1–43.
97. Lähteenmäki P, Rasi V, Luukkainen T, Myllyä G. Coagulation factors in women using oral contraceptives or intrauterine contraceptive devices immediately after abortion. Am J Obstet Gynecol 1981;141:175–9.
98. Martin CW, Brown AH, Baird DT. A pilot study of the effect of methotrexate or combined oral contraceptive on bleeding patterns after induction of abortion with mifepristone and a prostaglandin pessary. Contraception 1998;58:99–103. http://dx.doi.org/10.1016/S0010-7824(98)00072-9
99. Niswonger JW, London GD, Anderson GV, Wolfe L. Oral contraceptives during immediate postabortal period. Obstet Gynecol 1968;32:325–7.
100. Peterson WF. Contraceptive therapy following therapeutic abortion: an analysis. Obstet Gynecol 1974;44:853–7.
101. Tang OS, Gao PP, Cheng L, Lee SW, Ho PC. A randomized double-blind placebo-controlled study to assess the effect of oral contraceptive pills on the outcome of medical abortion with mifepristone and misoprostol. Hum Reprod 1999;14:722–5. http://dx.doi.org/10.1093/humrep/14.3.722
102. Tang OS, Xu J, Cheng L, Lee SW, Ho PC. The effect of contraceptive pills on the measured blood loss in medical termination of pregnancy by mifepristone and misoprostol: a randomized placebo controlled trial. Hum Reprod 2002;17:99–102. http://dx.doi.org/10.1093/humrep/17.1.99
103. Fine PM, Tryggestad J, Meyers NJ, Sangi-Haghpeykar H. Safety and acceptability with the use of a contraceptive vaginal ring after surgical or medical abortion. Contraception 2007;75:367–71. http://dx.doi.org/10.1016/j.contraception.2007.01.009
104. Gillum LA, Mamidipudi SK, Johnston SC. Ischemic stroke risk with oral contraceptives: a meta-analysis. JAMA 2000;284:72–8. http://dx.doi.org/10.1001/jama.284.1.72
105. Jick SS, Walker AM, Stergachis A, Jick H. Oral contraceptives and breast cancer. Br J Cancer 1989;59:618–21. http://dx.doi.org/10.1038/bjc.1989.125
106. Khader YS, Rice J, John L, Abueita O. Oral contraceptives use and the risk of myocardial infarction: a meta-analysis. Contraception 2003;68:11–7. http://dx.doi.org/10.1016/S0010-7824(03)00073-8
107. Lawson DH, Davidson JF, Jick H. Oral contraceptive use and venous thromboembolism: absence of an effect of smoking. BMJ 1977;2:729–30. http://dx.doi.org/10.1136/bmj.2.6089.729
108. Lidegaard O, Edström B, Kreiner S. Oral contraceptives and venous thromboembolism. A case-control study. Contraception 1998;57:291–301. http://dx.doi.org/10.1016/S0010-7824(98)00033-X
109. Nightingale AL, Lawrenson RA, Simpson EL, Williams TJ, MacRae KD, Farmer RD. The effects of age, body mass index, smoking and general health on the risk of venous thromboembolism in users of combined oral contraceptives. Eur J Contracept Reprod Health Care 2000;5:265–74. http://dx.doi.org/10.1080/13625180008500402
110. Petitti DB, Wingerd J, Pellegrin F, Ramcharan S. Risk of vascular disease in women. Smoking, oral contraceptives, noncontraceptive estrogens, and other factors. JAMA 1979;242:1150–4. http://dx.doi.org/10.1001/jama.1979.03300110022020
111. Rosenberg L, Palmer JR, Rao RS, Shapiro S. Low-dose oral contraceptive use and the risk of myocardial infarction. Arch Intern Med 2001;161:1065–70. http://dx.doi.org/10.1001/archinte.161.8.1065
112. Straneva P, Hinderliter A, Wells E, Lenahan H, Girdler S. Smoking, oral contraceptives, and cardiovascular reactivity to stress. Obstet Gynecol 2000;95:78–83.
113. Tanis BC, van den Bosch MA, Kemmeren JM, et al. Oral contraceptives and the risk of myocardial infarction. N Engl J Med 2001;345:1787–93. http://dx.doi.org/10.1056/NEJMoa003216
114. Van den Bosch MA, Kemmeren JM, Tanis BC, et al. The RATIO study: oral contraceptives and the risk of peripheral arterial disease in young women. J Thromb Hemost 2003;1:439–44.
115. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Venous thromboembolic disease and combined oral contraceptives: results of international multicentre case-control study. Lancet 1995;346:1575–82. http://dx.doi.org/10.1016/S0140-6736(95)91926-0
116. Collaborative Group for the Study of Stroke in Young Women. Oral contraceptives and stroke in young women. Associated risk factors. JAMA 1975;231:718–22. http://dx.doi.org/10.1001/jama.1975.03240190022010
117. Horton LG, Simmons KB, Curtis KM. Combined hormonal contraceptive use among obese women and risk for cardiovascular events: a systematic review. Contraception 2016. Epub June 1, 2016. http://dx.doi.org/10.1016/j.contraception.2016.05.014
118. Brunner Huber LR, Hogue CJ, Stein AD, Drews C, Zieman M. Body mass index and risk for oral contraceptive failure: a case-cohort study in South Carolina. Ann Epidemiol 2006;16:637–43. http://dx.doi.org/10.1016/j.annepidem.2006.01.001
119. Brunner Huber LR, Toth JL. Obesity and oral contraceptive failure: findings from the 2002 National Survey of Family Growth. Am J Epidemiol 2007;166:1306–11. http://dx.doi.org/10.1093/aje/kwm221
120. Brunner LR, Hogue CJ. The role of body weight in oral contraceptive failure: results from the 1995 national survey of family growth. Ann Epidemiol 2005;15:492–9. http://dx.doi.org/10.1016/j.annepidem.2004.10.009
121. Holt VL, Cushing-Haugen KL, Daling JR. Body weight and risk of oral contraceptive failure. Obstet Gynecol 2002;99:820–7.
122. Holt VL, Scholes D, Wicklund KG, Cushing-Haugen KL, Daling JR. Body mass index, weight, and oral contraceptive failure risk. Obstet Gynecol 2005;105:46–52. http://dx.doi.org/10.1097/01.AOG.0000149155.11912.52
123. Trussell J, Schwarz EB, Guthrie K. Obesity and oral contraceptive pill failure. Contraception 2009;79:334–8. http://dx.doi.org/10.1016/j.contraception.2008.11.017
124. Vessey M. Oral contraceptive failures and body weight: findings in a large cohort study. J Fam Plann Reprod Health Care 2001;27:90–1. http://dx.doi.org/10.1783/147118901101195092
125. Yamazaki M, Dwyer K, Sobhan M, et al. Effect of obesity on the effectiveness of hormonal contraceptives: an individual participant data meta-analysis. Contraception 2015;92:445–52. http://dx.doi.org/10.1016/j.contraception.2015.07.016
126. Zieman M, Guillebaud J, Weisberg E, Shangold GA, Fisher AC, Creasy GW. Contraceptive efficacy and cycle control with the Ortho Evra/Evra transdermal system: the analysis of pooled data. Fertil Steril 2002;77(Suppl 2):S13–8. http://dx.doi.org/10.1016/S0015-0282(01)03275-7
127. O'Connell KJ, Osborne LM, Westhoff C. Measured and reported weight change for women using a vaginal contraceptive ring vs. a low-dose oral contraceptive. Contraception 2005;72:323–7. http://dx.doi.org/10.1016/j.contraception.2005.05.008

128. Paulen ME, Zapata LB, Cansino C, Curtis KM, Jamieson DJ. Contraceptive use among women with a history of bariatric surgery: a systematic review. Contraception 2010;82:86–94. http://dx.doi.org/10.1016/j.contraception.2010.02.008
129. Lidegaard Ø, Edström B, Kreiner S. Oral contraceptives and venous thromboembolism: a five-year national case-control study. Contraception 2002;65:187–96. http://dx.doi.org/10.1016/S0010-7824(01)00307-9
130. Croft P, Hannaford PC. Risk factors for acute myocardial infarction in women: evidence from the Royal College of General Practitioners' oral contraception study. BMJ 1989;298:165–8. http://dx.doi.org/10.1136/bmj.298.6667.165
131. D'Avanzo B, La Vecchia C, Negri E, Parazzini F, Franceschi S. Oral contraceptive use and risk of myocardial infarction: an Italian case-control study. J Epidemiol Community Health 1994;48:324–5. http://dx.doi.org/10.1136/jech.48.3.324
132. Dunn NR, Faragher B, Thorogood M, et al. Risk of myocardial infarction in young female smokers. Heart 1999;82:581–3. http://dx.doi.org/10.1136/hrt.82.5.581
133. Hannaford PC, Croft PR, Kay CR. Oral contraception and stroke. Evidence from the Royal College of General Practitioners' Oral Contraception Study. Stroke 1994;25:935–42. http://dx.doi.org/10.1161/01.STR.25.5.935
134. Heinemann LA, Lewis MA, Spitzer WO, Thorogood M, Guggenmoos-Holzmann I, Bruppacher R; Transnational Research Group on Oral Contraceptives and the Health of Young Women. Thromboembolic stroke in young women. A European case-control study on oral contraceptives. Contraception 1998;57:29–37. http://dx.doi.org/10.1016/S0010-7824(97)00204-7
135. Kemmeren JM, Tanis BC, van den Bosch MA, et al. Risk of Arterial Thrombosis in Relation to Oral Contraceptives (RATIO) study: oral contraceptives and the risk of ischemic stroke. Stroke 2002;33:1202–8. http://dx.doi.org/10.1161/01.STR.0000015345.61324.3F
136. Lewis MA, Heinemann LA, Spitzer WO, MacRae KD, Bruppacher R. The use of oral contraceptives and the occurrence of acute myocardial infarction in young women. Results from the Transnational Study on Oral Contraceptives and the Health of Young Women. Contraception 1997;56:129–40. http://dx.doi.org/10.1016/S0010-7824(97)00118-2
137. Lidegaard O. Oral contraception and risk of a cerebral thromboembolic attack: results of a case-control study. BMJ 1993;306:956–63. http://dx.doi.org/10.1136/bmj.306.6883.956
138. Lidegaard O. Oral contraceptives, pregnancy and the risk of cerebral thromboembolism: the influence of diabetes, hypertension, migraine and previous thrombotic disease. Br J Obstet Gynaecol 1995;102:153–9. http://dx.doi.org/10.1111/j.1471-0528.1995.tb09070.x
139. Lubianca JN, Faccin CS, Fuchs FD. Oral contraceptives: a risk factor for uncontrolled blood pressure among hypertensive women. Contraception 2003;67:19–24. http://dx.doi.org/10.1016/S0010-7824(02)00429-8
140. Narkiewicz K, Graniero GR, D'Este D, Mattarei M, Zonzin P, Palatini P. Ambulatory blood pressure in mild hypertensive women taking oral contraceptives. A case-control study. Am J Hypertens 1995;8:249–53. http://dx.doi.org/10.1016/0895-7061(95)96212-3
141. Siritho S, Thrift AG, McNeil JJ, You RX, Davis SM, Donnan GA; Melbourne Risk Factor Study (MERFS) Group. Risk of ischemic stroke among users of the oral contraceptive pill: The Melbourne Risk Factor Study (MERFS) Group. Stroke 2003;34:1575–80. http://dx.doi.org/10.1161/01.STR.0000077925.16041.6B
142. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Ischaemic stroke and combined oral contraceptives: results of an international, multicentre, case-control study. Lancet 1996;348:498–505. http://dx.doi.org/10.1016/S0140-6736(95)12393-8
143. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Acute myocardial infarction and combined oral contraceptives: results of an international multicentre case-control study. Lancet 1997;349:1202–9. http://dx.doi.org/10.1016/S0140-6736(97)02358-1
144. Lubianca JN, Moreira LB, Gus M, Fuchs FD. Stopping oral contraceptives: an effective blood pressure-lowering intervention in women with hypertension. J Hum Hypertens 2005;19:451–5. http://dx.doi.org/10.1038/sj.jhh.1001841
145. Aberg H, Karlsson L, Melander S. Studies on toxaemia of pregnancy with special reference to blood pressure. II. Results after 6–11 years' follow-up. Ups J Med Sci 1978;83:97–102. http://dx.doi.org/10.3109/03009737809179119
146. Carmichael SM, Taylor MM, Ayers CR. Oral contraceptives, hypertension, and toxemia. Obstet Gynecol 1970;35:371–6.
147. Meinel H, Ihle R, Laschinski M. [Effect of hormonal contraceptives on blood pressure following pregnancy-induced hypertension]. Zentralbl Gynakol 1987;109:527–31.
148. Pritchard JA, Pritchard SA. Blood pressure response to estrogen-progestin oral contraceptive after pregnancy-induced hypertension. Am J Obstet Gynecol 1977;129:733–9 http://dx.doi.org/10.1016/0002-9378(77)90390-8.
149. Sibai BM, Taslimi MM, el-Nazer A, Amon E, Mabie BC, Ryan GM. Maternal-perinatal outcome associated with the syndrome of hemolysis, elevated liver enzymes, and low platelets in severe preeclampsia-eclampsia. Am J Obstet Gynecol 1986;155:501–7. http://dx.doi.org/10.1016/0002-9378(86)90266-8
150. Sibai BM, Ramadan MK, Chari RS, Friedman SA. Pregnancies complicated by HELLP syndrome (hemolysis, elevated liver enzymes, and low platelets): subsequent pregnancy outcome and long-term prognosis. Am J Obstet Gynecol 1995;172:125–9. http://dx.doi.org/10.1016/0002-9378(95)90099-3
151. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Haemorrhagic stroke, overall stroke risk, and combined oral contraceptives: results of an international, multicentre, case-control study. Lancet 1996;348:505–10. http://dx.doi.org/10.1016/S0140-6736(95)12394-6
152. Sidney S, Petitti DB, Soff GA, Cundiff DL, Tolan KK, Quesenberry CP Jr. Venous thromboembolic disease in users of low-estrogen combined estrogen-progestin oral contraceptives. Contraception 2004;70:3–10. http://dx.doi.org/10.1016/j.contraception.2004.02.010
153. Andersen BS, Olsen J, Nielsen GL, et al. Third generation oral contraceptives and heritable thrombophilia as risk factors of non-fatal venous thromboembolism. Thromb Haemost 1998;79:28–31.
154. Aznar J, Mira Y, Vayá A, et al. Factor V Leiden and prothrombin G20210A mutations in young adults with cryptogenic ischemic stroke. Thromb Haemost 2004;91:1031–4.
155. Bennet L, Odeberg H. Resistance to activated protein C, highly prevalent amongst users of oral contraceptives with venous thromboembolism. J Intern Med 1998;243:27–32. http://dx.doi.org/10.1046/j.1365-2796.1998.00310.x
156. Bloemenkamp KW, Rosendaal FR, Helmerhorst FM, Vandenbroucke JP. Higher risk of venous thrombosis during early use of oral contraceptives in women with inherited clotting defects.[comment]. Arch Intern Med 2000;160:49–52. http://dx.doi.org/10.1001/archinte.160.1.49

157. Bloemenkamp KW, Helmerhorst FM, Rosendaal FR, Vandenbroucke JP, Büller HR. Enhancement by factor V Leiden mutation of risk of deep-vein thrombosis associated with oral contraceptives containing a third-generation progestagen. Lancet 1995;346:1593–6. http://dx.doi.org/10.1016/S0140-6736(95)91929-5
158. de Bruijn SF, Stam J, Koopman MM, Vandenbroucke JP; The Cerebral Venous Sinus Thrombosis Study Group. Case-control study of risk of cerebral sinus thrombosis in oral contraceptive users and in [correction of who are] carriers of hereditary prothrombotic conditions. BMJ 1998;316:589–92. http://dx.doi.org/10.1136/bmj.316.7131.589
159. Emmerich J, Rosendaal FR, Cattaneo M, et al; Study Group for Pooled-Analysis in Venous Thromboembolism. Combined effect of factor V Leiden and prothrombin 20210A on the risk of venous thromboembolism—pooled analysis of 8 case-control studies including 2310 cases and 3204 controls. Thromb Haemost 2001;86:809–16.
160. Gadelha T, André C, Jucá AA, Nucci M. Prothrombin 20210A and oral contraceptive use as risk factors for cerebral venous thrombosis. Cerebrovasc Dis 2005;19:49–52. http://dx.doi.org/10.1159/000081911
161. Legnani C, Palareti G, Guazzaloca G, et al. Venous thromboembolism in young women; role of thrombophilic mutations and oral contraceptive use. Eur Heart J 2002;23:984–90. http://dx.doi.org/10.1053/euhj.2001.3082
162. Martinelli I, Battaglioli T, Bucciarelli P, Passamonti SM, Mannucci PM. Risk factors and recurrence rate of primary deep vein thrombosis of the upper extremities. Circulation 2004;110:566–70. http://dx.doi.org/10.1161/01.CIR.0000137123.55051.9B
163. Martinelli I, Sacchi E, Landi G, Taioli E, Duca F, Mannucci PM. High risk of cerebral-vein thrombosis in carriers of a prothrombin-gene mutation and in users of oral contraceptives.[comment]. N Engl J Med 1998;338:1793–7. http://dx.doi.org/10.1056/NEJM199806183382502
164. Martinelli I, Taioli E, Bucciarelli P, Akhavan S, Mannucci PM. Interaction between the G20210A mutation of the prothrombin gene and oral contraceptive use in deep vein thrombosis. Arterioscler Thromb Vasc Biol 1999;19:700–3. http://dx.doi.org/10.1161/01.ATV.19.3.700
165. Middeldorp S, Meinardi JR, Koopman MM, et al. A prospective study of asymptomatic carriers of the factor V Leiden mutation to determine the incidence of venous thromboembolism. [comment]. Ann Intern Med 2001;135:322–7. http://dx.doi.org/10.7326/0003-4819-135-5-200109040-00008
166. Pabinger I, Schneider B; The GTH Study Group on Natural Inhibitors. Thrombotic risk of women with hereditary antithrombin III-, protein C- and protein S-deficiency taking oral contraceptive medication. Thromb Haemost 1994;71:548–52.
167. Pezzini A, Grassi M, Iacoviello L, et al. Inherited thrombophilia and stratification of ischaemic stroke risk among users of oral contraceptives. J Neurol Neurosurg Psychiatry 2007;78:271–6. http://dx.doi.org/10.1136/jnnp.2006.101675
168. Santamaría A, Mateo J, Oliver A, et al. Risk of thrombosis associated with oral contraceptives of women from 97 families with inherited thrombophilia: high risk of thrombosis in carriers of the G20210A mutation of the prothrombin gene. Haematologica 2001;86:965–71.
169. Slooter AJ, Rosendaal FR, Tanis BC, Kemmeren JM, van der Graaf Y, Algra A. Prothrombotic conditions, oral contraceptives, and the risk of ischemic stroke. J Thromb Haemost 2005;3:1213–7. http://dx.doi.org/10.1111/j.1538-7836.2005.01442.x
170. Spannagl M, Heinemann LA, Schramm W. Are factor V Leiden carriers who use oral contraceptives at extreme risk for venous thromboembolism? Eur J Contracept Reprod Health Care 2000;5:105–12. http://dx.doi.org/10.1080/13625180008500383
171. van Boven HH, Vandenbroucke JP, Briët E, Rosendaal FR. Gene-gene and gene-environment interactions determine risk of thrombosis in families with inherited antithrombin deficiency. Blood 1999;94:2590–4.
172. van Vlijmen EF, Brouwer JL, Veeger NJ, Eskes TK, de Graeff PA, van der Meer J. Oral contraceptives and the absolute risk of venous thromboembolism in women with single or multiple thrombophilic defects: results from a retrospective family cohort study. Arch Intern Med 2007;167:282–9. http://dx.doi.org/10.1001/archinte.167.3.282
173. Vandenbroucke JP, Koster T, Rosendaal FR, Briët E, Reitsma PH, Bertina RM. Increased risk of venous thrombosis in oral-contraceptive users who are carriers of factor V Leiden mutation.[comment]. Lancet 1994;344:1453–7. http://dx.doi.org/10.1016/S0140-6736(94)90286-0
174. Vayá A, Mira Y, Mateo J, et al. Prothrombin G20210A mutation and oral contraceptive use increase upper-extremity deep vein thrombotic risk. Thromb Haemost 2003;89:452–7.
175. Martinelli I, Battaglioli T, Burgo I, Di Domenico S, Mannucci PM. Oral contraceptive use, thrombophilia and their interaction in young women with ischemic stroke. Haematologica 2006;91:844–7.
176. Tepper NK, Marchbanks PA, Curtis KM. Superficial venous disease and combined hormonal contraceptives: a systematic review. Contraception 2015;S0010-7824(15)00128-6.
177. Tepper NK, Paulen ME, Marchbanks PA, Curtis KM. Safety of contraceptive use among women with peripartum cardiomyopathy: a systematic review. Contraception 2010;82:95–101. http://dx.doi.org/10.1016/j.contraception.2010.02.004
178. The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown and Co; 1994.
179. Bernatsky S, Clarke A, Ramsey-Goldman R, et al. Hormonal exposures and breast cancer in a sample of women with systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1178–81. http://dx.doi.org/10.1093/rheumatology/keh282
180. Bernatsky S, Ramsey-Goldman R, Gordon C, et al. Factors associated with abnormal Pap results in systemic lupus erythematosus. Rheumatology (Oxford) 2004;43:1386–9. http://dx.doi.org/10.1093/rheumatology/keh331
181. Chopra N, Koren S, Greer WL, et al. Factor V Leiden, prothrombin gene mutation, and thrombosis risk in patients with antiphospholipid antibodies. J Rheumatol 2002;29:1683–8.
182. Esdaile JM, Abrahamowicz M, Grodzicky T, et al. Traditional Framingham risk factors fail to fully account for accelerated atherosclerosis in systemic lupus erythematosus. Arthritis Rheum 2001;44:2331–7. http://dx.doi.org/10.1002/1529-0131(200110)44:10<2331::AID-ART395≥3.0.CO;2-I
183. Julkunen HA. Oral contraceptives in systemic lupus erythematosus: side-effects and influence on the activity of SLE. Scand J Rheumatol 1991;20:427–33. http://dx.doi.org/10.3109/03009749109096822
184. Julkunen HA, Kaaja R, Friman C. Contraceptive practice in women with systemic lupus erythematosus. Br J Rheumatol 1993;32:227–30. http://dx.doi.org/10.1093/rheumatology/32.3.227
185. Jungers P, Dougados M, Pélissier C, et al. Influence of oral contraceptive therapy on the activity of systemic lupus erythematosus. Arthritis Rheum 1982;25:618–23. http://dx.doi.org/10.1002/art.1780250603
186. Manzi S, Meilahn EN, Rairie JE, et al. Age-specific incidence rates of myocardial infarction and angina in women with systemic lupus erythematosus: comparison with the Framingham Study. Am J Epidemiol 1997;145:408–15. http://dx.doi.org/10.1093/oxfordjournals.aje.a009122

187. McAlindon T, Giannotta L, Taub N, D'Cruz D, Hughes G. Environmental factors predicting nephritis in systemic lupus erythematosus. Ann Rheum Dis 1993;52:720–4. http://dx.doi.org/10.1136/ard.52.10.720
188. McDonald J, Stewart J, Urowitz MB, Gladman DD. Peripheral vascular disease in patients with systemic lupus erythematosus. Ann Rheum Dis 1992;51:56–60. http://dx.doi.org/10.1136/ard.51.1.56
189. Mintz G, Gutiérrez G, Delezé M, Rodríguez E. Contraception with progestagens in systemic lupus erythematosus. Contraception 1984;30:29–38. http://dx.doi.org/10.1016/0010-7824(84)90076-3
190. Petri M. Musculoskeletal complications of systemic lupus erythematosus in the Hopkins Lupus Cohort: an update. Arthritis Care Res 1995;8:137–45. http://dx.doi.org/10.1002/art.1790080305
191. Petri M. Lupus in Baltimore: evidence-based 'clinical pearls' from the Hopkins Lupus Cohort. Lupus 2005;14:970–3. http://dx.doi.org/10.1191/0961203305lu2230xx
192. Petri M, Kim MY, Kalunian KC, et al; OC-SELENA Trial. Combined oral contraceptives in women with systemic lupus erythematosus. N Engl J Med 2005;353:2550–8. http://dx.doi.org/10.1056/NEJMoa051135
193. Sánchez-Guerrero J, Uribe AG, Jiménez-Santana L, et al. A trial of contraceptive methods in women with systemic lupus erythematosus. N Engl J Med 2005;353:2539–49. http://dx.doi.org/10.1056/NEJMoa050817
194. Sarabi ZS, Chang E, Bobba R, et al. Incidence rates of arterial and venous thrombosis after diagnosis of systemic lupus erythematosus. Arthritis Rheum 2005;53:609–12. http://dx.doi.org/10.1002/art.21314
195. Schaedel ZE, Dolan G, Powell MC. The use of the levonorgestrel-releasing intrauterine system in the management of menorrhagia in women with hemostatic disorders. Am J Obstet Gynecol 2005;193:1361–3. http://dx.doi.org/10.1016/j.ajog.2005.05.002
196. Somers E, Magder LS, Petri M. Antiphospholipid antibodies and incidence of venous thrombosis in a cohort of patients with systemic lupus erythematosus. J Rheumatol 2002;29:2531–6.
197. Urowitz MB, Bookman AA, Koehler BE, Gordon DA, Smythe HA, Ogryzlo MA. The bimodal mortality pattern of systemic lupus erythematosus. Am J Med 1976;60:221–5. http://dx.doi.org/10.1016/0002-9343(76)90431-9
198. Choojitarom K, Verasertniyom O, Totemchokchyakarn K, Nantiruj K, Sumethkul V, Janwityanujit S. Lupus nephritis and Raynaud's phenomenon are significant risk factors for vascular thrombosis in SLE patients with positive antiphospholipid antibodies. Clin Rheumatol 2008;27:345–51. http://dx.doi.org/10.1007/s10067-007-0721-z
199. Wahl DG, Guillemin F, de Maistre E, Perret C, Lecompte T, Thibaut G. Risk for venous thrombosis related to antiphospholipid antibodies in systemic lupus erythematosus—a meta-analysis. Lupus 1997;6:467–73. http://dx.doi.org/10.1177/096120339700600510
200. Farr SL, Folger SG, Paulen ME, Curtis KM. Safety of contraceptive methods for women with rheumatoid arthritis: a systematic review. Contraception 2010;82:64–71. http://dx.doi.org/10.1016/j.contraception.2010.02.003
201. Tepper NK, Whiteman MK, Zapata LB, Marchbanks PA, Curtis KM. Safety of hormonal contraceptives among women with migraine: a systematic review. Contraception 2016. Epub May 3, 2016. http:// dx.doi.org/10.1016/j.contraception.2016.04.016
202. Xu Z, Li Y, Tang S, Huang X, Chen T. Current use of oral contraceptives and the risk of first-ever ischemic stroke: A meta-analysis of observational studies. Thromb Res 2015;136:52–60. http://dx.doi.org/10.1016/j.thromres.2015.04.021
203. Etminan M, Takkouche B, Isorna FC, Samii A. Risk of ischaemic stroke in people with migraine: systematic review and meta-analysis of observational studies. BMJ 2005;330:63. http://dx.doi.org/10.1136/bmj.38302.504063.8F
204. Schürks M, Rist PM, Bigal ME, Buring JE, Lipton RB, Kurth T. Migraine and cardiovascular disease: systematic review and meta-analysis. BMJ 2009;339:b3914. http://dx.doi.org/10.1136/bmj.b3914
205. Spector JT, Kahn SR, Jones MR, Jayakumar M, Dalal D, Nazarian S. Migraine headache and ischemic stroke risk: an updated meta-analysis. Am J Med 2010;123:612–24. http://dx.doi.org/10.1016/j.amjmed.2009.12.021
206. Zapata LB, Oduyebo T, Whiteman MK, Marchbanks PA, Curtis KM. Contraceptive use among women with multiple sclerosis: a systematic review. Contraception. In press 2016.
207. Pagano HP, Zapata LB, Berry-Bibee EN, Nanda K, Curtis KM. Safety of hormonal contraception and intrauterine devices among women with depressive and bipolar disorders: a systematic review. Contraception 2016. Epub June 27, 2016. http://dx.doi.org/10.1016/j.contraception.2016.06.012
208. Iyer V, Farquhar C, Jepson R. Oral contraceptive pills for heavy menstrual bleeding. Cochrane Database Syst Rev 2000;(2):CD000154.
209. Davis L, Kennedy SS, Moore J, Prentice A. Oral contraceptives for pain associated with endometriosis. Cochrane Database Syst Rev 2007;(3):CD001019.
210. Hendrix SL, Alexander NJ. Primary dysmenorrhea treatment with a desogestrel-containing low-dose oral contraceptive. Contraception 2002;66:393–9. http://dx.doi.org/10.1016/S0010-7824(02)00414-6
211. Proctor ML, Roberts H, Farquhar CM. Combined oral contraceptive pill (OCP) as treatment for primary dysmenorrhoea. Cochrane Database Syst Rev 2001;(4):CD002120.
212. Gaffield ME, Kapp N, Curtis KM. Combined oral contraceptive and intrauterine device use among women with gestational trophoblastic disease. Contraception 2009;80:363–71. http://dx.doi.org/10.1016/j.contraception.2009.03.022
213. Smith JS, Green J, Berrington de Gonzalez A, et al. Cervical cancer and use of hormonal contraceptives: a systematic review. Lancet 2003;361:1159–67. http://dx.doi.org/10.1016/S0140-6736(03)12949-2
214. Black MM, Barclay THC, Polednak A, Kwon CS, Leis HP Jr, Pilnik S. Family history, oral contraceptive usage, and breast cancer. Cancer 1983;51:2147–51. http://dx.doi.org/10.1002/1097-0142(19830601)51:11<2147::AID-CNCR2820511133≥3.0.CO;2-X
215. Brinton LA, Hoover R, Szklo M, Fraumeni JF Jr. Oral contraceptives and breast cancer. Int J Epidemiol 1982;11:316–22. http://dx.doi.org/10.1093/ije/11.4.316
216. Brohet RM, Goldgar DE, Easton DF, et al. Oral contraceptives and breast cancer risk in the international BRCA1/2 carrier cohort study: a report from EMBRACE, GENEPSO, GEO-HEBON, and the IBCCS Collaborating Group. J Clin Oncol 2007;25:3831–6. http://dx.doi.org/10.1200/JCO.2007.11.1179
217. Claus EB, Stowe M, Carter D. Oral contraceptives and the risk of ductal breast carcinoma in situ. Breast Cancer Res Treat 2003;81:129–36. http://dx.doi.org/10.1023/A:1025728524310
218. Collaborative Group on Hormonal Factors in Breast Cancer. Familial breast cancer: collaborative reanalysis of individual data from 52 epidemiological studies including 58,209 women with breast cancer and 101,986 women without the disease. Lancet 2001;358:1389–99. http://dx.doi.org/10.1016/S0140-6736(01)06524-2
219. Grabrick DM, Hartmann LC, Cerhan JR, et al. Risk of breast cancer with oral contraceptive use in women with a family history of breast cancer.[comment]. JAMA 2000;284:1791–8. http://dx.doi.org/10.1001/jama.284.14.1791
220. Gronwald J, Byrski T, Huzarski T, et al. Influence of selected lifestyle factors on breast and ovarian cancer risk in BRCA1 mutation carriers from Poland. Breast Cancer Res Treat 2006;95:105–9. http://dx.doi.org/10.1007/s10549-005-9051-5

221. Haile RW, Thomas DC, McGuire V, et al; kConFab Investigators; Ontario Cancer Genetics Network Investigators. BRCA1 and BRCA2 mutation carriers, oral contraceptive use, and breast cancer before age 50. Cancer Epidemiol Biomarkers Prev 2006;15:1863–70. http://dx.doi.org/10.1158/1055-9965.EPI-06-0258
222. Harris NV, Weiss NS, Francis AM, Polissar L. Breast cancer in relation to patterns of oral contraceptive use. Am J Epidemiol 1982;116:643–51.
223. Hennekens CH, Speizer FE, Lipnick RJ, et al. A case-control study of oral contraceptive use and breast cancer. J Natl Cancer Inst 1984;72:39–42.
224. Jernström H, Loman N, Johannsson OT, Borg A, Olsson H. Impact of teenage oral contraceptive use in a population-based series of early-onset breast cancer cases who have undergone BRCA mutation testing. Eur J Cancer 2005;41:2312–20. http://dx.doi.org/10.1016/j.ejca.2005.03.035
225. Marchbanks PA, McDonald JA, Wilson HG, et al. Oral contraceptives and the risk of breast cancer. N Engl J Med 2002;346:2025–32. http://dx.doi.org/10.1056/NEJMoa013202
226. Milne RL, Knight JA, John EM, et al. Oral contraceptive use and risk of early-onset breast cancer in carriers and noncarriers of BRCA1 and BRCA2 mutations. Cancer Epidemiol Biomarkers Prev 2005;14:350–6. http://dx.doi.org/10.1158/1055-9965.EPI-04-0376
227. Narod SA, Dubé MP, Klijn J, et al. Oral contraceptives and the risk of breast cancer in BRCA1 and BRCA2 mutation carriers. J Natl Cancer Inst 2002;94:1773–9. http://dx.doi.org/10.1093/jnci/94.23.1773
228. Rosenberg L, Palmer JR, Rao RS, et al. Case-control study of oral contraceptive use and risk of breast cancer. Am J Epidemiol 1996;143:25–37. http://dx.doi.org/10.1093/oxfordjournals.aje.a008654
229. Silvera SA, Miller AB, Rohan TE. Oral contraceptive use and risk of breast cancer among women with a family history of breast cancer: a prospective cohort study. Cancer Causes Control 2005;16:1059–63. http://dx.doi.org/10.1007/s10552-005-0343-1
230. Ursin G, Henderson BE, Haile RW, et al. Does oral contraceptive use increase the risk of breast cancer in women with BRCA1/BRCA2 mutations more than in other women? Cancer Res 1997;57:3678–81.
231. Ursin G, Ross RK, Sullivan-Halley J, Hanisch R, Henderson B, Bernstein L. Use of oral contraceptives and risk of breast cancer in young women. Breast Cancer Res Treat 1998;50:175–84. http://dx.doi.org/10.1023/A:1006037823178
232. Polis CB, Phillips SJ, Curtis KM, et al. Hormonal contraceptive methods and risk of HIV acquisition in women: a systematic review of epidemiological evidence. Contraception 2014;90:360–90. http://dx.doi.org/10.1016/j.contraception.2014.07.009
233. Polis CB, Phillips SJ, Curtis KM. Hormonal contraceptive use and female-to-male HIV transmission: a systematic review of the epidemiologic evidence. AIDS 2013;27:493–505. http://dx.doi.org/10.1097/QAD.0b013e32835ad539
234. Phillips SJ, Polis CB, Curtis KM. The safety of hormonal contraceptives for women living with HIV and their sexual partners. Contraception 2016;93:11–6 http://dx.doi.org/10.1016/j.contraception.2015.10.002.
235. Phillips SJ, Curtis KM, Polis CB. Effect of hormonal contraceptive methods on HIV disease progression: a systematic review. AIDS 2013;27:787–94. http://dx.doi.org/10.1097/QAD.0b013e32835bb672
236. el-Raghy I, Back DJ, Osman F, Orme ML, Fathalla M. Contraceptive steroid concentrations in women with early active schistosomiasis: lack of effect of antischistosomal drugs. Contraception 1986;33:373–7. http://dx.doi.org/10.1016/0010-7824(86)90099-5
237. Gad-el-Mawla N, Abdallah A. Liver function in bilharzial females receiving contraceptive pills. Acta Hepatosplenol 1969;16:308–10.
238. Gad-el-Mawla N, el-Roubi O, Sabet S, Abdallah A. Plasma lipids and lipoproteins in bilharzial females during oral contraceptive therapy. J Egypt Med Assoc 1972;55:137–47.
239. Shaaban MM, Hammad WA, Falthalla MF, et al. Effects of oral contraception on liver function tests and serum proteins in women with active schistosomiasis. Contraception 1982;26:75–82. http://dx.doi.org/10.1016/0010-7824(82)90174-3
240. Shaaban MM, Ghaneimah SA, Mohamed MA, Abdel-Chani S, Mostafa SA. Effect of oral contraception on serum bile acid. Int J Gynaecol Obstet 1984;22:111–5. http://dx.doi.org/10.1016/0020-7292(84)90023-7
241. Sy FS, Osteria TS, Opiniano V, Gler S. Effect of oral contraceptive on liver function tests of women with schistosomiasis in the Philippines. Contraception 1986;34:283–94. http://dx.doi.org/10.1016/0010-7824(86)90009-0
242. Tagy AH, Saker ME, Moussa AA, Kolgah A. The effect of low-dose combined oral contraceptive pills versus injectable contraceptive (Depot Provera) on liver function tests of women with compensated bilharzial liver fibrosis. Contraception 2001;64:173–6. http://dx.doi.org/10.1016/S0010-7824(01)00248-7
243. Beck P, Wells SA. Comparison of the mechanisms underlying carbohydrate intolerance in subclinical diabetic women during pregnancy and during post-partum oral contraceptive steroid treatment. J Clin Endocrinol Metab 1969;29:807–18. http://dx.doi.org/10.1210/jcem-29-6-807
244. Kjos SL, Peters RK, Xiang A, Thomas D, Schaefer U, Buchanan TA. Contraception and the risk of type 2 diabetes mellitus in Latina women with prior gestational diabetes mellitus. JAMA 1998;280:533–8. http://dx.doi.org/10.1001/jama.280.6.533
245. Kung AW, Ma JT, Wong VC, et al. Glucose and lipid metabolism with triphasic oral contraceptives in women with history of gestational diabetes. Contraception 1987;35:257–69. http://dx.doi.org/10.1016/0010-7824(87)90027-8
246. Rådberg T, Gustafson A, Skryten A, Karlsson K. Metabolic studies in gestational diabetic women during contraceptive treatment: effects on glucose tolerance and fatty acid composition of serum lipids. Gynecol Obstet Invest 1982;13:17–29. http://dx.doi.org/10.1159/000299480
247. Skouby SO, Andersen O, Kühl C. Oral contraceptives and insulin receptor binding in normal women and those with previous gestational diabetes. Am J Obstet Gynecol 1986;155:802–7. http://dx.doi.org/10.1016/S0002-9378(86)80024-2
248. Skouby SO, Andersen O, Saurbrey N, Kühl C. Oral contraception and insulin sensitivity: in vivo assessment in normal women and women with previous gestational diabetes. J Clin Endocrinol Metab 1987;64:519–23. http://dx.doi.org/10.1210/jcem-64-3-519
249. Skouby SO, Mølsted-Pedersen L, Kühl C. Low dosage oral contraception in women with previous gestational diabetes. Obstet Gynecol 1982;59:325–8.
250. Xiang AH, Kawakubo M, Kjos SL, Buchanan TA. Long-acting injectable progestin contraception and risk of type 2 diabetes in Latino women with prior gestational diabetes mellitus. Diabetes Care 2006;29:613–7. http://dx.doi.org/10.2337/diacare.29.03.06.dc05-1940
251. Kjos SL, Shoupe D, Douyan S, et al. Effect of low-dose oral contraceptives on carbohydrate and lipid metabolism in women with recent gestational diabetes: results of a controlled, randomized, prospective study. Am J Obstet Gynecol 1990;163:1822–7. http://dx.doi.org/10.1016/0002-9378(90)90757-X
252. Rådberg T, Gustafson A, Skryten A, Karlsson K. Metabolic studies in women with previous gestational diabetes during contraceptive treatment: effects on serum lipids and high density lipoproteins. Acta Endocrinol (Copenh) 1982;101:134–9.

253. Skouby SO, Kühl C, Mølsted-Pedersen L, Petersen K, Christensen MS. Triphasic oral contraception: metabolic effects in normal women and those with previous gestational diabetes. Am J Obstet Gynecol 1985;153:495–500. http://dx.doi.org/10.1016/0002-9378(85)90460-0
254. Beck P, Arnett DM, Alsever RN, Eaton RP. Effect of contraceptive steroids on arginine- stimulated glucagon and insulin secretion in women. II. Carbohydrate and lipid physiology in insulin-dependent diabetics. Metabolism 1976;25:23–31 http://dx.doi.org/10.1016/0026-0495(76)90156-6.
255. Diab KM, Zaki MM. Contraception in diabetic women: comparative metabolic study of Norplant, depot medroxyprogesterone acetate, low dose oral contraceptive pill and CuT380A. J Obstet Gynaecol Res 2000;26:17–26. http://dx.doi.org/10.1111/j.1447-0756.2000.tb01195.x
256. Garg SK, Chase HP, Marshall G, Hoops SL, Holmes DL, Jackson WE. Oral contraceptives and renal and retinal complications in young women with insulin-dependent diabetes mellitus. JAMA 1994;271:1099–102. http://dx.doi.org/10.1001/jama.1994.03510380055037
257. Grigoryan OR, Grodnitskaya EE, Andreeva EN, Shestakova MV, Melnichenko GA, Dedov II. Contraception in perimenopausal women with diabetes mellitus. Gynecol Endocrinol 2006;22:198–206. http://dx.doi.org/10.1080/09513590600624317
258. Margolis KL, Adami H-O, Luo J, Ye W, Weiderpass E. A prospective study of oral contraceptive use and risk of myocardial infarction among Swedish women. Fertil Steril 2007;88:310–6. http://dx.doi.org/10.1016/j.fertnstert.2006.11.206
259. Petersen KR, Skouby SO, Jespersen J. Balance of coagulation activity with fibrinolysis during use of oral contraceptives in women with insulin-dependent diabetes mellitus. Int J Fertil Menopausal Stud 1995;40(Suppl 2):105–11.
260. Petersen KR, Skouby SO, Sidelmann J, Jespersen J. Assessment of endothelial function during oral contraception in women with insulin-dependent diabetes mellitus. Metabolism 1994;43:1379–83. http://dx.doi.org/10.1016/0026-0495(94)90031-0
261. Rådberg T, Gustafson A, Skryten A, Karlsson K. Oral contraception in diabetic women. A cross-over study on serum and high density lipoprotein (HDL) lipids and diabetes control during progestogen and combined estrogen/progestogen contraception. Horm Metab Res 1982;14:61–5.
262. Skouby SO, Jensen BM, Kühl C, Mølsted-Pedersen L, Svenstrup B, Nielsen J. Hormonal contraception in diabetic women: acceptability and influence on diabetes control and ovarian function of a nonalkylated estrogen/progestogen compound. Contraception 1985;32:23–31. http://dx.doi.org/10.1016/0010-7824(85)90113-1
263. Skouby SO, Mølsted-Pedersen L, Kühl C, Bennet P. Oral contraceptives in diabetic women: metabolic effects of four compounds with different estrogen/progestogen profiles. Fertil Steril 1986;46:858–64 http://dx.doi.org/10.1016/S0015-0282(16)49825-0.
264. Zapata LB, Paulen ME, Cansino C, Marchbanks PA, Curtis KM. Contraceptive use among women with inflammatory bowel disease: A systematic review. Contraception 2010;82:72–85. http://dx.doi.org/10.1016/j.contraception.2010.02.012
265. Kapp N, Tilley IB, Curtis KM. The effects of hormonal contraceptive use among women with viral hepatitis or cirrhosis of the liver: a systematic review. Contraception 2009;80:381–6. http://dx.doi.org/10.1016/j.contraception.2009.04.007
266. Kapp N, Curtis KM. Hormonal contraceptive use among women with liver tumors: a systematic review. Contraception 2009;80:387–90. http://dx.doi.org/10.1016/j.contraception.2009.01.021
267. Whiteman MK, Oduyebo T, Zapata LB, Walker S, Curtis KM. Contraceptive safety among women with cystic fibrosis: a systematic review. Contraception 2016. Epub June 7, 2016. http://dx.doi.org/10.1016/j.contraception.2016.05.016
268. Paulen ME, Folger SG, Curtis KM, Jamieson DJ. Contraceptive use among solid organ transplant patients: a systematic review. Contraception 2010;82:102–12. http://dx.doi.org/10.1016/j.contraception.2010.02.007
269. Aweeka FT, Rosenkranz SL, Segal Y, et al; NIAID AIDS Clinical Trials Group. The impact of sex and contraceptive therapy on the plasma and intracellular pharmacokinetics of zidovudine. AIDS 2006;20:1833–41. http://dx.doi.org/10.1097/01.aids.0000244202.18629.36
270. Kearney BP, Mathias A. Lack of effect of tenofovir disoproxil fumarate on pharmacokinetics of hormonal contraceptives. Pharmacotherapy 2009;29:924–9. http://dx.doi.org/10.1592/phco.29.8.924
271. Todd CS, Deese J, Wang M, et al; FEM-PrEP Study Group. Sino-implant (II)® continuation and effect of concomitant tenofovir disoproxil fumarate-emtricitabine use on plasma levonorgestrel concentrations among women in Bondo, Kenya. Contraception 2015;91:248–52. http://dx.doi.org/10.1016/j.contraception.2014.10.008
272. Murnane PM, Heffron R, Ronald A, et al; Partners PrEP Study Team. Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception. AIDS 2014;28:1825–30. http://dx.doi.org/10.1097/QAD.0000000000000290
273. Kasonde M, Niska RW, Rose C, et al. Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir-emtricitabine or placebo in Botswana. PLoS One 2014;9:e90111. http://dx.doi.org/10.1371/journal.pone.0090111
274. Callahan R, Nanda K, Kapiga S, et al; FEM-PrEP Study Group. Pregnancy and contraceptive use among women participating in the FEM-PrEP trial. J Acquir Immune Defic Syndr 2015;68:196–203. http://dx.doi.org/10.1097/QAI.0000000000000413
275. Patel RC, Onono M, Gandhi M, et al. Pregnancy rates in HIV-positive women using contraceptives and efavirenz-based or nevirapine-based antiretroviral therapy in Kenya: a retrospective cohort study. Lancet HIV 2015;2:e474–82. http://dx.doi.org/10.1016/S2352-3018(15)00184-8
276. Pyra M, Heffron R, Mugo NR, et al; Partners in Prevention HSV/HIV Transmission Study and Partners PrEP Study Teams. Effectiveness of hormonal contraception in HIV-infected women using antiretroviral therapy. AIDS 2015;29:2353–9. http://dx.doi.org/10.1097/QAD.0000000000000827
277. Clark RA, Theall K. Population-based study evaluating association between selected antiretroviral therapies and potential oral contraceptive failure. J Acquir Immune Defic Syndr 2004;37:1219–20. http://dx.doi.org/10.1097/01.qai.0000136724.15758.ae
278. Landolt NK, Phanuphak N, Ubolyam S, et al. Efavirenz, in contrast to nevirapine, is associated with unfavorable progesterone and antiretroviral levels when coadministered with combined oral contraceptives. J Acquir Immune Defic Syndr 2013;62:534–9. http://dx.doi.org/10.1097/QAI.0b013e31827e8f98
279. Sevinsky H, Eley T, Persson A, et al. The effect of efavirenz on the pharmacokinetics of an oral contraceptive containing ethinyl estradiol and norgestimate in healthy HIV-negative women. Antivir Ther 2011;16:149–56. http://dx.doi.org/10.3851/IMP1725
280. Landolt NK, Phanuphak N, Ubolyam S, et al. Significant decrease of ethinylestradiol with nevirapine, and of etonogestrel with efavirenz in HIV-positive women. J Acquir Immune Defic Syndr 2014;66:e50–2.
281. Schöller-Gyüre M, Kakuda TN, Woodfall B, et al. Effect of steady-state etravirine on the pharmacokinetics and pharmacodynamics of ethinylestradiol and norethindrone. Contraception 2009;80:44–52. http://dx.doi.org/10.1016/j.contraception.2009.01.009

282. Myer L, Carter RJ, Katyal M, Toro P, El-Sadr WM, Abrams EJ. Impact of antiretroviral therapy on incidence of pregnancy among HIV-infected women in Sub-Saharan Africa: a cohort study. PLoS Med 2010;7:e1000229. http://dx.doi.org/10.1371/journal.pmed.1000229
283. Nanda K, Delany-Moretlwe S, Dubé K, et al. Nevirapine-based antiretroviral therapy does not reduce oral contraceptive effectiveness. AIDS 2013;27(Suppl 1):S17–25. http://dx.doi.org/10.1097/QAD.0000000000000050
284. Stuart GS, Moses A, Corbett A, et al. Combined oral contraceptives and antiretroviral PK/PD in Malawian women: pharmacokinetics and pharmacodynamics of a combined oral contraceptive and a generic combined formulation antiretroviral in Malawi. J Acquir Immune Defic Syndr 2011;58:e40–3. http://dx.doi.org/10.1097/QAI.0b013e31822b8bf8
285. Mildvan D, Yarrish R, Marshak A, et al. Pharmacokinetic interaction between nevirapine and ethinyl estradiol/norethindrone when administered concurrently to HIV-infected women. J Acquir Immune Defic Syndr 2002;29:471–7. http://dx.doi.org/10.1097/00042560-200204150-00007
286. Muro E, Droste JA, Hofstede HT, Bosch M, Dolmans W, Burger DM. Nevirapine plasma concentrations are still detectable after more than 2 weeks in the majority of women receiving single-dose nevirapine: implications for intervention studies. J Acquir Immune Defic Syndr 2005;39:419–2. http://dx.doi.org/10.1097/01.qai.0000167154.37357.f9
287. Crauwels HM, van Heeswijk RP, Buelens A, Stevens M, Hoetelmans RM. Lack of an effect of rilpivirine on the pharmacokinetics of ethinylestradiol and norethindrone in healthy volunteers. Int J Clin Pharmacol Ther 2014;52:118–28. http://dx.doi.org/10.5414/CP201943
288. Zhang J, Chung E, Yones C, et al. The effect of atazanavir/ritonavir on the pharmacokinetics of an oral contraceptive containing ethinyl estradiol and norgestimate in healthy women. Antivir Ther 2011;16:157–64. http://dx.doi.org/10.3851/IMP1724
289. Sekar VJ, Lefebvre E, Guzman SS, et al. Pharmacokinetic interaction between ethinyl estradiol, norethindrone and darunavir with low-dose ritonavir in healthy women. Antivir Ther 2008;13:563–9.
290. Glaxo Smith Kline. Lexiva (fosamprenavir calcium) [Package insert]. Research Triangle Park, NC: Glaxo Smith Kline; 2015.
291. Vogler MA, Patterson K, Kamemoto L, et al. Contraceptive efficacy of oral and transdermal hormones when co-administered with protease inhibitors in HIV-1-infected women: pharmacokinetic results of ACTG trial A5188. J Acquir Immune Defic Syndr 2010;55:473–82. http://dx.doi.org/10.1097/QAI.0b013e3181eb5ff5
292. Fröhlich M, Burhenne J, Martin-Facklam M, et al. Oral contraception does not alter single dose saquinavir pharmacokinetics in women. Br J Clin Pharmacol 2004;57:244–52 http://dx.doi.org/10.1111/j.1365-2125.2003.01983.x.
293. Boehringer Ingelheim Pharmaceuticals. Aptivus (tipranavir) [Package insert]. Ridgefield, CT; 2005.
294. Bristol-Myers Squibb. Reyataz (atazanavir sulfate) [Package insert]. Princeton, NJ; 2003.
295. Abel S, Russell D, Whitlock LA, Ridgway CE, Muirhead GJ. Effect of maraviroc on the pharmacokinetics of midazolam, lamivudine/zidovudine, and ethinyloestradiol/levonorgestrel in healthy volunteers. Br J Clin Pharmacol 2008;65(Suppl 1):19–26. http://dx.doi.org/10.1111/j.1365-2125.2008.03132.x
296. Anderson MS, Hanley WD, Moreau AR, et al. Effect of raltegravir on estradiol and norgestimate plasma pharmacokinetics following oral contraceptive administration in healthy women. Br J Clin Pharmacol 2011;71:616–20. http://dx.doi.org/10.1111/j.1365-2125.2010.03885.x
297. Song IH, Borland J, Chen S, Wajima T, Peppercorn AF, Piscitelli SC. Dolutegravir has no effect on the pharmacokinetics of oral contraceptives with norgestimate and ethinyl estradiol. Ann Pharmacother 2015;49:784–9. http://dx.doi.org/10.1177/1060028015580637
298. Gilead Sciences. Vitekta (elvitegravir) [Package insert]. Foster City, CA; 2012.
299. Back DJ, Bates M, Bowden A, et al. The interaction of phenobarbital and other anticonvulsants with oral contraceptive steroid therapy. Contraception 1980;22:495–503. http://dx.doi.org/10.1016/0010-7824(80)90102-X
300. Doose DR, Wang SS, Padmanabhan M, Schwabe S, Jacobs D, Bialer M. Effect of topiramate or carbamazepine on the pharmacokinetics of an oral contraceptive containing norethindrone and ethinyl estradiol in healthy obese and nonobese female subjects. Epilepsia 2003;44:540–9. http://dx.doi.org/10.1046/j.1528-1157.2003.55602.x
301. Fattore C, Cipolla G, Gatti G, et al. Induction of ethinylestradiol and levonorgestrel metabolism by oxcarbazepine in healthy women. Epilepsia 1999;40:783–7. http://dx.doi.org/10.1111/j.1528-1157.1999.tb00779.x
302. Rosenfeld WE, Doose DR, Walker SA, Nayak RK. Effect of topiramate on the pharmacokinetics of an oral contraceptive containing norethindrone and ethinyl estradiol in patients with epilepsy. Epilepsia 1997;38:317–23. http://dx.doi.org/10.1111/j.1528-1157.1997.tb01123.x
303. Christensen J, Petrenaite V, Atterman J, et al. Oral contraceptives induce lamotrigine metabolism: evidence from a double-blind, placebo-controlled trial. Epilepsia 2007;48:484–9. http://dx.doi.org/10.1111/j.1528-1167.2007.00997.x
304. Contin M, Albani F, Ambrosetto G, et al. Variation in lamotrigine plasma concentrations with hormonal contraceptive monthly cycles in patients with epilepsy. Epilepsia 2006;47:1573–5. http://dx.doi.org/10.1111/j.1528-1167.2006.00558.x
305. Reimers A, Helde G, Brodtkorb E. Ethinyl estradiol, not progestogens, reduces lamotrigine serum concentrations. Epilepsia 2005;46:1414–7. http://dx.doi.org/10.1111/j.1528-1167.2005.10105.x
306. Sabers A, Buchholt JM, Uldall P, Hansen EL. Lamotrigine plasma levels reduced by oral contraceptives. Epilepsy Res 2001;47:151–4. http://dx.doi.org/10.1016/S0920-1211(01)00305-9
307. Sabers A, Ohman I, Christensen J, Tomson T. Oral contraceptives reduce lamotrigine plasma levels. Neurology 2003;61:570–1. http://dx.doi.org/10.1212/01.WNL.0000076485.09353.7A
308. Back DJ, Breckenridge AM, MacIver M, et al. The effects of ampicillin on oral contraceptive steroids in women. Br J Clin Pharmacol 1982;14:43–8. http://dx.doi.org/10.1111/j.1365-2125.1982.tb04932.x
309. Back DJ, Grimmer SF, Orme ML, Proudlove C, Mann RD, Breckenridge AM. Evaluation of Committee on Safety of Medicines yellow card reports on oral contraceptive-drug interactions with anticonvulsants and antibiotics. Br J Clin Pharmacol 1988;25:527–32. http://dx.doi.org/10.1111/j.1365-2125.1988.tb03341.x
310. Back DJ, Tjia J, Martin C, et al. The lack of interaction between temafloxacin and combined oral contraceptive steroids. Contraception 1991;43:317–23. http://dx.doi.org/10.1016/0010-7824(91)90070-V
311. Bacon JF, Shenfield GM. Pregnancy attributable to interaction between tetracycline and oral contraceptives. BMJ 1980;280:293. http://dx.doi.org/10.1136/bmj.280.6210.293
312. Bainton R. Interaction between antibiotic therapy and contraceptive medication. Oral Surg Oral Med Oral Pathol 1986;61:453–5. http://dx.doi.org/10.1016/0030-4220(86)90385-3
313. Bollen M. Use of antibiotics when taking the oral contraceptive pill. [comment]. Aust Fam Physician 1995;24:928–9.
314. Bromham DR, Cartmill RS. Knowledge and use of secondary contraception among patients requesting termination of pregnancy. BMJ 1993;306:556–7. http://dx.doi.org/10.1136/bmj.306.6877.556

315. Côté J. Interaction of griseofulvin and oral contraceptives.[comment]. J Am Acad Dermatol 1990;22:124–5. http://dx.doi.org/10.1016/S0190-9622(08)80010-2
316. Csemiczky G, Alvendal C, Landgren BM. Risk for ovulation in women taking a low-dose oral contraceptive (Microgynon) when receiving antibacterial treatment with a fluoroquinolone (ofloxacin). Adv Contracept 1996;12:101–9. http://dx.doi.org/10.1007/BF01849631
317. de Groot AC, Eshuis H, Stricker BH. Inefficacy of oral contraception during use of minocycline [Dutch]. Ned Tijdschr Geneeskd 1990;134:1227–9.
318. DeSano EA Jr, Hurley SC. Possible interactions of antihistamines and antibiotics with oral contraceptive effectiveness. Fertil Steril 1982;37:853–4 http://dx.doi.org/10.1016/S0015-0282(16)46350-8.
319. Donley TG, Smith RF, Roy B. Reduced oral contraceptive effectiveness with concurrent antibiotic use: a protocol for prescribing antibiotics to women of childbearing age. Compendium 1990;11:392–6.
320. Friedman CI, Huneke AL, Kim MH, Powell J. The effect of ampicillin on oral contraceptive effectiveness. Obstet Gynecol 1980;55:33–7.
321. Grimmer SF, Allen WL, Back DJ, Breckenridge AM, Orme M, Tjia J. The effect of cotrimoxazole on oral contraceptive steroids in women. Contraception 1983;28:53–9. http://dx.doi.org/10.1016/S0010-7824(83)80005-5
322. Helms SE, Bredle DL, Zajic J, Jatjoura D, Brodell RT, Krishnarao I. Oral contraceptive failure rates and oral antibiotics. J Am Acad Dermatol 1997;36:705–10. http://dx.doi.org/10.1016/S0190-9622(97)80322-2
323. Hempel E, Böhm W, Carol W, Klinger G. [Enzyme induction by drugs and hormonal contraception]. Zentralbl Gynakol 1973;95:1451–7.
324. Hempel E, Zorn C, Graf K. [Effect of chemotherapy agents and antibiotics on hormonal contraception]. Z Arztl Fortbild (Jena) 1978;72:924–6.
325. Hetényi G. Possible interactions between antibiotics and oral contraceptives. Ther Hung 1989;37:86–9.
326. Hughes BR, Cunliffe WJ. Interactions between the oral contraceptive pill and antibiotics.[comment]. Br J Dermatol 1990;122:717–8. http://dx.doi.org/10.1111/j.1365-2133.1990.tb07299.x
327. Joshi JV, Joshi UM, Sankholi GM, et al. A study of interaction of low-dose combination oral contraceptive with Ampicillin and Metronidazole. Contraception 1980;22:643–52. http://dx.doi.org/10.1016/0010-7824(80)90089-X
328. Kakouris H, Kovacs GT. Pill failure and nonuse of secondary precautions. Br J Fam Plann 1992;18:41–4.
329. Kakouris H, Kovacs GT. How common are predisposing factors to pill failure among pill users? Br J Fam Plann 1994;20:33–5.
330. Kovacs GT, Riddoch G, Duncombe P, et al. Inadvertent pregnancies in oral contraceptive users. Med J Aust 1989;150:549–51.
331. Lequeux A. [Pregnancy under oral contraceptives after treatment with tetracycline]. Louv Med 1980;99:413–4.
332. London BM, Lookingbill DP. Frequency of pregnancy in acne patients taking oral antibiotics and oral contraceptives. Arch Dermatol 1994;130:392–3. http://dx.doi.org/10.1001/archderm.1994.01690030128027
333. Maggiolo F, Puricelli G, Dottorini M, Caprioli S, Bianchi W, Suter F. The effect of ciprofloxacin on oral contraceptive steroid treatments. Drugs Exp Clin Res 1991;17:451–4.
334. Murphy AA, Zacur HA, Charache P, Burkman RT. The effect of tetracycline on levels of oral contraceptives. Am J Obstet Gynecol 1991;164:28–33. http://dx.doi.org/10.1016/0002-9378(91)90617-Z
335. Neely JL, Abate M, Swinker M, D'Angio R. The effect of doxycycline on serum levels of ethinyl estradiol, norethindrone, and endogenous progesterone. Obstet Gynecol 1991;77:416–20.
336. Pillans PI, Sparrow MJ. Pregnancy associated with a combined oral contraceptive and itraconazole.[comment]. N Z Med J 1993;106:436.
337. Scholten PC, Droppert RM, Zwinkels MG, Moesker HL, Nauta JJ, Hoepelman IM. No interaction between ciprofloxacin and an oral contraceptive. Antimicrob Agents Chemother 1998;42:3266–8.
338. Silber TJ. Apparent oral contraceptive failure associated with antibiotic administration. J Adolesc Health Care 1983;4:287–9. http://dx.doi.org/10.1016/S0197-0070(83)80014-X
339. Sparrow MJ. Pill method failures. N Z Med J 1987;100:102–5.
340. Sparrow MJ. Pregnancies in reliable pill takers. N Z Med J 1989;102:575–7.
341. Sparrow MJ. Pill method failures in women seeking abortion: fourteen years experience. N Z Med J 1998;111:386–8.
342. van Dijke CP, Weber JC. Interaction between oral contraceptives and griseofulvin. Br Med J (Clin Res Ed) 1984;288:1125–6. http://dx.doi.org/10.1136/bmj.288.6424.1125-a
343. Wermeling DP, Chandler MH, Sides GD, Collins D, Muse KN. Dirithromycin increases ethinyl estradiol clearance without allowing ovulation. Obstet Gynecol 1995;86:78–84. http://dx.doi.org/10.1016/0029-7844(95)00075-3
344. Young LK, Farquhar CM, McCowan LM, Roberts HE, Taylor J. The contraceptive practices of women seeking termination of pregnancy in an Auckland clinic. N Z Med J 1994;107:189–92.
345. Abrams LS, Skee D, Natarajan J, Wong FA. Pharmacokinetic overview of Ortho Evra/Evra. Fertil Steril 2002;77(Suppl 2):S3–12. http://dx.doi.org/10.1016/S0015-0282(01)03261-7
346. Dogterom P, van den Heuvel MW, Thomsen T. Absence of pharmacokinetic interactions of the combined contraceptive vaginal ring NuvaRing with oral amoxicillin or doxycycline in two randomised trials. Clin Pharmacokinet 2005;44:429–38. http://dx.doi.org/10.2165/00003088-200544040-00007
347. Devenport MH, Crook D, Wynn V, Lees LJ. Metabolic effects of low-dose fluconazole in healthy female users and non-users of oral contraceptives. Br J Clin Pharmacol 1989;27:851–9. http://dx.doi.org/10.1111/j.1365-2125.1989.tb03449.x
348. Hilbert J, Messig M, Kuye O, Friedman H. Evaluation of interaction between fluconazole and an oral contraceptive in healthy women. Obstet Gynecol 2001;98:218–23.
349. Kovács I, Somos P, Hámori M. Examination of the potential interaction between ketoconazole (Nizoral) and oral contraceptives with special regard to products of low hormone content (Rigevidon, anteovin). Ther Hung 1986;34:167–70.
350. Lunell NO, Pschera H, Zador G, Carlström K. Evaluation of the possible interaction of the antifungal triazole SCH 39304 with oral contraceptives in normal healthy women. Gynecol Obstet Invest 1991;32:91–7. http://dx.doi.org/10.1159/000293003
351. McDaniel PA, Caldroney RD. Oral contraceptives and griseofulvin interactions. Drug Intell Clin Pharm 1986;20:384.
352. Meyboom RH, van Puijenbroek EP, Vinks MH, Lastdrager CJ. Disturbance of withdrawal bleeding during concomitant use of itraconazole and oral contraceptives. N Z Med J 1997;110:300.
353. Rieth H, Sauerbrey N. [Interaction studies with fluconazole, a new triazole antifungal drug]. Wien Med Wochenschr 1989;139:370–4.
354. Sinofsky FE, Pasquale SA. The effect of fluconazole on circulating ethinyl estradiol levels in women taking oral contraceptives. Am J Obstet Gynecol 1998;178:300–4. http://dx.doi.org/10.1016/S0002-9378(98)80016-1

355. van Puijenbroek EP, Feenstra J, Meyboom RH. [Pill cycle disturbance in simultaneous use of itraconazole and oral contraceptives]. Ned Tijdschr Geneeskd 1998;142:146–9.
356. Van Puijenbroek EP, Egberts AC, Meyboom RH, Leufkens HG. Signalling possible drug-drug interactions in a spontaneous reporting system: delay of withdrawal bleeding during concomitant use of oral contraceptives and itraconazole. Br J Clin Pharmacol 1999;47:689–93. http://dx.doi.org/10.1046/j.1365-2125.1999.00957.x
357. Verhoeven CH, van den Heuvel MW, Mulders TM, Dieben TO. The contraceptive vaginal ring, NuvaRing, and antimycotic co-medication. Contraception 2004;69:129–32. http://dx.doi.org/10.1016/j.contraception.2003.10.001
358. Back DJ, Breckenridge AM, Grimmer SF, Orme ML, Purba HS. Pharmacokinetics of oral contraceptive steroids following the administration of the antimalarial drugs primaquine and chloroquine. Contraception 1984;30:289–95. http://dx.doi.org/10.1016/0010-7824(84)90092-1
359. Croft AM, Herxheimer A. Adverse effects of the antimalaria drug, mefloquine: due to primary liver damage with secondary thyroid involvement? BMC Public Health 2002;2:6. http://dx.doi.org/10.1186/1471-2458-2-6
360. Karbwang J, Looareesuwan S, Back DJ, Migasana S, Bunnag D, Breckenridge AM. Effect of oral contraceptive steroids on the clinical course of malaria infection and on the pharmacokinetics of mefloquine in Thai women. Bull World Health Organ 1988;66:763–7.
361. McGready R, Stepniewska K, Seaton E, et al. Pregnancy and use of oral contraceptives reduces the biotransformation of proguanil to cycloguanil. Eur J Clin Pharmacol 2003;59:553–7. http://dx.doi.org/10.1007/s00228-003-0651-x
362. Wanwimolruk S, Kaewvichit S, Tanthayaphinant O, Suwannarach C, Oranratnachai A. Lack of effect of oral contraceptive use on the pharmacokinetics of quinine. Br J Clin Pharmacol 1991;31:179–81. http://dx.doi.org/10.1111/j.1365-2125.1991.tb05509.x
363. Back DJ, Breckenridge AM, Crawford F, et al. The effect of rifampicin on norethisterone pharmacokinetics. Eur J Clin Pharmacol 1979;15:193–7. http://dx.doi.org/10.1007/BF00563105
364. Back DJ, Breckenridge AM, Crawford FE, et al. The effect of rifampicin on the pharmacokinetics of ethynylestradiol in women. Contraception 1980;21:135–43. http://dx.doi.org/10.1016/0010-7824(80)90125-0
365. Barditch-Crovo P, Trapnell CB, Ette E, et al. The effects of rifampin and rifabutin on the pharmacokinetics and pharmacodynamics of a combination oral contraceptive. Clin Pharmacol Ther 1999;65:428–38. http://dx.doi.org/10.1016/S0009-9236(99)70138-4
366. Bolt HM, Bolt M, Kappus H. Interaction of rifampicin treatment with pharmacokinetics and metabolism of ethinyloestradiol in man. Acta Endocrinol (Copenh) 1977;85:189–97.
367. Gupta KC, Ali MY. Failure of oral contraceptive with rifampicin. Med J Zambia 1980;15:23.
368. Hirsch A. [Letter: Sleeping pills]. Nouv Presse Med 1973;2:2957.
369. Hirsch A, Tillement JP, Chretien J. Effets contrariants de la rifampicine sur les contraceptifs oraux: a propos de trois grossesses non desiree chez trois malades. Rev Fr Mal Respir 1975;2:174–82.
370. Joshi JV, Joshi UM, Sankolli GM, et al. A study of interaction of a low-dose combination oral contraceptive with anti-tubercular drugs. Contraception 1980;21:617–29. http://dx.doi.org/10.1016/0010-7824(80)90034-7
371. Kropp R. [Rifampicin and oral contraceptives (author's transl)]. Prax Pneumol 1974;28:270–2.
372. LeBel M, Masson E, Guilbert E, et al. Effects of rifabutin and rifampicin on the pharmacokinetics of ethinylestradiol and norethindrone. J Clin Pharmacol 1998;38:1042–50. http://dx.doi.org/10.1177/009127009803801109
373. Meyer B, Müller F, Wessels P, Maree J. A model to detect interactions between roxithromycin and oral contraceptives. Clin Pharmacol Ther 1990;47:671–4. http://dx.doi.org/10.1038/clpt.1990.92
374. Nocke-Finck L, Breuer H, Reimers D. Dtsch Med Wochenschr 1973;98:1521–3. http://dx.doi.org/10.1055/s-0028-1107071
375. Piguet B, Muglioni JF, Chaline G. [Letter: Oral contraception and rifampicin]. Nouv Presse Med 1975;04:115–6.
376. Reimers D, Jezek A. [The simultaneous use of rifampicin and other antitubercular agents with oral contraceptives]. Prax Pneumol 1971;25:255–62.
377. Skolnick JL, Stoler BS, Katz DB, Anderson WH. Rifampin, oral contraceptives, and pregnancy. JAMA 1976;236:1382. http://dx.doi.org/10.1001/jama.1976.03270130044027
378. Szoka PR, Edgren RA. Drug interactions with oral contraceptives: compilation and analysis of an adverse experience report database. Fertil Steril 1988;49(Suppl 2):31S–8S.
379. Berry-Bibee E, Kim MJ, Simmons K, Pagano P, Curtis K. Drug interactions between hormonal contraceptives and psychotropic drugs: a systematic review. Contraception. In press 2016.
380. Berry-Bibee E, Kim MJ, Tepper N, Riley H, Curtis K. The safety of St John's wort and hormonal contraceptives: a systematic review. Contraception. In press 2016.

Appendix E

Classifications for Barrier Methods

Classifications for barrier contraceptive methods include those for condoms, which include male latex condoms, male polyurethane condoms, and female condoms; spermicides; and diaphragm with spermicide or cervical cap (Box E1) (Table E1).

Women with conditions that make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention might not be appropriate for those who cannot use them consistently and correctly because of the relatively higher typical-use failure rates of these methods. Women should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX E1. Categories for classifying barrier methods

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE E1. Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category: Condom	Category: Spermicide	Category: Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History				
Pregnancy	NA	NA	NA	**Clarification:** None of these methods are relevant for contraception during known pregnancy. However, for women who remain at risk for STDs/HIV during pregnancy, the correct and consistent use of condoms is recommended.
Age				
a. Menarche to <40 years	1	1	1	—
b. ≥40 years	1	1	1	—
Parity				
a. Nulliparous	1	1	1	—
b. Parous	1	1	2	**Clarification:** Risk for cervical cap failure is higher in parous women than in nulliparous women.
Postpartum (breastfeeding and nonbreastfeeding)				
a. <6 weeks postpartum	1	1	NA	**Clarification:** Diaphragm and cap are unsuitable until uterine involution is complete.
b. ≥6 weeks postpartum	1	1	1	—
Postabortion				
a. First trimester	1	1	1	—
b. Second trimester	1	1	1	**Clarification:** Diaphragm and cap are unsuitable until 6 weeks after second trimester abortion.
c. Immediate postseptic abortion	1	1	1	—
Past ectopic pregnancy	1	1	1	—
History of pelvic surgery	1	1	1	—
Smoking				
a. Age <35 years	1	1	1	—
b. Age ≥35 years				
i. <15 cigarettes per day	1	1	1	—
ii. ≥15 cigarettes per day	1	1	1	—
Obesity				
a. BMI ≥30 kg/m^2	1	1	1	**Comment:** Severe obesity might make diaphragm and cap placement difficult.
b. Menarche to <18 years and BMI ≥30 kg/m^2	1	1	1	

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category			Clarifications/Evidence/Comments
	Condom	Spermicide	Diaphragm (with spermicide)/Cap	
History of bariatric surgery				
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	—
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	—
Cardiovascular Disease				
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	1	1	—
Hypertension				
Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Adequately controlled hypertension	1	1	1	—
b. Elevated blood pressure levels (properly taken measurements)				
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1	1	1	—
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1	1	1	—
c. Vascular disease	1	1	1	—
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	1	1	1	—
Deep venous thrombosis/Pulmonary embolism				
a. History of DVT/PE, not receiving anticoagulant therapy				
i. Higher risk for recurrent DVT/PE (one or more risk factors)	1	1	1	—
• History of estrogen-associated DVT/PE				
• Pregnancy-associated DVT/PE				
• Idiopathic DVT/PE				
• Known thrombophilia, including antiphospholipid syndrome				
• Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer				
• History of recurrent DVT/PE				
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	1	1	—
b. Acute DVT/PE	1	1	1	—
c. DVT/PE and established anticoagulant therapy for at least 3 months				
i. Higher risk for recurrent DVT/PE (one or more risk factors)	1	1	1	
• Known thrombophilia, including antiphospholipid syndrome				
• Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer				
• History of recurrent DVT/PE				
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	1	1	—
d. Family history (first-degree relatives)	1	1	1	—
e. Major surgery				
i. With prolonged immobilization	1	1	1	—
ii. Without prolonged immobilization	1	1	1	—
f. Minor surgery without immobilization	1	1	1	—

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category: Condom	Spermicide	Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; or protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
Superficial venous disorders				
a. Varicose veins	1	1	1	—
b. Superficial venous thrombosis (acute or history)	1	1	1	—
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	—
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	—
Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	—
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1	1	2	—
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (*1*)				
i. <6 months	1	1	1	—
ii. ≥6 months	1	1	1	—
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (*1*)	1	1	1	—
Rheumatic Diseases				
Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Positive (or unknown) antiphospholipid antibodies	1	1	1	—
b. Severe thrombocytopenia	1	1	1	—
c. Immunosuppressive therapy	1	1	1	—
d. None of the above	1	1	1	—
Rheumatoid arthritis				
a. Receiving immunosuppressive therapy	1	1	1	—
b. Not receiving immunosuppressive therapy	1	1	1	—
Neurologic Conditions				
Headaches				—
a. Nonmigraine (mild or severe)	1	1	1	—
b. Migraine				
i. Without aura (This category of migraine includes menstrual migraine.)	1	1	1	**Comment:** Menstrual migraine is a subtype of migraine without aura. For more information see *The International Headache Society Classification, 3rd edition* (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
ii. With aura	1	1	1	—
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	—
Multiple sclerosis				
a. With prolonged immobility	1	1	1	—
b. Without prolonged immobility	1	1	1	—
Depressive Disorders				
Depressive disorders	1	1	1	—
Reproductive Tract Infections and Disorders				
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	1	1	1	**Clarification:** If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category: Condom	Category: Spermicide	Category: Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments
Endometriosis	1	1	1	—
Benign ovarian tumors (including cysts)	1	1	1	—
Severe dysmenorrhea	1	1	1	—
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Suspected gestational trophoblastic disease (immediate postevacuation)				
i. Uterine size first trimester	1	1	1	—
ii. Uterine size second trimester	1	1	1	—
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)				
i. Undetectable/nonpregnant β–hCG levels	1	1	1	—
ii. Decreasing β–hCG levels	1	1	1	—
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	1	1	1	—
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	1	1	1	—
Cervical ectropion	1	1	1	—
Cervical intraepithelial neoplasia	1	1	1	**Clarification:** The cap should not be used. Diaphragm use has no restrictions.
Cervical cancer (awaiting treatment)	1	2	1	**Clarification:** The cap should not be used. Diaphragm use has no restrictions. **Comment:** Repeated and high-dose use of the spermicide nonoxynol-9 can cause vaginal and cervical irritation or abrasions.
Breast disease Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Undiagnosed mass	1	1	1	—
b. Benign breast disease	1	1	1	—
c. Family history of cancer	1	1	1	—
d. Breast cancer				
i. Current	1	1	1	—
ii. Past and no evidence of current disease for 5 years	1	1	1	—
Endometrial hyperplasia	1	1	1	—
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	—
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	—
Uterine fibroids	1	1	1	—
Anatomical abnormalities	1	1	NA	**Clarification:** The diaphragm cannot be used in certain cases of prolapse. Cap use is not appropriate for a woman with markedly distorted cervical anatomy.
Pelvic inflammatory disease				
a. Past PID				
i. With subsequent pregnancy	1	1	1	—
ii. Without subsequent pregnancy	1	1	1	—
b. Current PID	1	1	1	—
Sexually transmitted diseases				
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	1	1	1	—
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	1	1	1	—
c. Other factors related to STDs	1	1	1	—
HIV				
High risk for HIV	1	4	4	**Evidence:** Repeated and high-dose use of the spermicide nonoxynol-9 was associated with increased risk for genital lesions, which might increase the risk for HIV infection (*2*). **Comment:** Diaphragm use is assigned category 4 because of concerns about the spermicide, not the diaphragm.

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category: Condom	Category: Spermicide	Category: Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	3	3	**Comment:** Use of spermicides or diaphragms (with spermicide) can disrupt the cervical mucosa, which might increase viral shedding and HIV transmission to noninfected sex partners.
Other Infections				
Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	—
b. Fibrosis of the liver	1	1	1	—
Tuberculosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Nonpelvic	1	1	1	—
b. Pelvic	1	1	1	—
Malaria	1	1	1	—
History of toxic shock syndrome	1	1	3	**Comment:** Toxic shock syndrome has been reported in association with contraceptive sponge and diaphragm use.
Urinary tract infection	1	1	2	**Comment:** Use of diaphragms and spermicides might increase risk for urinary tract infection.
Endocrine Conditions				
Diabetes Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. History of gestational disease	1	1	1	—
b. Nonvascular disease				
i. Non-insulin dependent	1	1	1	—
ii. Insulin dependent	1	1	1	—
c. Nephropathy, retinopathy, or neuropathy	1	1	1	—
d. Other vascular disease or diabetes of >20 years' duration	1	1	1	—
Thyroid disorders				
a. Simple goiter	1	1	1	—
b. Hyperthyroid	1	1	1	—
c. Hypothyroid	1	1	1	—
Gastrointestinal Conditions				
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	1	1	—
Gallbladder disease				
a. Symptomatic				
i. Treated by cholecystectomy	1	1	1	—
ii. Medically treated	1	1	1	—
iii. Current	1	1	1	—
b. Asymptomatic	1	1	1	—
History of cholestasis				
a. Pregnancy related	1	1	1	—
b. Past COC related	1	1	1	—
Viral hepatitis				
a. Acute or flare	1	1	1	—
b. Carrier	1	1	1	—
c. Chronic	1	1	1	—
Cirrhosis Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Mild (compensated)	1	1	1	—
b. Severe (decompensated)	1	1	1	—

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category: Condom	Category: Spermicide	Category: Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments
Liver tumors				
Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Benign				
i. Focal nodular hyperplasia	1	1	1	—
ii. Hepatocellular adenoma	1	1	1	—
b. Malignant (hepatoma)	1	1	1	—
Respiratory Conditions				
Cystic fibrosis	1	1	1	—
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
Anemias				
Thalassemia	1	1	1	—
Sickle cell disease	1	1	1	—
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
Iron deficiency anemia	1	1	1	—
Solid Organ Transplantation				
Solid organ transplantation				
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	1	1	1	—
b. Uncomplicated	1	1	1	—
Drug Interactions				
Antiretroviral therapy				**Clarification:** No drug interaction between ARV therapy and barrier method use is known. However, HIV infection is classified as category 3 for spermicides and diaphragms (see HIV section).
a. Nucleoside reverse transcriptase inhibitors (NRTIs)				
i. Abacavir (ABC)	1	3	3	
ii. Tenofovir (TDF)	1	3	3	
iii. Zidovudine (AZT)	1	3	3	
iv. Lamivudine (3TC)	1	3	3	
v. Didanosine (DDI)	1	3	3	
vi. Emtricitabine (FTC)	1	3	3	
vii. Stavudine (D4T)	1	3	3	
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)				
i. Efavirenz (EFV)	1	3	3	
ii. Etravirine (ETR)	1	3	3	
iii. Nevirapine (NVP)	1	3	3	
iv. Rilpivirine (RPV)	1	3	3	
c. Ritonavir-boosted protease inhibitors				
i. Ritonavir-boosted atazanavir (ATV/r)	1	3	3	
ii. Ritonavir-boosted darunavir (DRV/r)	1	3	3	
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1	3	3	
iv. Ritonavir-boosted lopinavir (LPV/r)	1	3	3	
v. Ritonavir-boosted saquinavir (SQV/r)	1	3	3	
vi. Ritonavir-boosted tipranavir (TPV/r)	1	3	3	
d. Protease inhibitors without ritonavir				
i. Atazanavir (ATV)	1	3	3	
ii. Fosamprenavir (FPV)	1	3	3	
iii. Indinavir (IDV)	1	3	3	
iv. Nelfinavir (NFV)	1	3	3	
e. CCR5 co-receptor antagonists				
i. Maraviroc (MVC)	1	3	3	
f. HIV integrase strand transfer inhibitors				
i. Raltegravir (RAL)	1	3	3	
ii. Dolutegravir (DTG)	1	3	3	
iii. Elvitegravir (EVG)	1	3	3	
g. Fusion inhibitors				
i. Enfuvirtide	1	3	3	
Anticonvulsant therapy				
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, or oxcarbazepine)	1	1	1	—
b. Lamotrigine	1	1	1	—

See table footnotes on page 87.

TABLE E1. (*Continued*) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

Condition	Category			Clarifications/Evidence/Comments
	Condom	Spermicide	Diaphragm (with spermicide)/Cap	
Antimicrobial therapy				
a. Broad-spectrum antibiotics	1	1	1	—
b. Antifungals	1	1	1	—
c. Antiparasitics	1	1	1	—
d. Rifampin or rifabutin therapy	1	1	1	—
Psychotropic medications				
a. SSRIs	1	1	1	—
St. John's wort	1	1	1	—
Allergy to latex	3	1	3	**Clarification:** The condition of allergy to latex does not apply to plastic condoms/diaphragms.

Abbreviations: ARV = antiretroviral; BMI = body mass index; COC = combined oral contraceptive; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; NA = not applicable; PE = pulmonary embolism; PID = pelvic inflammatory disease; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease.

References

1. The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown and Co; 1994.
2. Wilkinson D, Ramjee G, Tholandi M, Rutherford G. Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men. Cochrane Database Syst Rev 2002;4(CD003936):CD003936.

Appendix F

Classifications for Fertility Awareness–Based Methods

Fertility awareness–based (FAB) methods of family planning involve identifying the fertile days of the menstrual cycle, whether by observing fertility signs such as cervical secretions and basal body temperature or by monitoring cycle days (Box F1) (Table F1). FAB methods can be used in combination with abstinence or barrier methods during the fertile time. If barrier methods are used, see the Classifications for Barrier Methods (Appendix E).

No medical conditions worsen because of FAB methods. In general, FAB methods can be used without concern for health effects in persons who choose them. However, several conditions make their use more complex. The existence of these conditions suggests that 1) use of these methods should be delayed until the condition is corrected or resolved, or 2) persons using FAB methods need special counseling, and a provider with particular training in use of these methods is generally necessary to ensure correct use.

Women with conditions that make pregnancy an unacceptable risk should be advised that FAB methods might not be appropriate for them because of the relatively higher typical-use failure rates of these methods. Symptoms-based and calendar-based methods do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX F1. Definitions for terms associated with fertility awareness–based methods

- **Symptoms-based methods:** FAB methods based on observation of fertility signs (e.g., cervical secretions or basal body temperature) such as the cervical mucus method, the symptothermal method, and the TwoDay method.
- **Calendar-based methods:** FAB methods based on calendar calculations such as the calendar rhythm method and the standard days method.
- **Accept:** No medical reason exists to deny the particular FAB method to a woman in this circumstance.
- **Caution:** The method normally is provided in a routine setting but with extra preparation and precautions. For FAB methods, this usually means that special counseling might be needed to ensure correct use of the method by a woman in this circumstance.
- **Delay:** Use of this method should be delayed until the condition is evaluated or corrected. Alternative temporary methods of contraception should be offered.

Abbreviation: FAB = fertility awareness–based.

TABLE F1. Fertility awareness–based methods, including symptoms-based and calendar-based methods

Condition	Category: Symptoms-based method	Category: Calendar-based method	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History			
Pregnancy	NA	NA	**Clarification:** FAB methods are not relevant during pregnancy.
Life stage			**Comment:** Menstrual irregularities are common in postmenarche and perimenopause and might complicate the use of FAB methods.
a. Postmenarche	Caution	Caution	
b. Perimenopause	Caution	Caution	
Breastfeeding			**Comment:** Use of FAB methods when breastfeeding might be less effective than when not breastfeeding.
a. <6 weeks postpartum	Delay	Delay	**Comment:** Women who are primarily breastfeeding and are amenorrheic are unlikely to have sufficient ovarian function to produce detectable fertility signs and hormonal changes during the first 6 months postpartum. However, the likelihood of resumption of fertility increases with time postpartum and with substitution of breast milk by other foods.
b. ≥6 weeks	Caution	Delay	
c. After menses begin	Caution	Caution	**Clarification:** When the woman notices fertility signs, particularly cervical secretions, she can use a symptoms-based method. First postpartum menstrual cycles in breastfeeding women vary significantly in length. Return to regularity takes several cycles. When she has had at least three postpartum menses and her cycles are regular again, she can use a calendar-based method. When she has had at least four postpartum menses and her most recent cycle lasted 26–32 days, she can use the standard days method. Before that time, a barrier method should be offered if the woman plans to use a FAB method later.
Postpartum (nonbreastfeeding women)			
a. <4 weeks	Delay	Delay	**Clarification:** Nonbreastfeeding women are not likely to have detectable fertility signs or hormonal changes before 4 weeks postpartum. Although the risk for pregnancy is low, ovulation before first menses is common; therefore, a method appropriate for the postpartum period should be offered.
b. ≥4 weeks	Accept	Delay	**Clarification:** Nonbreastfeeding women are likely to have sufficient ovarian function to produce detectable fertility signs, hormonal changes, or both at this time; likelihood increases rapidly with time postpartum. Women can use calendar-based methods as soon as they have completed three postpartum menses. Methods appropriate for the postpartum period should be offered before that time.
Postabortion	Caution	Delay	**Clarification:** After abortion, women are likely to have sufficient ovarian function to produce detectable fertility signs, hormonal changes, or both; likelihood increases with time postabortion. Women can start using calendar-based methods after they have had at least one postabortion menses (e.g., women who before this pregnancy primarily had cycles of 26–32 days can then use the standard days method). Methods appropriate for the postabortion period should be offered before that time.
Reproductive Tract Infections and Disorders			
Irregular vaginal bleeding	Delay	Delay	**Clarification:** Presence of this condition makes FAB methods unreliable. Therefore, barrier methods should be recommended until the bleeding pattern is compatible with proper method use. The condition should be evaluated and treated as necessary.
Vaginal discharge	Delay	Accept	**Clarification:** Because vaginal discharge makes recognition of cervical secretions difficult, the condition should be evaluated and treated if needed before providing methods based on cervical secretions.
Other			
Use of drugs that affect cycle regularity, hormones, or fertility signs	Caution /Delay	Caution/Delay	**Clarification:** Use of certain mood-altering drugs such as lithium, tricyclic antidepressants, and antianxiety therapies, as well as certain antibiotics and anti-inflammatory drugs, might alter cycle regularity or affect fertility signs. The condition should be carefully evaluated and a barrier method offered until the degree of effect has been determined or the drug is no longer being used.
Diseases that elevate body temperature			**Clarification:** Elevated temperatures might make basal body temperature difficult to interpret but have no effect on cervical secretions. Thus, use of a method that relies on temperature should be delayed until the acute febrile disease abates. Temperature-based methods are not appropriate for women with chronically elevated temperatures. In addition, some chronic diseases interfere with cycle regularity, making calendar-based methods difficult to interpret.
a. Chronic diseases	Caution	Accept	
b. Acute diseases	Delay	Accept	

Abbreviations: FAB = fertility awareness–based; NA = not applicable.

Appendix G

Lactational Amenorrhea Method

The Bellagio Consensus provided the scientific basis for defining the conditions under which breastfeeding can be used safely and effectively for birth-spacing purposes; programmatic guidelines were developed at a meeting of family planning experts for its use as a method of family planning, and the method was then given the name the lactational amenorrhea method (*1*,*2*). These guidelines include the following three criteria, all of which must be met to ensure adequate protection from an unplanned pregnancy: 1) amenorrhea; 2) fully or nearly fully breastfeeding (no interval of >4–6 hours between breastfeeds); and 3) <6 months postpartum.

All major medical organizations recommend exclusive breastfeeding for the first 6 months of life, with continuing breastfeeding through the first year and beyond for as long as mutually desired (*3*). No medical conditions exist for which use of the lactational amenorrhea method for contraception is restricted. However, breastfeeding might not be recommended for women or infants with certain conditions.

Women with conditions that make pregnancy an unacceptable risk should be advised that the lactational amenorrhea method might not be appropriate for them because of its relatively higher typical-use failure rates. The lactational amenorrhea method does not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using this method should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

HIV Infection

HIV can be transmitted from mother to infant through breastfeeding. Therefore, in the United States, where replacement feeding is affordable, feasible, acceptable, sustainable, and safe, breastfeeding for women with HIV is not recommended (*3*,*4*).

Other Medical Conditions

The American Academy of Pediatrics (AAP) also recommends against breastfeeding for women with active untreated tuberculosis disease, untreated brucellosis, varicella, H1N1 influenza, or positivity for human T-cell lymphotropic virus types I or II or for those who have herpes simplex lesions on a breast. In addition, infants with classic galactosemia should not breastfeed (*3*).

Medication Used During Breastfeeding

AAP recommends that the benefits of breastfeeding outweigh the risk of exposure to most therapeutic agents via human milk. More information about specific drugs and radioactive compounds is provided by AAP (*5*) and LactMed (http://toxnet.nlm.nih.gov).

References

1. Kennedy KI, Rivera R, McNeilly AS. Consensus statement on the use of breastfeeding as a family planning method. Contraception 1989;39:477–96. http://dx.doi.org/10.1016/0010-7824(89)90103-0
2. Labbok M, Cooney K, Coly S. Guidelines: breastfeeding, family planning, and the Lactational Amenorrhea Method-LAM. Washington, DC: Institute for Reproductive Health; 1994.
3. American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk [Policy statement]. Pediatrics 2012;129:e827–41. http://dx.doi.org/10.1542/peds.2011-3552
4. Perinatal HIV Guidelines Working Group. Public Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. Rockville, MD: Public Health Service Task Force; 2009.
5. Sachs HC; Committee On Drugs. The transfer of drugs and therapeutics into human breast milk: an update on selected topics. Pediatrics 2013;132:e796–809. http://dx.doi.org/10.1542/peds.2013-1985

Appendix H

Coitus Interruptus (Withdrawal)

Coitus interruptus, also known as withdrawal, is a traditional family planning method in which the man completely removes his penis from the vagina and away from the external genitalia of the female partner before he ejaculates. Coitus interruptus prevents sperm from entering the woman's vagina, thereby preventing contact between spermatozoa and the ovum.

This method might be appropriate for couples

- who are highly motivated and able to use this method effectively;
- with religious or philosophical reasons for not using other methods of contraception;
- who need contraception immediately and have entered into a sexual act without alternative methods available;
- who need a temporary method while awaiting the start of another method; or
- who have intercourse infrequently.

Some benefits of coitus interruptus are that the method, if used correctly, does not affect breastfeeding and is always available for primary use or use as a back-up method. In addition, coitus interruptus involves no economic cost or use of chemicals and has no directly associated health risks. Coitus interruptus does not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using this method should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

Coitus interruptus is unforgiving of incorrect use, and its effectiveness depends on the willingness and ability of the couple to use withdrawal with every act of intercourse. Women with conditions that make pregnancy an unacceptable risk should be advised that coitus interruptus might not be appropriate for them because of its relatively higher typical-use failure rates.

Appendix I

Female and Male Sterilization

Tubal sterilization for women and vasectomy for men are permanent, safe, and highly effective methods of contraception. In general, no medical conditions absolutely restrict a person's eligibility for sterilization (with the exception of known allergy or hypersensitivity to any materials used to complete the sterilization method). However, certain conditions place a woman at high surgical risk; in these cases, careful consideration should be given to the risks and benefits of other acceptable alternatives, including long-acting, highly effective, reversible methods and vasectomy. Female and male sterilization do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

Because these methods are intended to be irreversible, persons who choose sterilization should be certain that they want to prevent pregnancy permanently. Most persons who choose sterilization remain satisfied with their decision. However, a small proportion of women regret this decision (1%–26% from different studies, with higher rates of regret reported by women who were younger at sterilization) (*1*,*2*). Regret among men about vasectomy has been reported to be approximately 5% (*3*), similar to the proportion of women who report regretting their husbands' vasectomy (6%) (*4*). Therefore, all persons should be appropriately counseled about the permanency of sterilization and the availability of highly effective, reversible methods of contraception.

References

1. Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. Obstet Gynecol 1999;93:889–95.
2. Peterson HB. Sterilization. Obstet Gynecol 2008;111:189–203. http://dx.doi.org/10.1097/01.AOG.0000298621.98372.62
3. Ehn BE, Liljestrand J. A long-term follow-up of 108 vasectomized men. Good counselling routines are important. Scand J Urol Nephrol 1995;29:477–81. http://dx.doi.org/10.3109/00365599509180030
4. Jamieson DJ, Kaufman SC, Costello C, Hillis SD, Marchbanks PA, Peterson HB; US Collaborative Review of Sterilization Working Group. A comparison of women's regret after vasectomy versus tubal sterilization. Obstet Gynecol 2002;99:1073–9.

Appendix J

Classifications for Emergency Contraception

A copper-containing intrauterine device (Cu-IUD) can be used within 5 days of unprotected intercourse as an emergency contraceptive. However, when the time of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after intercourse, if necessary, as long as the insertion does not occur >5 days after ovulation. The eligibility criteria for interval Cu-IUD insertion also apply for the insertion of Cu-IUDs as emergency contraception (Box J1) (Table J1).

Classifications for emergency contraceptive pills (ECPs) are given for ulipristal acetate (UPA), levonorgestrel (LNG), and combined oral contraceptives (COCs). Cu-IUDs, UPA, LNG, and COCs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX J1. Categories for classifying emergency contraception

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE J1. Classifications for emergency contraception, including the copper-containing intrauterine device, ulipristal acetate, levonorgestrel, and combined oral contraceptives*

Condition	Category				Clarifications/Evidence/Comments
	Cu-IUD	UPA	LNG	COC	
Personal Characteristics and Reproductive History					
Pregnancy	4	NA	NA	NA	**Clarification (IUD):** The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion. **Clarification (ECPs):** Although this method is not indicated for a woman with a known or suspected pregnancy, no harm to the woman, the course of her pregnancy, or the fetus if ECPs are inadvertently used is known to exist. **Evidence:** Evidence suggests that poor pregnancy outcomes are rare among pregnant women who used ECPs during conception cycle or early in pregnancy *(1)*.
Breastfeeding	1	1	1	1	**Clarification (UPA):** Breastfeeding is not recommended for 24 hours after taking UPA because it is excreted in breast milk, with highest concentrations in the first 24 hours, and maximum maternal serum levels are reached 1–3 hours after administration. Mean UPA concentrations in breast milk decrease markedly from 0 to 24–48 hours and then slowly decrease over 5 days *(2)*. Breast milk should be expressed and discarded for 24 hours after taking UPA. **Evidence:** Breastfeeding outcomes do not seem to differ between women exposed to LNG and those who are not exposed. One pharmacokinetic study demonstrated that LNG passes to breast milk but in minimal quantities *(1)*.
Past ectopic pregnancy	1	1	1	1	—
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	—
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	**Comment:** Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhea, vomiting, or both. Because of these malabsorptive concerns, an emergency IUD might be more appropriate than ECPs.

See table footnotes on page 94.

TABLE J1. (*Continued*) Classifications for emergency contraception, including the copper-containing intrauterine device, ulipristal acetate, levonorgestrel, and combined oral contraceptives*

Condition	Category				Clarifications/Evidence/Comments
	Cu-IUD	UPA	LNG	COC	
Cardiovascular Disease					
History of severe cardiovascular disease (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	**Comment:** The duration of ECP use is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.
Rheumatic Diseases					
Rheumatoid arthritis					
a. Receiving immunosuppressive therapy	2	1	1	1	—
b. Not receiving immunosuppressive therapy	1	1	1	1	—
Neurologic Conditions					
Migraine	1	1	1	2	**Comment:** The duration of ECP use is less than that of regular use of COCs and thus would be expected to have less clinical impact.
Gastrointestinal Conditions					
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	1	1	1	—
Severe liver disease (including jaundice) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	**Comment:** The duration of ECP use is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.
Solid Organ Transplantation					
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	1	1	1	—
b. Uncomplicated	2	1	1	1	—
Other					
Repeated ECP use	1	1	1	1	**Clarification:** Recurrent ECP use is an indication that the woman requires further counseling about other contraceptive options. Frequently repeated ECP use might be harmful for women with conditions classified as 2, 3, or 4 for CHC or POC use. **Evidence:** In one case-control study, risk for ectopic pregnancy compared with intrauterine pregnancy did not increase after repeated use of LNG ECPs compared with nonuse *(1)*.
Sexual assault	2	1	1	1	**Clarification (IUD):** Women who have experienced sexual assault are at increased risk for STDs. According to CDC STD treatment guidelines, routine presumptive treatment of chlamydia, gonorrhea, and trichomonas is recommended after sexual assault *(3)*. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (category 4).
Obesity (BMI ≥30 kg/m^2)	1	2	2	2	**Clarification (ECPs):** ECPs might be less effective among women with BMI ≥30 kg/m^2 than among women with BMI <25 kg/m^2. Despite this, no safety concerns exist. **Evidence:** Limited evidence from secondary data analyses suggests that women with BMI ≥30 kg/m^2 experience an increased risk for pregnancy after use of LNG compared with women with BMI <25 kg/m^2. Two analyses suggest obese women might also experience an increased risk for pregnancy after use of UPA compared with nonobese women, although this increase was not significant in one study *(4)*.
CYP3A4 inducers (e.g., bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate, efavirenz, and lumacaftor)	1	2	2	2	**Clarification (ECPs):** Strong CYP3A4 inducers might reduce the effectiveness of ECPs. **Evidence:** According to labelling information, rifampin markedly decreases UPA levels by ≥90%, which might decrease its efficacy *(2)*. Therefore, theoretical concerns extend to use of other CYP3A4 inducers as well as to COC and LNG ECPs, which have metabolic pathways similar to those of UPA. A small pharmacokinetic study found that concomitant efavirenz use decreased LNG levels in women taking LNG ECPs (0.75 mg) by 56% compared with LNG ECPs alone *(5)*.

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; ECP = emergency contraceptive pill; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG = levonorgestrel; NA = not applicable; POC = progestin-only contraceptive; POP = progestin-only pill; STD = sexually transmitted disease; UPA = ulipristal acetate.

References

1. Jatlaoui TC, Riley H, Curtis KM. Safety data for levonorgestrel, ulipristal acetate and Yuzpe regimens for emergency contraception. Contraception 2016;93:93–112. http://dx.doi.org/10.1016/j.contraception.2015.11.001
2. Watson Pharmaceuticals. Ella [Prescribing information]. Morristown, NJ; 2010. https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf
3. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-03).
4. Jatlaoui TC, Curtis KM. Safety and effectiveness data for emergency contraceptive pills among women with obesity: a systematic review. Contraception 2016. Epub May 24, 2016. http://dx.doi.org/10.1016/j.contraception.2016.05.002
5. Carten ML, Kiser JJ, Kwara A, Mawhinney S, Cu-Uvin S. Pharmacokinetic interactions between the hormonal emergency contraception, levonorgestrel (Plan B), and efavirenz. Infect Dis Obstet Gynecol 2012;2012:137192.

Appendix K

Summary of Classifications for Hormonal Contraceptive Methods and Intrauterine Devices

Health-care providers can use the summary table as a quick reference guide to the classifications for hormonal contraceptive methods and intrauterine contraception to compare classifications across these methods (Box K1) (Table K1). See the respective appendix for each method for clarifications to the numeric categories, as well as for summaries of the evidence and additional comments. Hormonal contraceptives and intrauterine devices do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX K1. Categories for classifying hormonal contraceptives and intrauterine devices

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE K1. Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
Personal Characteristics And Reproductive History						
Pregnancy	4*	4*	NA*	NA*	NA*	NA*
Age	Menarche to <20 years: 2 ≥20 years: 1	Menarche to <20 years: 2 ≥20 years: 1	Menarche to <18 years: 1 18–45 years: 1 >45 years: 1	Menarche to <18 years: 2 18–45 years: 1 >45 years: 2	Menarche to <18 years: 1 18–45 years: 1 >45 years: 1	Menarche to <40 years: 1 ≥40 years: 2
Parity						
a. Nulliparous	2	2	1	1	1	1
b. Parous	1	1	1	1	1	1
Breastfeeding						
a. <21 days postpartum	—	—	2*	2*	2*	4*
b. 21 to <30 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	2*	2*	2*	3*
ii. Without other risk factors for VTE	—	—	2*	2*	2*	3*
c. 30–42 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	1*	1*	1*	3*
ii. Without other risk factors for VTE	—	—	1*	1*	1*	2*
d. >42 days postpartum	—	—	1*	1*	1*	2*

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
Postpartum (nonbreastfeeding women)						
a. <21 days postpartum	—	—	1	1	1	4
b. 21–42 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	1	1	1	3*
ii. Without other risk factors for VTE	—	—	1	1	1	2
c. >42 days postpartum	—	—	1	1	1	1
Postpartum (including cesarean delivery)						
a. <10 minutes after delivery of the placenta						
i. Breastfeeding	1*	2*	—	—	—	—
ii. Nonbreastfeeding	1*	1*	—	—	—	—
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2*	2*	—	—	—	—
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1*	1*	—	—	—	—
d. Postpartum sepsis	4	4	—	—	—	—
Postabortion						
a. First trimester	1*	1*	1*	1*	1*	1*
b. Second trimester	2*	2*	1*	1*	1*	1*
c. Immediate postseptic abortion	4	4	1*	1*	1*	1*
Past ectopic pregnancy	1	1	1	1	2	1
History of pelvic surgery (see Postpartum [Including Cesarean Delivery] section)	1	1	1	1	1	1
Smoking						
a. Age <35 years	1	1	1	1	1	2
b. Age ≥35 years						
i. <15 cigarettes per day	1	1	1	1	1	3
ii. ≥15 cigarettes per day	1	1	1	1	1	4
Obesity						
a. BMI ≥30 kg/m^2	1	1	1	1	1	2
b. Menarche to <18 years and BMI ≥30 kg/m^2	1	1	1	2	1	2
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).						
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	1	1
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	3	COCs: 3 Patch and ring: 1
Cardiovascular Disease						
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	2	2*	3*	2*	3/4*
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).						
a. Adequately controlled hypertension	1*	1*	1*	2*	1*	3*

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD		Implants		DMPA	POP		CHCs
b. Elevated blood pressure levels (properly taken measurements)									
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1*	1*		1*		2*	1*		3*
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1*	2*		2*		3*	2*		4*
c. Vascular disease	1*	2*		2*		3*	2*		4*
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	1	1		1		1	1		2
Deep venous thrombosis/ Pulmonary embolism									
a. History of DVT/PE, not receiving anticoagulant therapy									
i. Higher risk for recurrent DVT/PE (one or more risk factors) • History of estrogen-associated DVT/PE • Pregnancy-associated DVT/PE • Idiopathic DVT/PE • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	1	2		2		2	2		4
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	2		2		2	2		3
b. Acute DVT/PE	2	2		2		2	2		4
c. DVT/PE and established anticoagulant therapy for at least 3 months									
i. Higher risk for recurrent DVT/PE (one or more risk factors) • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer • History of recurrent DVT/PE	2	2		2		2	2		4*
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2		2		2	2		3*
d. Family history (first-degree relatives)	1	1		1		1	1		2
e. Major surgery									
i. With prolonged immobilization	1	2		2		2	2		4
ii. Without prolonged immobilization	1	1		1		1	1		2
f. Minor surgery without immobilization	1	1		1		1	1		1
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1*	2*		2*		2*	2*		4*
Superficial venous disorders									
a. Varicose veins	1	1		1		1	1		1
b. Superficial venous thrombosis (acute or history)	1	1		1		1	1		3*
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	Initiation 2	Continuation 3	Initiation 2	Continuation 3	3	Initiation 2	Continuation 3	4

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants		DMPA		POP		CHCs
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		2		Initiation 2	Continuation 3	3		Initiation 2	Continuation 3	4
Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).											
a. Uncomplicated	1		1		1		1		1		2
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1		1		1		1		1		4
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).											
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) *(1)*											
i. <6 months	2		2		1		1		1		4
ii. ≥6 months	2		2		1		1		1		3
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) *(1)*.	2		2		2		2		2		4
Rheumatic Diseases											
Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation					Initiation	Continuation			
a. Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*
b. Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*
c. Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*
d. None of the above	1*	1*	2*		2*		2*	2*	2*		2*
Rheumatoid arthritis	Initiation	Continuation	Initiation	Continuation							
a. Receiving immunosuppressive therapy	2	1	2	1	1		2/3*		1		2
b. Not receiving immunosuppressive therapy	1		1		1		2		1		2
Neurologic Conditions											
Headaches											
a. Nonmigraine (mild or severe)	1		1		1		1		1		1*
b. Migraine											
i. Without aura (This category of migraine includes menstrual migraine.)	1		1		1		1		1		2*
ii. With aura	1		1		1		1		1		4*
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		1*		1*		1*		1*
Multiple sclerosis											
a. With prolonged immobility	1		1		1		2		1		3
b. Without prolonged immobility	1		1		1		2		1		1
Depressive Disorders											
Depressive disorders	1*		1*		1*		1*		1*		1*
Reproductive Tract Infections and Disorders											
Vaginal bleeding patterns			Initiation	Continuation							
a. Irregular pattern without heavy bleeding	1		1	1	2		2		2		1
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2*		1*	2*	2*		2*		2*		1*

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	Initiation 4*	Continuation 2*	Initiation 4*	Continuation 2*	3*	3*	2*	2*
Endometriosis	2		1		1	1	1	1
Benign ovarian tumors (including cysts)	1		1		1	1	1	1
Severe dysmenorrhea	2		1		1	1	1	1
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).								
a. Suspected gestational trophoblastic disease (immediate postevacuation)								
i. Uterine size first trimester	1*		1*		1*	1*	1*	1*
ii. Uterine size second trimester	2*		2*		1*	1*	1*	1*
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation	Continuation	Initiation	Continuation				
i. Undetectable/nonpregnant β-hCG levels	1*	1*	1*	1*	1*	1*	1*	1*
ii. Decreasing β-hCG levels	2*	1*	2*	1*	1*	1*	1*	1*
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2*	1*	2*	1*	1*	1*	1*	1*
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*	1*	1*	1*
Cervical ectropion	1		1		1	1	1	1
Cervical intraepithelial neoplasia	1		2		2	2	1	2
Cervical cancer (awaiting treatment)	Initiation 4	Continuation 2	Initiation 4	Continuation 2	2	2	1	2
Breast disease Breast cancer is associated with increased risk of adverse health events as a result of pregnancy (Box 2).								
a. Undiagnosed mass	1		2		2*	2*	2*	2*
b. Benign breast disease	1		1		1	1	1	1
c. Family history of cancer	1		1		1	1	1	1
d. Breast cancer								
i. Current	1		4		4	4	4	4
ii. Past and no evidence of current disease for 5 years	1		3		3	3	3	3
Endometrial hyperplasia	1		1		1	1	1	1
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation 4	Continuation 2	Initiation 4	Continuation 2	1	1	1	1
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		1	1	1	1
Uterine fibroids	2		2		1	1	1	1
Anatomical abnormalities								
a. Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion)	4		4		—	—	—	—
b. Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion	2		2		—	—	—	—
Pelvic inflammatory disease								
a. Past PID	Initiation	Continuation	Initiation	Continuation				
i. With subsequent pregnancy	1	1	1	1	1	1	1	1
ii. Without subsequent pregnancy	2	2	2	2	1	1	1	1
b. Current PID	4	2*	4	2*	1	1	1	1

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
Sexually transmitted diseases	Initiation	Continuation	Initiation	Continuation				
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1	1	1	1
b. Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis)	2	2	2	2	1	1	1	1
c. Other factors related to STDs	2*	2	2*	2	1	1	1	1
HIV								
	Initiation	Continuation	Initiation	Continuation				
High risk for HIV	2	2	2	2	1	1*	1	1
HIV infection	—	—	—	—	1*	1*	1*	1*
For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).								
a. Clinically well receiving ARV therapy	1	1	1	1	—	—	—	—
b. Not clinically well or not receiving ARV therapy	2	1	2	1	—	—	—	—
Other Infections								
Schistosomiasis								
Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).								
a. Uncomplicated	1		1		1	1	1	1
b. Fibrosis of the liver (if severe, see Cirrhosis)	1		1		1	1	1	1
Tuberculosis	Initiation	Continuation	Initiation	Continuation				
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).								
a. Nonpelvic	1	1	1	1	1*	1*	1*	1*
b. Pelvic	4	3	4	3	1*	1*	1*	1*
Malaria	1		1		1	1	1	1
Endocrine Conditions								
Diabetes								
Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk of adverse health events as a result of pregnancy (Box 2).								
a. History of gestational disease	1		1		1	1	1	1
b. Nonvascular disease								
i. Non-insulin dependent	1		2		2	2	2	2
ii. Insulin dependent	1		2		2	2	2	2
c. Nephropathy, retinopathy, or neuropathy	1		2		2	3	2	3/4*
d. Other vascular disease or diabetes of >20 years' duration	1		2		2	3	2	3/4*
Thyroid disorders								
a. Simple goiter	1		1		1	1	1	1
b. Hyperthyroid	1		1		1	1	1	1
c. Hypothyroid	1		1		1	1	1	1
Gastrointestinal Conditions								
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1		1		1	2	2	2/3*
Gallbladder disease								
a. Symptomatic								
i. Treated by cholecystectomy	1		2		2	2	2	2
ii. Medically treated	1		2		2	2	2	3
iii. Current	1		2		2	2	2	3
b. Asymptomatic	1		2		2	2	2	2
History of cholestasis								
a. Pregnancy related	1		1		1	1	1	2
b. Past COC related	1		2		2	2	2	3

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs	
Viral hepatitis								Initiation	Continuation
a. Acute or flare	1		1		1	1	1	3/4*	2
b. Carrier	1		1		1	1	1	1	1
c. Chronic	1		1		1	1	1	1	1
Cirrhosis									
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).									
a. Mild (compensated)	1		1		1	1	1	1	
b. Severe (decompensated)	1		3		3	3	3	4	
Liver tumors									
Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).									
a. Benign									
i. Focal nodular hyperplasia	1		2		2	2	2	2	
ii. Hepatocellular adenoma	1		3		3	3	3	4	
b. Malignant (hepatoma)	1		3		3	3	3	4	
Respiratory Conditions									
Cystic fibrosis	1*		1*		1*	2*	1*	1*	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).									
Anemias									
Thalassemia	2		1		1	1	1	1	
Sickle cell disease	2		1		1	1	1	2	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).									
Iron-deficiency anemia	2		1		1	1	1	1	
Solid Organ Transplantation									
Solid organ transplantation	Initiation	Continuation	Initiation	Continuation					
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).									
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	2	3	2	2	2	2	4	
b. Uncomplicated	2	2	2	2	2	2	2	2*	
Drug Interactions									
Antiretroviral therapy	Initiation	Continuation	Initiation	Continuation					
a. Nucleoside reverse transcriptase inhibitors (NRTIs)									
i. Abacavir (ABC)	1/2*	1*	1/2*	1*	1	1	1	1	
ii. Tenofovir (TDF)	1/2*	1*	1/2*	1*	1	1	1	1	
iii. Zidovudine (AZT)	1/2*	1*	1/2*	1*	1	1	1	1	
iv. Lamivudine (3TC)	1/2*	1*	1/2*	1*	1	1	1	1	
v. Didanosine (DDI)	1/2*	1*	1/2*	1*	1	1	1	1	
vi. Emtricitabine (FTC)	1/2*	1*	1/2*	1*	1	1	1	1	
vii. Stavudine (D4T)	1/2*	1*	1/2*	1*	1	1	1	1	
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)									
i. Efavirenz (EFV)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	
ii. Etravirine (ETR)	1/2*	1*	1/2*	1*	1	1	1	1	
iii. Nevirapine (NVP)	1/2*	1*	1/2*	1*	1	1	1	1	
iv. Rilpivirine (RPV)	1/2*	1*	1/2*	1*	1	1	1	1	
c. Ritonavir-boosted protease inhibitors									
i. Ritonavir-boosted atazanavir (ATV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	
ii. Ritonavir-boosted darunavir (DRV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	
iv. Ritonavir-boosted lopinavir (LPV/r)	1/2*	1*	1/2*	1*	1	1	1	1	
v. Ritonavir-boosted saquinavir (SQV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	
vi. Ritonavir-boosted tipranavir (TPV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*	

See table footnotes on page 103.

TABLE K1. (*Continued*) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
d. Protease inhibitors without ritonavir								
i. Atazanavir (ATV)	1/2*	1*	1/2*	1*	1	1	1	2*
ii. Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*	2*	2*	3*
iii. Indinavir (IDV)	1/2*	1*	1/2*	1*	1	1	1	1
iv. Nelfinavir (NFV)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
e. CCR5 co-receptor antagonists								
i. Maraviroc (MVC)	1/2*	1*	1/2*	1*	1	1	1	1
f. HIV integrase strand transfer inhibitors								
i. Raltegravir (RAL)	1/2*	1*	1/2*	1*	1	1	1	1
ii. Dolutegravir (DTG)	1/2*	1*	1/2*	1*	1	1	1	1
iii. Elvitegravir (EVG)	1/2*	1*	1/2*	1*	1	1	1	1
g. Fusion inhibitors								
i. Enfuvirtide	1/2*	1*	1/2*	1*	1	1	1	1
Anticonvulsant therapy								
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	1		1		2*	1*	3*	3*
b. Lamotrigine	1		1		1	1	1	3*
Antimicrobial therapy								
a. Broad-spectrum antibiotics	1		1		1	1	1	1
b. Antifungals	1		1		1	1	1	1
c. Antiparasitics	1		1		1	1	1	1
d. Rifampin or rifabutin therapy	1		1		2*	1*	3*	3*
Psychotropic medications								
a. SSRIs	1		1		1	1	1	1
St. John's wort	1		1		2	1	2	2

Abbreviations: BMI = body mass index; COC = combined oral contraceptive; Cu-IUD = copper-containing IUD; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus.; IUD = intrauterine device; LDL = low-density lipoprotein; LNG-IUD = levonorgestrel-releasing IUD; NA = not applicable; PE = pulmonary embolism; PID = pelvic inflammatory disease; POP = progestin-only pill; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease.
* Consult the appendix for this contraceptive method for a clarification to this classification.

References

1. The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown & Co; 1994.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR*'s free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Readers who have difficulty accessing this PDF file may access the HTML file at http://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm?s_cid=rr6503a1_w. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Executive Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to *mmwrq@cdc.gov.*

All material in the *MMWR* Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

ISSN: 1057-5987 (Print)

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 60 / No. 26

July 8, 2011

Drug Overdose Deaths — Florida, 2003–2009

In the United States in 2007, unintentional poisonings were the second leading cause of injury death (after motor-vehicle crashes) (*1*); approximately 93% of all unintentional poisoning deaths were caused by drug poisoning, also known as drug overdose (*2*). From 1990 to 2001 in Florida, the nonsuicidal poisoning death rate increased 325% (*3*). To characterize recent trends in drug overdose death rates in Florida, CDC analyzed data from the Florida Medical Examiners Commission. This report summarizes the results of that analysis, which found that, from 2003 to 2009, the number of annual deaths in which medical examiner testing showed lethal concentrations of one or more drugs increased 61.0%, from 1,804 to 2,905, and the death rate increased 47.5%, from 10.6 to 15.7 per 100,000 population. During 2003–2009, death rates increased for all substances except cocaine and heroin. The death rate for prescription drugs increased 84.2%, from 7.3 to 13.4 per 100,000 population. The greatest increase was observed in the death rate from oxycodone (264.6%), followed by alprazolam (233.8%) and methadone (79.2%). By 2009, the number of deaths involving prescription drugs was four times the number involving illicit drugs. These findings indicate the need to strengthen interventions aimed at reducing overdose deaths from prescription drugs in Florida. Medical examiner records are a timely, population-based source for data regarding overdose deaths from specific drugs. The data in this report and subsequent analyses can be used to design and measure the effectiveness of interventions.

Florida has a system of regional state medical examiners whose jurisdiction includes all drug-related deaths. Drug overdose data were obtained for the period 2003–2009 from datasets of the Florida Medical Examiners Commission, which contain information on 34 types of drugs frequently abused, including ethanol (grain or beverage alcohol), prescription drugs, and illicit drugs (*4*). Drug-related deaths are divided into two categories: 1) drug-caused deaths, for which postmortem medical examiner toxicology testing determined that drugs were present in lethal amounts; and 2) drug-present deaths, for which drugs were found in nonlethal amounts. This analysis included only drug-caused deaths, referred to in this report as drug overdose deaths.

Using U.S. Census resident population estimates, annual drug overdose death rates per 100,000 population were calculated for all drugs, prescription drugs, illicit drugs (including specifically heroin and cocaine), opioid analgesics (including specifically methadone, hydrocodone, oxycodone, and morphine), benzodiazepines (including specifically alprazolam), and ethanol. To test for the statistical significance of changes in death rates from 2003 to 2009, z-tests were conducted in categories with annual counts >100, and examination of overlapping confidence intervals from gamma distributions was used with counts <100.

During 2003–2009, a total of 16,550 drug overdose deaths were recorded by Florida medical examiners. The annual number of deaths increased 61.0%, from 1,804 to 2,905, and the death rate increased 47.5%, from 10.6 to 15.7 per 100,000 population. In 2009, approximately eight drug overdose deaths occurred each day. During 2003–2009, 85.9% of drug overdose deaths were unintentional, 11.1% were suicides, 2.6% were of undetermined intent, and 0.4% were homicides or pending. Prescription medications were implicated in 76.1%

INSIDE

873 Cephalosporin Susceptibility Among *Neisseria gonorrhoeae* Isolates — United States, 2000–2010
878 Update to CDC's *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period
884 Vital Signs: Colorectal Cancer Screening, Incidence, and Mortality — United States, 2002–2010
890 Notes from the Field: Botulism Caused by Consumption of Commercially Produced Potato Soups Stored Improperly — Ohio and Georgia, 2011
891 QuickStats

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

of all drug overdose deaths, and illicit drugs were implicated in 33.9% of deaths; in 10.0% of deaths, both prescription and illicit drugs were found in lethal concentrations.

In 85.5% of all drug overdose deaths, at least one of the seven specific drugs examined in this study was detected at a lethal concentration. Analysis of drug-specific death rates revealed different trends for different drugs during 2003–2009 (Table, Figure).

The death rate for prescription drugs increased 84.2%, from 7.3 to 13.4 per 100,000 population from 2003 to 2009. The greatest increase in death rate was observed for the prescription drug oxycodone (264.6%), followed by alprazolam (233.8%), methadone (79.2%), hydrocodone (34.9%), and morphine (26.2%). Conversely, the death rate for heroin decreased 62.2% from 2003 to 2009, and the death rate for cocaine increased until 2007 and then decreased 39.1% from 2007 to 2009 (Table).

In 2003, among the seven specific drugs examined, the highest death rate was for cocaine (3.2 per 100,000 population), followed by methadone (2.2), oxycodone (1.7), heroin (1.4), morphine and alprazolam (1.3), and hydrocodone (1.1). In 2009, the number of deaths involving prescription drugs was four times the number involving illicit drugs, and the highest death rate was for oxycodone (6.4 per 100,00 population), followed by alprazolam (4.4), methadone (3.9), cocaine (2.8), morphine (1.6), hydrocodone (1.4), and heroin (0.5) (Figure).

Reported by

Bruce Goldberger, PhD, W.R. Maples Center for Forensic Medicine, Univ of Florida College of Medicine. Jon Thogmartin, MD, State of Florida District Six Medical Examiner. Hal Johnson, MPH, Substance Abuse Program Office, Florida Dept of Children and Families. Leonard Paulozzi, MD, Rose Rudd, MSPH, Div of Unintentional Injury Prevention, National Center for Injury Prevention and Control; Aybaniz Ibrahimova, MD, EIS Officer, CDC. ***Corresponding contributor:*** *Leonard Paulozzi, lpaulozzi@cdc.gov.*

Editorial Note

This report documents an increasing problem with fatal overdoses of prescription drugs, based on Florida medical examiner data, which are more timely and specific than national data available from death certificates. Recent national data indicate increasing numbers of deaths involving opioid analgesics and cocaine through 2006 (*5*). This report indicates a worsening problem in Florida with overdoses involving prescription drugs, especially oxycodone and alprazolam, and a recent sharp decline in cocaine-related deaths. Large national increases in rates of emergency department visits involving oxycodone and alprazolam occurred during 2004–2009 (*6*).

Similar recent changes in drug-specific death counts have been reported by the Office of the State Medical Examiner in Kentucky. From 2007 to 2009, the number of deaths involving oxycodone in Kentucky doubled, the number

The *MMWR* series of publications is published by the Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

Suggested citation: Centers for Disease Control and Prevention. [Article title]. MMWR 2011;60:[inclusive page numbers].

Centers for Disease Control and Prevention

Thomas R. Frieden, MD, MPH, *Director*
Harold W. Jaffe, MD, MA, *Associate Director for Science*
James W. Stephens, PhD, *Director, Office of Science Quality*
Stephen B. Thacker, MD, MSc, *Deputy Director for Surveillance, Epidemiology, and Laboratory Services*
Stephanie Zaza, MD, MPH, *Director, Epidemiology and Analysis Program Office*

MMWR Editorial and Production Staff

Ronald L. Moolenaar, MD, MPH, *Editor,* MMWR *Series*
John S. Moran, MD, MPH, *Deputy Editor,* MMWR *Series*
Robert A. Gunn, MD, MPH, *Associate Editor,* MMWR *Series*
Teresa F. Rutledge, *Managing Editor,* MMWR *Series*
Douglas W. Weatherwax, *Lead Technical Writer-Editor*
Donald G. Meadows, MA, Jude C. Rutledge, *Writer-Editors*
Martha F. Boyd, *Lead Visual Information Specialist*
Malbea A. LaPete, Julia C. Martinroe,
Stephen R. Spriggs, Terraye M. Starr
Visual Information Specialists
Quang M. Doan, MBA, Phyllis H. King
Information Technology Specialists

MMWR Editorial Board

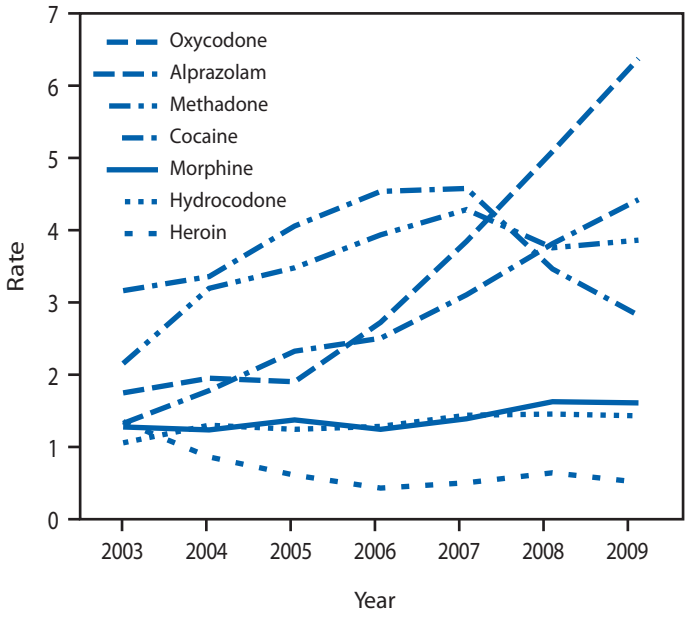
William L. Roper, MD, MPH, Chapel Hill, NC, Chairman
Virginia A. Caine, MD, Indianapolis, IN
Jonathan E. Fielding, MD, MPH, MBA, Los Angeles, CA
David W. Fleming, MD, Seattle, WA
William E. Halperin, MD, DrPH, MPH, Newark, NJ
King K. Holmes, MD, PhD, Seattle, WA
Deborah Holtzman, PhD, Atlanta, GA
John K. Iglehart, Bethesda, MD
Dennis G. Maki, MD, Madison, WI
Patricia Quinlisk, MD, MPH, Des Moines, IA
Patrick L. Remington, MD, MPH, Madison, WI
Barbara K. Rimer, DrPH, Chapel Hill, NC
John V. Rullan, MD, MPH, San Juan, PR
William Schaffner, MD, Nashville, TN
Anne Schuchat, MD, Atlanta, GA
Dixie E. Snider, MD, MPH, Atlanta, GA
John W. Ward, MD, Atlanta, GA

TABLE. Annual drug overdose death rates* for selected substances — Florida, 2003–2009

Substance	Year							% change 2003 to 2009§
	2003	2004	2005	2006	2007	2008	2009†	
Prescription drugs	**7.3**	**8.2**	**8.6**	**9.5**	**11.0**	**11.9**	**13.4**	**84.2**
Benzodiazepines	2.2	2.6	3.2	3.5	4.0	5.0	5.9	168.4
Alprazolam	1.3	1.8	2.3	2.5	3.1	3.8	4.4	233.8
Opioid analgesics	6.7	7.7	7.9	8.8	10.3	11.0	12.5	86.1
Oxycodone	1.7	2.0	1.9	2.7	3.8	5.1	6.4	264.6
Methadone	2.2	3.2	3.5	3.9	4.3	3.8	3.9	79.2
Hydrocodone	1.1	1.3	1.2	1.3	1.4	1.5	1.4	34.9
Morphine	1.3	1.2	1.4	1.2	1.4	1.6	1.6	26.2
Other prescription drugs¶	0.3	0.5	0.6	0.5	0.6	0.6	0.8	141.6
Illicit drugs	**4.3**	**4.4**	**4.9**	**5.1**	**5.1**	**4.1**	**3.4**	**-21.4**
Heroin	1.4	0.9	0.6	0.4	0.5	0.6	0.5	-62.2
Cocaine	3.2	3.4	4.1	4.5	4.6	3.5	2.8	-10.8
Other illicit drugs**	0.3	0.6	0.5	0.4	0.3	0.3	0.2	-4.1
Ethanol (alcohol)	**1.5**	**1.6**	**1.7**	**1.8**	**2.3**	**2.4**	**2.8**	**81.4**
All substances††	**10.6**	**11.7**	**12.1**	**13.1**	**14.3**	**14.6**	**15.7**	**47.5**

* Per 100,000 population. Based on U.S. Census resident population estimates. Available at http://www.census.gov/popest/states/states.html.
† The addition of buprenorphine, oxymorphone, and zolpidem to the list of monitored drugs resulted in small numbers of additional deaths in 2009, including 12 among all substances.
§ Except for cocaine ($p = 0.06$) and other illicit drugs ($p = 0.9$), all the changes from 2003 to 2009 were statistically significant ($p<0.05$). Percentage change might not match calculations based on table data because of rounding.
¶ Includes amphetamine, carisoprodol/meprobamate, ketamine, and zolpidem.
** Includes methamphetamine, inhalants, ecstasy, hallucinogens, and other illicit drugs.
†† Many deaths had several drugs contributing to the death; thus, the sum of the rates in each column exceeds the total death rate.

FIGURE. Annual drug overdose death rates* for selected prescription and illicit drugs — Florida, 2003–2009



* Per 100,000 population. Based on U.S. Census resident population estimates. Available at http://www.census.gov/popest/states/states.html.

involving alprazolam increased tenfold, and the numbers involving cocaine or methadone declined (*7*). Whether these specific trends with oxycodone and alprazolam are nationwide, regional, or indicative of common risk factors in Florida and Kentucky is unknown.

Since 2007, Florida has seen the proliferation of hundreds of pain clinics that prescribe large quantities of oxycodone and alprazolam, some of which is ultimately used for nonmedical purposes. Many of the customers of such clinics reportedly reside in Appalachian states such as Kentucky, and travel to Florida to obtain drugs for resale in their home states (*8*). In 2009, Florida passed legislation establishing standards for pain management clinics (*9*). The new legislation established more stringent licensure requirements, put a limit on the amount that could be prescribed when patients pay cash, and required tamper-resistant prescription forms. The impact of this legislation has not yet been determined. The dispensing of frequently abused prescription drugs, such as opioid analgesics and benzodiazepines, by pharmacies can be tracked using state prescription drug monitoring programs, now operational in 35 states (*10*). However, Florida does not yet have an operational prescription drug monitoring program.

The findings in this report are subject to at least five limitations. First, the analysis did not include all drug overdose deaths in Florida because the Florida Medical Examiners Commission collects data only on frequently abused drugs. Second, the death rates did not include Florida residents who died out of state but did include a small number of nonresidents who died in Florida. Third, reporting of deaths might have been incomplete from some medical examiner jurisdictions. Fourth, a few drugs were included in 2009 totals that were not tracked during 2003–2008. Finally, although the availability

What is already known on this topic?

In the United States in 2007, unintentional poisonings were the second leading cause of injury death. Approximately 93% of all unintentional poisoning deaths were caused by drug overdose. From 1990 to 2001 in Florida, the nonsuicidal poisoning death rate increased 325%.

What is added by this report?

The death rate from overdoses of prescription drugs in Florida increased 84.2% from 2003 to 2009, whereas the death rate from heroin overdose declined 62.2% and the death rate from cocaine overdose increased until 2007 and then declined 39.1% from 2007 to 2009. Among prescription drugs, the death rates for oxycodone and alprazolam increased 264.6% and 233.8%, respectively.

What are the implications for public health practice?

To address the increase in drug overdose deaths caused by prescription drugs, regulatory and public health agencies can implement surveillance systems that are able to count drug overdoses, describe patterns of drug use, and assess the impact of drug overdose prevention measures.

and scope of toxicologic testing were unchanged during 2003–2009, testing protocols among the nine laboratories in Florida providing the service are not standardized.

To address the increase in drug overdose deaths from prescription drugs, states need to implement surveillance systems that are able to track patterns of drug use and the impact of prevention measures. In addition, tighter regulation of pain clinics in all states might be necessary to prevent the migration of unethical clinics to jurisdictions without adequate regulation. Controls placed on wholesale distributors of frequently abused prescription drugs might prevent them from supplying unethical pain clinics. State and urban medical examiners can publish drug-specific overdose statistics to improve the timeliness of drug mortality surveillance.

References

1. CDC. Web-based Injury Statistics Query and Reporting System (WISQARS). Available at http://www.cdc.gov/injury/wisqars/index.html. Accessed June 30, 2011.
2. CDC. CDC Wide-Ranging Online Data for Epidemiologic Research (WONDER). Available at http://wonder.cdc.gov. Accessed June 30, 2011.
3. CDC. Unintentional and undetermined poisoning deaths—11 states, 1990–2001. MMWR 2004;53:233–8.
4. Florida Department of Law Enforcement. Drugs identified in deceased persons by Florida medical examiners. Tallahassee, FL: Florida Department of Law Enforcement; 2010. Available at http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/publications.aspx. Accessed June 30, 2011.
5. Warner M, Chen LH, Makuc DM. Increase in fatal poisonings involving opioid analgesics in the United States, 1999–2006. NCHS data brief No. 22. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2009. Available at http://www.cdc.gov/nchs/data/databriefs/db22.htm. Accessed July 6, 2011.
6. Office of Applied Studies, Substance Abuse and Mental Health Services Administration. The DAWN report: highlights of the 2009 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2010. Available at http://oas.samhsa.gov/2k10/dawn034/edhighlights.cfm. Accessed June 30, 2011.
7. Office of the Medical Examiner. 2009 calendar year annual report. Louisville, KY: Office of the Medical Examiner; 2010.
8. Satz MJ. Interim report of the Broward County Grand Jury: the proliferation of pain clinics in South Florida. Ft. Lauderdale, FL: Seventeenth Judicial Circuit; 2009. Available at http://sao17.state.fl.us/pill%20mill%20grand%20jury.pdf. Accessed June 30, 2011.
9. Florida Department of Health. Pain clinic registration. Tallahassee, FL: Florida Department of Health; 2011. Available at http://www.doh.state.fl.us/mqa/medical/me_pain.html. Accessed June 30, 2011.
10. Alliance of States with Prescription Monitoring Programs. About the Alliance. Available at http://www.pmpalliance.org/node/2. Accessed July 6, 2011.

Cephalosporin Susceptibility Among *Neisseria gonorrhoeae* Isolates — United States, 2000–2010

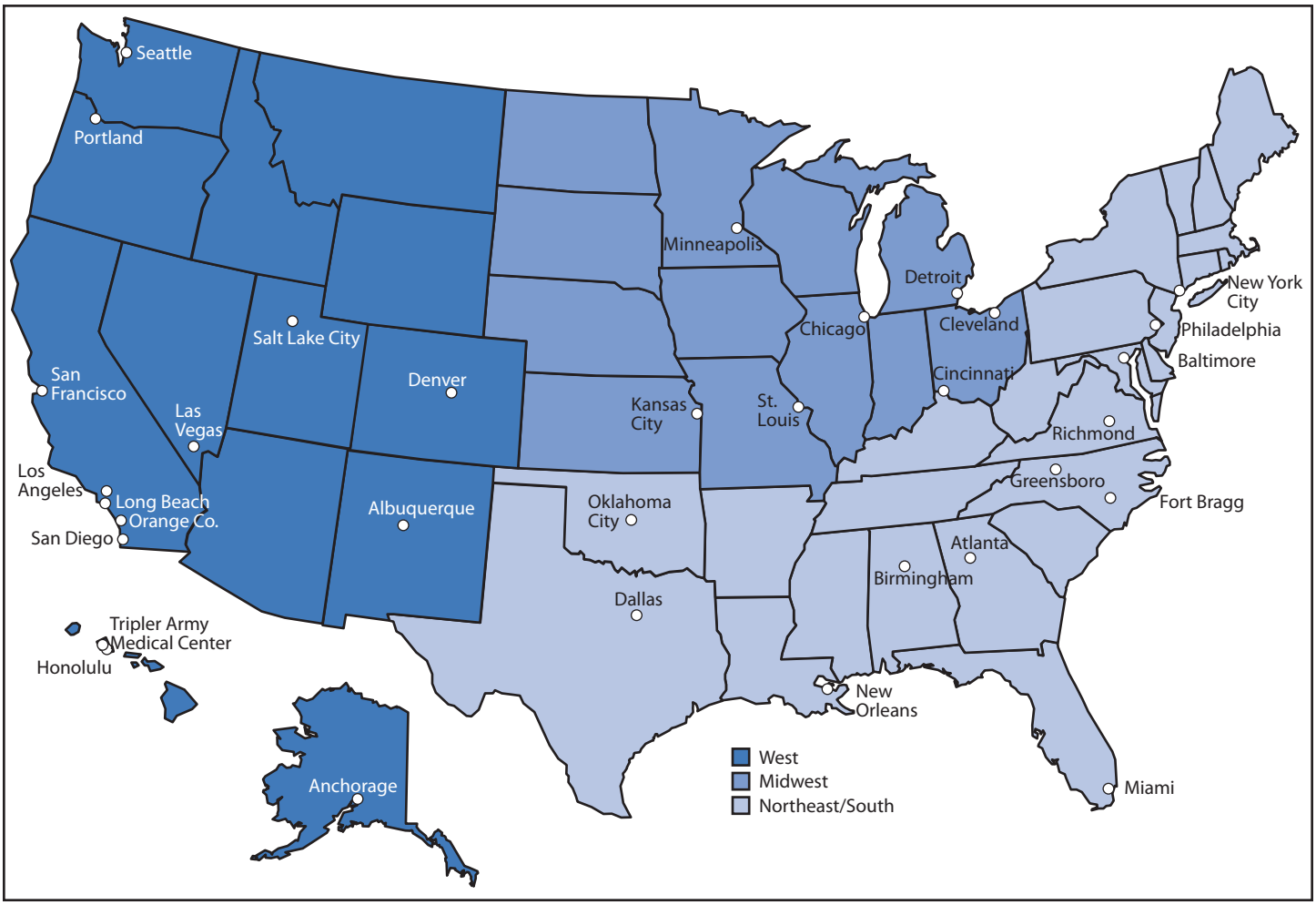
Neisseria gonorrhoeae is a major cause of pelvic inflammatory disease, ectopic pregnancy, and infertility, and it can facilitate human immunodeficiency virus (HIV) transmission (*1*). Emergence of gonococcal resistance to penicillin and tetracycline occurred during the 1970s and became widespread during the early 1980s. More recently, resistance to fluoroquinolones developed. Resistance was documented first in Asia, then emerged in the United States in Hawaii followed by other western states. It then became prevalent in all other regions of the United States. In Hawaii, fluoroquinolone resistance was first noted among heterosexuals; however, resistance in the United States initially became prevalent among men who have sex with men (MSM) before generalizing to heterosexuals. This emergence of resistance led CDC, in 2007, to discontinue recommending any fluoroquinolone regimens for the treatment of gonorrhea (*2–3*). CDC now recommends dual therapy for gonorrhea with a cephalosporin (ceftriaxone 250 mg) plus either azithromycin or doxycycline (*4*). This report summarizes trends in cephalosporin susceptibility among *N. gonorrhoeae* isolates in the United States during 2000–2010 using data from the Gonococcal Isolate Surveillance Project (GISP). During that period, the percentage of isolates with elevated minimum inhibitory concentrations (MICs) to cephalosporins (≥0.25 μg/mL for cefixime and ≥0.125 μg/mL for ceftriaxone) increased from 0.2% in 2000 to 1.4% in 2010 for cefixime and from 0.1% in 2000 to 0.3% in 2010 for ceftriaxone. Although cephalosporins remain an effective treatment for gonococcal infections, health-care providers should be vigilant for treatment failure and are requested to report its occurrence to state and local health departments. State and local public health departments should promote maintenance of laboratory capability to culture *N. gonorrhoeae* to allow testing of isolates for cephalosporin resistance. They also should develop enhanced surveillance and response protocols for gonorrhea treatment failures and report gonococcal treatment failures to CDC.

GISP is a CDC-sponsored, sentinel surveillance system that monitors antimicrobial susceptibilities in *N. gonorrhoeae* through ongoing testing of approximately 5,900 male urethral gonococcal isolates obtained annually from consecutive symptomatic men at 25–30 sexually transmitted disease (STD) clinics in the United States; approximately 4% of all reported gonorrhea cases among men are included annually (*5*). Antibiotic susceptibility is measured by MIC, the lowest concentration of an antibiotic that inhibits visible growth of the bacteria. MICs to cephalosporins (cefixime and ceftriaxone) among gonococcal isolates collected during 2000–2010 were analyzed. Cefixime susceptibilities were not determined during 2007–2008 because cefixime was unavailable in the United States during that period. Decreased antibiotic susceptibility for cefixime or ceftriaxone is defined by the Clinical and Laboratory Standards Institute (CLSI) as MICs ≥0.5 μg/mL; criteria for cefixime and ceftriaxone resistance in *N. gonorrhoeae* have not been defined (*6*). Because few isolates exhibited decreased susceptibility and increases in MICs can precede the emergence of resistance, the percentage of isolates with elevated MICs (≥0.25 μg/mL for cefixime and ≥0.125 μg/mL for ceftriaxone) was assessed to determine if MICs to cephalosporins were increasing with time. These breakpoints were used in GISP for surveillance purposes. The analyses were stratified by U.S. census region and sex of sex partner. The South and Northeast regions were combined because fewer samples are collected in the eastern half of the country compared with the western half (Figure 1). Sex of sex partner was categorized as MSM or men who have sex exclusively with women (MSW). Resistance to penicillin (MIC ≥2.0 μg/mL), tetracycline (MIC ≥2.0 μg/mL), and ciprofloxacin (MIC ≥1.0 μg/mL), a fluoroquinolone, were assessed. Cochran-Armitage trend tests were performed to assess statistical significance ($p<0.05$).

An average of 5,865 isolates (range: 5,367–6,552) were tested annually during 2000–2010. Overall, the percentage of isolates with cefixime MICs ≥0.25 μg/mL increased from 0.2% to 1.4% during 2000–2010 ($p<0.001$). The percentage of isolates with ceftriaxone MICs ≥0.125 μg/mL increased from 0.1% to 0.3% during 2000–2010 ($p = 0.047$). From 2000 to 2010, in the western region, the percentage of isolates with cefixime MICs ≥0.25 μg/mL increased from 0% to 3.3% ($p<0.001$), and the percentage of isolates with ceftriaxone MICs ≥0.125 μg/mL increased from 0% to 0.5% ($p<0.001$) (Table). In the western region, the most prominent increases in cefixime MICs were observed in Honolulu, Hawaii (0% in 2000 and 7.7% in 2010 [$p<0.001$]), and in California (0% in 2000 and 4.5% in 2010 [$p<0.001$]). An increase in ceftriaxone MICs also was observed in California (0% in 2000 and 0.6% in 2010 [$p = 0.001$]).

Among MSM, the percentage of isolates with cefixime MICs ≥0.25 μg/mL increased from 0% in 2000 to 4.0% during 2010 ($p<0.001$), and the percentage of isolates with ceftriaxone MICs ≥0.125 μg/mL increased from 0% to 0.9% ($p<0.001$). Overall, no statistically significant increases occurred in cefixime or ceftriaxone MICs among MSW (Figure 2). Regionally, increases in the percentage of isolates with cefixime MICs ≥0.25 μg/mL

FIGURE 1. Sentinel sites participating in the Gonococcal Isolate Surveillance Project — United States, 2000–2010*



* Sites had continuous participation during 2000–2010 with the following exceptions (and years of participation): Anchorage (2000–2003); Detroit (2003–2010); Fort Bragg (2000–2002); Greensboro (2002–2010); Kansas City (2000–2001 and 2007–2010); Los Angeles (2003–2010); Las Vegas (2002–2010); Long Beach (2000–2007); New York City (2006–2010); Oklahoma City (2003–2010); Richmond (2007–2010); Salt Lake City (2003); St. Louis (2000–2004); and Tripler Army Medical Center (2001–2006 and 2009–2010).

among MSM were observed in all regions during 2000–2010 (West: 0% in 2000 and 5.0% in 2010 [p<0.001]; Midwest: 0% in 2000 and 3.4% in 2010 [p = 0.001]; Northeast and South: 0% in 2000 and 0.9% in 2010 [p = 0.035]). A significant increase among MSW was identified in the West (0% in 2000 and 1.3% in 2010 [p<0.001]); however, no change occurred in the Midwest (0.3% in 2000 and 0.1% in 2010), and a significant decrease occurred in the Northeast and South (0.4% in 2000 and 0% in 2010 [p<0.001]). For isolates with ceftriaxone MICs ≥0.125 μg/mL, significant regional increases were observed among MSM in the West (0% in 2000 and 0.8% in 2010 [p<0.001]) and Midwest (0% in 2000 and 2.0% in 2010 [p = 0.046]) and among MSW in the West (0% in 2000 and 0.2% in 2010 [p = 0.008]); no significant increases were observed among MSM or MSW in other regions.

During 2009–2010, 13 (0.11%) of 11,323 isolates had decreased susceptibility to cefixime (MICs = 0.5 μg/mL), compared with seven (0.02%) of 41,462 isolates during 2000–2006 (p<0.001) (isolates were not tested for cefixime susceptibility during 2007–2008). All 2009–2010 isolates with decreased susceptibility to cefixime were resistant to tetracycline and ciprofloxacin, all but one were resistant to penicillin, and none exhibited decreased susceptibility to azithromycin (≥2 μg/mL). Twelve of the men from whom the isolates were obtained were MSM; 10 men resided in the West, and three in the Midwest. No isolates had decreased susceptibility to ceftriaxone during 2000–2010.

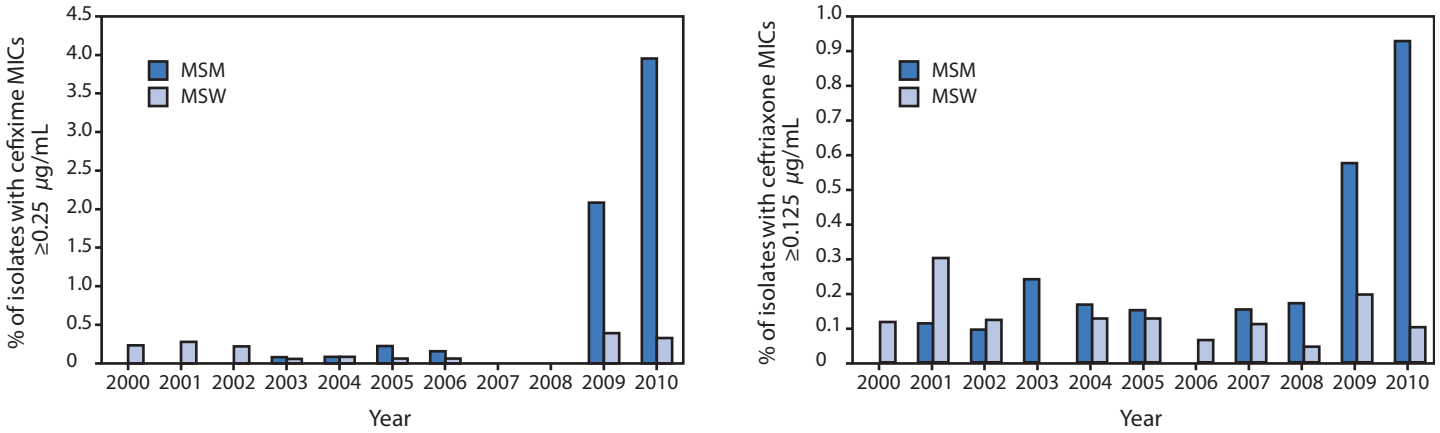
TABLE. Number and percentage of gonorrhea isolates with cefixime MICs ≥0.25 μg/mL and ceftriaxone MICs ≥0.125 μg/mL, by region — Gonococcal Isolate Surveillance Project, United States, 2000–2010

	Cefixime											
	West*			Midwest*			Northeast/South*			Total*		
Year	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested
2000	0	(0.0)	1,910	3	(0.2)	1,565	7	(0.4)	1,986	**10**	**(0.2)**	**5,461**
2001	4	(0.2)	2,066	1	(0.1)	1,561	7	(0.4)	1,845	**12**	**(0.2)**	**5,472**
2002	0	(0.0)	2,163	1	(0.1)	1,273	8	(0.4)	1,931	**9**	**(0.2)**	**5,367**
2003	1	(0.0)	2,558	0	(0.0)	1,628	3	(0.1)	2,366	**4**	**(0.1)**	**6,552**
2004	2	(0.1)	2,540	2	(0.1)	1,673	2	(0.1)	2,109	**6**	**(0.1)**	**6,322**
2005	5	(0.2)	2,551	0	(0.0)	1,409	1	(0.0)	2,239	**6**	**(0.1)**	**6,199**
2006	4	(0.2)	2,489	0	(0.0)	1,420	1	(0.0)	2,180	**5**	**(0.1)**	**6,089**
2007	—	—	—	—	—	—	—	—	—	—	—	—
2008	—	—	—	—	—	—	—	—	—	—	—	—
2009	37	(1.9)	1,924	7	(0.5)	1,398	1	(0.0)	2,308	**45**	**(0.8)**	**5,630**
2010	68	(3.3)	2,072	6	(0.5)	1,146	3	(0.1)	2,475	**77**	**(1.4)**	**5,693**

	Ceftriaxone											
	West*			Midwest			Northeast/South			Total*		
Year	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested	No.	(%)	No. of specimens tested
2000	0	(0.0)	1,910	5	(0.3)	1,565	0	(0.0)	1,986	**5**	**(0.1)**	**5,461**
2001	4	(0.2)	2,065	5	(0.3)	1,561	7	(0.4)	1,845	**16**	**(0.3)**	**5,471**
2002	0	(0.0)	2,163	1	(0.1)	1,273	6	(0.3)	1,931	**7**	**(0.1)**	**5,367**
2003	3	(0.1)	2,558	0	(0.0)	1,628	0	(0.0)	2,366	**3**	**(0.0)**	**6,552**
2004	3	(0.1)	2,540	3	(0.2)	1,673	3	(0.1)	2,109	**9**	**(0.1)**	**6,322**
2005	0	(0.0)	2,551	1	(0.1)	1,409	7	(0.3)	2,239	**8**	**(0.1)**	**6,199**
2006	1	(0.0)	2,489	0	(0.0)	1,420	2	(0.1)	2,180	**3**	**(0.0)**	**6,089**
2007	1	(0.0)	2,195	5	(0.4)	1,405	1	(0.0)	2,409	**7**	**(0.1)**	**6,009**
2008	4	(0.2)	1,906	0	(0.0)	1,407	0	(0.0)	2,410	**4**	**(0.1)**	**5,723**
2009	11	(0.6)	1,924	5	(0.4)	1,398	0	(0.0)	2,308	**16**	**(0.3)**	**5,630**
2010	11	(0.5)	2,072	4	(0.3)	1,146	4	(0.2)	2,475	**19**	**(0.3)**	**5,693**

Abbreviation: MICs = minimum inhibitory concentrations.
* Region had a statistically significant (p<0.05) trend (increase or decrease) during 2000–2010, by the Cochran-Armitage test for trend.

FIGURE 2. Percentage of gonorrhea isolates with cefixime MICs ≥0.25 μg/mL and ceftriaxone MICs ≥0.125 μg/mL, by sex of sex partner — Gonococcal Isolate Surveillance Project, United States, 2000–2010



Abbreviations: MICs = minimum inhibitory concentrations; MSM = men who have sex with men; MSW = men who have sex exclusively with women.

What is already known on this topic?

Cephalosporins are a critical component of CDC-recommended gonorrhea treatment; however, declining cephalosporin susceptibility and cephalosporin treatment failures have been reported in Asia and Europe.

What is added by this report?

This report describes current trends in cephalosporin susceptibility among *Neisseria gonorrhoeae* isolates in the United States: minimum inhibitory concentrations (MICs) to cephalosporins are increasing, suggesting that susceptibility to cephalosporins might be declining. The prevalence of isolates with elevated MICs remains low overall.

What are the implications for public health practice?

Health-care providers should use ceftriaxone and azithromycin for treatment of gonorrhea, remain vigilant for gonorrhea cephalosporin treatment failures, and report treatment failures to their local or state health departments. Local and state health departments should promote the maintenance of local gonococcal culture capacity, establish options for local gonococcal antibiotic susceptibility testing, consider enhancing surveillance for cephalosporin-resistant gonorrhea, and report gonorrhea cases with cephalosporin treatment failure to CDC.

Reported by

Carlos del Rio, MD, Rollins School of Public Health, Emory Univ, Atlanta, Georgia. Geraldine Hall, PhD, Dept of Clinical Pathology, Cleveland Clinic, Cleveland, Ohio. Edward W. Hook, Div of Infectious Disease, MD, Univ of Alabama at Birmingham. William L.H. Whittington, Dept of Medicine, Univ of Washington. Robert D. Kirkcaldy, MD, John R. Papp, PhD, Hillard Weinstock, MD, Div of STD Prevention, National Center for HIV, Hepatitis, STD, and TB Prevention; Erin L. Murray, PhD, EIS Officer, CDC. ***Corresponding contributor:*** *Robert D. Kirkcaldy, rkirkcaldy@cdc.gov, 404-639-8659.*

Editorial Note

The epidemiologic pattern of cephalosporin susceptibility in the West and among MSM during 2009–2010 is similar to that previously observed during the emergence of fluoroquinolone-resistant *N. gonorrhoeae* in the United States (*2–3,7*). Although the history of fluoroquinolone-resistant *N. gonorrhoeae* might not predict the patterns of decreasing cephalosporin susceptibility, the observed trends are concerning. During 2001–2010, decreased gonococcal susceptibility to cephalosporins and reported treatment failures have been documented in Asia (*8*). Recently, two cases of gonococcal treatment failure were reported from Norway among heterosexual men with gonococcal urethritis treated with cefixime (*9*), and a pharyngeal isolate with a ceftriaxone MIC = 2.0 μg/mL was identified from a female commercial sex worker in Japan (*10*).

The potential emergence of gonococcal cephalosporin resistance is of particular concern because the U.S. gonorrhea control strategy relies upon effective antibiotic therapy. Previously, the emergence and spread of gonococcal antibiotic resistance in the United States was addressed by changing the recommended antibiotics for treatment. No other well-studied and effective antibiotic treatment options or combinations currently are available. The emergence of gonococcal cephalosporin resistance would substantially limit available treatment options.

In light of the diminished resources available to STD control programs and the past inability to prevent emergence of resistance, the eventual emergence of cephalosporin resistance appears likely. Actions undertaken now could delay the spread of cephalosporin-resistant strains and mitigate the public health consequences. Effective treatment of gonorrhea is essential and now requires two antibiotics. The findings in this report suggest that gonococcal resistance to cefixime might emerge in the United States before resistance to ceftriaxone. Ceftriaxone is the most effective cephalosporin for treatment of gonorrhea and should be used for treatment of gonorrhea in combination with azithromycin or doxycycline (*4*). Azithromycin is preferred over doxycycline for dual therapy with ceftriaxone; of the 2009–2010 isolates with decreased susceptibility to cefixime, none exhibited decreased susceptibility to azithromycin, and all of them exhibited tetracycline resistance. Based on the findings in this report, CDC currently is recommending ceftriaxone 250 mg intramuscularly and azithromycin 1 g orally as the most effective treatment for uncomplicated gonorrhea.

In addition to effective treatment, prompt recognition of cephalosporin-resistant gonorrhea is critical. Although GISP has been successful in identifying important shifts in gonococcal epidemiology and antimicrobial susceptibility, its effectiveness should be complemented through partnerships with local health departments and health-care providers. Clinicians should remain vigilant for treatment failures (evidenced by persistent symptoms or a positive follow-up test despite treatment) among patients treated for gonorrhea with CDC-recommended antibiotics and obtain specimens for gonococcal culture from patients with possible treatment failure. Clinicians caring for patients with gonorrhea, particularly MSM in the western United States, might consider having patients return 1 week after treatment for test-of-cure with culture, preferably, or with nucleic acid amplification tests (NAATs).

If a patient experiences cefixime treatment failure, clinicians should re-treat the patient with 250 mg ceftriaxone intramuscularly and 2 g azithromycin orally (*4*). If a patient experiences a ceftriaxone treatment failure, clinicians should consult with an infectious disease expert and CDC regarding re-treatment. These patients should return for tests-of-cure

within 1 week, preferably with culture, or, if culture is not available, with NAAT. If the follow-up NAAT result is positive, a specimen for culture should be obtained. Clinicians also should ensure that the patient's sex partners from the preceding 2 months are tested for gonorrhea (preferably with culture) and empirically treated with ceftriaxone 250 mg intramuscularly and azithromycin 2 g orally. Finally, these treatment failures should be reported to the local or state health department within 24 hours. Laboratorians are requested to report gonococcal isolates with decreased cefixime or ceftriaxone susceptibility (≥0.5 μg/mL) to their local or state health departments within 24 hours of identification. Local and state health departments are requested to report these cases immediately to CDC (gispinfo@cdc.gov or 404-639-8659). Isolates can be submitted to CDC's Neisseria Reference Laboratory for confirmation susceptibility testing.*

Local and state health departments also should promote maintenance of local gonococcal culture capacity, despite the widespread use of NAATs. Gonococcal antibiotic susceptibility testing (AST), necessary for identification of resistant isolates, only can be performed with culture specimens. Health departments should establish options for local availability of gonococcal cultures and AST, and consider enhancing surveillance for cephalosporin-resistant gonorrhea. Options for local culture and AST availability might involve building or enhancing local gonorrhea reference laboratory testing capacity, partnering with regional clinical laboratories or academic institutions, or sending isolates to CDC for susceptibility testing. Enhanced surveillance might include monitoring of multiple cases from the same patient reported within 30–60 days, often discarded as presumed duplicates. Finally, effective alternative antibiotics or antibiotic combinations for the treatment of gonorrhea are needed urgently; thus, the development of novel antibiotics and clinical trials to study combinations of existing antibiotics is necessary.

The findings in this report are subject to at least two limitations. First, data available in GISP only include results from urethral gonococcal isolates from males attending publicly funded STD clinics. Second, the clinical significance of shifts in MICs below CLSI criteria for decreased susceptibility is unclear, and transient increases and decreases in cephalosporin MICs have been observed previously in GISP. However, in light of similar trends in other regions of the world, the patterns observed in GISP with higher MICs in isolates from the west and MSM, and the ability of *N. gonorrhoeae* to develop resistance, the increasing MICs to cephalosporins in the United States are concerning. Vigilance of clinicians and enhanced surveillance by local and state health departments will be critical for early detection of treatment failures.

*Instructions available at http://www.cdc.gov/std/gonorrhea/arg/specimen_shipping_instructions1-29-08.pdf.

Acknowledgments

Collaborating state and local health departments. Participating STD clinic and regional laboratory staff members. Alesia Harvey, Michael Grabenstein, Kevin Pettus, Samera Bowers, Gail Bolan, MD, Kimberly Workowski, MD, Div of STD Prevention, National Center for HIV, Hepatitis, STD, and TB Prevention, CDC.

References

1. Fleming D, Wasserheit J. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Trans Infect 1999;75:3–17.
2. CDC. Fluoroquinolone-resistance in *Neisseria gonorrhoeae*, Hawaii, 1999, and decreased susceptibility to azithromycin in *N. gonorrhoeae*, Missouri, 1999. MMWR 2000;49:833–7.
3. CDC. Update to CDC's sexually transmitted diseases treatment guidelines, 2006: fluoroquinolones no longer recommended for treatment of gonococcal infections. MMWR 2007;56:332–6.
4. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).
5. CDC. Sexually transmitted disease surveillance supplement 2007, Gonococcal isolate surveillance project annual report 2007. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at http://www.cdc.gov/std/gisp2007/gispsurvsupp2007short.pdf. Accessed June 28, 2011.
6. National Committee for Clinical Laboratory Standards. Approved standard M100-38 performance standards for antimicrobial susceptibility testing. Wayne, PA: National Committee for Clinical Laboratory Standards;1998.
7. Wang S, Harvey A, Conner S, et al. Antimicrobial resistance for *Neisseria gonorrhoeae* in the United States, 1988 to 2003: the spread of fluoroquinolone resistance. Ann Intern Med 2007;147:81–8.
8. Tapsall J. *Neisseria gonorrhoeae* and emerging resistance to extended spectrum cephalosporins. Curr Opin Infect Dis 2009;22:87–91.
9. Unemo M, Golparian D, Syversen G, et al. Two cases of verified clinical failures using internationally recommended first-line cefixime for gonorrhoeae treatment, Norway, 2010. Eurosurveillance 2010;15:19721–3.
10. Ohnishi M, Saika T, Hoshina S, et al. Ceftriaxone-resistant *Neisseria gonorrhoeae*, Japan. Emerg Infect Dis 2011;17:148–9.

Update to CDC's *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period

Initiation of contraception during the postpartum period is important to prevent unintended pregnancy and short birth intervals, which can lead to negative health outcomes for mother and infant (*1*). In 2010, CDC published *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (US MEC), providing evidence-based guidance for choosing a contraceptive method based on the relative safety of contraceptive methods for women with certain characteristics or medical conditions, including women who are postpartum (*2*). Recently, CDC assessed evidence regarding the safety of combined hormonal contraceptive use during the postpartum period. This report summarizes that assessment and the resulting updated guidance. These updated recommendations state that postpartum women should not use combined hormonal contraceptives during the first 21 days after delivery because of the high risk for venous thromboembolism (VTE) during this period. During 21–42 days postpartum, women without risk factors for VTE generally can initiate combined hormonal contraceptives, but women with risk factors for VTE (e.g., previous VTE or recent cesarean delivery) generally should not use these methods. After 42 days postpartum, no restrictions on the use of combined hormonal contraceptives based on postpartum status apply.

Importance of Contraception During the Postpartum Period

Half of all pregnancies in the United States are unintended, and these pregnancies have been associated with adverse pregnancy behaviors and outcomes, including later entry into prenatal care, decreased likelihood of smoking cessation, increased incidence of low birth weight, and decreased breastfeeding (*3*). In addition, short interpregnancy intervals can lead to negative consequences such as low birth weight and preterm birth (*4*). The postpartum period is an important time to initiate contraception because women are accessing the health-care system and might have increased motivation to avoid another pregnancy. Ovulation can occur as early as 25 days postpartum among nonbreastfeeding women, underscoring the importance of initiating contraception in the very early postpartum period (*5*).

However, safety of contraceptive use among postpartum women also must be considered. Hematologic changes that occur normally during pregnancy, including an increase in coagulation factors and fibrinogen and a decrease in natural anticoagulants, result in an increased risk for VTE during the postpartum period. In addition, many postpartum women have additional risk factors that further increase their risk for VTE, such as age ≥35 years, smoking, or recent cesarean delivery. This is of concern when considering postpartum contraception options because combined hormonal contraceptives (i.e., those that contain both estrogen and progestin) are themselves associated with a small increased risk for VTE among healthy women of reproductive age (*6*).

Rationale and Methods

US MEC, first published by CDC in 2010, was adapted from *Medical Eligibility Criteria for Contraceptive Use*, published by the World Health Organization (WHO) (*2*), which has been publishing global evidence-based contraceptive guidance since 1996. Although CDC adapted a small number of WHO recommendations and added a few new recommendations for U.S. health-care providers, the majority of the recommendations in the WHO guidance and US MEC are the same. Recommendations are provided using categories "1" to "4," based on the balance of benefits and harms signifying whether or not the contraceptive method is safe for use among women with a particular medical condition or characteristic; category 1 represents a method that is safe to use without restriction and category 4 represents an unacceptable health risk (Table 1). CDC is committed to ensuring that these recommendations remain up-to-date and based on the best available scientific evidence. An update can be triggered either by identification of new evidence or by any evidence-based updates made to the WHO global guidance.

In 2010, based on new evidence (*7*), WHO updated its guidance on the safety of combined hormonal contraceptives among postpartum nonbreastfeeding women to be more restrictive regarding the use of combined hormonal contraceptives during the first 42 days postpartum, particularly among women with other risk factors for VTE (*6*).

TABLE 1. Updated recommendations for combined hormonal contraceptives, including combined oral contraceptives, combined hormonal patch, and combined vaginal ring, during the postpartum period among nonbreastfeeding women

Condition	Category*	Clarifications/Evidence
Postpartum (nonbreastfeeding women)		
a. <21 days	4	**Evidence:** There is no direct evidence examining the risk for VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk for VTE in healthy reproductive age women, might pose an additional risk if used during this time. Risk for pregnancy during the first 21 days postpartum is very low, but increases after that point; ovulation before first menses is common.
b. 21–42 days		
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a "4"; for example, smoking, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, and peripartum cardiomyopathy. **Evidence:** There is no direct evidence examining the risk for VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk for VTE in healthy reproductive age women, might pose an additional risk if used during this time.
ii. Without other risk factors for VTE	2	
c. >42 days	1	

Abbreviations: VTE = venous thromboembolism; CHC = combined hormonal contraceptive; BMI = body mass index (weight [kg] / height [m^2]).
* Categories: 1 = a condition for which there is no restriction for the use of the contraceptive method, 2 = a condition for which the advantages of using the method generally outweigh the theoretical or proven risks, 3 = a condition for which the theoretical or proven risks usually outweigh the advantages of using the method, 4 = a condition that represents an unacceptable health risk if the contraceptive method is used.

Recommendations for breastfeeding women were not changed. Because of this WHO update, CDC initiated a process to assess whether its guidance similarly should be updated. Before this process, US MEC recommended that women less than 21 days postpartum generally should not use combined hormonal contraceptives, but that after that time, combined hormonal contraceptives could be used without restriction.

From a systematic review conducted by WHO and CDC and used in the consultation to update the WHO guidance, evidence from 13 studies showed that the risk for VTE among women within the first 42 days postpartum is 22-fold to 84-fold greater than the risk among nonpregnant, nonpostpartum reproductive age women (*7*). The risk is highest immediately after delivery, declining rapidly during the first 21 days, but not returning to baseline until 42 days postpartum in most studies. Use of combined hormonal contraceptives, which can cause a small increased risk for VTE in healthy reproductive age women, might theoretically pose an additional risk if used during this time. However, no evidence was identified regarding risk for VTE among postpartum women using combined hormonal contraceptives. The evidence also is limited by the small number of studies that report risk for VTE at precise intervals during the postpartum period and report baseline risk for VTE in a reference population for comparison with the risk among postpartum women. Evidence also was examined regarding the return to fertility among nonbreastfeeding postpartum women and indicated that ovulation can occur as early as 25 days postpartum, although fertile ovulation likely will not occur until at least 42 days postpartum (*5*).

As part of the CDC assessment, CDC recruited 13 persons from outside the agency to serve as ad hoc reviewers of the WHO revised recommendations; they were selected based on their expertise in thromboembolic disease, hematology, and family planning. The reviewers were asked to participate in a January 2011 teleconference with CDC, during which participants would review the evidence base and assess whether WHO's revised recommendations were suitable for use in the United States. A key issue identified was that immediate postpartum use of combined hormonal contraceptives would impose a high risk for VTE without any substantial benefit in pregnancy prevention because most nonlactating women will not have a fertile ovulation until at least 42 days postpartum (*5*). Women with risk factors for VTE in addition to being postpartum (e.g., obesity or cesarean delivery) are already at elevated risk for VTE; use of combined hormonal contraceptives theoretically would further compound that risk. Finally, access to contraceptive methods was a concern of the group; however, unlike methods that require a visit to

a provider (e.g., implants and intrauterine devices [IUDs]), combined hormonal contraceptives can be started by the woman herself at the appropriate time if given a prescription or sample in advance (either before hospital discharge or at a postpartum visit).

Recommendations for Use of Combined Hormonal Contraceptives During the Postpartum Period

CDC recommends the following updated guidelines for the safety of combined hormonal contraceptives in postpartum women who are not breastfeeding (Table 1). In women who are <21 days postpartum, use of combined hormonal contraceptives represents an unacceptable health risk and should not be used (category 4). In women who are 21–42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (category 2). In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives because of postpartum status (category 1). Nonetheless, any other medical conditions still should be taken into consideration when determining the safety of the contraceptive method.

Separate recommendations in the 2010 US MEC for combined hormonal contraceptive use among women who are breastfeeding remain unchanged (*2*). These recommendations are based on evidence regarding potential negative effects of hormonal contraceptive use on breastfeeding, such as decreased duration of breastfeeding and higher rates of supplemental feeding (*8*). Among women who are breastfeeding and are <1 month postpartum, combined hormonal contraceptives are given a category 3 because of concerns about the effects of estrogen on breastfeeding duration and success. After 1 month, combined hormonal contraceptive use is given a category 2 for breastfeeding women. However, some of the updated recommendations based on risk for VTE in postpartum women now supersede the breastfeeding recommendations. For example, combined hormonal contraception is now classified as a category 4 (unacceptable health risk) for all postpartum women, regardless of breastfeeding status, for the first 21 days (Table 2).

Health-care providers assessing a woman's individual risk also should consider any other characteristics or medical conditions that might impact the classification. For postpartum women, this might include examining the recommendations for other risk factors for VTE, such as known thrombogenic mutations (category 4) or history of VTE with risk factors for recurrence (category 4), both of which pose an unacceptable health risk for combined hormonal contraceptive use, whether or not women are postpartum (*2*).

Recommendations for Use of Other Contraceptive Methods During the Postpartum Period

Recommendations for use of other contraceptives, including progestin-only hormonal contraceptives, remain unchanged and many are good options for postpartum women (Table 3). Progestin-only hormonal methods, including progestin-only pills, depot medroxyprogesterone acetate injections, and implants, are safe for postpartum women, including women who are breastfeeding, and can be initiated immediately postpartum (categories 1 and 2). IUDs, including the levonorgestrel-releasing IUD and copper-bearing IUD, also can be inserted postpartum, including immediately after delivery (categories 1 and 2) and are not associated with an increase in complications. Although IUD expulsion rates are somewhat higher when insertion occurs within 28 days of delivery, continuation rates at 6 months are similar among women who receive an IUD postpartum and those who plan for delayed insertion (*9,10*). Condoms can be used anytime (category 1), and the diaphragm and cap should be started at 6 weeks postpartum (category 1 after 6 weeks). In addition, women who have completed their childbearing might wish to consider sterilization at this time. Postpartum contraception is important for the health of mother and infant, and education for both health-care providers and women should focus on the range of contraception options and the safety of most of these methods during the postpartum period.

TABLE 2. Updated recommendations for combined hormonal contraceptives, including combined oral contraceptives, combined hormonal patch, and combined vaginal ring, during the postpartum period among breastfeeding women

Condition	Category*	Clarifications/Evidence
Postpartum (breastfeeding women†)		**Clarification:** The U.S. Department of Health and Human Services recommends that infants should be exclusively breastfed during the first 4–6 months of life, preferably for a full 6 months. Ideally, breastfeeding should continue through the first year of life. **Evidence:** Clinical studies demonstrate conflicting results about effects on milk volume in women exposed to COCs during lactation; no consistent effect on infant weight has been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants. Theoretical concerns about effects of CHCs on breast milk production are greater in the early postpartum period when milk flow is being established.
a. <21 days	4	**Evidence:** There is no direct evidence examining the risk for VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk for VTE in healthy reproductive age women, might pose an additional risk if used during this time. Risk of pregnancy during the first 21 days postpartum is very low, but increases after that point; ovulation before first menses is common.
b. 21 to <30 days		
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a "4"; for example, smoking, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, and peripartum cardiomyopathy. **Evidence:** There is no direct evidence examining the risk for VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk for VTE in healthy reproductive age women, might pose an additional risk if used during this time.
ii. Without other risk factors for VTE	3	
c. 30–42 days		
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	**Clarification:** For women with other risk factors for VTE, these risk factors might increase the classification to a "4"; for example, smoking, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, and peripartum cardiomyopathy. **Evidence:** There is no direct evidence examining the risk for VTE among postpartum women using CHCs. VTE risk is elevated during pregnancy and postpartum; this risk is most pronounced in the first weeks after delivery, declining to near baseline levels by 42 days postpartum. Use of CHCs, which increases the risk for VTE in healthy reproductive age women, might pose an additional risk if used during this time.
ii. Without other risk factors for VTE	2	
d. >42 days	2	

Abbreviations: VTE = venous thromboembolism; CHC = combined hormonal contraceptive; BMI = body mass index (weight [kg] / height [m^2]); COC = combined oral contraceptives.

* Categories: 1 = a condition for which there is no restriction for the use of the contraceptive method, 2 = a condition for which the advantages of using the method generally outweigh the theoretical or proven risks, 3 = a condition for which the theoretical or proven risks usually outweigh the advantages of using the method, 4 = a condition that represents an unacceptable health risk if the contraceptive method is used.

† The breastfeeding recommendations are divided by month in *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*. They have been divided by days for purposes of integration with the postpartum recommendations.

TABLE 3. Summary of recommendations and risk classifications* for hormonal contraceptive methods and intrauterine devices during the postpartum period

Condition	COC/P/R	POP	DMPA	Implants	LNG-IUD	Cu-IUD
Postpartum (nonbreastfeeding women)						
a. <21 days	4	1	1	1		
b. 21 days to 42 days						
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, postcesarean delivery, preeclampsia or smoking)	3†	1	1	1		
ii. Without other risk factors for VTE	2	1	1	1		
c. >42 days	1	1	1	1		
Postpartum (breastfeeding women§)						
a. <21 days	4	2	2	2		
b. 21 to <30 days						
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia or smoking)	3†	2	2	2		
ii. Without other risk factors for VTE	3	2	2	2		
c. 30–42 days						
i. With other risk factors for VTE (such as age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥30, postpartum hemorrhage, postcesarean delivery, preeclampsia or smoking)	3†	1	1	1		
ii. Without other risk factors for VTE	2	1	1	1		
d. >42 days	2	1	1	1		
Postpartum (breastfeeding or nonbreastfeeding women, including postcesarean delivery)						
a. <10 min after delivery of the placenta					2	1
b. 10 min after delivery of the placenta to <4 wks					2	2
c. ≥4 wks					1	1
d. Puerperal sepsis					4	4

Abbreviations: COC = combined oral contraceptives; P = combined hormonal patch; R = combined vaginal ring; POP = progestin-only pill; DMPA = depot medroxyprogesterone acetate; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing IUD; Cu-IUD = copper-bearing IUD; VTE = venous thromboembolism; CHC = combined hormonal contraceptive; BMI = body mass index (weight [kg] / height [m^2]).

* Categories: 1 = a condition for which there is no restriction for the use of the contraceptive method, 2 = a condition for which the advantages of using the method generally outweigh the theoretical or proven risks, 3 = a condition for which the theoretical or proven risks usually outweigh the advantages of using the method, 4 = a condition that represents an unacceptable health risk if the contraceptive method is used.

† Clarification: For women with other risk factors for VTE, these risk factors might increase the classification to a "4"; for example, smoking, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, and peripartum cardiomyopathy.

§ The breastfeeding recommendations are divided by month in *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*. They have been divided by days for purposes of integration with the postpartum recommendations.

Reported by

Naomi K. Tepper, MD, Kathryn M. Curtis, PhD, Denise J. Jamieson, MD, Polly A. Marchbanks, PhD, Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. ***Corresponding contributor:*** *Naomi K. Tepper, ntepper@cdc.gov, 770-488-6506.*

Acknowledgments

Ad hoc reviewers: David Eisenberg, MD, Washington Univ and Planned Parenthood of the St. Louis Region and Southwest Missouri, St. Louis, Missouri. Alisa Goldberg, MD, Brigham and Women's Hospital, Boston, Massachusetts. Michael Policar, MD, Univ of California, San Francisco; Emily Jackson, MD, Los Angeles, California. Andra James, MD, Duke Univ, Durham, North Carolina. Andrew Kaunitz, MD, Univ of Florida, Jacksonville, Florida. Barbara Konkle, MD, Puget Sound Blood Center, Seattle, Washington. Hal Lawrence, MD, Mary Mitchell, American College of Obstetricians and Gynecologists, Washington, DC. Charles Lockwood, MD, Yale Univ, New Haven, Connecticut. Susan Moskosky, MS, US Dept of Health and Human Svcs, Rockville, Maryland. Deborah Nucatola, MD, Planned Parenthood Federation of America, New York; Carolyn Westhoff, MD, Columbia Univ, New York, New York. Additional reviewers: Emily Godfrey, MD, Herbert Peterson, MD, Univ of North Carolina, Chapel Hill, North Carolina. Maria Steenland, MPH, National Center for Chronic Disease Prevention and Health Promotion, CDC.

References

1. CDC. Contraceptive use among postpartum women—12 states and New York City, 2004–2006. MMWR 2009;58:821–6.
2. CDC. U.S. medical eligibility criteria for contraceptive use, 2010: adapted from the World Health Organization medical eligibility criteria for contraceptive use, 4th edition. MMWR 2010;59(No. RR-4).
3. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. Stud Family Plann 2008;39:18–38.
4. Zhu BP. Effect of interpregnancy interval on birth outcomes: findings from three recent US studies. Int J Gynecol Obstet 2005;89(Suppl 1):S25–33.
5. Jackson E, Glasier A. Return of ovulation and menses in postpartum, non-lactating women: a systematic review. Obstet Gynecol 2011;117:657–62.
6. World Health Organization. Combined hormonal contraceptive use during the postpartum period. Geneva, Switzerland: World Health Organization; 2010. Available at http://www.who.int/reproductivehealth/publications/family_planning/rhr_10_15/en/index.html. Accessed June 30, 2011.
7. Jackson E, Curtis K, Gaffield M. Risk of venous thromboembolism during the postpartum period: a systematic review. Obstet Gynecol 2011;117:691–703.
8. Kapp N, Curtis KM. Combined oral contraceptive use among breastfeeding women: a systematic review. Contraception 2010;82:10–6.
9. Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review. Contraception 2009;80:327–36.
10. Chen BA, Reeves MF, Hayes JL, Hohmann HL, Perriera LK, Creinin MD. Postplacental or delayed insertion of the levonorgestrel intrauterine device after vaginal delivery: a randomized controlled trial. Obstet Gynecol 2010;116:1079–87.

Vital Signs: Colorectal Cancer Screening, Incidence, and Mortality — United States, 2002–2010

On July 5, this report was posted as an MMWR *Early Release on the* MMWR *website (http://www.cdc.gov/mmwr).*

Abstract

Background: Screening lowers colorectal cancer (CRC) incidence and mortality. CRC is preventable through the removal of premalignant polyps and is curable if diagnosed early. Increased CRC screening and reduced CRC incidence and mortality are among the *Healthy People 2020* objectives.

Methods: CRC screening data are reported using information from 2002–2010 Behavioral Risk Factor Surveillance System surveys. State-specific CRC incidence and mortality data were drawn from the United States Cancer Statistics. Annual percentage changes (APCs) in incidence and death rates from 2003 to 2007 were calculated by state.

Results: From 2002 to 2010, the percentage of persons aged 50–75 years who were adequately screened for colorectal cancer increased from 52.3% to 65.4%. In 2007, CRC incidence ranged from 34.3 per 100,000 population in Utah to 56.9 in North Dakota; death rates ranged from 12.3 per 100,000 in Utah to 21.1 in the District of Columbia (DC). From 2003 to 2007, CRC incidence declined significantly in 35 states, and mortality declined in 49 states and DC, with APCs ranging from 1.0% per year in Alabama to 6.3% per year in Rhode Island.

Conclusions: CRC incidence and mortality have declined in recent years throughout the United States, and CRC screening has increased.

Implications for Public Health Practice: Continued declines in incidence and mortality are expected as past and current public health emphasis on the importance of CRC screening become evident with the increase in screening. To ensure these gains continue, CRC screening should be accessible and used as recommended by all eligible persons in the United States.

Introduction

Colorectal cancer (CRC) is the second most commonly diagnosed cancer and the second leading cause of cancer mortality in the United States among cancers that affect both men and women (*1*). Strong evidence indicates that screening for CRC reduces the incidence of and mortality from the disease (*2*). Screening tests for CRC, including fecal occult blood testing (FOBT), sigmoidoscopy, and colonoscopy, used at appropriate intervals, reduce incidence and mortality through prevention (identification and removal of premalignant polyps) and early detection (*2*). Since 1996, the United States Preventive Services Task Force (USPSTF) and other organizations have recommended CRC screening for persons aged ≥50 years. In 2008, updated guidelines from USPSTF recommended that routine screening continue only until age 75 years, based on review of the risks and benefits of screening (*2*). Despite the evidence linking CRC screening to lower incidence and mortality, a significant number of age-eligible persons in the United States have not received potentially life-saving screening.

Healthy People 2020 (HP 2020) objectives call for reducing the incidence of CRC to 38.6 per 100,000 population, reducing the death rate to 14.5 per 100,000 population, and increasing the prevalence of CRC screening to 70.5% (*3*). This report updates CRC screening prevalence data with data from the 2010 Behavioral Risk Factor Surveillance System (BRFSS) survey and presents state-specific data for CRC incidence and death rates for 2007 and annual percentage changes from 2003 to 2007.

Methods

BRFSS is a state-based, random–digit-dialed telephone survey of the civilian, noninstitutionalized adult population that collects information on health risk behaviors, preventive health practices, and health-care access in the United States (*4*). Survey data were available for all 50 states (except for Hawaii in 2004) and the District of Columbia (DC). For 2010, the median Council of American Survey and Research Organizations (CASRO) response rate for BRFSS was 54.6%, and the median cooperation rate was 76.9% (*4*).

During 2002–2010, every 2 years, respondents aged ≥50 years were asked whether they have ever used a "special kit at home to determine whether the stool contains blood (fecal occult blood test [FOBT])," whether they have ever had a "tube

inserted into the rectum to view the colon for signs of cancer or other health problems (sigmoidoscopy or colonoscopy)," and when these tests were last performed. CDC calculated the percentage of adults who reported having had an FOBT within the past year or lower endoscopy (i.e., sigmoidoscopy or colonoscopy) within the preceding 10 years, enabling comparison with previous reports (*5*). This analysis is restricted to persons aged 50–75 years, in accordance with the USPSTF recommended age range for screening (*2*). Respondents who refused to answer, had a missing answer, or who answered "don't know/not sure" were excluded from the analysis. Data were weighted to the age, sex, and racial/ethnic distribution of each state's adult population using intercensal estimates and were age-standardized to the 2010 BRFSS population.

United States Cancer Statistics (USCS) (*1*) provides official federal statistics on cancer incidence (newly diagnosed cases) and cancer deaths in each state, using data from the National Program of Cancer Registries (NPCR) and/or the Surveillance, Epidemiology, and End Results (SEER) Program and from the National Vital Statistics System. In 2007, the most recent year for which incidence data were available, 49 states and DC met USCS data criteria representing 99.2% of the U.S. population. Incidence trend analyses included new cases of colorectal cancer diagnosed during 2003–2007 from NPCR/SEER registries that met USCS criteria for every year of the study period; 48 states and DC, representing 97.2% of the U.S. population, were included. Incident colorectal cancers were coded according to the *International Classification of Disease for Oncology, Third Edition* (ICD-O-3).

Cancer mortality statistics are based on information from all death certificates filed in the 50 states and DC and therefore cover 100% of the U.S. population. All reported deaths with CRC identified as the underlying cause of death according to the *International Classification of Diseases, Tenth Revision* (ICD-10) during 2003–2007 were included in this analysis. For trends in incidence and mortality, annual percentage changes (APCs) are reported, using the weighted least squares method and the joinpoint regression program. Population estimates for the denominators of incidence and death rates were from the U.S. Census, as modified by SEER (*1*). Data were age-adjusted to the 2000 U.S. standard population by the direct method; corresponding 95% confidence limits (CLs) were calculated as modified gamma intervals (*6*). Rates and APCs are shown for all races/ethnicities, and all age groups combined for each state.

Results

The 2010 BRFSS survey was administered to 236,186 persons aged 50–75 years. In this population, the overall age-adjusted combined CRC screening (FOBT and lower endoscopy) increased from 52.3% in 2002 to 65.4% in 2010 (Table, Figure 1). From 2002 to 2010, FOBT use declined from 21.1% to 11.8%.

During 2003–2007, a total of 722,542 CRC cases were reported in the United States. Overall age-adjusted CRC incidence rates decreased from 52.3 per 100,000 in 2003 to 45.5 per 100,000 in 2007 (an APC of 3.4% per year), representing 65,994 fewer new cases of cancer than expected during this period (2003–2007) compared with 2002. In 2007, North Dakota reported the highest CRC incidence (56.9 per 100,000) and Utah reported the lowest (34.3) (Figure 2). CRC incidence rates decreased significantly in 35 states from 2003 to 2007, with Maryland reporting the largest percentage decrease in CRC incidence (6.5% per year) (Table).

During 2003–2007, a total of 268,783 CRC deaths were reported in the United States. The overall age-adjusted CRC death rate decreased from 19.0 per 100,000 in 2003 to 16.7 per 100,000 in 2007 (an APC of 3.0% per year), representing 31,800 fewer deaths than expected during this period (2003–2007) compared with 2002. In 2007, DC reported the highest CRC mortality (21.1 per 100,000), and Colorado and Montana reported the lowest (14.1 per 100,000) (Figure 2). CRC mortality rates decreased significantly in 49 states and DC from 2003-2007, with Rhode Island reporting the largest decrease in CRC mortality (6.3% per year).

Conclusion and Comments

CRC incidence decreased by 3.4% per year, and the CRC death rate decreased by 3.0% per year from 2003 to 2007 in the United States. These decreases in CRC incidence and mortality represent approximately 66,000 fewer new cases and 32,000 fewer deaths than expected from 2003 to 2007, compared with 2002. A total of 35 states had significant decreases in CRC incidence. Forty-nine states and DC experienced a statistically significant decrease in CRC mortality, with the largest declines occurring in states with some of the highest screening prevalence. Approximately 50% of the improvement in mortality can be attributed to increased screening, with 35% attributed to reductions in risk factors such as smoking and obesity, and 12% to improved CRC treatment (*7*). For incidence, CRC screening and changes in risk factors each accounted for 50% of the decline (*7*).

The decreases in CRC incidence and mortality from 2003 to 2007 were part of a larger U.S. trend from 1975 to 2007 (Figure 3). According to SEER statistics, beginning in 1975, CRC incidence increased from 59.5 per 100,000 population to 66.3 in 1985, before declining steadily to 44.7 in 2007. The CRC death rate declined from 28.6 in 1976 to 16.7 in 2007 (http://seer.cancer.gov/csr/1975_2007/index.html). However, CRC incidence and death rates overall remained above the

TABLE. Annual percentage change (APC)* in colorectal cancer death and incidence† rates from 2003 to 2007, and percentage of respondents aged 50–75 years with up-to-date screening in 2010, by state/area — United States

	Mortality		Incidence		Screening§	
State/Area	APC 2003 to 2007	(95% CL)	APC 2003 to 2007	(95% CL)	%	(95% CL)
United States	**-3.0**	**(-4.2, -1.7)**	**-3.4**	**(-3.7, -3.2)**	**65.4**	**(65.0, 65.8)**
Alabama	-1.0	(-1.3, -0.7)	-0.7¶	(-2.2, 0.8)	63.4	(61.3, 65.4)
Alaska	-1.5	(-2.3, -0.8)	-6.2¶	(-17.0, 6.1)	59.3	(55.0, 63.5)
Arizona	-2.0	(-2.3, -1.6)	-6.3	(-9.0, -3.4)	63.4	(60.5, 66.3)
Arkansas	-3.0	(-4.4, -1.7)	-3.0	(-5.3, -0.6)	59.4	(56.8, 62.0)
California	-2.2	(-2.3, -2.1)	-1.9	(-3.4, -0.4)	64.1	(62.7, 65.5)
Colorado	-4.6	(-8.6, -0.4)	-3.9	(-7.4, -0.4)	66.0	(64.5, 67.5)
Connecticut	-5.1	(-6.3, -3.8)	-4.7	(-7.5, -1.8)	75.6	(73.6, 77.4)
Delaware	-2.1	(-2.4, -1.7)	-1.7¶	(-6.4, 3.3)	71.0	(68.5, 73.3)
District of Columbia	-1.6	(-1.9, -1.2)	-5.1¶	(-13.6, 4.1)	70.7	(68.2, 73.2)
Florida	-2.9	(-3.5, -2.2)	-4.5	(-5.7, -3.3)	67.3	(65.7, 68.9)
Georgia	-3.1	(-4.1, -2.1)	-2.7	(-5.1, -0.3)	67.4	(65.2, 69.4)
Hawaii	-1.5	(-1.8, -1.1)	-2.9¶	(-6.1, 0.4)	62.0	(59.8, 64.2)
Idaho	-1.9	(-2.4, -1.4)	-3.6	(-6.3, -0.8)	57.0	(55.0, 58.9)
Illinois	-2.1	(-2.4, -1.9)	-2.4	(-4.0, -0.7)	59.4	(57.0, 61.7)
Indiana	-3.6	(-5.4, -1.8)	-3.6	(-4.8, -2.4)	61.8	(60.1, 63.6)
Iowa	-2.8	(-3.6, -1.9)	-3.0	(-5.1, -0.9)	63.8	(61.8, 65.7)
Kansas	-1.7	(-2.0, -1.4)	-3.6	(-6.4, -0.7)	63.7	(62.1, 65.3)
Kentucky	-1.6	(-2.0, -1.3)	-2.5	(-3.5, -1.5)	62.4	(60.2, 64.5)
Louisiana	-4.5	(-6.6, -2.3)	-2.2	(-4.1, -0.3)	60.8	(58.9, 62.6)
Maine	-2.5	(-2.9, -2.2)	-4.0	(-6.6, -1.4)	73.7	(72.1, 75.2)
Maryland	-3.1	(-3.6, -2.7)	-6.5	(-9.0, -4.0)	72.6	(70.8, 74.3)
Massachusetts	-5.3	(-7.0, -3.5)	-6.0	(-7.4, -4.7)	75.8	(74.4, 77.2)
Michigan	-2.4	(-2.6, -2.1)	-3.5	(-5.6, -1.5)	70.1	(68.5, 71.6)
Minnesota	-2.4	(-2.9, -2.0)	-2.4	(-4.0, -0.7)	70.7	(68.7, 72.5)
Mississippi	-0.1¶	(-0.4, 0.1)	-2.1¶	(-4.4, 0.3)	58.2	(56.3, 60.0)
Missouri	-3.6	(-5.2, -2.0)	-2.7¶	(-5.5, 0.1)	63.5	(61.0, 66.0)
Montana	-1.6	(-2.0, -1.3)	-2.2	(-4.3, 0.0)	58.7	(56.8, 60.7)
Nebraska	-1.5	(-1.7, -1.3)	-1.0¶	(-4.7, 2.9)	60.4	(58.6, 62.1)
Nevada	-1.1	(-1.5, -0.8)	NS	NS	57.7	(54.4, 61.0)
New Hampshire	-2.3	(-2.7, -2.0)	-4.6	(-8.5, -0.5)	75.7	(73.9, 77.4)
New Jersey	-2.8	(-3.0, -2.5)	-4.0	(-6.3, -1.7)	65.5	(63.8, 67.2)
New Mexico	-1.2	(-1.5, -0.9)	-3.6	(-6.4, -0.7)	60.1	(58.2, 62.1)
New York	-4.7	(-5.7, -3.7)	-3.8	(-5.5, -2.2)	70.1	(68.4, 71.7)
North Carolina	-2.2	(-2.7, -1.8)	-2.4¶	(-5.9, 1.1)	68.9	(67.2, 70.5)
North Dakota	-2.3	(-3.2, -1.5)	-1.4¶	(-7.5, 5.1)	58.4	(56.3, 60.5)
Ohio	-2.1	(-2.3, -1.9)	-2.7	(-4.5, -0.9)	63.4	(61.7, 65.1)
Oklahoma	-1.0	(-1.2, -0.8)	-1.4	(-2.4, -0.4)	54.9	(53.1, 56.6)
Oregon	-1.6	(-1.9, -1.4)	-4.3	(-6.1, -2.5)	64.8	(62.7, 66.8)
Pennsylvania	-3.4	(-4.2, -2.6)	-2.8	(-3.9, -1.7)	67.0	(65.4, 68.6)
Rhode Island	-6.3	(-10.3, -2.2)	-1.9¶	(-5.4, 1.7)	74.7	(72.8, 76.4)
South Carolina	-1.9	(-2.5, -1.4)	-5.6	(-7.5, -3.6)	65.1	(63.0, 67.2)
South Dakota	-4.3	(-7.1, -1.5)	-3.4¶	(-8.0, 1.5)	64.4	(62.4, 66.4)
Tennessee	-1.4	(-1.8, -1.1)	NS	NS	61.2	(58.8, 63.6)
Texas	-2.5	(-2.9, -2.2)	-2.9	(-3.8, -1.9)	59.9	(57.9, 61.7)
Utah	-4.4	(-7.1, -1.7)	-4.8	(-8.1, -1.4)	67.5	(65.8, 69.1)
Vermont	-2.2	(-2.7, -1.7)	-3.3¶	(-9.8, 3.6)	71.7	(70.0, 73.3)
Virginia	-3.8	(-5.2, -2.4)	-4.5	(-6.0, -2.9)	68.1	(65.6, 70.6)
Washington	-3.6	(-5.3, -1.8)	-4.5	(-7.0, -1.9)	72.4	(71.3, 73.4)
West Virginia	-3.1	(-5.4, -0.7)	-4.2	(-6.6, -1.7)	54.7	(52.3, 57.0)
Wisconsin	-4.4	(-6.2, -2.6)	-6.0	(-10.2, -1.6)	68.9	(66.6, 71.2)
Wyoming	-3.3	(-5.0, -1.6)	-2.8¶	(-11.0, 6.2)	57.6	(55.7, 59.5)

Abbreviation: CL = confidence limits; NS = not shown; state did not meet United States Cancer Statistics (USCS) publication criteria for 2003–2007.

Sources: Mortality data are provided by the National Vital Statistics System, covering 100% of the U.S. population.

Cancer incidence combines cancer registry data from the National Program of Cancer Registries and the Surveillance, Epidemiology and End Results Program that met USCS publication criteria for 2003–2007, covering 97.2% of the U.S. population. Additional information available at http://www.cdc.gov/uscs.

Colorectal cancer screening data are from the 2010 Behavioral Risk Factor Surveillance System (BRFSS) survey. Available at http://www.cdc.gov/brfss.

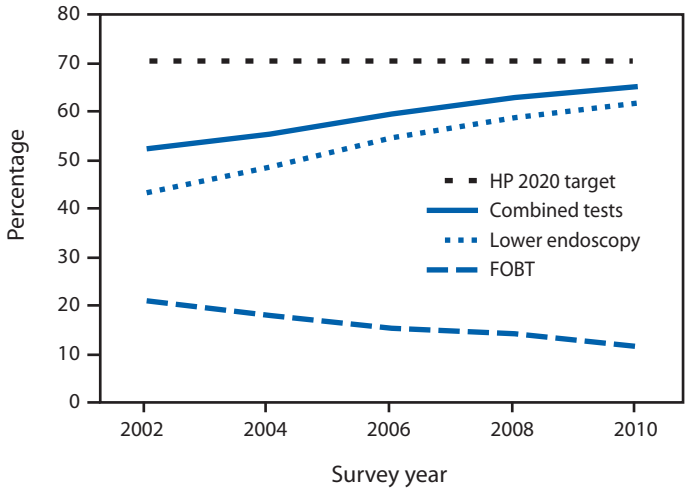
* Calculated using weighted least squares method and joinpoint regression modeling.

† Per 100,000 population, age-adjusted to the 2000 U.S. standard population.

§ Percentage of persons aged 50–75 years who reported receiving a fecal occult blood test within 1 year or a lower endoscopy (i.e., sigmoidoscopy or colonoscopy) within 10 years; age-standardized to the 2010 BRFSS population aged 50–75 years.

¶ The APC was not significantly different from zero ($p \geq 0.05$).

FIGURE 1. Percentage of respondents aged 50–75 years who reported receiving a fecal occult blood test (FOBT) within 1 year and/or a lower endoscopy* within 10 years and *Healthy People 2020* (HP 2020) target — Behavioral Risk Factor Surveillance System (BRFSS) surveys, United States, 2002, 2004, 2006, 2008, and 2010†



* Sigmoidoscopy or colonoscopy.
† Age-standardized to the population aged 50–75 years in the 2010 BRFSS survey.

HP 2020 targets of 38.6 per 100,000 and 14.5 per 100,000, respectively (Figure 3).

The prevalence of being up-to-date with CRC screening improved with 65.4% reporting being screened at recommended intervals (*2*). This represents a substantial improvement in the past decade; only 40.9% of U.S. residents reported CRC screening in 1997 (*8*). Endoscopy is currently the predominant screening modality in the United States; 61.8% of U.S. residents aged 50–75 years reported lower endoscopy within the past 10 years. A recent report estimated that, in 2005, colonoscopy use prevented an estimated 7,000 CRC deaths, but an additional 14,000 CRC deaths could have been prevented that year if more persons had undergone colonoscopy (*9*). If the HP 2020 target for CRC screening (70.5%) is met, almost 1,000 additional deaths will be averted per year (*10*).

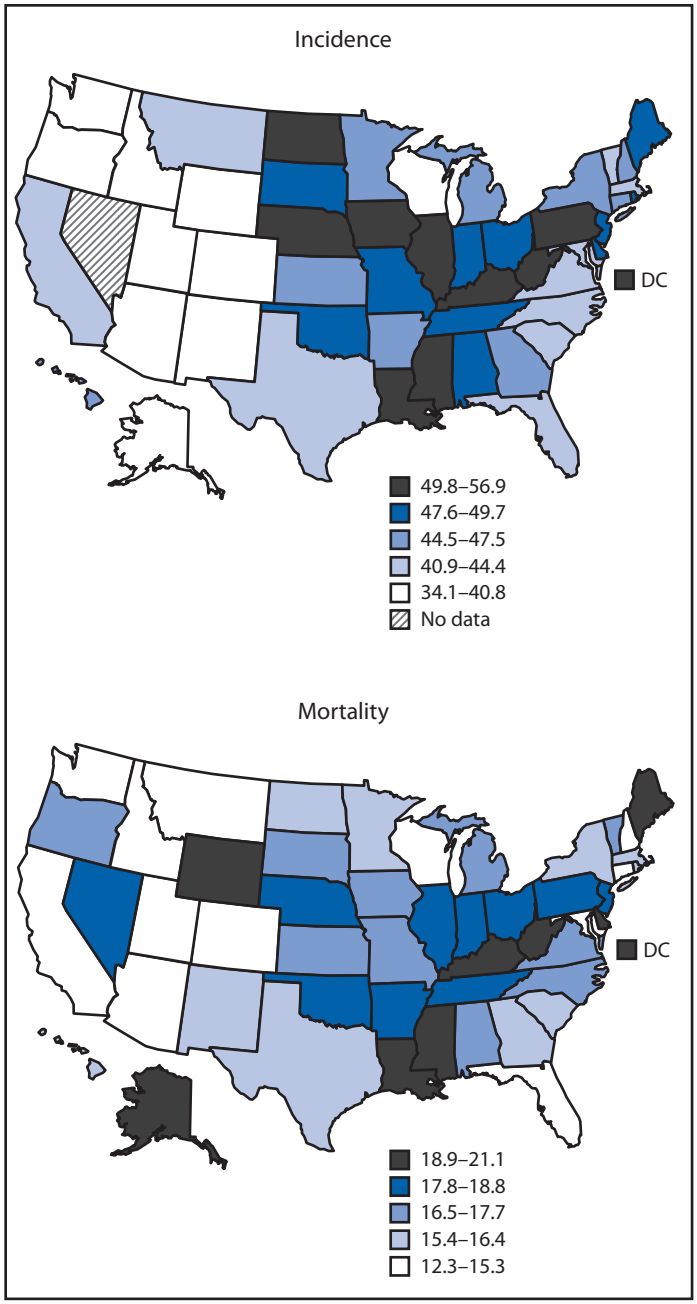
More than one third of respondents reported not being up-to-date with screening. A recent review of predictors of CRC screening found that physician recommendation continues to be a major facilitator of screening and a barrier when no recommendation is made (*11*). Lack of knowledge about CRC screening, lack of health insurance, lower income and education, and being from a racial or ethnic minority group were additional barriers to screening (*11*). A survey of U.S. and Canada residents regarding their preference for CRC screening reported that 31% of survey respondents in the United States would choose not to be screened for CRC even when their preferred screening test was offered (*12*). Given provider influence on patients' use of CRC screening, this appears to provide an opportunity to recommend screening to eligible patients.

The medical and societal costs of CRC are substantial. Estimated direct medical costs for CRC care in 2010 were $14 billion, with projected costs of up to $20 billion by 2020 (*13*). In 2006, estimated lost productivity costs for persons who died from CRC were $15.3 billion (*14*). This equals $288,468 of lost productivity per CRC death in 2006 (*14*). Screening costs per person vary by test. The lifetime (age 50–80 years) average per person cost of screening ranges from $71 per person for guaiac-based FOBT to $1,397 per person for colonoscopy (*15*).

CDC established the Colorectal Cancer Control Program in 2009, funding a total of 22 states and four tribal organizations to promote CRC screening and increase population-level screening rates to 80% and, subsequently, to reduce CRC incidence and mortality. In 2010, three additional states were funded, bringing the total number of grantees to 29. Grantees work through partnership with state and local organizations, Federally Qualified Health Centers, and other health-care systems that will be critical to effect population-level change. Many of the program strategies draw from the *Community Guide to Preventive Services*, which has identified evidence-based interventions to increase cancer screening in communities by targeting providers and the general population (available at http://www.thecommunityguide.org/index.html.)

Implementation of the Affordable Care Act is expected to remove financial barriers to CRC screening. However, additional effort will be needed to improve population-based screening and outcomes. Targeting systems-level changes and providers might be an effective method to improve CRC screening and follow-up in health-care systems. For example, from 2005 to 2009, Kaiser Northern California doubled its up-to-date CRC screening from 35% to 69% among commercially insured enrollees and increased screening for Medicare enrollees from 46% to 75% (*16*) by implementing a highly organized screening program based on evidence-based recommendations from the *Community Guide*. These strategies also have been effective at the community-level to improve CRC screening (*17*). State health departments should build on existing infrastructure and seek opportunities to develop highly-organized screening service delivery systems and enhance assurance of screening service delivery. State health departments could work with Medicaid to institute policies that facilitate systematic screening programs for the Medicaid population and design systems that allow linkage of Medicaid enrollee data to other datasets, if such linkages are allowed by the state or jurisdiction. This would enable identification and active recruitment for screening, and develop program registries to monitor participation, diagnostic follow-up, treatment initiation and long-term outcomes.

FIGURE 2. Colorectal cancer incidence and death rates* — United States, 2007

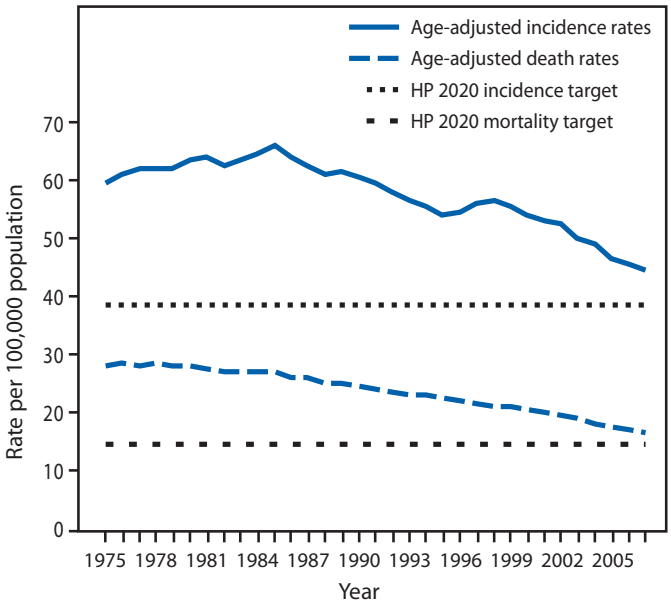


Sources: Cancer incidence combines cancer registry data from the National Program of Cancer Registries and the Surveillance, Epidemiology, and End Results Program that meet United States Cancer Statistics publication criteria for 2007, covering 99.2% of the U.S. population. Additional information available at http://www.cdc.gov/uscs.

Mortality data are provided by the National Vital Statistics System, covering 100% of the U.S. population.

* Per 100,000 population, age-adjusted to the 2000 U.S. standard population.

FIGURE 3. Age-adjusted colorectal cancer incidence and death rates* and *Healthy People 2020* (HP 2020) targets — United States, 1975–2007



Sources: Incidence data are provided from nine areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, and Atlanta) of the Surveillance, Epidemiology, and End Results (SEER) Program. Additional information available at http://seer.cancer.gov.

Mortality data are provided by U.S. Mortality Files of the National Vital Statistics System.

* Per 100,000 population, age-adjusted to the 2000 U.S. standard population.

The findings in this report are subject to at least four limitations. First, because BRFSS is administered by telephone, only adults living in households with landline telephones are represented; therefore, the results might not be representative of the entire U.S. population. Adults living in wireless-only households tend to be younger, to have lower incomes, and to be members of minority populations, which might result in overestimates (*18*). Second, responses are self-reported and not confirmed by review of medical records. Third, the survey response rate was relatively low and variable among states. Fourth, the percentages of adults who reported having had an FOBT in the past year and/or lower endoscopy within the preceding 10 years are presented to enable comparison with previous reports. However, USPSTF states that modeling evidence suggests CRC screening using any of the following three regimens will be approximately equally effective in life-years gained: 1) annual FOBT, 2) sigmoidoscopy every 5 years combined with FOBT every 3 years, or 3) colonoscopy at intervals of 10 years (*2*).

Recent significant improvements in CRC screening in the United States have contributed to reductions in incidence and death rates, but HP 2020 targets have not yet been reached. Adherence to recommended CRC screening recommendations will prevent more CRC cases and deaths.

Key Points

- Colorectal cancer (CRC) incidence decreased 13% and mortality decreased 12% from 2003 to 2007, a decline of approximately 66,000 cases and 32,000 deaths compared with 2002.
- Screening prevented approximately half of the expected new CRC cases and deaths during 2003–2007 (33,000 new cases and 16,000 deaths).
- A total of $288,468 in productivity was lost per CRC death in 2006.
- Approximately 22 million U.S. residents aged 50–75 years have never been screened for CRC.
- Innovative systems-level changes should be developed to make screening available, affordable, and routine for all adults aged 50–75 years.
- Additional information is available at http://www.cdc.gov/vitalsigns.

Reported by

Lisa C. Richardson, MD, Eric Tai, MD, Sun Hee Rim, MPH, Djenaba Joseph, MD, Marcus Plescia, MD. Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion. ***Corresponding contributor:*** *Lisa C. Richardson, lrichardson@cdc.gov; 770-488-4351.*

References

1. US Cancer Statistics Working Group. United States Cancer Statistics (USCS): 1999–2007 incidence and mortality data. Atlanta, GA: U.S. Department of Health and Human Services, CDC, National Cancer Institute; 2010. Available at http://www.cdc.gov/uscs. Accessed June 7, 2011.
2. US Preventive Services Task Force. Screening for colorectal cancer. Rockville, MD: Agency for Healthcare Research and Quality; 2008. Available at http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm. Accessed June 7, 2011.
3. US Department of Health and Human Services. Healthy people 2020. Available at http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx. Accessed June 7, 2011.
4. CDC. Behavioral Risk Factor Surveillance System. Atlanta, GA: US Department of Health and Human Services, CDC; 2010. Available at http://www.cdc.gov/brfss. Accessed June 7, 2011.
5. CDC. Vital signs: colorectal cancer screening among adults aged 50–75 years—United States, 2008. MMWR 2010;59:808–12.
6. Tiwari RC, Clegg LX, Zou Z. Efficient interval estimation of age-adjusted cancer rates. Stat Methods Med Res 2006;15:547–69.
7. Edwards BK, Ward E, Kohler BA, et al. Annual report to the nation on the status of cancer, 1975–2006, featuring colorectal cancer trends and impact of interventions (risk factors, screening, and treatment) to reduce future rates. Cancer 2010;116:544–73.
8. CDC. Screening for colorectal cancer—United States, 1997. MMWR 1999;48:116–21.
9. Stock C, Knudsen AB, Lansdorp-Vogelaar I, Haug U, Brenner H. Colorectal cancer mortality prevented by use and attributable to nonuse of colonoscopy. Gastrointest Endosc 2011;73:435–43.e5.
10. Farley TA, Dalal MA, Mostashari F, Frieden TR. Deaths preventable in the U.S. by improvements in use of clinical preventive services. Am J Prev Med 2010;38:600–9.
11. Beydoun HA, Beydoun MA. Predictors of colorectal cancer screening behaviors among average-risk older adults in the United States. Cancer Causes Control 2008;19:339–59.
12. Marshall DA, Johnson FR, Kulin NA, et al. How do physician assessments of patient preferences for colorectal cancer screening tests differ from actual preferences? A comparison in Canada and the United States using a stated-choice survey. Health Econ 2009;18:1420–39.
13. Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010–2020. J Natl Cancer Inst 2011;103:117–28.
14. Ekwueme DU, Guy GP, Li C, Rim SH, Parelkar P, Chen SC. The health burden and economic costs of cutaneous melanoma mortality by race/ethnicity–United States, 2000–2006. J Am Acad Derm. In press.
15. Lansdorp-Vogelaar I, van Ballegooijen M, Zauber AG, Habbema JD, Kuipers EJ. Effect of rising chemotherapy costs on the cost savings of colorectal cancer screening. J Natl Cancer Inst 2009;101:1412–22.
16. Agency for Healthcare Research and Quality. Integrated system nearly doubles colorectal cancer screening rate through distribution of inhome kit and followup with nonresponders. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2010. Available at http://innovations.ahrq.gov/content.aspx?id=2900. Accessed June 7, 2011.
17. Lebwohl B, Neugut AI, Stavsky E, et al. Effect of a patient navigator program on the volume and quality of colonoscopy. J Clin Gastroenterol 2011;45:e47–53.
18. Blumberg SJ, Luke JV, Ganesh N, Davern ME, Boudreaux MH, Soderberg K. Wireless substitution: state-level estimates from the National Health Interview Survey, January 2007–June 2010. Natl Health Stat Report 2011;(39):1–26.

Notes from the Field

Botulism Caused by Consumption of Commercially Produced Potato Soups Stored Improperly — Ohio and Georgia, 2011

In January and April 2011, CDC provided antitoxin for treatment of two persons with toxin type A botulism associated with consumption of potato soup produced by two companies. On January 28, 2011, an Ohio resident, aged 29 years, was hospitalized after 5 days of progressive dizziness, blurred vision, dysphagia, and difficulty breathing. The patient required mechanical ventilation and botulism antitoxin. On January 18, he had tasted potato soup from a bulging plastic container, noted a bad taste, and discarded the remainder. The soup had been purchased on December 7, 2010, from the refrigerated section of a local grocer, but it had been kept unrefrigerated for 42 days. He was hospitalized for 57 days and then was transferred with residual weakness to a rehabilitation facility.

On April 8, 2011, a Georgia resident, aged 41 years, was hospitalized after 4 days of progressive dizziness and dysphagia. The patient developed respiratory distress, required mechanical ventilation, and was treated with botulism antitoxin. On April 3, she had tasted potato soup purchased from a local grocer, noted a sour taste, and discarded the remainder. The soup, stored in a plastic container labeled "keep refrigerated" in letters 1/8 inch tall, had been purchased on March 16, but had been left unrefrigerated for 18 days. She was hospitalized for 16 days and then was transferred with residual weakness to a rehabilitation facility.

Botulism is caused by a paralyzing toxin produced by *Clostridium botulinum* bacteria. *C. botulinum* spores are present in soil and can be found on raw produce, especially potatoes and other root vegetables (*1*). If a low-acid food such as potato soup is stored unrefrigerated in an anaerobic environment (e.g., a sealed container), without a barrier to bacterial growth, spores can germinate, resulting in bacterial growth and botulinum toxin production (*2*). Because heating food to a temperature of 185°F (85°C) for 5 minutes inactivates the toxin, proper preparation also is an important safeguard (*3*).

Improper storage has been documented in previous botulism outbreaks associated with commercially produced, chilled foods. Since 1975, 19 U.S. botulism cases were linked to six such products. Demand for prepared, chilled foods is increasing (*4*). Labels advising refrigeration might be ignored or not noticed, and do not warn about the danger of consuming unrefrigerated food. The Food and Drug Administration is reexamining labeling requirements. Storage at an improper temperature also can occur before products reach consumers (*5*). To inhibit the growth of *C. botulinum* and other microbes, an acidifying agent or other microbial inhibitor, such as citric or phosphoric acid, can be added to prepared, chilled foods before they are sealed in a package. This procedure was used successfully to reduce the danger of botulism from commercial garlic-in-oil products after two outbreaks (*6*).

Reported by

Mandy P. Seaman, Alana C. Sulka, Gwinnett County, Georgia Board of Health. Melissa Tobin D'Angelo, Georgia Dept of Community Health. Mitchell A. Blass, St. Joseph's Hospital, Atlanta, Georgia. Randy L. Mills, Ohio State Univ Hospitals East, Columbus; Jane Carmean, Ohio Dept of Health. Carolina Lúquez, Susan Maslanka, Kelly A. Jackson, Barbara E. Mahon, Patricia M. Griffin, Div of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases; Katherine A. O'Connor, Ethel V. Taylor, EIS officers, CDC. ***Corresponding contributor:*** *Katherine A. O'Connor, kaoconnor@cdc.gov, 404-639-0195.*

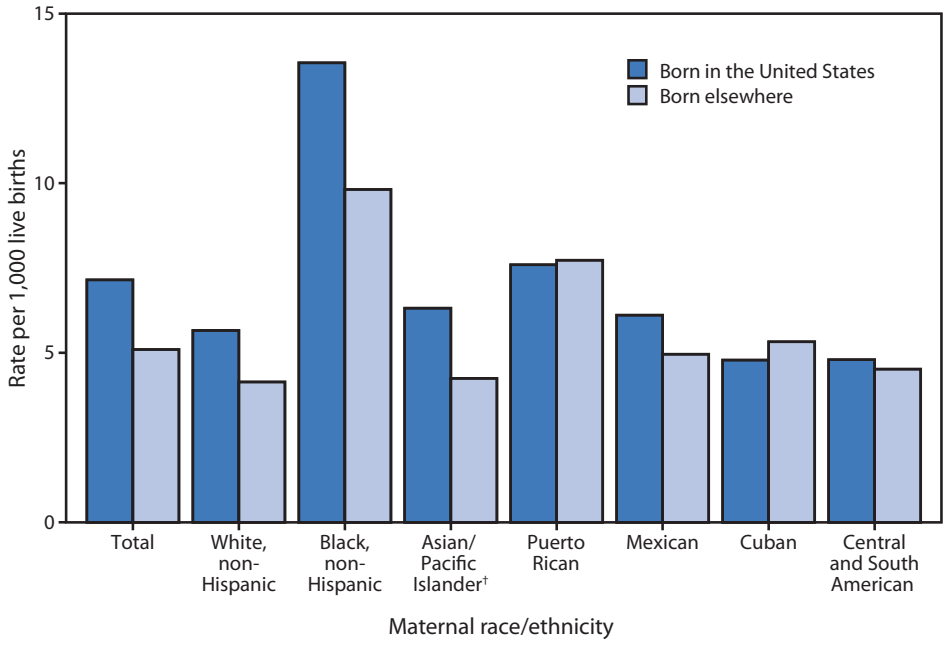
References

1. Angulo FJ, Getz J, Taylor JP, et al. A large outbreak of botulism: the hazardous baked potato. J Infect Dis 1998;178:172–7.
2. Sheth AN, Wiersma P, Atrubin D, et al. International outbreak of severe botulism with prolonged toxemia caused by commercial carrot juice. Clin Infect Dis 2008;47:1245–51.
3. Sobel J. Botulism. Clin Infect Dis 2005;41:1167–73.
4. Peck MW. *Clostridium botulinum* and the safety of minimally heated, chilled foods: an emerging issue? J Appl Microbiol 2006;101:556–70.
5. Kalluri P, Crowe C, Reller M, et al. An outbreak of foodborne botulism associated with food sold at a salvage store in Texas. Clin Infect Dis 2003;37:1490–5.
6. Morse DL, Pickard LK, Guzewich JJ, Devine BD, Shayegani M. Garlic-in-oil associated botulism: episode leads to product modification. Am J Public Health 1990;80:1372–3.

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Infant Mortality Rates, by Mother's Place of Birth and Race/Ethnicity — United States,* 2007



* Includes all 50 states and the District of Columbia.
† Includes persons of Hispanic and non-Hispanic ethnicity.

In 2007, the mortality rate for infants of mothers born in the United States (7.15 per 1,000 live births) was 40% higher than the rate for infants of mothers born outside the United States (5.10). Mortality rates for infants of non-Hispanic white, non-Hispanic black, and Asian/Pacific Islander mothers were significantly higher for infants of mothers born in the United States compared with infants of mothers born elsewhere. Among Hispanic populations, only mothers of Mexican descent born in the United States had infants with higher mortality rates compared with infants of mothers born elsewhere. Differences for other racial/ethnic populations were not statistically significant.

Source: Mathews TJ, MacDorman MF. Infant mortality statistics from the 2007 period linked birth/infant death data set. Natl Vital Stat Rep 2011;59(6). Available at http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_06.pdf.

Notifiable Diseases and Mortality Tables

TABLE I. Provisional cases of infrequently reported notifiable diseases (<1,000 cases reported during the preceding year) — United States, week ending July 2, 2011 (26th week)*

Disease	Current week	Cum 2011	5-year weekly average†	Total cases reported for previous years					States reporting cases during current week (No.)
				2010	2009	2008	2007	2006	
Anthrax	—	—	—	—	1	—	1	1	
Arboviral diseases§,¶:									
California serogroup virus disease	—	—	2	75	55	62	55	67	
Eastern equine encephalitis virus disease	—	—	0	10	4	4	4	8	
Powassan virus disease	—	—	0	8	6	2	7	1	
St. Louis encephalitis virus disease	—	—	1	10	12	13	9	10	
Western equine encephalitis virus disease	—	—	—	—	—	—	—	—	
Babesiosis	8	61	3	NN	NN	NN	NN	NN	NY (8)
Botulism, total	—	39	3	112	118	145	144	165	
foodborne	—	4	0	7	10	17	32	20	
infant	—	29	2	80	83	109	85	97	
other (wound and unspecified)	—	6	1	25	25	19	27	48	
Brucellosis	2	32	2	115	115	80	131	121	NE (1), TX (1)
Chancroid	—	10	0	24	28	25	23	33	
Cholera	—	18	0	13	10	5	7	9	
Cyclosporiasis§	2	61	7	179	141	139	93	137	VA (1), FL (1)
Diphtheria	—	—	—	—	—	—	—	—	
Haemophilus influenzae,** invasive disease (age <5 yrs):									
serotype b	—	3	0	23	35	30	22	29	
nonserotype b	—	54	4	200	236	244	199	175	
unknown serotype	2	130	4	223	178	163	180	179	PA (1), OR (1)
Hansen disease§	—	21	2	98	103	80	101	66	
Hantavirus pulmonary syndrome§	—	7	1	20	20	18	32	40	
Hemolytic uremic syndrome, postdiarrheal§	2	47	7	266	242	330	292	288	NY (1), TN (1)
Influenza-associated pediatric mortality§,††	—	108	2	61	358	90	77	43	
Listeriosis	3	207	18	821	851	759	808	884	FL (1), TN (1), CA (1)
Measles§§	1	127	3	63	71	140	43	55	NY (1)
Meningococcal disease, invasive¶¶:									
A, C, Y, and W-135	—	99	5	280	301	330	325	318	
serogroup B	—	54	4	135	174	188	167	193	
other serogroup	—	5	0	12	23	38	35	32	
unknown serogroup	2	238	10	406	482	616	550	651	NY (1), MO (1)
Novel influenza A virus infections***	—	1	0	4	43,774	2	4	NN	
Plague	—	1	0	2	8	3	7	17	
Poliomyelitis, paralytic	—	—	—	—	1	—	—	—	
Polio virus Infection, nonparalytic§	—	—	—	—	—	—	—	NN	
Psittacosis§	—	1	0	4	9	8	12	21	
Q fever, total§	—	30	4	131	113	120	171	169	
acute	—	19	2	106	93	106	—	—	
chronic	—	11	0	25	20	14	—	—	
Rabies, human	—	1	0	2	4	2	1	3	
Rubella†††	—	3	0	5	3	16	12	11	
Rubella, congenital syndrome	—	—	—	—	2	—	—	1	
SARS-CoV§	—	—	—	—	—	—	—	—	
Smallpox§	—	—	—	—	—	—	—	—	
Streptococcal toxic-shock syndrome§	1	62	2	148	161	157	132	125	NY (1)
Syphilis, congenital (age <1 yr)§§§	—	72	8	377	423	431	430	349	
Tetanus	—	4	0	10	18	19	28	41	
Toxic-shock syndrome (staphylococcal)§	—	39	2	82	74	71	92	101	
Trichinellosis	—	7	0	7	13	39	5	15	
Tularemia	2	34	5	124	93	123	137	95	MO (1), WA (1)
Typhoid fever	3	170	7	468	397	449	434	353	NE (1), GA (1), CA (1)
Vancomycin-intermediate *Staphylococcus aureus*§	—	26	1	91	78	63	37	6	
Vancomycin-resistant *Staphylococcus aureus*§	—	—	—	2	1	—	2	1	
Vibriosis (noncholera *Vibrio* species infections)§	12	182	12	848	789	588	549	NN	MD (2), GA (1), FL (5), TX (1), CA (3)
Viral hemorrhagic fever¶¶¶	—	—	—	1	NN	NN	NN	NN	
Yellow fever	—	—	—	—	—	—	—	—	

See Table 1 footnotes on next page.

TABLE I. (*Continued*) Provisional cases of infrequently reported notifiable diseases (<1,000 cases reported during the preceding year) — United States, week ending July 2, 2011 (26th week)*

—: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts.

* Case counts for reporting years 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf.

† Calculated by summing the incidence counts for the current week, the 2 weeks preceding the current week, and the 2 weeks following the current week, for a total of 5 preceding years. Additional information is available at http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/5yearweeklyaverage.pdf.

§ Not reportable in all states. Data from states where the condition is not reportable are excluded from this table except starting in 2007 for the arboviral diseases, STD data, TB data, and influenza-associated pediatric mortality, and in 2003 for SARS-CoV. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis.htm.

¶ Includes both neuroinvasive and nonneuroinvasive. Updated weekly from reports to the Division of Vector-Borne Infectious Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ArboNET Surveillance). Data for West Nile virus are available in Table II.

** Data for H. influenzae (all ages, all serotypes) are available in Table II.

†† Updated weekly from reports to the Influenza Division, National Center for Immunization and Respiratory Diseases. Since October 3, 2010, 112 influenza-associated pediatric deaths occurring during the 2010-11 influenza season have been reported.

§§ The one measles case reported for the current week was imported.

¶¶ Data for meningococcal disease (all serogroups) are available in Table II.

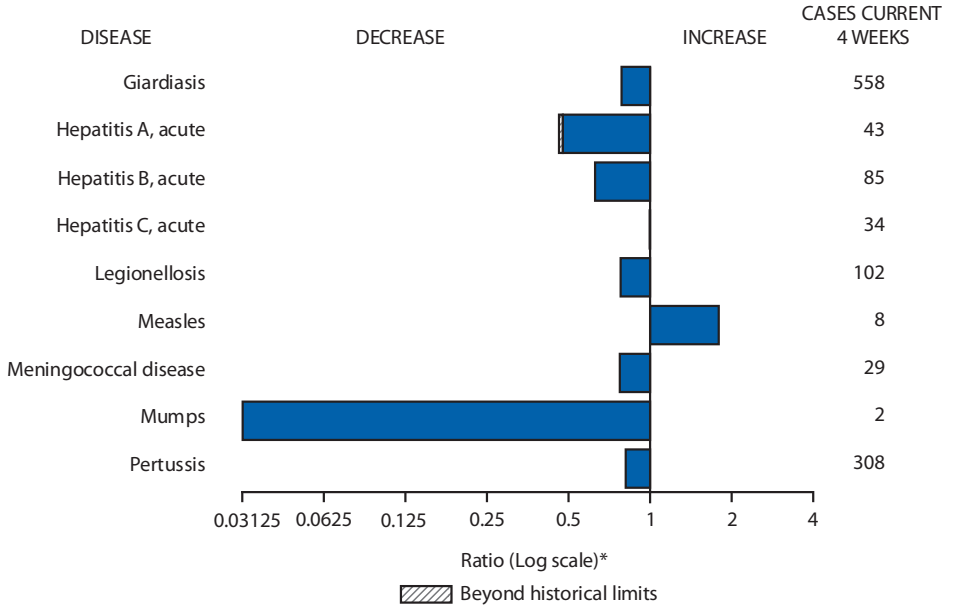
*** CDC discontinued reporting of individual confirmed and probable cases of 2009 pandemic influenza A (H1N1) virus infections on July 24, 2009. During 2009, four cases of human infection with novel influenza A viruses, different from the 2009 pandemic influenza A (H1N1) strain, were reported to CDC. The four cases of novel influenza A virus infection reported to CDC during 2010, and the one case reported during 2011, were identified as swine influenza A (H3N2) virus and are unrelated to the 2009 pandemic influenza A (H1N1) virus. Total case counts for 2009 were provided by the Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD).

††† No rubella cases were reported for the current week.

§§§ Updated weekly from reports to the Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

¶¶¶ There was one case of viral hemorrhagic fever reported during week 12 of 2010. The one case report was confirmed as lassa fever. See Table II for dengue hemorrhagic fever.

FIGURE I. Selected notifiable disease reports, United States, comparison of provisional 4-week totals July 2, 2011, with historical data



* Ratio of current 4-week total to mean of 15 4-week totals (from previous, comparable, and subsequent 4-week periods for the past 5 years). The point where the hatched area begins is based on the mean and two standard deviations of these 4-week totals.

Notifiable Disease Data Team and 122 Cities Mortality Data Team

Jennifer Ward, MS

Deborah A. Adams
Willie J. Anderson
Lenee Blanton
Rosaline Dhara
Pearl C. Sharp
Michael S. Wodajo

TABLE II. Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	*Chlamydia trachomatis* infection					Coccidioidomycosis					Cryptosporidiosis				
	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010
United States	9,778	25,748	31,142	625,202	639,499	79	0	570	8,041	NN	59	92	374	1,990	3,103
New England	844	839	2,043	21,493	19,843	—	0	1	1	NN	—	5	29	94	245
Connecticut	152	234	1,557	4,721	4,817	—	0	0	—	NN	—	0	24	24	77
Maine†	—	57	100	1,453	1,229	—	0	0	—	NN	—	0	7	3	29
Massachusetts	527	404	860	11,015	10,247	—	0	0	—	NN	—	2	9	32	64
New Hampshire	34	53	81	1,433	1,153	—	0	1	1	NN	—	1	3	15	33
Rhode Island†	104	69	154	2,129	1,773	—	0	0	—	NN	—	0	2	1	10
Vermont†	27	26	84	742	624	—	0	0	—	NN	—	1	5	19	32
Mid. Atlantic	1,583	3,315	5,069	79,834	83,710	—	0	1	3	NN	14	15	38	324	314
New Jersey	77	481	684	10,763	13,115	—	0	0	—	NN	—	1	4	18	13
New York (Upstate)	702	713	2,099	17,807	16,091	—	0	0	—	NN	7	3	13	68	62
New York City	172	1,145	2,612	26,023	31,249	—	0	0	—	NN	—	2	6	30	35
Pennsylvania	632	953	1,228	25,241	23,255	—	0	1	3	NN	7	8	26	208	204
E.N. Central	785	4,034	7,039	92,849	100,560	1	0	3	23	NN	2	23	137	426	819
Illinois	—	1,103	1,320	22,119	29,696	—	0	0	—	NN	—	1	21	4	98
Indiana	282	453	3,376	14,135	9,115	—	0	0	—	NN	—	4	15	41	123
Michigan	365	937	1,398	23,446	25,176	1	0	3	16	NN	1	5	18	109	151
Ohio	—	997	1,134	22,236	25,311	—	0	3	7	NN	—	7	24	138	177
Wisconsin	138	467	559	10,913	11,262	—	0	0	—	NN	1	8	65	134	270
W.N. Central	336	1,437	1,634	34,016	35,949	1	0	1	2	NN	8	11	99	169	498
Iowa	11	206	240	5,079	5,340	—	0	0	—	NN	—	3	25	24	109
Kansas	—	189	287	4,452	4,879	—	0	0	—	NN	—	1	6	3	44
Minnesota	U	287	361	5,596	7,707	U	0	0	—	NN	U	1	22	—	149
Missouri	316	524	766	13,680	12,795	—	0	0	—	NN	4	3	29	59	79
Nebraska†	—	101	218	2,923	2,555	1	0	1	2	NN	2	3	26	59	57
North Dakota	—	39	90	664	1,118	—	0	0	—	NN	2	0	9	13	11
South Dakota	9	64	93	1,622	1,555	—	0	0	—	NN	—	1	6	11	49
S. Atlantic	2,611	5,113	6,543	134,569	128,316	—	0	2	3	NN	13	18	53	382	468
Delaware	90	83	220	2,200	2,169	—	0	0	—	NN	—	0	1	3	3
District of Columbia	67	105	180	2,542	2,716	—	0	0	—	NN	—	0	1	3	2
Florida	700	1,486	1,706	37,674	37,315	—	0	0	—	NN	6	6	19	98	179
Georgia	946	930	2,384	25,956	21,747	—	0	0	—	NN	1	4	11	128	146
Maryland†	—	471	1,125	10,404	11,780	—	0	2	3	NN	6	1	3	30	16
North Carolina	—	756	1,477	22,257	22,612	—	0	0	—	NN	—	0	17	36	35
South Carolina†	493	531	946	14,472	12,996	—	0	0	—	NN	—	2	8	45	26
Virginia†	240	658	970	16,998	15,186	—	0	0	—	NN	—	1	5	27	55
West Virginia	75	78	121	2,066	1,795	—	0	0	—	NN	—	0	5	12	6
E.S. Central	1,202	1,826	3,314	45,820	45,542	—	0	0	—	NN	3	4	19	72	89
Alabama†	—	542	1,566	13,101	12,629	—	0	0	—	NN	—	1	13	8	36
Kentucky	283	268	2,352	8,064	8,001	—	0	0	—	NN	1	1	6	22	27
Mississippi	595	392	614	9,928	11,113	—	0	0	—	NN	—	0	2	12	6
Tennessee†	324	583	795	14,727	13,799	—	0	0	—	NN	2	1	5	30	20
W.S. Central	403	3,294	4,723	79,781	90,209	—	0	1	1	NN	11	5	33	107	155
Arkansas†	403	307	440	8,238	7,759	—	0	0	—	NN	—	0	3	8	16
Louisiana	—	346	1,052	6,679	14,764	—	0	1	1	NN	—	0	6	10	19
Oklahoma	—	228	1,371	5,319	6,598	—	0	0	—	NN	—	0	8	—	32
Texas†	—	2,369	3,107	59,545	61,088	—	0	0	—	NN	11	4	24	89	88
Mountain	759	1,679	2,155	41,955	41,217	65	0	432	6,402	NN	7	10	30	217	239
Arizona	206	515	697	12,282	13,469	65	0	427	6,316	NN	1	1	3	15	15
Colorado	269	412	848	12,198	9,531	—	0	0	—	NN	2	2	10	62	59
Idaho†	—	63	199	1,403	1,972	—	0	0	—	NN	1	1	7	30	44
Montana†	—	63	85	1,635	1,519	—	0	1	2	NN	3	1	5	30	28
Nevada†	188	196	380	5,399	5,049	—	0	4	44	NN	—	0	7	3	8
New Mexico†	63	203	1,183	4,969	5,348	—	0	4	31	NN	—	2	12	48	44
Utah	33	130	175	3,231	3,285	—	0	2	6	NN	—	1	5	20	29
Wyoming†	—	38	90	838	1,044	—	0	2	3	NN	—	0	3	9	12
Pacific	1,255	3,758	6,559	94,885	94,153	12	0	143	1,606	NN	1	11	27	199	276
Alaska	—	115	157	2,728	3,094	—	0	0	—	NN	—	0	3	5	2
California	724	2,860	5,763	72,799	71,403	12	0	143	1,605	NN	1	6	19	122	155
Hawaii	—	108	138	2,335	3,121	—	0	0	—	NN	—	0	0	—	1
Oregon	257	250	524	6,871	5,917	—	0	1	1	NN	—	3	13	68	80
Washington	274	409	520	10,152	10,618	—	0	0	—	NN	—	0	9	4	38
Territories															
American Samoa	—	0	0	—	—	—	0	0	—	NN	N	0	0	N	N
C.N.M.I.	—	—	—	—	—	—	—	—	—	NN	—	—	—	—	—
Guam	—	4	81	189	545	—	0	0	—	NN	—	0	0	—	—
Puerto Rico	—	105	349	3,065	3,253	—	0	0	—	NN	N	0	0	N	N
U.S. Virgin Islands	—	14	27	328	281	—	0	0	—	NN	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Dengue Virus Infection†									
	Dengue Fever§					Dengue Hemorrhagic Fever¶				
	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010
United States	—	4	52	45	170	—	0	2	—	3
New England	—	0	3	1	1	—	0	0	—	—
Connecticut	—	0	0	—	—	—	0	0	—	—
Maine**	—	0	2	—	1	—	0	0	—	—
Massachusetts	—	0	0	—	—	—	0	0	—	—
New Hampshire	—	0	0	—	—	—	0	0	—	—
Rhode Island**	—	0	1	—	—	—	0	0	—	—
Vermont**	—	0	1	1	—	—	0	0	—	—
Mid. Atlantic	—	2	25	19	54	—	0	1	—	2
New Jersey	—	0	5	—	5	—	0	0	—	—
New York (Upstate)	—	0	5	—	7	—	0	1	—	1
New York City	—	1	17	10	37	—	0	1	—	1
Pennsylvania	—	0	3	9	5	—	0	0	—	—
E.N. Central	—	0	5	5	13	—	0	1	—	—
Illinois	—	0	1	2	—	—	0	0	—	—
Indiana	—	0	2	1	4	—	0	0	—	—
Michigan	—	0	2	—	3	—	0	0	—	—
Ohio	—	0	2	—	5	—	0	0	—	—
Wisconsin	—	0	2	2	1	—	0	1	—	—
W.N. Central	—	0	6	—	11	—	0	1	—	—
Iowa	—	0	1	—	1	—	0	0	—	—
Kansas	—	0	1	—	1	—	0	0	—	—
Minnesota	U	0	1	—	8	U	0	0	—	—
Missouri	—	0	0	—	—	—	0	0	—	—
Nebraska**	—	0	6	—	—	—	0	0	—	—
North Dakota	—	0	0	—	1	—	0	0	—	—
South Dakota	—	0	0	—	—	—	0	1	—	—
S. Atlantic	—	1	19	11	71	—	0	1	—	1
Delaware	—	0	0	—	—	—	0	0	—	—
District of Columbia	—	0	0	—	—	—	0	0	—	—
Florida	—	1	14	10	57	—	0	1	—	1
Georgia	—	0	2	—	5	—	0	0	—	—
Maryland**	—	0	0	—	—	—	0	0	—	—
North Carolina	—	0	2	1	—	—	0	0	—	—
South Carolina**	—	0	3	—	4	—	0	0	—	—
Virginia**	—	0	3	—	4	—	0	0	—	—
West Virginia	—	0	1	—	1	—	0	0	—	—
E.S. Central	—	0	2	—	1	—	0	0	—	—
Alabama**	—	0	2	—	—	—	0	0	—	—
Kentucky	—	0	1	—	—	—	0	0	—	—
Mississippi	—	0	0	—	—	—	0	0	—	—
Tennessee**	—	0	0	—	1	—	0	0	—	—
W.S. Central	—	0	1	—	—	—	0	1	—	—
Arkansas**	—	0	0	—	—	—	0	1	—	—
Louisiana	—	0	0	—	—	—	0	0	—	—
Oklahoma	—	0	1	—	—	—	0	0	—	—
Texas**	—	0	1	—	—	—	0	0	—	—
Mountain	—	0	2	3	5	—	0	0	—	—
Arizona	—	0	2	2	1	—	0	0	—	—
Colorado	—	0	0	—	—	—	0	0	—	—
Idaho**	—	0	1	—	1	—	0	0	—	—
Montana**	—	0	1	—	1	—	0	0	—	—
Nevada**	—	0	1	—	1	—	0	0	—	—
New Mexico**	—	0	0	—	1	—	0	0	—	—
Utah	—	0	1	1	—	—	0	0	—	—
Wyoming**	—	0	0	—	—	—	0	0	—	—
Pacific	—	0	7	6	14	—	0	0	—	—
Alaska	—	0	0	—	1	—	0	0	—	—
California	—	0	5	2	9	—	0	0	—	—
Hawaii	—	0	0	—	—	—	0	0	—	—
Oregon	—	0	0	—	—	—	0	0	—	—
Washington	—	0	2	4	4	—	0	0	—	—
Territories										
American Samoa	—	0	0	—	—	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—
Guam	—	0	0	—	—	—	0	0	—	—
Puerto Rico	—	33	454	254	2,728	—	0	20	1	83
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.

* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.

† Updated weekly from reports to the Division of Vector-Borne Infectious Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ArboNET Surveillance).

§ Dengue Fever includes cases that meet criteria for Dengue Fever with hemorrhage, other clinical and unknown case classifications.

¶ DHF includes cases that meet criteria for dengue shock syndrome (DSS), a more severe form of DHF.

** Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Ehrlichiosis/Anaplasmosis†														
	Ehrlichia chaffeensis					*Anaplasma phagocytophilum*					Undetermined				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	20	6	109	163	272	12	15	145	108	891	5	1	13	39	47
New England	—	0	2	2	3	—	1	8	11	48	—	0	1	1	2
Connecticut	—	0	0	—	—	—	0	6	—	14	—	0	0	—	—
Maine§	—	0	1	1	2	—	0	2	6	12	—	0	0	—	—
Massachusetts	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
New Hampshire	—	0	1	1	1	—	0	3	5	8	—	0	1	1	2
Rhode Island§	—	0	1	—	—	—	0	6	—	13	—	0	0	—	—
Vermont§	—	0	0	—	—	—	0	1	—	1	—	0	0	—	—
Mid. Atlantic	4	1	7	15	43	11	4	18	58	91	2	0	2	3	6
New Jersey	—	0	2	—	33	—	0	6	—	42	—	0	0	—	1
New York (Upstate)	4	0	7	12	7	11	3	18	48	46	2	0	2	3	4
New York City	—	0	1	3	2	—	0	3	10	3	—	0	0	—	—
Pennsylvania	—	0	1	—	1	—	0	1	—	—	—	0	1	—	1
E.N. Central	—	0	4	8	20	—	1	45	3	293	—	0	6	13	24
Illinois	—	0	2	5	8	—	0	2	—	1	—	0	1	2	3
Indiana	—	0	0	—	—	—	0	0	—	—	—	0	3	9	10
Michigan	—	0	1	1	—	—	0	1	—	1	—	0	1	1	—
Ohio	—	0	3	2	1	—	0	1	1	—	—	0	0	—	—
Wisconsin	—	0	1	—	11	—	1	45	2	291	—	0	3	1	11
W.N. Central	1	1	13	47	63	—	2	77	12	423	3	0	11	17	5
Iowa	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Kansas	—	0	2	2	4	—	0	1	—	1	—	0	0	—	—
Minnesota	U	0	12	—	—	U	0	75	1	418	U	0	11	—	—
Missouri	1	0	13	45	59	—	0	3	11	4	3	0	9	15	5
Nebraska§	—	0	1	—	—	—	0	0	—	—	—	0	1	1	—
North Dakota	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
South Dakota	—	0	0	—	—	—	0	0	—	—	—	0	1	1	—
S. Atlantic	11	3	18	68	99	1	1	4	19	29	—	0	1	1	1
Delaware	—	0	2	10	10	—	0	1	1	3	—	0	0	—	—
District of Columbia	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Florida	—	0	3	10	4	—	0	1	3	1	—	0	0	—	—
Georgia	1	0	3	8	15	—	0	1	5	1	—	0	1	1	1
Maryland§	2	0	2	9	11	—	0	2	1	10	—	0	1	—	—
North Carolina	8	0	13	15	33	1	0	4	7	10	—	0	0	—	—
South Carolina§	—	0	1	—	2	—	0	1	—	—	—	0	0	—	—
Virginia§	—	1	8	16	23	—	0	1	2	4	—	0	1	—	—
West Virginia	—	0	1	—	1	—	0	0	—	—	—	0	0	—	—
E.S. Central	4	0	11	23	34	—	0	2	5	7	—	0	1	1	7
Alabama§	—	0	3	—	5	—	0	2	2	1	N	0	0	N	N
Kentucky	1	0	2	7	5	—	0	0	—	—	—	0	0	—	1
Mississippi	—	0	1	—	1	—	0	1	—	1	—	0	0	—	1
Tennessee§	3	0	7	16	23	—	0	2	3	5	—	0	1	1	5
W.S. Central	—	0	87	—	9	—	0	9	—	—	—	0	1	—	—
Arkansas§	—	0	5	—	—	—	0	2	—	—	—	0	0	—	—
Louisiana	—	0	0	—	1	—	0	0	—	—	—	0	0	—	—
Oklahoma	—	0	82	—	7	—	0	7	—	—	—	0	0	—	—
Texas§	—	0	1	—	1	—	0	1	—	—	—	0	1	—	—
Mountain	—	0	0	—	—	—	0	0	—	—	—	0	1	2	—
Arizona	—	0	0	—	—	—	0	0	—	—	—	0	1	2	—
Colorado	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Idaho§	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Montana§	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Nevada§	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
New Mexico§	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Utah	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
Wyoming§	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
Pacific	—	0	1	—	1	—	0	0	—	—	—	0	1	1	2
Alaska	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
California	—	0	1	—	1	—	0	0	—	—	—	0	1	1	2
Hawaii	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Oregon	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
Washington	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
Territories															
American Samoa	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
Puerto Rico	N	0	0	N	N	N	0	0	N	N	N	0	0	N	N
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Cumulative total *E. ewingii* cases reported for year 2010 = 10, and 5 cases reported for 2011.
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Giardiasis					Gonorrhea					*Haemophilus influenzae*, invasive† All ages, all serotypes				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	124	296	549	6,121	8,769	2,123	5,823	7,484	138,686	147,727	22	62	141	1,629	1,659
New England	2	25	55	433	753	125	102	206	2,550	2,653	—	4	12	93	95
Connecticut	—	5	12	93	134	59	42	150	1,091	1,257	—	1	6	27	21
Maine§	2	3	11	54	87	—	2	7	81	98	—	0	2	14	6
Massachusetts	—	13	25	176	325	58	48	80	1,140	1,066	—	2	6	37	49
New Hampshire	—	2	10	38	91	—	3	7	61	72	—	0	2	8	7
Rhode Island§	—	1	7	7	35	7	5	15	151	132	—	0	2	3	8
Vermont§	—	3	10	65	81	1	0	8	26	28	—	0	3	4	4
Mid. Atlantic	32	61	106	1,272	1,465	333	715	1,121	17,216	16,774	8	11	32	349	318
New Jersey	—	8	22	128	198	16	116	172	2,706	2,812	—	2	7	56	53
New York (Upstate)	15	22	72	431	502	115	111	271	2,747	2,538	3	3	18	89	86
New York City	7	17	30	393	412	47	238	497	5,467	5,806	1	2	6	64	54
Pennsylvania	10	15	27	320	353	155	260	364	6,296	5,618	4	4	11	140	125
E.N. Central	1	50	99	927	1,514	199	1,046	2,091	24,065	27,102	—	11	19	282	265
Illinois	—	10	31	168	338	—	296	369	5,471	7,345	—	3	9	81	92
Indiana	—	6	15	95	180	79	109	1,018	3,614	2,608	—	2	7	49	55
Michigan	1	11	25	207	326	91	248	490	5,863	6,946	—	1	4	32	19
Ohio	—	16	29	311	404	—	320	383	6,895	7,910	—	2	7	79	63
Wisconsin	—	8	35	146	266	29	99	130	2,222	2,293	—	1	5	41	36
W.N. Central	14	27	73	442	891	91	297	363	7,024	6,994	4	4	10	84	113
Iowa	3	5	12	113	134	2	37	57	907	823	—	0	0	—	1
Kansas	—	2	10	38	107	—	39	62	859	1,026	1	0	2	11	12
Minnesota	U	9	33	—	329	U	38	62	744	1,058	U	0	5	—	42
Missouri	8	8	26	160	168	89	146	181	3,614	3,262	1	1	5	43	41
Nebraska§	1	4	9	83	95	—	22	49	567	566	1	0	3	20	9
North Dakota	2	0	12	19	10	—	3	11	61	95	1	0	6	9	8
South Dakota	—	1	5	29	48	1	12	20	272	164	—	0	1	1	—
S. Atlantic	30	64	127	1,253	1,785	696	1,470	1,862	35,814	37,898	4	14	30	407	419
Delaware	—	0	5	13	15	7	17	48	434	486	—	0	2	3	5
District of Columbia	—	1	5	11	30	20	38	70	920	1,027	—	0	0	—	—
Florida	22	29	75	542	946	187	382	486	9,532	9,936	3	5	12	142	104
Georgia	4	14	51	396	351	296	315	874	7,910	7,349	—	3	7	76	100
Maryland§	2	4	10	108	153	—	125	246	2,575	3,371	1	2	4	38	32
North Carolina	N	0	0	N	N	—	257	490	7,229	7,548	—	2	9	48	62
South Carolina§	—	2	9	50	60	132	161	257	4,102	3,920	—	1	5	35	55
Virginia§	2	8	32	111	214	44	116	185	2,707	4,036	—	1	8	56	50
West Virginia	—	0	8	22	16	10	14	26	405	225	—	0	9	9	11
E.S. Central	3	4	11	74	79	279	495	1,007	12,155	12,258	2	3	10	110	105
Alabama§	3	4	11	74	79	—	160	406	3,971	3,667	—	1	4	32	18
Kentucky	N	0	0	N	N	71	73	712	2,148	2,018	1	0	4	16	19
Mississippi	N	0	0	N	N	135	115	197	2,576	3,075	—	0	2	10	9
Tennessee§	N	0	0	N	N	73	140	194	3,460	3,498	1	2	5	52	59
W.S. Central	3	5	17	78	173	105	852	1,664	20,035	24,126	3	2	26	66	81
Arkansas§	3	2	9	48	49	105	101	138	2,494	2,275	3	0	3	17	13
Louisiana	—	2	12	30	74	—	102	509	1,802	4,199	—	0	4	22	18
Oklahoma	—	0	5	—	50	—	78	332	1,562	1,921	—	1	19	26	44
Texas§	N	0	0	N	N	—	593	867	14,177	15,731	—	0	4	1	6
Mountain	15	28	58	539	805	135	189	255	4,785	4,675	—	5	12	153	184
Arizona	1	3	8	61	71	40	64	95	1,691	1,618	—	2	6	62	70
Colorado	12	12	27	269	336	54	47	92	1,129	1,301	—	1	5	39	49
Idaho§	1	3	9	64	103	—	2	14	48	51	—	0	2	9	11
Montana§	1	1	6	24	59	—	1	5	35	60	—	0	1	2	2
Nevada§	—	2	11	34	27	30	33	103	982	908	—	0	2	9	5
New Mexico§	—	2	6	26	48	7	28	98	768	537	—	1	4	23	22
Utah	—	4	13	47	136	4	4	9	113	180	—	0	3	8	20
Wyoming§	—	1	5	14	25	—	0	3	19	20	—	0	1	1	5
Pacific	24	49	129	1,103	1,304	160	624	807	15,042	15,247	1	3	10	85	79
Alaska	—	2	7	34	43	—	20	34	459	687	—	0	2	9	13
California	18	33	68	759	806	111	512	695	12,411	12,388	—	0	6	12	15
Hawaii	—	0	4	14	28	—	14	26	298	346	—	0	3	14	11
Oregon	—	8	20	156	233	10	23	40	602	503	1	1	6	49	36
Washington	6	8	57	140	194	39	57	86	1,272	1,323	—	0	2	1	4
Territories															
American Samoa	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	1	—	2	—	0	17	6	49	—	0	0	—	—
Puerto Rico	—	1	7	11	40	—	6	12	173	143	—	0	0	—	1
U.S. Virgin Islands	—	0	0	—	—	—	2	7	49	65	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Data for H. influenzae (age <5 yrs for serotype b, nonserotype b, and unknown serotype) are available in Table I.
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Hepatitis (viral, acute), by type														
	A					B					C				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	7	24	74	486	758	17	57	167	1,059	1,573	10	17	39	447	400
New England	—	1	6	12	59	—	0	5	21	32	—	1	4	24	34
Connecticut	—	0	4	5	14	—	0	4	7	9	—	0	3	15	20
Maine†	—	0	1	1	4	—	0	2	5	9	—	0	2	5	2
Massachusetts	—	0	5	3	35	—	0	3	8	8	—	0	1	1	12
New Hampshire	—	0	1	—	—	—	0	1	1	4	N	0	0	N	N
Rhode Island†	—	0	1	1	6	U	0	0	U	U	U	0	0	U	U
Vermont†	—	0	1	2	—	—	0	0	—	2	—	0	1	3	—
Mid. Atlantic	—	4	12	96	121	2	5	11	128	158	3	1	6	35	51
New Jersey	—	1	4	10	36	—	1	4	26	43	—	0	4	—	10
New York (Upstate)	—	1	4	25	25	2	1	9	24	26	3	0	3	21	26
New York City	—	1	6	33	34	—	1	5	39	48	—	0	1	—	1
Pennsylvania	—	1	3	28	26	—	1	4	39	41	—	0	2	14	14
E.N. Central	—	4	9	84	88	—	6	23	131	264	2	3	12	95	48
Illinois	—	1	3	15	24	—	2	7	35	66	—	0	1	1	—
Indiana	—	0	3	10	9	—	1	6	15	37	—	0	5	37	18
Michigan	—	1	5	34	29	—	2	5	44	68	2	1	7	54	22
Ohio	—	1	5	22	17	—	1	16	25	63	—	0	1	2	5
Wisconsin	—	0	2	3	9	—	0	3	12	30	—	0	1	1	3
W.N. Central	—	1	25	17	24	—	2	16	62	61	—	0	6	2	6
Iowa	—	0	3	2	4	—	0	1	5	10	—	0	0	—	—
Kansas	—	0	2	3	7	—	0	2	7	4	—	0	1	2	—
Minnesota	U	0	22	2	1	U	0	15	2	2	U	0	6	—	3
Missouri	—	0	1	5	10	—	2	4	40	35	—	0	1	—	2
Nebraska†	—	0	4	3	2	—	0	3	7	9	—	0	1	—	1
North Dakota	—	0	3	—	—	—	0	0	—	—	—	0	0	—	—
South Dakota	—	0	2	2	—	—	0	1	1	1	—	0	0	—	—
S. Atlantic	—	5	14	112	169	6	14	33	301	437	4	4	11	106	90
Delaware	—	0	1	1	5	—	0	1	—	17	U	0	0	U	U
District of Columbia	—	0	0	—	1	—	0	0	—	3	—	0	0	—	2
Florida	—	2	7	39	61	4	4	11	103	151	1	1	5	26	24
Georgia	—	1	4	27	19	—	2	8	42	94	—	1	3	15	12
Maryland†	—	0	2	11	12	—	1	4	26	31	1	0	2	17	14
North Carolina	—	0	4	12	30	2	2	16	66	34	2	0	7	31	24
South Carolina†	—	0	2	5	18	—	1	4	13	30	—	0	1	—	—
Virginia†	—	1	6	12	22	—	1	7	32	46	—	0	2	8	8
West Virginia	—	0	5	5	1	—	0	18	19	31	—	0	5	9	6
E.S. Central	3	0	6	21	21	4	8	14	187	161	1	3	8	80	72
Alabama†	—	0	2	1	4	—	1	4	34	33	—	0	1	5	3
Kentucky	—	0	6	3	9	—	3	8	59	53	—	2	6	37	50
Mississippi	—	0	1	2	1	—	1	3	18	17	U	0	0	U	U
Tennessee†	3	0	5	15	7	4	3	8	76	58	1	1	5	38	19
W.S. Central	3	2	15	48	69	4	8	67	125	245	—	2	11	41	36
Arkansas†	—	0	1	—	—	—	1	4	20	35	—	0	1	—	1
Louisiana	—	0	1	1	5	—	1	4	18	25	—	0	2	4	1
Oklahoma	—	0	4	1	1	—	2	16	25	38	—	1	10	21	12
Texas†	3	2	11	46	63	4	4	45	62	147	—	0	3	16	22
Mountain	1	2	5	37	90	—	2	7	43	68	—	1	4	33	29
Arizona	—	0	2	7	41	—	0	3	11	14	U	0	0	U	U
Colorado	—	0	2	14	21	—	0	5	10	18	—	0	3	12	8
Idaho†	1	0	1	5	6	—	0	1	2	4	—	0	2	6	7
Montana†	—	0	1	2	4	—	0	0	—	—	—	0	1	2	—
Nevada†	—	0	3	4	6	—	0	3	15	22	—	0	2	6	2
New Mexico†	—	0	1	3	3	—	0	2	4	3	—	0	1	4	9
Utah	—	0	2	—	6	—	0	1	1	7	—	0	2	1	3
Wyoming†	—	0	1	2	3	—	0	1	—	—	—	0	1	2	—
Pacific	—	4	15	59	117	1	4	25	61	147	—	1	12	31	34
Alaska	—	0	1	1	—	—	0	1	4	1	U	0	1	U	U
California	—	3	15	39	90	—	2	22	23	99	—	0	4	9	15
Hawaii	—	0	2	4	5	—	0	1	5	3	U	0	0	U	U
Oregon	—	0	2	5	11	—	1	3	17	24	—	0	3	10	8
Washington	—	0	2	10	11	1	1	4	12	20	—	0	5	12	11
Territories															
American Samoa	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	5	8	4	—	0	8	28	48	—	0	8	10	40
Puerto Rico	—	0	2	3	9	—	0	3	4	12	N	0	0	N	N
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Legionellosis					Lyme disease					Malaria				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	24	47	128	934	1,345	586	328	1,828	6,717	13,752	15	26	114	495	676
New England	—	3	16	39	85	5	69	457	1,060	4,503	—	1	20	17	49
Connecticut	—	1	6	11	12	—	34	151	603	1,619	—	0	20	1	2
Maine†	—	0	3	3	3	1	9	62	116	198	—	0	1	2	4
Massachusetts	—	1	10	17	52	—	11	208	94	1,835	—	1	5	9	36
New Hampshire	—	0	5	3	5	—	12	69	174	708	—	0	2	2	1
Rhode Island†	—	0	4	1	11	—	0	40	4	38	—	0	4	—	5
Vermont†	—	0	2	4	2	4	4	28	69	105	—	0	1	3	1
Mid. Atlantic	10	14	53	238	319	536	145	662	4,113	4,604	1	8	22	110	221
New Jersey	—	2	18	24	53	234	41	311	1,379	2,010	—	1	6	8	52
New York (Upstate)	5	5	19	88	90	127	35	159	757	826	1	1	6	20	33
New York City	—	2	17	37	57	—	4	30	4	314	—	3	13	58	106
Pennsylvania	5	5	19	89	119	175	61	279	1,973	1,454	—	1	4	24	30
E.N. Central	3	9	44	161	281	—	23	373	390	1,954	1	3	9	52	65
Illinois	—	1	14	17	71	—	1	17	12	72	—	1	6	20	25
Indiana	2	1	5	33	25	—	0	7	16	48	—	0	2	5	7
Michigan	1	2	20	39	48	—	1	14	22	28	1	0	4	9	9
Ohio	—	4	15	71	108	—	0	9	7	10	—	1	5	17	19
Wisconsin	—	0	5	1	29	—	19	345	333	1,796	—	0	2	1	5
W.N. Central	—	2	9	31	54	—	3	188	16	1,036	—	1	45	6	26
Iowa	—	0	2	4	4	—	0	7	11	50	—	0	2	2	6
Kansas	—	0	2	4	6	—	0	1	3	8	—	0	2	2	3
Minnesota	U	0	8	—	15	U	3	181	—	973	U	0	45	—	3
Missouri	—	1	5	21	18	—	0	1	—	1	—	0	3	—	4
Nebraska†	—	0	1	—	5	—	0	2	2	3	—	0	1	2	8
North Dakota	—	0	1	1	2	—	0	10	—	—	—	0	1	—	—
South Dakota	—	0	2	1	4	—	0	0	—	1	—	0	1	—	2
S. Atlantic	8	9	22	178	260	44	57	178	1,032	1,492	9	7	41	179	180
Delaware	—	0	2	3	8	2	10	32	290	370	—	0	1	3	2
District of Columbia	—	0	3	4	13	—	0	5	9	15	—	0	1	5	8
Florida	3	3	9	72	79	5	1	8	34	26	2	2	7	46	55
Georgia	1	1	4	10	35	—	0	2	5	6	3	1	7	37	30
Maryland†	2	1	6	27	60	20	17	103	351	675	1	1	21	39	31
North Carolina	2	1	6	30	22	5	0	9	23	34	3	0	13	17	18
South Carolina†	—	0	2	5	7	—	0	3	5	20	—	0	1	1	3
Virginia†	—	1	9	22	31	12	19	82	298	332	—	1	5	31	33
West Virginia	—	0	2	5	5	—	0	29	17	14	—	0	1	—	—
E.S. Central	1	2	10	68	70	1	0	3	16	27	1	0	3	12	11
Alabama†	—	0	2	10	7	—	0	2	5	—	—	0	1	3	2
Kentucky	—	0	4	13	13	—	0	1	—	2	—	0	1	4	3
Mississippi	—	0	3	8	9	—	0	0	—	—	—	0	2	1	—
Tennessee†	1	1	8	37	41	1	0	3	11	25	1	0	2	4	6
W.S. Central	—	3	13	42	59	—	1	29	17	44	—	1	18	21	39
Arkansas†	—	0	2	4	11	—	0	0	—	—	—	0	1	2	1
Louisiana	—	0	3	6	2	—	0	1	—	—	—	0	1	—	1
Oklahoma	—	0	2	2	6	—	0	0	—	—	—	0	1	2	3
Texas†	—	2	11	30	40	—	1	29	17	44	—	1	17	17	34
Mountain	—	2	10	44	83	—	0	3	5	11	—	1	4	31	27
Arizona	—	1	7	15	25	—	0	1	3	2	—	0	4	14	11
Colorado	—	0	2	4	16	—	0	1	1	—	—	0	3	11	9
Idaho†	—	0	1	4	1	—	0	2	—	2	—	0	1	1	—
Montana†	—	0	1	—	4	—	0	1	—	1	—	0	1	—	1
Nevada†	—	0	2	8	15	—	0	1	—	—	—	0	2	3	3
New Mexico†	—	0	2	4	2	—	0	1	1	4	—	0	1	2	—
Utah	—	0	2	8	16	—	0	1	—	2	—	0	0	—	3
Wyoming†	—	0	2	1	4	—	0	0	—	—	—	0	0	—	—
Pacific	2	5	21	133	134	—	3	11	68	81	3	4	10	67	58
Alaska	—	0	2	—	—	—	0	1	—	3	—	0	2	3	2
California	2	4	15	119	114	—	2	9	50	52	2	2	10	48	33
Hawaii	—	0	1	1	1	N	0	0	N	N	—	0	1	2	2
Oregon	—	0	2	4	8	—	0	3	18	22	—	0	3	5	6
Washington	—	0	6	9	11	—	0	4	—	4	1	0	5	9	15
Territories															
American Samoa	N	0	0	N	N	N	0	0	N	N	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	1	—	—	—	0	0	—	—	—	0	0	—	—
Puerto Rico	—	0	1	—	1	N	0	0	N	N	—	0	1	—	4
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Meningococcal disease, invasive† All serogroups					Mumps					Pertussis				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	2	14	53	396	453	—	10	73	144	2,172	81	547	2,925	5,931	7,705
New England	—	0	4	20	11	—	0	2	1	20	3	9	24	160	174
Connecticut	—	0	1	3	1	—	0	0	—	11	—	1	8	18	27
Maine§	—	0	1	3	3	—	0	1	—	1	3	1	8	58	15
Massachusetts	—	0	2	9	2	—	0	2	1	5	—	4	13	48	114
New Hampshire	—	0	1	1	—	—	0	2	—	3	—	1	4	27	5
Rhode Island§	—	0	1	—	—	—	0	0	—	—	—	0	7	7	10
Vermont§	—	0	3	4	5	—	0	0	—	—	—	0	4	2	3
Mid. Atlantic	1	1	6	44	45	—	2	68	19	1,916	19	39	125	618	441
New Jersey	—	0	1	3	13	—	1	6	9	307	—	2	10	47	68
New York (Upstate)	1	0	4	12	9	—	0	5	3	643	14	12	81	202	166
New York City	—	0	3	16	11	—	0	60	7	951	—	1	19	24	25
Pennsylvania	—	0	2	13	12	—	0	16	—	15	5	18	70	345	182
E.N. Central	—	2	7	50	78	—	1	7	37	36	—	112	198	1,309	1,818
Illinois	—	0	2	14	17	—	1	3	24	11	—	21	50	286	325
Indiana	—	0	2	6	17	—	0	1	—	3	—	11	26	89	295
Michigan	—	0	4	5	11	—	0	1	5	14	—	29	57	401	503
Ohio	—	1	2	17	18	—	0	5	8	7	—	32	80	390	578
Wisconsin	—	0	2	8	15	—	0	1	—	1	—	13	26	143	117
W.N. Central	1	1	4	27	32	—	0	4	19	72	4	36	501	494	567
Iowa	—	0	1	6	7	—	0	1	4	34	—	8	36	77	226
Kansas	—	0	1	2	4	—	0	1	3	3	—	2	9	43	85
Minnesota	U	0	2	—	2	U	0	4	1	3	U	0	469	171	5
Missouri	1	0	2	9	13	—	0	3	6	8	3	6	43	140	182
Nebraska§	—	0	2	7	5	—	0	1	1	23	1	3	13	37	48
North Dakota	—	0	1	1	1	—	0	3	4	—	—	0	30	24	—
South Dakota	—	0	1	2	—	—	0	1	—	1	—	0	2	2	21
S. Atlantic	—	2	8	74	82	—	0	4	10	38	24	36	106	641	685
Delaware	—	0	1	1	—	—	0	0	—	—	—	0	2	10	6
District of Columbia	—	0	1	—	—	—	0	1	—	2	—	0	2	2	3
Florida	—	1	5	31	40	—	0	2	2	8	6	6	15	138	136
Georgia	—	0	2	5	6	—	0	2	1	2	—	4	13	85	101
Maryland§	—	0	1	7	4	—	0	1	1	8	1	2	6	41	58
North Carolina	—	0	3	12	9	—	0	2	4	5	7	3	35	108	136
South Carolina§	—	0	1	7	7	—	0	1	—	3	—	5	25	75	155
Virginia§	—	0	2	9	14	—	0	2	2	8	10	7	41	137	81
West Virginia	—	0	1	2	2	—	0	0	—	2	—	1	41	45	9
E.S. Central	—	1	3	17	22	—	0	1	3	9	3	12	35	178	387
Alabama§	—	0	2	9	4	—	0	1	1	6	2	3	11	72	113
Kentucky	—	0	1	—	9	—	0	0	—	1	1	3	16	44	135
Mississippi	—	0	1	2	3	—	0	1	2	—	—	1	10	8	35
Tennessee§	—	0	2	6	6	—	0	1	—	2	—	3	11	54	104
W.S. Central	—	1	12	31	52	—	1	15	44	42	7	39	297	472	1,466
Arkansas§	—	0	1	7	5	—	0	1	1	3	—	2	18	29	75
Louisiana	—	0	2	5	11	—	0	2	—	4	—	0	3	10	22
Oklahoma	—	0	2	5	13	—	0	1	1	—	—	0	92	17	14
Texas§	—	1	10	14	23	—	1	14	42	35	7	32	187	416	1,355
Mountain	—	1	4	33	37	—	0	4	3	11	13	42	100	843	588
Arizona	—	0	1	8	9	—	0	1	—	4	3	14	29	347	202
Colorado	—	0	2	8	12	—	0	1	2	5	7	10	63	252	66
Idaho§	—	0	1	3	5	—	0	1	—	—	3	2	15	45	78
Montana§	—	0	2	3	1	—	0	0	—	—	—	2	16	72	32
Nevada§	—	0	1	3	6	—	0	1	—	—	—	0	7	15	15
New Mexico§	—	0	1	1	3	—	0	2	1	—	—	3	11	59	37
Utah	—	0	2	7	1	—	0	1	—	2	—	5	16	49	152
Wyoming§	—	0	1	—	—	—	0	1	—	—	—	0	2	4	6
Pacific	—	4	26	100	94	—	0	3	8	28	8	126	1,710	1,216	1,579
Alaska	—	0	1	1	1	—	0	1	1	1	—	0	6	16	12
California	—	2	17	69	58	—	0	3	2	18	—	112	1,569	930	1,302
Hawaii	—	0	1	3	1	—	0	1	2	2	1	1	6	18	34
Oregon	—	0	3	16	20	—	0	1	3	1	1	5	11	98	148
Washington	—	0	8	11	14	—	0	1	—	6	6	12	131	154	83
Territories															
American Samoa	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	0	—	—	—	3	15	12	381	—	0	14	31	1
Puerto Rico	—	0	1	—	—	—	0	1	—	—	—	0	1	1	1
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Data for meningococcal disease, invasive caused by serogroups A, C, Y, and W-135; serogroup B; other serogroup; and unknown serogroup are available in Table I.
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Rabies, animal					Salmonellosis					Shiga toxin-producing *E. coli* (STEC)†				
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	16	61	172	1,113	2,095	537	807	1,812	15,104	18,734	61	94	264	1,782	1,872
New England	—	4	18	56	136	3	25	209	543	1,310	—	2	27	61	115
Connecticut	—	0	8	—	65	—	0	187	187	491	—	0	27	27	60
Maine§	—	1	3	26	30	2	2	8	53	55	—	0	3	13	4
Massachusetts	—	0	0	—	—	—	16	52	204	552	—	0	9	5	33
New Hampshire	—	0	6	7	4	1	3	12	67	85	—	0	3	13	12
Rhode Island§	—	0	3	8	12	—	1	9	10	100	—	0	1	—	1
Vermont§	—	1	3	15	25	—	1	5	22	27	—	0	2	3	5
Mid. Atlantic	10	15	33	322	544	63	89	217	1,855	2,293	5	9	30	192	186
New Jersey	—	0	0	—	—	—	16	57	234	455	—	2	9	31	44
New York (Upstate)	10	7	19	146	239	34	25	63	483	512	2	4	12	63	65
New York City	—	0	4	7	126	4	21	53	451	545	—	1	6	27	17
Pennsylvania	—	8	17	169	179	25	32	80	687	781	3	3	13	71	60
E.N. Central	1	2	27	33	79	7	81	203	1,452	2,651	1	10	48	175	323
Illinois	—	1	11	15	33	—	26	61	524	949	—	1	9	18	68
Indiana	—	0	3	4	—	—	10	61	143	284	—	2	10	36	54
Michigan	1	1	5	14	27	7	13	49	281	395	1	2	7	54	70
Ohio	—	0	12	—	19	—	19	42	324	629	—	2	11	44	56
Wisconsin	N	0	0	N	N	—	11	50	180	394	—	2	16	23	75
W.N. Central	2	2	40	39	124	38	48	121	913	1,143	11	13	49	236	352
Iowa	—	0	3	—	8	3	9	34	202	186	—	2	16	50	62
Kansas	1	1	4	17	34	6	7	18	140	169	—	1	7	39	34
Minnesota	U	0	34	—	15	U	4	30	—	323	U	1	20	—	101
Missouri	—	0	6	—	32	24	16	43	374	294	5	4	14	89	107
Nebraska§	1	0	3	15	29	5	4	13	98	93	4	1	5	39	34
North Dakota	—	0	6	7	6	—	0	15	20	13	2	0	10	6	3
South Dakota	—	0	0	—	—	—	3	17	79	65	—	1	4	13	11
S. Atlantic	2	20	52	530	596	225	260	624	4,439	4,367	16	18	31	427	265
Delaware	—	0	0	—	—	—	3	11	53	55	—	0	2	6	3
District of Columbia	—	0	0	—	—	—	1	7	13	47	—	0	1	1	6
Florida	—	0	29	51	121	130	108	226	1,855	1,939	5	6	15	188	82
Georgia	—	0	0	—	—	17	38	142	747	739	1	2	7	43	39
Maryland§	—	6	14	127	182	15	19	54	340	369	3	2	8	42	37
North Carolina	—	0	0	—	—	45	30	241	682	432	5	2	10	53	23
South Carolina§	N	0	0	N	N	7	25	99	329	352	—	0	4	13	13
Virginia§	—	11	27	298	254	11	20	68	384	355	2	3	9	74	56
West Virginia	2	0	30	54	39	—	0	14	36	79	—	0	5	7	6
E.S. Central	1	3	7	64	102	48	56	175	1,052	1,104	5	5	22	115	100
Alabama§	—	1	7	43	44	17	18	52	288	294	—	1	4	18	24
Kentucky	1	0	4	8	10	13	9	32	167	212	1	1	6	15	15
Mississippi	—	0	0	—	—	—	19	65	287	289	—	0	12	8	10
Tennessee§	—	1	4	13	48	18	16	53	310	309	4	3	12	74	51
W.S. Central	—	7	54	49	409	63	111	515	1,758	2,068	1	8	151	123	100
Arkansas§	—	0	10	37	13	14	13	43	227	191	1	0	4	16	24
Louisiana	—	0	0	—	—	—	13	52	141	478	—	0	2	3	9
Oklahoma	—	0	30	12	6	—	10	95	164	196	—	1	55	12	7
Texas§	—	6	30	—	390	49	85	381	1,226	1,203	—	6	95	92	60
Mountain	—	0	5	7	26	27	46	113	997	1,191	3	11	33	222	221
Arizona	N	0	0	N	N	3	15	43	305	380	—	2	14	44	28
Colorado	—	0	0	—	—	17	10	24	245	259	—	3	21	55	81
Idaho§	—	0	2	—	1	3	3	9	75	73	2	3	7	43	23
Montana§	N	0	0	N	N	4	2	6	50	50	1	1	4	16	22
Nevada§	—	0	2	1	2	—	4	21	75	110	—	0	6	16	11
New Mexico§	—	0	2	4	6	—	6	19	94	117	—	1	6	19	15
Utah	—	0	3	2	1	—	5	17	129	177	—	1	8	21	31
Wyoming§	—	0	4	—	16	—	1	8	24	25	—	0	3	8	10
Pacific	—	2	15	13	79	63	101	288	2,095	2,607	19	13	46	231	210
Alaska	—	0	2	9	11	—	1	4	30	42	—	0	1	—	1
California	—	0	10	—	59	43	75	232	1,581	1,819	9	8	36	153	94
Hawaii	—	0	0	—	—	6	6	13	147	151	—	0	3	4	15
Oregon	—	0	2	4	9	—	7	20	115	291	—	2	11	31	31
Washington	—	0	14	—	—	14	15	42	222	304	10	2	20	43	69
Territories															
American Samoa	N	0	0	N	N	—	0	1	—	2	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	0	—	—	—	0	3	6	6	—	0	0	—	—
Puerto Rico	2	0	6	20	24	—	6	25	42	266	—	0	0	—	—
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Includes E. coli O157:H7; Shiga toxin-positive, serogroup non-O157; and Shiga toxin-positive, not serogrouped.
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Shigellosis					Spotted Fever Rickettsiosis (including RMSF)†									
						Confirmed					Probable				
	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010
United States	180	253	742	4,610	6,744	6	2	11	47	64	56	22	245	373	527
New England	—	3	20	77	183	—	0	0	—	—	—	0	1	1	1
Connecticut	—	0	18	18	69	—	0	0	—	—	—	0	0	—	—
Maine§	—	0	4	14	3	—	0	0	—	—	—	0	1	—	1
Massachusetts	—	2	16	42	96	—	0	0	—	—	—	0	0	—	—
New Hampshire	—	0	2	1	5	—	0	0	—	—	—	0	1	—	—
Rhode Island§	—	0	4	—	9	—	0	0	—	—	—	0	1	1	—
Vermont§	—	0	1	2	1	—	0	0	—	—	—	0	0	—	—
Mid. Atlantic	8	15	74	282	911	—	0	1	3	2	—	1	6	12	43
New Jersey	—	3	16	40	211	—	0	0	—	1	—	0	4	—	30
New York (Upstate)	6	3	18	90	82	—	0	0	—	1	—	0	3	2	2
New York City	1	4	14	101	163	—	0	0	—	—	—	0	2	5	6
Pennsylvania	1	4	56	51	455	—	0	1	3	—	—	0	2	5	5
E.N. Central	1	16	37	258	958	—	0	1	—	—	1	1	7	21	38
Illinois	—	6	20	64	599	—	0	1	—	—	—	0	4	11	18
Indiana§	—	1	4	27	26	—	0	1	—	—	1	0	3	8	12
Michigan	1	4	9	73	121	—	0	0	—	—	—	0	1	—	1
Ohio	—	4	15	94	166	—	0	0	—	—	—	0	2	2	4
Wisconsin	—	0	4	—	46	—	0	0	—	—	—	0	1	—	3
W.N. Central	3	14	52	175	1,441	—	0	2	5	5	9	4	17	93	106
Iowa	—	1	4	9	29	—	0	0	—	—	—	0	1	1	2
Kansas§	—	3	12	31	150	—	0	0	—	—	—	0	0	—	—
Minnesota	U	0	4	—	25	U	0	0	—	—	U	0	2	—	—
Missouri	3	8	41	128	1,218	—	0	2	5	3	9	4	17	92	103
Nebraska§	—	0	10	4	15	—	0	1	—	2	—	0	1	—	1
North Dakota	—	0	0	—	—	—	0	0	—	—	—	0	1	—	—
South Dakota	—	0	2	3	4	—	0	0	—	—	—	0	0	—	—
S. Atlantic	99	64	130	1,787	993	6	1	5	30	40	42	6	59	125	144
Delaware§	—	0	1	1	34	—	0	1	1	1	—	0	2	7	9
District of Columbia	—	0	3	6	18	—	0	1	1	—	—	0	0	—	—
Florida§	77	34	99	1,295	378	1	0	1	3	2	1	0	2	3	6
Georgia	14	13	26	254	352	—	0	4	15	33	—	0	0	—	—
Maryland§	3	2	8	43	51	—	0	1	1	—	—	0	5	6	19
North Carolina	4	3	36	119	71	4	0	3	5	3	41	1	47	73	69
South Carolina§	—	1	5	25	35	—	0	1	3	—	—	0	2	8	6
Virginia§	1	2	8	40	53	1	0	2	1	1	—	2	12	26	35
West Virginia	—	0	66	4	1	—	0	0	—	—	—	0	1	2	—
E.S. Central	2	13	29	242	373	—	0	3	3	10	2	5	26	90	159
Alabama§	1	5	15	88	62	—	0	1	—	1	—	1	6	18	29
Kentucky	—	1	6	30	164	—	0	1	—	6	—	0	0	—	—
Mississippi	—	2	7	58	19	—	0	1	—	—	—	0	4	1	9
Tennessee§	1	4	14	66	128	—	0	3	3	3	2	4	20	71	121
W.S. Central	46	55	503	1,028	1,133	—	0	8	—	1	—	1	235	7	31
Arkansas§	3	2	7	30	23	—	0	2	—	—	—	0	28	1	11
Louisiana	—	5	13	49	130	—	0	0	—	—	—	0	1	—	1
Oklahoma	—	2	161	40	150	—	0	5	—	—	—	0	202	4	9
Texas§	43	46	338	909	830	—	0	1	—	1	—	0	5	2	10
Mountain	7	17	32	336	309	—	0	5	6	2	2	0	7	24	4
Arizona	1	7	19	101	165	—	0	4	6	—	—	0	7	19	—
Colorado§	2	2	7	40	40	—	0	1	—	—	1	0	1	2	—
Idaho§	1	0	3	9	11	—	0	0	—	—	—	0	1	—	1
Montana§	3	1	15	102	4	—	0	0	—	2	—	0	0	—	1
Nevada§	—	0	6	10	17	—	0	0	—	—	—	0	0	—	—
New Mexico§	—	3	10	52	56	—	0	0	—	—	—	0	0	—	1
Utah	—	1	4	21	16	—	0	0	—	—	—	0	1	—	1
Wyoming§	—	0	1	1	—	—	0	0	—	—	1	0	1	3	—
Pacific	14	23	63	425	443	—	0	2	—	4	—	0	0	—	1
Alaska	—	0	2	3	—	N	0	0	N	N	N	0	0	N	N
California	12	18	59	329	351	—	0	2	—	4	—	0	0	—	—
Hawaii	—	1	3	27	31	N	0	0	N	N	N	0	0	N	N
Oregon	—	1	4	26	30	—	0	0	—	—	—	0	0	—	1
Washington	2	1	22	40	31	—	0	1	—	—	—	0	0	—	—
Territories															
American Samoa	—	1	1	1	1	N	0	0	N	N	N	0	0	N	N
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	2	1	5	N	0	0	N	N	N	0	0	N	N
Puerto Rico	—	0	1	—	3	N	0	0	N	N	N	0	0	N	N
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Illnesses with similar clinical presentation that result from Spotted fever group rickettsia infections are reported as Spotted fever rickettsioses. Rocky Mountain spotted fever (RMSF) caused by Rickettsia rickettsii, is the most common and well-known spotted fever.
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	*Streptococcus pneumoniae*,† invasive disease										Syphilis, primary and secondary				
	All ages					Age <5									
	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010	Current week	Previous 52 weeks		Cum 2011	Cum 2010
		Med	Max				Med	Max				Med	Max		
United States	59	283	937	7,682	9,401	9	23	101	594	1,151	58	258	363	5,684	6,478
New England	4	11	79	221	513	—	1	5	24	67	3	8	19	194	226
Connecticut	—	0	49	8	232	—	0	3	6	20	2	1	8	32	42
Maine§	4	2	13	80	78	—	0	1	3	5	—	0	3	9	14
Massachusetts	—	0	3	14	51	—	0	3	6	35	—	5	14	113	143
New Hampshire	—	2	8	66	72	—	0	1	4	3	—	0	3	12	10
Rhode Island§	—	0	36	8	27	—	0	3	—	1	1	0	7	23	15
Vermont§	—	1	6	45	53	—	0	2	5	3	—	0	2	5	2
Mid. Atlantic	4	22	81	548	985	1	3	27	77	149	8	31	46	684	834
New Jersey	—	6	29	102	438	—	1	4	25	38	—	4	10	100	124
New York (Upstate)	1	2	10	55	100	1	1	9	31	76	5	3	20	91	51
New York City	3	13	42	391	447	—	0	14	21	35	—	15	31	326	467
Pennsylvania	N	0	0	N	N	N	0	0	N	N	3	7	13	167	192
E.N. Central	3	65	110	1,772	1,929	—	4	10	101	170	—	30	56	576	952
Illinois	N	0	0	N	N	N	0	0	N	N	—	13	23	217	470
Indiana	—	14	32	369	434	—	1	4	16	33	—	3	14	74	75
Michigan	2	14	29	415	441	—	1	4	24	53	—	4	10	92	135
Ohio	—	25	45	710	747	—	2	7	49	59	—	9	21	171	249
Wisconsin	1	9	24	278	307	—	0	3	12	25	—	1	4	22	23
W.N. Central	—	5	35	91	505	—	1	5	4	69	—	7	18	135	139
Iowa	N	0	0	N	N	N	0	0	N	N	—	0	3	11	9
Kansas	N	0	0	N	N	N	0	0	N	N	—	0	3	7	10
Minnesota	U	2	24	—	382	U	0	5	—	56	U	3	10	56	42
Missouri	N	0	0	N	N	N	0	0	N	N	—	2	9	59	73
Nebraska§	—	2	9	73	85	—	0	1	4	11	—	0	2	2	5
North Dakota	—	0	18	18	38	—	0	1	—	2	—	0	1	—	—
South Dakota	N	0	0	N	N	N	0	0	N	N	—	0	1	—	—
S. Atlantic	22	68	170	2,168	2,523	4	6	22	165	317	14	62	178	1,491	1,474
Delaware	—	1	6	33	21	—	0	1	—	—	3	0	4	12	3
District of Columbia	—	1	3	28	51	—	0	1	4	7	1	3	8	99	73
Florida	16	23	68	880	955	3	3	13	80	127	1	23	44	540	519
Georgia	1	19	54	488	817	—	2	7	40	97	1	10	130	236	315
Maryland§	3	10	32	322	294	1	1	4	18	35	—	8	17	200	131
North Carolina	N	0	0	N	N	N	0	0	N	N	—	7	19	180	235
South Carolina§	2	8	25	292	318	—	1	3	18	37	4	4	10	109	62
Virginia§	N	0	0	N	N	N	0	0	N	N	4	5	16	114	133
West Virginia	—	1	48	125	67	—	0	6	5	14	—	0	2	1	3
E.S. Central	4	19	36	568	643	2	1	4	34	62	14	15	34	330	432
Alabama§	N	0	0	N	N	N	0	0	N	N	—	3	11	80	129
Kentucky	N	0	0	N	N	N	0	0	N	N	2	2	16	55	65
Mississippi	N	0	0	N	N	N	0	0	N	N	10	3	16	75	95
Tennessee§	4	19	36	568	643	2	1	4	34	62	2	5	11	120	143
W.S. Central	12	31	368	1,120	1,137	2	4	30	100	150	6	38	71	827	992
Arkansas§	1	3	26	144	108	—	0	3	11	11	6	3	10	96	131
Louisiana	—	3	11	97	61	—	0	2	8	16	—	7	36	171	204
Oklahoma	N	0	0	N	N	N	0	0	N	N	—	1	6	25	52
Texas§	11	26	333	879	968	2	3	27	81	123	—	23	33	535	605
Mountain	10	32	72	1,101	1,105	—	3	8	82	154	—	12	24	271	279
Arizona	1	12	45	526	540	—	1	5	38	70	—	4	9	101	109
Colorado	9	11	23	345	322	—	1	4	25	45	—	2	8	54	64
Idaho§	N	0	0	N	N	N	0	0	N	N	—	0	2	4	2
Montana§	N	0	0	N	N	N	0	0	N	N	—	0	2	2	2
Nevada§	N	0	0	N	N	N	0	0	N	N	—	3	9	73	42
New Mexico§	—	3	13	150	105	—	0	2	9	13	—	1	4	31	22
Utah	—	3	8	63	128	—	0	3	10	24	—	0	5	6	38
Wyoming§	—	0	15	17	10	—	0	1	—	2	—	0	0	—	—
Pacific	—	2	11	93	61	—	0	2	7	13	13	51	66	1,176	1,150
Alaska	—	2	11	92	61	—	0	2	7	13	—	0	0	—	3
California	N	0	0	N	N	N	0	0	N	N	7	42	57	983	979
Hawaii	—	0	3	1	—	—	0	0	—	—	—	0	5	7	21
Oregon	N	0	0	N	N	N	0	0	N	N	3	1	7	43	30
Washington	N	0	0	N	N	N	0	0	N	N	3	6	13	143	117
Territories															
American Samoa	N	0	0	N	N	N	0	0	N	N	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—
Puerto Rico	—	0	0	—	—	—	0	0	—	—	—	4	12	121	121
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.
* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.
† Includes drug resistant and susceptible cases of invasive Streptococcus pneumoniae disease among children <5 years and among all ages. Case definition: Isolation of S. pneumoniae from a normally sterile body site (e.g., blood or cerebrospinal fluid).
§ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE II. (*Continued*) Provisional cases of selected notifiable diseases, United States, weeks ending July 2, 2011, and July 3, 2010 (26th week)*

Reporting area	Varicella (chickenpox)					West Nile virus disease†									
						Neuroinvasive					Nonneuroinvasive§				
	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010	Current week	Previous 52 weeks Med	Previous 52 weeks Max	Cum 2011	Cum 2010
United States	156	248	367	6,122	9,122	—	0	71	1	21	—	0	53	1	33
New England	—	17	46	443	616	—	0	3	—	—	—	0	2	—	1
Connecticut	—	5	15	139	190	—	0	2	—	—	—	0	2	—	1
Maine¶	—	5	16	115	107	—	0	0	—	—	—	0	0	—	—
Massachusetts	—	4	17	103	165	—	0	2	—	—	—	0	1	—	—
New Hampshire	—	1	9	9	73	—	0	1	—	—	—	0	0	—	—
Rhode Island¶	—	0	5	17	18	—	0	0	—	—	—	0	0	—	—
Vermont¶	—	2	10	60	63	—	0	0	—	—	—	0	0	—	—
Mid. Atlantic	23	31	55	871	1,004	—	0	19	—	—	—	0	13	—	—
New Jersey	22	9	39	358	366	—	0	3	—	—	—	0	6	—	—
New York (Upstate)	N	0	0	N	N	—	0	9	—	—	—	0	7	—	—
New York City	—	0	0	—	—	—	0	7	—	—	—	0	4	—	—
Pennsylvania	1	19	41	513	638	—	0	3	—	—	—	0	3	—	—
E.N. Central	1	68	118	1,618	3,062	—	0	15	—	—	—	0	7	—	—
Illinois	—	17	31	419	753	—	0	10	—	—	—	0	4	—	—
Indiana¶	—	5	18	123	225	—	0	2	—	—	—	0	2	—	—
Michigan	1	20	38	537	955	—	0	6	—	—	—	0	1	—	—
Ohio	—	20	57	538	816	—	0	1	—	—	—	0	1	—	—
Wisconsin	—	3	22	1	313	—	0	0	—	—	—	0	1	—	—
W.N. Central	7	12	42	198	482	—	0	7	—	—	—	0	11	—	10
Iowa	N	0	0	N	N	—	0	1	—	—	—	0	2	—	—
Kansas¶	—	4	15	56	209	—	0	1	—	—	—	0	3	—	3
Minnesota	U	0	0	—	—	U	0	1	—	—	U	0	3	—	—
Missouri	—	5	24	97	224	—	0	1	—	—	—	0	0	—	—
Nebraska¶	—	0	5	3	5	—	0	3	—	—	—	0	7	—	4
North Dakota	7	0	10	23	29	—	0	2	—	—	—	0	2	—	1
South Dakota	—	1	7	19	15	—	0	2	—	—	—	0	3	—	2
S. Atlantic	6	35	64	1,023	1,316	—	0	6	—	—	—	0	4	—	3
Delaware¶	—	0	3	5	19	—	0	0	—	—	—	0	0	—	—
District of Columbia	—	0	1	8	15	—	0	1	—	—	—	0	1	—	—
Florida¶	5	15	38	516	653	—	0	3	—	—	—	0	1	—	—
Georgia	N	0	0	N	N	—	0	1	—	—	—	0	3	—	3
Maryland¶	N	0	0	N	N	—	0	3	—	—	—	0	2	—	—
North Carolina	N	0	0	N	N	—	0	0	—	—	—	0	0	—	—
South Carolina¶	—	0	8	11	74	—	0	1	—	—	—	0	0	—	—
Virginia¶	1	9	25	242	302	—	0	1	—	—	—	0	1	—	—
West Virginia	—	7	32	241	253	—	0	0	—	—	—	0	0	—	—
E.S. Central	—	5	15	166	182	—	0	1	—	2	—	0	3	1	1
Alabama¶	—	5	14	157	175	—	0	0	—	1	—	0	1	—	1
Kentucky	N	0	0	N	N	—	0	1	—	—	—	0	1	—	—
Mississippi	—	0	3	9	7	—	0	1	—	1	—	0	2	1	—
Tennessee¶	N	0	0	N	N	—	0	1	—	—	—	0	2	—	—
W.S. Central	115	43	258	1,359	1,730	—	0	16	—	3	—	0	3	—	—
Arkansas¶	—	3	17	119	120	—	0	3	—	—	—	0	1	—	—
Louisiana	—	2	5	48	44	—	0	3	—	2	—	0	1	—	—
Oklahoma	N	0	0	N	N	—	0	1	—	—	—	0	0	—	—
Texas¶	115	37	247	1,192	1,566	—	0	15	—	1	—	0	2	—	—
Mountain	3	14	50	383	670	—	0	18	1	13	—	0	15	—	17
Arizona	—	0	0	—	—	—	0	13	1	12	—	0	9	—	9
Colorado¶	3	5	31	146	233	—	0	5	—	1	—	0	11	—	7
Idaho¶	N	0	0	N	N	—	0	0	—	—	—	0	1	—	—
Montana¶	—	2	28	92	145	—	0	0	—	—	—	0	0	—	—
Nevada¶	N	0	0	N	N	—	0	0	—	—	—	0	1	—	1
New Mexico¶	—	1	8	23	63	—	0	6	—	—	—	0	2	—	—
Utah	—	4	26	115	216	—	0	1	—	—	—	0	1	—	—
Wyoming¶	—	0	3	7	13	—	0	1	—	—	—	0	1	—	—
Pacific	1	2	6	61	60	—	0	8	—	3	—	0	6	—	1
Alaska	—	1	5	29	22	—	0	0	—	—	—	0	0	—	—
California	—	0	3	6	20	—	0	8	—	3	—	0	6	—	1
Hawaii	1	1	4	26	18	—	0	0	—	—	—	0	0	—	—
Oregon	N	0	0	N	N	—	0	0	—	—	—	0	0	—	—
Washington	N	0	0	N	N	—	0	1	—	—	—	0	1	—	—
Territories															
American Samoa	N	0	0	N	N	—	0	0	—	—	—	0	0	—	—
C.N.M.I.	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Guam	—	0	4	16	17	—	0	0	—	—	—	0	0	—	—
Puerto Rico	1	7	31	59	314	—	0	0	—	—	—	0	0	—	—
U.S. Virgin Islands	—	0	0	—	—	—	0	0	—	—	—	0	0	—	—

C.N.M.I.: Commonwealth of Northern Mariana Islands.
U: Unavailable. —: No reported cases. N: Not reportable. NN: Not Nationally Notifiable. Cum: Cumulative year-to-date counts. Med: Median. Max: Maximum.

* Case counts for reporting year 2010 and 2011 are provisional and subject to change. For further information on interpretation of these data, see http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/ProvisionalNationa%20NotifiableDiseasesSurveillanceData20100927.pdf. Data for TB are displayed in Table IV, which appears quarterly.

† Updated weekly from reports to the Division of Vector-Borne Infectious Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ArboNET Surveillance). Data for California serogroup, eastern equine, Powassan, St. Louis, and western equine diseases are available in Table I.

§ Not reportable in all states. Data from states where the condition is not reportable are excluded from this table, except starting in 2007 for the domestic arboviral diseases and influenza-associated pediatric mortality, and in 2003 for SARS-CoV. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis.htm.

¶ Contains data reported through the National Electronic Disease Surveillance System (NEDSS).

TABLE III. Deaths in 122 U.S. cities,* week ending July 2, 2011 (26th week)

Reporting area	All causes, by age (years)						P&I†
	All Ages	≥65	45–64	25–44	1–24	<1	Total
New England	448	315	88	30	7	8	50
Boston, MA	126	77	29	13	4	3	13
Bridgeport, CT	21	11	4	6	—	—	2
Cambridge, MA	12	7	4	—	1	—	1
Fall River, MA	18	13	5	—	—	—	—
Hartford, CT	50	38	8	3	1	—	7
Lowell, MA	27	24	2	1	—	—	3
Lynn, MA	5	4	1	—	—	—	1
New Bedford, MA	24	19	5	—	—	—	2
New Haven, CT	29	22	3	3	1	—	6
Providence, RI	41	28	9	2	—	2	3
Somerville, MA	1	1	—	—	—	—	—
Springfield, MA	35	25	7	1	—	2	4
Waterbury, CT	14	12	2	—	—	—	2
Worcester, MA	45	34	9	1	—	1	6
Mid. Atlantic	1,685	1,181	362	81	34	26	88
Albany, NY	47	36	5	2	2	2	2
Allentown, PA	33	25	5	2	1	—	6
Buffalo, NY	54	39	11	3	1	—	—
Camden, NJ	21	6	5	5	1	4	2
Elizabeth, NJ	9	6	2	1	—	—	1
Erie, PA	54	43	8	3	—	—	2
Jersey City, NJ	9	5	3	1	—	—	2
New York City, NY	967	683	207	45	16	15	48
Newark, NJ	15	6	7	—	1	1	2
Paterson, NJ	24	16	6	1	1	—	1
Philadelphia, PA	134	85	40	4	2	3	7
Pittsburgh, PA§	32	20	9	2	—	1	—
Reading, PA	38	32	5	1	—	—	—
Rochester, NY	71	44	18	5	4	—	4
Schenectady, NY	10	8	1	1	—	—	1
Scranton, PA	24	17	7	—	—	—	1
Syracuse, NY	84	69	12	2	1	—	8
Trenton, NJ	35	23	7	2	3	—	—
Utica, NY	6	4	2	—	—	—	—
Yonkers, NY	18	14	2	1	1	—	1
E.N. Central	1,851	1,214	465	106	41	25	127
Akron, OH	40	31	7	2	—	—	5
Canton, OH	35	23	10	2	—	—	2
Chicago, IL	201	132	50	14	5	—	13
Cincinnati, OH	83	51	23	6	—	3	5
Cleveland, OH	227	155	53	11	4	4	12
Columbus, OH	170	104	49	11	5	1	12
Dayton, OH	111	84	22	3	1	1	8
Detroit, MI	142	58	54	18	9	3	4
Evansville, IN	39	29	6	3	—	1	1
Fort Wayne, IN	70	44	18	5	2	1	3
Gary, IN	10	6	3	—	—	1	1
Grand Rapids, MI	60	46	11	2	—	1	6
Indianapolis, IN	232	140	64	16	7	5	14
Lansing, MI	43	31	10	2	—	—	6
Milwaukee, WI	71	44	22	2	3	—	6
Peoria, IL	46	33	9	3	—	1	3
Rockford, IL	63	44	14	1	4	—	7
South Bend, IN	60	46	10	2	—	2	10
Toledo, OH	98	70	23	3	1	1	7
Youngstown, OH	50	43	7	—	—	—	2
W.N. Central	525	324	126	36	22	17	32
Des Moines, IA	58	43	8	2	3	2	6
Duluth, MN	U	U	U	U	U	U	U
Kansas City, KS	26	15	5	3	3	—	1
Kansas City, MO	74	54	10	7	1	2	3
Lincoln, NE	49	33	13	1	—	2	1
Minneapolis, MN	U	U	U	U	U	U	U
Omaha, NE	61	43	14	1	1	2	5
St. Louis, MO	155	77	44	15	11	8	11
St. Paul, MN	U	U	U	U	U	U	U
Wichita, KS	102	59	32	7	3	1	5
S. Atlantic	1,169	751	289	74	37	18	64
Atlanta, GA	140	77	48	8	6	1	7
Baltimore, MD	150	81	44	17	3	5	13
Charlotte, NC	134	91	27	8	5	3	8
Jacksonville, FL	146	96	35	10	3	2	7
Miami, FL	105	71	18	6	10	—	6
Norfolk, VA	48	32	11	2	2	1	—
Richmond, VA	48	31	9	6	1	1	4
Savannah, GA	54	35	14	5	—	—	6
St. Petersburg, FL	53	43	5	3	2	—	1
Tampa, FL	167	116	39	6	3	3	8
Washington, D.C.	114	68	39	3	2	2	3
Wilmington, DE	10	10	—	—	—	—	1
E.S. Central	879	579	220	48	15	17	65
Birmingham, AL	188	120	51	10	2	5	18
Chattanooga, TN	77	62	10	5	—	—	4
Knoxville, TN	110	78	22	4	4	2	8
Lexington, KY	66	48	10	3	3	2	2
Memphis, TN	196	119	57	14	3	3	16
Mobile, AL	65	44	14	6	1	—	4
Montgomery, AL	34	23	7	1	1	2	3
Nashville, TN	143	85	49	5	1	3	10
W.S. Central	1,060	676	240	80	43	21	52
Austin, TX	79	50	12	11	3	3	2
Baton Rouge, LA	54	37	10	3	2	2	—
Corpus Christi, TX	75	45	17	3	6	4	2
Dallas, TX	174	105	41	13	9	6	10
El Paso, TX	101	72	16	10	3	—	—
Fort Worth, TX	U	U	U	U	U	U	U
Houston, TX	159	102	32	15	7	3	13
Little Rock, AR	U	U	U	U	U	U	U
New Orleans, LA	U	U	U	U	U	U	U
San Antonio, TX	262	170	68	16	5	3	11
Shreveport, LA	37	26	8	2	1	—	4
Tulsa, OK	119	69	36	7	7	—	10
Mountain	1,003	644	248	72	22	16	73
Albuquerque, NM	157	90	40	20	4	3	17
Boise, ID	67	44	16	4	2	1	8
Colorado Springs, CO	68	50	13	3	—	2	4
Denver, CO	82	48	25	7	1	1	4
Las Vegas, NV	265	188	63	9	3	1	22
Ogden, UT	33	16	13	1	1	2	3
Phoenix, AZ	U	U	U	U	U	U	U
Pueblo, CO	33	21	10	2	—	—	1
Salt Lake City, UT	136	83	33	13	5	2	11
Tucson, AZ	162	104	35	13	6	4	3
Pacific	1,365	911	335	70	36	13	123
Berkeley, CA	12	6	4	—	—	2	—
Fresno, CA	106	70	27	1	6	2	14
Glendale, CA	33	26	7	—	—	—	4
Honolulu, HI	70	48	18	4	—	—	8
Long Beach, CA	71	47	19	3	2	—	9
Los Angeles, CA	231	140	64	16	8	3	24
Pasadena, CA	19	18	1	—	—	—	2
Portland, OR	127	79	33	10	3	2	7
Sacramento, CA	191	130	50	8	3	—	19
San Diego, CA	155	107	33	8	4	3	8
San Francisco, CA	35	27	4	4	—	—	4
San Jose, CA	U	U	U	U	U	U	U
Santa Cruz, CA	24	13	8	3	—	—	4
Seattle, WA	100	62	24	9	4	1	4
Spokane, WA	53	39	10	2	2	—	8
Tacoma, WA	138	99	33	2	4	—	8
Total¶	**9,985**	**6,595**	**2,373**	**597**	**257**	**161**	**674**

U: Unavailable. —: No reported cases.

* Mortality data in this table are voluntarily reported from 122 cities in the United States, most of which have populations of >100,000. A death is reported by the place of its occurrence and by the week that the death certificate was filed. Fetal deaths are not included.

† Pneumonia and influenza.

§ Because of changes in reporting methods in this Pennsylvania city, these numbers are partial counts for the current week. Complete counts will be available in 4 to 6 weeks.

¶ Total includes unknown ages.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit MMWR's free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Data presented by the Notifiable Disease Data Team and 122 Cities Mortality Data Team in the weekly *MMWR* are provisional, based on weekly reports to CDC by state health departments. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30333 or to *mmwrq@cdc.gov.*

All material in the *MMWR* Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

U.S. Government Printing Office: 2011-723-011/21058 Region IV ISSN: 0149-2195

CDC

MMWR™

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Recommendations and Reports December 17, 2010 / Vol. 59 / No. RR-12

Sexually Transmitted Diseases Treatment Guidelines, 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

The *MMWR* series of publications is published by the Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

Suggested Citation: Centers for Disease Control and Prevention. [Title]. MMWR 2010;59(No. RR-#):[inclusive page numbers].

Centers for Disease Control and Prevention

Thomas R. Frieden, MD, MPH
Director
Harold W. Jaffe, MD, MA
Associate Director for Science
James W. Stephens, PhD
Office of the Associate Director for Science
Stephen B. Thacker, MD, MSc
Deputy Director for Surveillance, Epidemiology, and Laboratory Services
Stephanie Zaza, MD, MPH
Director, Epidemiology and Analysis Program Office

Editorial and Production Staff

Ronald L. Moolenaar, MD, MPH
Editor, MMWR *Series*
Christine G. Casey, MD
Deputy Editor, MMWR *Series*
Teresa F. Rutledge
Managing Editor, MMWR *Series*
David C. Johnson
Lead Technical Writer-Editor
Rachel J. Wilson
Project Editor
Martha F. Boyd
Lead Visual Information Specialist
Malbea A. LaPete
Stephen R. Spriggs
Terraye M. Starr
Visual Information Specialists
Quang M. Doan, MBA
Phyllis H. King
Information Technology Specialists

Editorial Board

William L. Roper, MD, MPH, Chapel Hill, NC, Chairman
Virginia A. Caine, MD, Indianapolis, IN
Jonathan E. Fielding, MD, MPH, MBA, Los Angeles, CA
David W. Fleming, MD, Seattle, WA
William E. Halperin, MD, DrPH, MPH, Newark, NJ
King K. Holmes, MD, PhD, Seattle, WA
Deborah Holtzman, PhD, Atlanta, GA
John K. Iglehart, Bethesda, MD
Dennis G. Maki, MD, Madison, WI
Patricia Quinlisk, MD, MPH, Des Moines, IA
Patrick L. Remington, MD, MPH, Madison, WI
Barbara K. Rimer, DrPH, Chapel Hill, NC
John V. Rullan, MD, MPH, San Juan, PR
William Schaffner, MD, Nashville, TN
Anne Schuchat, MD, Atlanta, GA
Dixie E. Snider, MD, MPH, Atlanta, GA
John W. Ward, MD, Atlanta, GA

CONTENTS

Introduction 1
Methods 1
Clinical Prevention Guidance 2
  STD/HIV Prevention Counseling 2
  Prevention Methods 4
  Partner Management 7
  Reporting and Confidentiality 8
Special Populations 8
  Pregnant Women 8
  Adolescents 10
  Children 11
  Persons in Correctional Facilities 11
  Men Who Have Sex with Men 12
  Women Who Have Sex with Women 13
HIV Infection: Detection, Counseling, and Referral 14
Diseases Characterized by Genital, Anal, or Perianal Ulcers 18
  Chancroid 19
  Genital HSV Infections 20
  Granuloma Inguinale (Donovanosis) 25
  Lymphogranuloma Venereum 26
  Syphilis 26
    Congenital Syphilis 36
Management of Persons Who Have a History of Penicillin Allergy 39
Diseases Characterized by Urethritis and Cervicitis 40
  Urethritis 40
  Nongonococcal Urethritis 41
  Cervicitis 43
Chlamydial Infections 44
Gonococcal Infections 49
Diseases Characterized by Vaginal Discharge 56
  Bacterial Vaginosis 56
  Trichomoniasis 58
  Vulvovaginal Candidiasis 61
Pelvic Inflammatory Disease 63
Epididymitis 67
Human Papillomavirus (HPV) Infection 69
Genital Warts 70
Cervical Cancer Screening for Women Who Attend STD Clinics or Have a History of STDs 74
Vaccine-Preventable STDs 78
  Hepatitis A 78
  Hepatitis B 80
Hepatitis C 85
Proctitis, Proctocolitis, and Enteritis 87
Ectoparasitic Infections 88
  Pediculosis Pubis 88
  Scabies 89
Sexual Assault and STDs 90
References 96
Terms and Abbreviations Used in This Report 109

Sexually Transmitted Diseases Treatment Guidelines, 2010

Prepared by
Kimberly A. Workowski, MD[1,2]
Stuart Berman, MD[1]
[1]*Division of STD Prevention*
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
[2]*Emory University, Atlanta, Georgia*

Summary

*These guidelines for the treatment of persons who have or are at risk for sexually transmitted diseases (STDs) were updated by CDC after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta on April 18–30, 2009. The information in this report updates the 2006 Guidelines for Treatment of Sexually Transmitted Diseases (*MMWR *2006;55[No. RR–11]). Included in these updated guidelines is new information regarding 1) the expanded diagnostic evaluation for cervicitis and trichomoniasis; 2) new treatment recommendations for bacterial vaginosis and genital warts; 3) the clinical efficacy of azithromycin for chlamydial infections in pregnancy; 4) the role of* Mycoplasma genitalium *and trichomoniasis in urethritis/cervicitis and treatment-related implications; 5) lymphogranuloma venereum proctocolitis among men who have sex with men; 6) the criteria for spinal fluid examination to evaluate for neurosyphilis; 7) the emergence of azithromycin-resistant* Treponema pallidum*; 8) the increasing prevalence of antimicrobial-resistant* Neisseria gonorrhoeae*; 9) the sexual transmission of hepatitis C; 10) diagnostic evaluation after sexual assault; and 11) STD prevention approaches.*

Introduction

The term sexually transmitted diseases (STDs) is used to refer to a variety of clinical syndromes caused by pathogens that can be acquired and transmitted through sexual activity. Physicians and other health-care providers play a critical role in preventing and treating STDs. These guidelines for the treatment of STDs are intended to assist with that effort. Although these guidelines emphasize treatment, prevention strategies and diagnostic recommendations also are discussed.

These recommendations should be regarded as a source of clinical guidance and not prescriptive standards; health-care providers should always consider the clinical circumstances of each person in the context of local disease prevalence. They are applicable to various patient-care settings, including family-planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are essential to STD/human immunodeficiency virus (HIV) prevention efforts.

Corresponding Author: Kimberly Workowski, MD, Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 10 Corporate Square, Corporate Square Blvd, MS E02, Atlanta, GA 30333. Telephone: 404-639-1898; Fax: 404-639-8610; kgw2@cdc.gov.

Methods

These guidelines were developed using a multistage process. Beginning in 2008, CDC staff members and public and private sector experts knowledgeable in the field of STDs systematically reviewed literature using an evidence-based approach (e.g., published abstracts and peer-reviewed journal articles), focusing on the common STDs and information that had become available since publication of the *2006 Guidelines for Treatment of Sexually Transmitted Diseases* (*1*). CDC staff members and STD experts developed background papers and tables of evidence that summarized the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. CDC staff then developed a draft document on the basis of this evidence-based review. In April 2009, this information was presented at a meeting of invited consultants (including public- and private-sector professionals knowledgeable in the treatment of patients with STDs), where all evidence from the literature reviews pertaining to STD management was discussed.

Specifically, participants identified key questions regarding STD treatment that emerged from the literature reviews and discussed the information available to answer those questions. Discussion focused on four principal outcomes of STD therapy for each individual disease: 1) treatment of infection based on microbiologic eradication; 2) alleviation of signs and symptoms; 3) prevention of sequelae; and 4) prevention

of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy [DOT]) of specific regimens also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and answered the questions using the available evidence. In addition, the consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

The sections on hepatitis B virus (HBV) and hepatitis A virus (HAV) infections are based on previously published recommendations of the Advisory Committee on Immunization Practices (ACIP) (*2–4*). The recommendations for STD screening during pregnancy and cervical cancer screening were developed after CDC staff reviewed the published recommendations from other professional organizations, including the American College of Obstetricians and Gynecologists (ACOG), United States Preventive Services Task Force (USPSTF), and ACIP.

Throughout this report, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*. When more than one therapeutic regimen is recommended, the sequence is alphabetized unless the choices for therapy are prioritized based on efficacy, convenience, or cost. For those infections with more than one recommended regimen, almost all regimens have similar efficacy and similar rates of intolerance or toxicity unless otherwise specified. Recommended regimens should be used primarily; alternative regimens can be considered in instances of significant drug allergy or other contraindications to the recommended regimens.

Clinical Prevention Guidance

The prevention and control of STDs are based on the following five major strategies:

- education and counseling of persons at risk on ways to avoid STDs through changes in sexual behaviors and use of recommended prevention services;
- identification of asymptomatically infected persons and of symptomatic persons unlikely to seek diagnostic and treatment services;
- effective diagnosis, treatment, and counseling of infected persons;
- evaluation, treatment, and counseling of sex partners of persons who are infected with an STD; and
- pre-exposure vaccination of persons at risk for vaccine-preventable STDs.

Primary prevention of STDs begins with changing the sexual behaviors that place persons at risk for infection. Health-care providers have a unique opportunity to provide education and counseling to their patients (*5,6*). As part of the clinical interview, health-care providers should routinely and regularly obtain sexual histories from their patients and address management of risk reduction as indicated in this report. Guidance in obtaining a sexual history is available in *Contraceptive Technology, 19th edition* (*7*) and in the curriculum provided by CDC's STD/HIV Prevention Training Centers (http://www.stdhivpreventiontraining.org). Effective interviewing and counseling skills, characterized by respect, compassion, and a nonjudgmental attitude toward all patients, are essential to obtaining a thorough sexual history and to delivering prevention messages effectively. Key techniques that can be effective in facilitating rapport with patients include the use of 1) open-ended questions (e.g., "Tell me about any new sex partners you've had since your last visit," and "What's your experience with using condoms been like?"); 2) understandable language ("Have you ever had a sore or scab on your penis?"); and 3) normalizing language ("Some of my patients have difficulty using a condom with every sex act. How is it for you?"). The "Five P's" approach to obtaining a sexual history is an example of an effective strategy for eliciting information concerning five key areas of interest (Box 1).

Efforts should be made to ensure that all patients are treated regardless of individual circumstances (e.g., ability to pay, citizenship or immigration status, language spoken, or specific sex practices). Patients seeking treatment or screening for a particular STD should be evaluated for all common STDs. All patients should be informed about all the STDs for which they are being tested and notified about tests for common STDs (e.g., genital herpes) that are available but not being performed.

STD/HIV Prevention Counseling

USPSTF recommends high-intensity behavioral counseling for all sexually active adolescents and for adults at increased risk for STDs and HIV (*5,6*). All providers should routinely obtain a sexual history from their patients and encourage risk-reduction using various strategies; effective delivery of prevention messages requires that providers communicate general risk-reduction messages relevant to the client and that providers educate the client about specific actions that can reduce the risk for STD/HIV transmission (e.g., abstinence, condom use, limiting the number of sex partners, modifying sexual practices, and vaccination), each of which is discussed separately in this report (see Prevention Methods). Prevention counseling is most effective if provided in a nonjudgmental and empathetic manner appropriate to the patient's culture, language, sex, sexual orientation, age, and developmental level.

Box 1. The Five P's: Partners, Prevention of Pregnancy, Protection from STDs, Practices, and Past History of STDs

1. Partners
   - "Do you have sex with men, women, or both?"
   - "In the past 2 months, how many partners have you had sex with?"
   - "In the past 12 months, how many partners have you had sex with?"
   - "Is it possible that any of your sex partners in the past 12 months had sex with someone else while they were still in a sexual relationship with you?"
2. Prevention of pregnancy
   - "What are you doing to prevent pregnancy?"
3. Protection from STDs
   - "What do you do to protect yourself from STDs and HIV?"
4. Practices
   - "To understand your risks for STDs, I need to understand the kind of sex you have had recently."
   - "Have you had vaginal sex, meaning 'penis in vagina sex'?" If yes, "Do you use condoms: never, sometimes, or always?"
   - "Have you had anal sex, meaning 'penis in rectum/anus sex'?" If yes, "Do you use condoms: never, sometimes, or always?"
   - "Have you had oral sex, meaning 'mouth on penis/vagina'?"

For condom answers:
- If "never:" "Why don't you use condoms?"
- If "sometimes:" "In what situations (or with whom) do you not use condoms?"

5. Past history of STDs
   - "Have you ever had an STD?"
   - "Have any of your partners had an STD?"

Additional questions to identify HIV and viral hepatitis risk include:
- "Have you or any of your partners ever injected drugs?"
- "Have any of your partners exchanged money or drugs for sex?"
- "Is there anything else about your sexual practices that I need to know about?"

Interactive counseling approaches directed at a patient's personal risk, the situations in which risk occurs, and the use of personalized goal-setting strategies are effective in STD/HIV prevention (*5,6*). One such approach, known as client-centered STD/HIV prevention counseling, involves tailoring a discussion of risk reduction to the patient's individual situation. Client-centered counseling can increase the likelihood that the patient undertakes or enhances current risk-reduction practices, especially among persons seeking STD care. One such approach, known as Project RESPECT, demonstrated that a brief counseling intervention led to a reduced frequency of STD/HIV risk-related behaviors and resulted in lowered acquisition rates for curable STDs, including trichomoniasis, chlamydia, gonorrhea, and syphilis (*8,9*). Practice models based on Project RESPECT have been successfully implemented in clinic-based settings. Other approaches use motivational interviewing to move clients toward achievable risk reduction goals. CDC provides additional information on these and other effective behavioral interventions at http://effectiveinterventions.org.

Interactive counseling can be used effectively by all health-care providers, counselors, and other clinical staff trained in counseling approaches. Extensive training is not a prerequisite for effective risk reduction counseling; however, the quality of counseling is improved when providers receive training in prevention counseling methods and skill-building approaches, providers are periodically observed when providing counseling and given immediate feedback by persons with expertise in the counseling approach, counselors are periodically evaluated and patients asked to evaluate their level of satisfaction, and providers have access to expert assistance or referral for challenging situations. Training in client-centered counseling is available through the CDC STD/HIV Prevention Training Centers (http://www.stdhivpreventiontraining.org).

In addition to individual prevention counseling, videos and large group presentations can provide explicit information concerning STDs and instruction to reduce disease transmission (e.g., how to use condoms correctly). Group-based strategies have been effective in reducing the occurrence of additional STDs among persons at high risk, including those attending STD clinics (*10*).

Because the incidence of some STDs, notably syphilis, is higher in HIV-infected persons, the use of client-centered STD counseling for HIV-infected persons has been strongly encouraged by public health agencies and other health organizations. Consensus guidelines issued by CDC, the Health Resources and Services Administration, the HIV Medicine Association of the Infectious Diseases Society of America, and the National Institutes of Health emphasize that STD/HIV risk assessment,

STD screening, and client-centered risk reduction counseling should be provided routinely to HIV-infected persons (*11*). Several specific methods have been designed for the HIV care setting (*12–14*), and additional information regarding these approaches is available at http://effectiveinterventions.org.

Prevention Methods

Abstinence and Reduction of Number of Sex Partners

A reliable way to avoid transmission of STDs is to abstain from oral, vaginal, and anal sex or to be in a long-term, mutually monogamous relationship with an uninfected partner. For persons who are being treated for an STD (or whose partners are undergoing treatment), counseling that encourages abstinence from sexual intercourse until completion of the entire course of medication is crucial. A more comprehensive discussion of abstinence and other sexual practices than can help persons reduce their risk for STDs is available in *Contraceptive Technology, 19th Edition* (7). For persons embarking on a mutually monogamous relationship, screening for common STDs before initiating sex might reduce the risk for future disease transmission.

Pre-exposure Vaccination

Pre-exposure vaccination is one of the most effective methods for preventing transmission of some STDs. Two human papillomavirus (HPV) vaccines are available for females aged 9–26 years to prevent cervical precancer and cancer (*15,16*): the quadrivalent HPV vaccine (Gardasil) and the bivalent HPV vaccine (Cervarix). Gardasil also prevents genital warts. Routine vaccination of females aged 11 or 12 years is recommended with either vaccine, as is catch-up vaccination for females aged 13–26 years. Gardasil can be administered to males aged 9–26 years to prevent genital warts (*17*). Details regarding HPV vaccination are available at www.cdc.gov/std/hpv.

Hepatitis B vaccination is recommended for all unvaccinated, uninfected persons being evaluated for an STD (*3,4*). In addition, hepatitis A and B vaccines are recommended for men who have sex with men (MSM) and injection-drug users (IDUs) (*2–4*); each of these vaccines should also be administered to HIV-infected persons who have not yet been infected with one or both types of hepatitis virus. Details regarding hepatitis A and B vaccination are available at http://www.cdc.gov/hepatitis.

Male Condoms

When used consistently and correctly, male latex condoms are highly effective in preventing the sexual transmission of HIV infection. In heterosexual serodiscordant relationships (i.e., those involving one infected and one uninfected partner) in which condoms were consistently used, HIV-negative partners were 80% less likely to become HIV-infected compared with persons in similar relationships in which condoms were not used (*18*).

Moreover, studies show condoms can reduce the risk for other STDs, including chlamydia, gonorrhea, and trichomoniasis; by limiting lower genital tract infections, condoms also might reduce the risk for women developing pelvic inflammatory disease (PID) (*19,20*). In addition, consistent and correct use of latex condoms also reduces the risk for genital herpes, syphilis, and chancroid when the infected area or site of potential exposure is covered, although data for this effect are more limited (*21–24*). Additional information is available at www.cdc.gov/condomeffectiveness/latex.htm.

Cohort studies have demonstrated that condoms protect against the acquisition of genital HPV infection. A prospective study among newly sexually active women who were attending college demonstrated that consistent and correct condom use was associated with a 70% reduction in risk for HPV transmission (*25*). Use of condoms also appears to reduce the risk for HPV-associated diseases (e.g., genital warts and cervical cancer) and mitigate the adverse consequences of infection with HPV. Condom use has been associated with higher rates of regression of cervical intraepithelial neoplasia (CIN) and clearance of HPV infection in women (*26*) and with regression of HPV-associated penile lesions in men (*27*).

Condoms are regulated as medical devices and are subject to random sampling and testing by the U.S. Food and Drug Administration (FDA). Each latex condom manufactured in the United States is tested electronically for holes before packaging. Rates of condom breakage during sexual intercourse and withdrawal are approximately two broken condoms per 100 condoms used in the United States. The failure of condoms to protect against STD transmission or unintended pregnancy usually results from inconsistent or incorrect use rather than condom breakage (*28*).

Male condoms made of materials other than latex are available in the United States. Two general categories of nonlatex condoms exist. The first type is made of polyurethane or other synthetic material and provides protection against STDs/HIV and pregnancy equal to that of latex condoms (*29*). These can be substituted for latex condoms by persons with latex allergy. Although they have had higher breakage and slippage rates when compared with latex condoms and are usually more costly, the pregnancy rates among women whose partners use these condoms are similar to those asociated with use of latex condoms (*30*).

The second type is natural membrane condoms (frequently called "natural" condoms or, incorrectly, "lambskin" condoms).

These condoms are usually made from lamb cecum and can have pores up to 1,500 nm in diameter. Although these pores do not allow the passage of sperm, they are more than 10 times the diameter of HIV and more than 25 times that of HBV (*29*). Moreover, laboratory studies demonstrate that viral STD transmission can occur with natural membrane condoms (*29*). Use of natural membrane condoms for prevention of STDs is not recommended.

Providers should advise their patients that condoms must be used consistently and correctly to be effective in preventing STDs; providing instructions about the correct use of condoms can be useful. Communicating the following recommendations can help ensure that patients use male condoms correctly:

- Use a new condom with each sex act (i.e., oral, vaginal, and anal).
- Carefully handle the condom to avoid damaging it with fingernails, teeth, or other sharp objects.
- Put the condom on after the penis is erect and before any genital, oral, or anal contact with the partner.
- Use only water-based lubricants (e.g., K-Y Jelly, Astroglide, AquaLube, and glycerin) with latex condoms. Oil-based lubricants (e.g., petroleum jelly, shortening, mineral oil, massage oils, body lotions, and cooking oil) can weaken latex and should not be used.
- Ensure adequate lubrication during vaginal and anal sex, which might require the use of exogenous water-based lubricants.
- To prevent the condom from slipping off, hold the condom firmly against the base of the penis during withdrawal, and withdraw while the penis is still erect.

Female Condoms

Laboratory studies indicate that the female condom (Reality) is an effective mechanical barrier to viruses, including HIV, and to semen. The first female condom approved for use in the United States consisted of a lubricated polyurethane sheath with a ring on each end that is inserted into the vagina. A newer version made from nitrile is now available in the United States.

A limited number of clinical studies have evaluated the efficacy of female condoms in providing protection from STDs, including HIV (*31,32*). Although female condoms are costly compared with male condoms, sex partners should consider using a female condom when a male condom cannot be used properly. The female condom also has been used for STDs/HIV protection during receptive anal intercourse (*33*); although it might provide some protection in this setting, its efficacy remains unknown.

Cervical Diaphragms

In observational studies, diaphragm use has been demonstrated to protect against cervical gonorrhea, chlamydia, and trichomoniasis (*34*). A recent trial examined the effect of use of a diaphragm plus polycarbophil (Replens) lubricant on HIV acquisition in women in Africa relative to male condom use alone. The study revealed that neither the diaphragm nor the lubricant gel provided additional protective effect when compared with the use of condoms alone (*35*). Likewise, no difference by study arm in the rate of acquisition of chlamydia or gonorrhea occurred; however, data from participants who reported following the protocol for the use of these products suggested that consistent use of the diaphragm plus gel might reduce acquisition of gonorrhea (*36*). Diaphragms should not be relied on as the sole source of protection against HIV infection. Diaphragm and nonoxynol-9 (N-9) spermicide use have been associated with an increased risk for bacterial urinary-tract infections in women (*37*).

Topical Microbicides and Spermicides

Studies examining nonspecific topical microbicides for the prevention of HIV and STD have demonstrated that these products are ineffective (*38,39*). Studies of spermicides containing N-9 have demonstrated that they should not be recommended for STDs/HIV prevention (*40*), and more recent randomized controlled trials have failed to show a protective effect against HIV acquisition for BufferGel (a vaginal buffering agent), Carraguard (a carrageenan derivative) (*41*), cellulose sulfate (an HIV entry inhibitor), (*42*) and SAVVY (1.0% C31G, a surfactant) (*43,44*).

Initial results from a study in which participants used 0.5% PRO2000 vaginal gel (a synthetic polyanion polymer that blocks cellular entry of HIV) on a daily basis appeared promising, reducing the rate of HIV acquisition by 30% relative to no gel (*45*). However, a recent randomized trial of approximately 9,000 women failed to show any protective effect (*46*).

Topical antiretroviral agents for the prevention of HIV appear more promising. Use of tenofovir gel during sexual intercourse significantly reduced the rate of HIV acquisition (i.e., by 39%) in a study of South African women (*47*). Additional studies are being undertaken to elucidate the optimal dosing regimens for this drug.

Other products remain under study, including VivaGel, a topical vaginal microbicide. A list of products under development is maintained by the Alliance for Microbicide Development at www.microbicide.org.

Condoms and N-9 Vaginal Spermicides

Condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the

transmission of HIV and other STDs (www.cdc.gov/condomeffectiveness/latex.htm). Furthermore, frequent use of spermicides containing N-9 has been associated with disruption of the genital epithelium, which might be associated with an increased risk for HIV transmission (*40*). Therefore, use of condoms lubricated with N-9 is not recommended for STD/HIV prevention; in addition, spermicide-coated condoms cost more, have a shorter shelf-life than other lubricated condoms, and have been associated with urinary-tract infection in young women (*37*).

Rectal Use of N-9 Spermicides

N-9 can damage the cells lining the rectum, which might provide a portal of entry for HIV and other sexually transmissible agents. Therefore, it should not used as a microbicide or lubricant during anal intercourse by MSM or by women.

Nonbarrier Contraception, Surgical Sterilization, and Hysterectomy

Contraceptive methods that are not mechanical barriers offer no protection against HIV or other STDs. Sexually active women who use hormonal contraception (i.e., oral contraceptives, Norplant, and Depo-Provera), have intrauterine devices (IUDs), have been surgically sterilized, or have had hysterectomies should be counseled regarding the use of condoms and the risk for STDs, including HIV infection, because these women might incorrectly perceive that they are not at risk for these diseases. Women who take oral contraceptives and are prescribed certain antibiotics should be counseled about potential interactions (*7*).

Male Circumcision

Although male circumcision should not be substituted for other HIV risk-reduction strategies, it has been shown to reduce the risk for HIV and some STDs in heterosexual men. Three randomized, controlled trials performed in regions of sub-Saharan Africa where generalized HIV epidemics involving predominantly heterosexual transmission were occurring demonstrated that male circumcision reduced the risk for HIV acquisition among men by 50%–60% (*48–50*). In these trials, circumcision was also protective against other STDs, including high-risk genital HPV infection and genital herpes (*51–54*). Despite these data, male circumcision has not been demonstrated to reduce the risk for HIV or other STDs among MSM (*55*). The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have recommended that male circumcision be scaled up as an effective intervention for the prevention of heterosexually acquired HIV infection (*56*). These organizations also recommend that countries with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision expand access to safe male circumcision services within the context of ensuring universal access to comprehensive HIV prevention, treatment, care, and support. Similar recommendations have not been made in the United States, although evidence regarding the role of male circumcision in the prevention of HIV/AIDS is under review (*57*).

Emergency Contraception (EC)

Women who might have been exposed to STDs during a recent act of unprotected intercourse also are at risk for pregnancy. Providers managing such women should offer counseling about the option of EC if pregnancy is not desired. In the United States, EC products are available over-the-counter to women aged ≥17 years and by prescription to younger women. If these EC pill products are not readily accessible, many commonly available brands of oral contraceptive pills can effectively provide EC, but women must be instructed to take an appropriate and specified number of tablets at one time. All oral EC regimens are efficacious when initiated as soon as possible after unprotected sex, but have some efficacy as long as 5 days later. EC is ineffective (but is also not harmful) if the woman is already pregnant (*58*). More information about EC is available in the 19th edition of *Contraceptive Technology* (*7*) or http://ec.princeton.edu/emergency-contraception.html.

Insertion of an IUD up to 7 days after unprotected sex can reduce pregnancy risk by more than 99% (*7*). However, this method is not advisable for a woman who may have untreated cervical gonorrhea or chlamydia, who is already pregnant, or who has other contraindications to IUD use.

Postexposure Prophylaxis (PEP) for HIV and STD

Guidelines for the use of PEP aimed at preventing HIV infection as a result of sexual exposure are available and are discussed in this report (see Sexual Assault and STDs). Genital hygiene methods (e.g., vaginal washing and douching) after sexual exposure are ineffective in protecting against HIV and STD and might increase the risk for bacterial vaginosis, some STDs, and HIV (59).

Pre-exposure Prophylaxis (PrEP) for HIV and STD

Antiretroviral therapy (ART) has the potential to impact transmission and acquisition of HIV. In HIV-infected persons, ART reduces viral load and presumably reduces infectiousness (*60*). In HIV-uninfected persons, ART might reduce susceptibility to infection, a concept supported both by animal studies and by a study of safety and acceptability involving West African women (*61,62*). A randomized, placebo-controlled

trial involving South African women recently demonstrated that use of tenofovir gel associated with sexual intercourse significantly reduced the rate of HIV and herpes simplex virus type 2 (HSV-2) acquisition by 39% and 51%, respectively (*47,63*).

Several large randomized controlled trials of PrEP are either underway or planned. These involve the oral use of non-nucleoside reverse transcriptase inhibitors (tenofovir or tenofovir-emtricitabine) or vaginal use of 1% tenofovir gel.

Retesting to Detect Repeat Infections

Retesting several months after a diagnosis of chlamydia or gonorrhea can detect repeat infection and potentially can be used to enhance population-based prevention (*64*). Further details on retesting can be found in the specific sections on chlamydia and gonorrhea within this report.

Partner Management

Partner management refers to a continuum of activities designed to increase the number of infected persons brought to treatment and disrupt transmission networks. Part of this continuum is partner notification — the process by which providers or public health authorities learn about the sex- and needle-sharing partners of infected patients and help to arrange for partner evaluation and treatment. Clinical-care providers can obtain this information and help to arrange for evaluation and treatment of sex partners directly or by cooperating with state and local health departments. The types and comprehensiveness of existing partner services and the specific STDs for which they are offered vary by provider, public health agency, and geographic area. Ideally, persons referred to such services should also receive health counseling and should be referred for other health services as appropriate.

Data are limited regarding whether partner notification effectively decreases exposure to STDs and whether it reduces the incidence and prevalence of these infections in a community. Nevertheless, evaluations of partner notification interventions have documented the important contribution this approach can make to case-finding in clinical and community contexts (*65*). When partners are treated, index patients have reduced risk for reinfection. Therefore, providers should encourage persons with STDs to notify their sex partners and urge them to seek medical evaluation and treatment. Further, providers can ask patients to bring partners with them when returning for treatment. Time spent with index patients to counsel them on the importance of notifying partners is associated with improved notification outcomes (*66*).

When patients diagnosed with chlamydia or gonorrhea indicate that their partners are unlikely to seek evaluation and treatment, providers can offer patient-delivered partner therapy (PDPT), a form of expedited partner therapy (EPT) in which partners of infected persons are treated without previous medical evaluation or prevention counseling. Because EPT might be prohibited in some states and is the topic of ongoing legislation in others (*67*), providers should visit www.cdc.gov/std/ept to obtain updated information for their individual jurisdiction. Any medication or prescription provided for PDPT should be accompanied by treatment instructions, appropriate warnings about taking medications (if the partner is pregnant or has an allergy to the medication), general health counseling, and a statement advising that partners seek personal medical evaluation, particularly women with symptoms of STDs or PID.

The evidence supporting PDPT is based on three clinical trials that included heterosexual men and women with chlamydia or gonorrhea. The trials and meta-analyses revealed that the magnitude of reduction in reinfection of index case-patients compared with patient referral differed according to the STD and the sex of the index case-patient (*68–71*). However, across trials, reductions in chlamydia prevalence at follow-up were approximately 20%; reductions in gonorrhea at follow-up were approximately 50%. Rates of notification increased in some trials and were equivalent to patient referral without PDPT in others. Existing data suggest that PDPT also might have a role in partner management for trichomoniasis; however, no single partner management intervention has been shown to be more effective than any other in reducing reinfection rates (*72,73*). No data support the use of PDPT in the routine management of patients with syphilis. No studies have been published involving PDPT for gonorrhea or chlamydia among MSM.

Public health program involvement with partner notification services varies by locale and by STD. Some programs have considered partner notification in a broader context, developing interventions to address sexual and social networks in which persons are exposed to STDs. Prospective evaluations incorporating the assessment of venues, community structure, and social and sexual contacts in conjunction with partner notification efforts have improved case-finding and illustrated transmission networks (*74,75*). While such efforts are beyond the scope of individual clinicians, support of and collaboration with STD programs by clinicians are critical to the success of social network-based interventions.

Certain evidence supports the use of the internet to facilitate partner notification (*76*), especially among MSM and in cases where no other identifying information is available, and many health departments now conduct formal internet partner notification (IPN) (http://www.ncsddc.org/upload/wysiwyg/documents/NGuidelinesforInternet.htm). Clinical providers are unlikely to participate directly in IPN. However, when discussing partner notification approaches with patients,

they should be aware of the value of the internet in this type of communication and should know where to refer patients who are interested in using the internet to notify partners about their diagnosis.

Reporting and Confidentiality

The accurate and timely reporting of STDs is integral to efforts to assess morbidity trends, allocate limited resources, and assist local health authorities in partner notification and treatment. STD/HIV and acquired immunodeficiency syndrome (AIDS) cases should be reported in accordance with state and local statutory requirements. Syphilis, gonorrhea, chlamydia, chancroid, HIV infection, and AIDS are reportable diseases in every state. Because the requirements for reporting other STDs differ by state, clinicians should be familiar with the reporting requirements applicable within their jurisdictions.

Reporting can be provider- or laboratory-based. Clinicians who are unsure of state and local reporting requirements should seek advice from state or local health departments or STD programs. STDs and HIV reports are kept strictly confidential. In most jurisdictions, such reports are protected by statute from subpoena. Before conducting a follow-up of a positive STD-test result, public health professionals should consult the patient's health-care provider to verify the diagnosis and to determine the treatments being received.

Special Populations

Pregnant Women

Intrauterine or perinatally transmitted STDs can have severely debilitating effects on pregnant women, their partners, and their fetuses. All pregnant women and their sex partners should be asked about STDs, counseled about the possibility of perinatal infections, and provided access to treatment, if needed.

Recommended Screening Tests

- All pregnant women in the United States should be screened for HIV infection as early in pregnancy as possible (77). Screening should be conducted after the woman is notified that she will be screened for HIV as part of the routine panel of prenatal tests, unless she declines (i.e., opt-out screening). For women who decline HIV testing, providers should address their objections, and when appropriate, continue to encourage testing strongly. Women who decline testing because they have had a previous negative HIV test should be informed of the importance of retesting during each pregnancy. Testing pregnant women and treating those who are infected are vital not only to maintain the health of the patient, but to reduce perinatal transmission of HIV through available antiretroviral and obstetrical interventions. Retesting in the third trimester (preferably before 36 weeks' gestation) is recommended for women at high risk for acquiring HIV infection (e.g., women who use illicit drugs, have STDs during pregnancy, have multiple sex partners during pregnancy, live in areas with high HIV prevalence, or have HIV-infected partners). Rapid HIV screening should be performed on any woman in labor who has an undocumented HIV status unless she declines. If a rapid HIV test result is positive in these women, antiretroviral prophylaxis should be administered without waiting for the results of the confirmatory test (*78*).
- A serologic test for syphilis should be performed on all pregnant women at the first prenatal visit (*79*). In populations in which the amount of prenatal care delivered is not optimal, rapid plasma reagin (RPR) card test screening (and treatment, if that test is reactive) should be performed at the time that a pregnancy is confirmed. Women who are at high risk for syphilis, live in areas of high syphilis morbidity, or are previously untested should be screened again early in the third trimester (at approximately 28 weeks' gestation) and at delivery. Some states require all women to be screened at delivery. Infants should not be discharged from the hospital unless the syphilis serologic status of the mother has been determined at least one time during pregnancy and preferably again at delivery. Any woman who delivers a stillborn infant should be tested for syphilis.
- All pregnant women should be routinely tested for hepatitis B surface antigen (HBsAg) during an early prenatal visit (i.e., a visit during the first trimester), even if they have been previously vaccinated or tested (*80*). Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., having had more than one sex partner in the previous 6 months, evaluation or treatment for an STD, recent or current injection-drug use, and an HBsAg-positive sex partner) and those with clinical hepatitis should be retested at the time of admission to the hospital for delivery. Pregnant women at risk for HBV infection also should be vaccinated. To avoid misinterpreting a transient positive HBsAg result during the 21 days after vaccination, HBsAg testing should be performed before vaccine administration. All laboratories that conduct HBsAg tests should use an FDA-cleared HBsAg test and perform testing according to the manufacturer's labeling, including testing of initially reactive specimens with a

licensed neutralizing confirmatory test. When pregnant women are tested for HBsAg at the time of admission for delivery, shortened testing protocols can be used, and initially reactive results should prompt expedited administration of immunoprophylaxis to infants (*80*).

- All pregnant women should be routinely screened for *Chlamydia trachomatis* (see Chlamydia Infections, Diagnostic Considerations) during the first prenatal visit (*81*). Women aged ≤25 years and those at increased risk for chlamydia (e.g., women who have a new or more than one sex partner) also should be retested during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant. Women found to have chlamydial infection during the first trimester should be retested within approximately 3–6 months, preferably in the third trimester. Screening during the first trimester might prevent the adverse effects of chlamydia during pregnancy, but supportive evidence for such screening is lacking.
- All pregnant women at risk for gonorrhea or living in an area in which the prevalence of *Neisseria gonorrhoeae* is high should be screened at the first prenatal visit for *N. gonorrhoeae* (*82*). Women aged <25 years are at highest risk for gonorrhea infection. Other risk factors for gonorrhea include a previous gonorrhea infection, other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, and drug use. Pregnant women found to have gonococcal infection during the first trimester should be retested within approximately 3–6 months, preferably in the third trimester. Uninfected pregnant women who remain at high risk for gonococcal infection also should be retested during the third trimester.
- All pregnant women at high risk for hepatitis C infection should be screened for hepatitis C antibodies (see Hepatitis C, Diagnostic Considerations) at the first prenatal visit. Women at high risk include those with a history of injection-drug use and those with a history of blood transfusion or organ transplantion before 1992.
- Pregnant women should undergo a Papanicolau (Pap) test at the same frequency as nonpregnant women, although recommendations for their management differ (*83,84*).

Other Tests

- Evidence does not support routine testing for bacterial vaginosis (BV) in pregnancy. For asymptomatic pregnant women at high risk for preterm delivery, evidence is insufficient to assess the balance of benefits and harms of screening for BV (*85*). Symptomatic women should be evaluated and treated (see Bacterial Vaginosis).
- Evidence does not support routine screening for *Trichomonas vaginalis* in asymptomatic pregnant women. Women who report symptoms should be evaluated and treated appropriately (see Trichomonas).
- Evidence does not support routine HSV-2 serologic screening among previously undiagnosed women during pregnancy.

Other Concerns

- Pregnant women who are HBsAg positive should be reported to the local or state health department to ensure that they are entered into a case-management system and that timely and appropriate prophylaxis is provided for their infants. Information concerning the pregnant woman's HBsAg status should be provided to the hospital in which delivery is planned and to the health-care provider who will care for the newborn. In addition, household and sex contacts of women who are HBsAg positive should be vaccinated.
- Women who are HBsAg positive should be provided with, or referred for, appropriate counseling and medical management. Pregnant women who are HBsAg positive should receive information regarding hepatitis B that addresses:
  - modes of transmission;
  - perinatal concerns (e.g., breastfeeding is not contraindicated);
  - prevention of HBV transmission, including the importance of postexposure prophylaxis for the newborn infant and hepatitis B vaccination for household contacts and sex partners; and
  - evaluation for and treatment of chronic HBV infection.
- No treatment is available for pregnant women infected with hepatitis C virus (HCV). However, all women with HCV infection should receive appropriate counseling and supportive care as needed (see Hepatitis C, Prevention). No vaccine is available to prevent HCV transmission.
- In the absence of lesions during the third trimester, routine serial cultures for herpes simplex virus (HSV) are not indicated for women who have a history of recurrent genital herpes. Prophylactic cesarean delivery is not indicated for women who do not have active genital lesions at the time of delivery.
- The presence of genital warts is not an indication for cesarean delivery.

For a more detailed discussion of STD testing and treatment among pregnant women, refer to the following references: *Prenatal screening for HIV: A Review of the evidence for the U.S. Preventive Services Task Force* (*86*); *Revised*

Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Setting (*77*); *Guidelines for Perinatal Care* (*87*); *Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status*: *A Practical Guide and Model Protocol* (*88*); *Viral Hepatitis in Pregnancy* (*89*); *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States — Recommendations of the Immunization Practices Advisory Committee (ACIP)* (*4*); *Screening for Chlamydial Infection: U.S. Preventive Services Task Force Recommendation Statement* (*81*); *Canadian guidelines on sexually transmitted infections* (*90*); *USPSTF recommendations for STI screening (91);* and *Screening for Bacterial Vaginosis in Pregnancy to Prevent Preterm Delivery: U.S. Preventive Services Task Force Recommendation Statement* (*85*).

Recommendations to screen pregnant women for STDs are based on disease severity and sequelae, prevalence in the population, costs, medicolegal considerations (e.g., state laws), and other factors. The screening recommendations in this report are generally broader (i.e., if followed, more women will be screened for more STDs than would by following other screening recommendations) and are also consistent with other CDC guidelines.

Adolescents

In the United States, prevalence rates of many sexually acquired infections are highest among adolescents (*92,93*). For example, the reported rates of chlamydia and gonorrhea are highest among females aged 15–19 years, and many persons acquire HPV infection during their adolescent years.

Persons who initiate sex early in adolescence are at higher risk for STDs, along with persons residing in detention facilities, attending STD clinics, young men having sex with men (YMSM), and youth who use injection drugs. Factors contributing to this increased risk during adolescence include having multiple sexual partners concurrently, having sequential sexual partnerships of limited duration, failing to use barrier protection consistently and correctly, having increased biologic susceptibility to infection, and experiencing multiple obstacles to accessing health care (*92*).

All 50 states and the District of Columbia explicitly allow minors to consent for their own health services for STDs. No state requires parental consent for STD care or requires that providers notify parents that an adolescent minor has received STD services, except in limited or unusual circumstances.

Protecting confidentiality for such care, particularly for adolescents enrolled in private health insurance plans, presents multiple problems. After a claim has been reported, many states mandate that health plans provide a written statement to a beneficiary indicating the benefits and charges covered or not covered by the health plan (i.e., explanation of benefit [EOB]). In addition, federal laws obligate notices to beneficiaries when claims are denied, including alerting consumers who need to pay for care until the allowable deductable is reached. For STD detection- and treatment-related care, an EOB or medical bill that is received by a parent might disclose services provided and list any laboratory tests performed. This type of mandated notification breeches confidentiality, and at a minimum, could prompt parents and guardians to question the costs and reasons for service provision.

Despite the high rates of infections documented in the adolescent population, providers frequently fail to inquire about sexual behaviors, assess STD risks, provide risk reduction counseling, and ultimately, fail to screen for asymptomatic infections during clinical encounters. Sexual health discussions should be appropriate for the patient's developmental level and should be aimed at identifying risk behaviors (e.g., unprotected oral, anal, or vaginal sex and drug-use behaviors). Careful, nonjudgmental, and thorough counseling is particularly vital for adolescents who might not feel comfortable acknowledging their engagement in behaviors that place them at high risk for STDs.

Screening Recommendations

Routine laboratory screening for common STDs is indicated for sexually active adolescents. The following screening recommendations summarize published federal agency and medical professional organizations' clinical guidelines for sexually active adolescents:

- Routine screening for *C. trachomatis* of all sexually active females aged ≤25 years is recommended annually (*81*). Evidence is insufficient to recommend routine screening for *C. trachomatis* in sexually active young men based on feasibility, efficacy, and cost-effectiveness. However, screening of sexually active young men should be considered in clinical settings associated with high prevalence of chlamydia (e.g., adolescent clinics, correctional facilities, and STD clinics) (*81,94*).
- Routine screening for *N. gonorrhoeae* in all sexually active women at risk for infection is recommended annually (*82*). Women aged <25 years are at highest risk for gonorrhea infection. Other risk factors that place women at increased risk include a previous gonorrhea infection, the presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, and drug use.
- HIV screening should be discussed with all adolescents and encouraged for those who are sexually active and those who use injection drugs (*77,95*).

- The routine screening of adolescents who are asymptomatic for certain STDs (e.g., syphilis, trichomoniasis, BV, HSV, HPV, HAV, and HBV) is not recommended. However, YMSM and pregnant adolescent females might require more thorough evaluation.
- Guidelines from USPSTF and ACOG recommend that cervical cancer screening begin at age 21 years (*96,97*), a recommendation based on the low incidence of cervical cancer and limited utility of screening for younger adolescents (*98*). However, the American Cancer Society (ACS) recommends that women start cervical screening with Pap tests 3 years after initiating sexual activity, but by no later than age 21 years (*99*).

Primary Prevention Recommendations

Primary prevention and anticipatory guidance to recognize symptoms and behaviors associated with STDs are strategies that can be incorporated into any or all types of health-care visits. The following recommendations for primary prevention of STDs (i.e., vaccination and counseling) are based on published federal agency and medical professional organizations' clinical guidelines for sexually active adolescents:

- The HPV vaccine, either Cervarix or Gardasil, is recommended for 11 and 12 year-old females. The vaccine series can be started at 9 years of age. Catch-up vaccination is recommended for females aged 13–26 years who have not yet received or completed the vaccine series (*16*). The quadrivalent (Gardasil) HPV vaccine can also be used in males and females aged 9–26 years to prevent genital warts (*17*).
- The HBV vaccination series is recommended for all adolescents. Adolescents who have not previously received hepatitis B vaccine should be vaccinated routinely at any age with an appropriate dose and schedule (*3,4*).
- The HAV vaccination series for children and adolescents aged 2–18 years should be offered in areas with existing hepatitis A vaccination programs. In areas without existing hepatitis A vaccination programs, catch-up vaccination of unvaccinated children aged 2–18 years can be considered (*2*).
- Information regarding HIV infection, testing, transmission, and implications of infection should be regarded as an essential component of the anticipatory guidance provided to all adolescents as part of health care (*77*).
- Health-care providers who care for children and adolescents should integrate sexuality education into clinical practice. Providers should counsel adolescents about the sexual behaviors that are associated with risk for acquiring STDs and should educate patients using evidence-based prevention strategies, all of which include a discussion about abstinence and other risk-reduction behaviors (e.g., consistent and correct condom use). USPSTF recommends high-intensity behavioral counseling to prevent STIs* for all sexually active adolescents (*6*).

Children

Management of children who have STDs requires close cooperation between clinicians, laboratorians, and child-protection authorities. Official investigations, when indicated, should be initiated promptly. Certain diseases (e.g., gonorrhea, syphilis, and chlamydia), if acquired after the neonatal period, are virtually 100% indicative of sexual contact. For other diseases (e.g., HPV infections and vaginitis), the association with sexual contact is not as clear (see Sexual Assault and STDs).

Persons in Correctional Facilities

Multiple studies have demonstrated that persons entering correctional facilities have high rates of STDs (including HIV) and viral hepatitis, especially those aged ≤35 years (*93*). Incarcerated persons are more likely to have low socioeconomic status, live in urban areas, and be ethnic and racial minorities. Risk behaviors for contracting STDs (e.g., having unprotected sex; having multiple sexual partners; using drugs and alcohol; and engaging in commercial, survival [prostitution to earn money for food, shelter, or drugs], or coerced sex) are common among incarcerated populations. Before incarceration, many have had limited access to medical care, especially to community-based clinical prevention services.

Although no comprehensive national guidelines regarding STD care and management have been developed for correctional populations, the utility of expanded STD services in correctional settings has been reported (*100*). Capacity to provide STD care also varies by type of correctional facility. For example, local juvenile detention facilities and jails are short-term facilities (often housing entrants for ≤1 year) where up to half of all entrants are released back to the community within 48 hours of arrest, thereby complicating efforts to provide comprehensive STD services. These services are likely more conducive to prisons and state juvenile confinement facilities, which are long-term, secure facilities where entrants are held for a longer period of time.

Most institutions, especially those for adults, do not routinely screen for STDs. Diagnostic testing of inmates with symptoms indicative of an STD is the more common practice in juvenile detention and jail facilities. However, screening for asymptomatic infections facilitates the identification and

* STI is the term used by USPSTF to describe the syndromes caused by various pathogens that can be acquired and transmitted through sexual activity.

treatment of persons with otherwise undetected infections, which not only eliminates complications for the individual, but reduces the prevalence of infection among detainees who are released back into the local community.

Females in juvenile detention facilities and young women ≤35 years of age have been reported to have high rates of chlamydia (*101*) and gonorrhea (*93*). Syphilis seroprevalence rates, which can indicate previous infection, are considerably higher among adult men and women than in adolescents, consistent with the overall national syphilis trends (*102*).

Chlamydia and Gonorrhea Screening

Universal screening of adolescent females for chlamydia and gonorrhea should be conducted at intake in juvenile detention or jail facilities. Universal screening of adult females should be conducted at intake among adult females up to 35 years of age (or on the basis of local institutional prevalence data).

Syphilis Screening

Universal screening should be conducted on the basis of the local area and institutional prevalence of early (primary, secondary, and early latent) infectious syphilis.

MSM

Subgroups of MSM are at high risk for HIV infection and other viral and bacterial STDs. The frequency of unsafe sexual practices and the reported rates of bacterial STDs and incident HIV infection declined substantially in MSM from the 1980s through the mid-1990s. However, since that time, increased rates of early syphilis (primary, secondary, or early latent), gonorrhea, and chlamydial infection and higher rates of unsafe sexual behaviors have been documented among MSM in the United States and virtually all industrialized countries (*103,104*). The effect of these behavioral changes on HIV transmission has not been ascertained, but preliminary data suggest that the incidence of HIV infection is increasing among MSM in some urban centers, particularly among MSM from racial and ethnic minority groups (*105*) and among those who use nonprescription drugs during sex, particularly methamphetamine and volatile nitrites (also known as "poppers"). These adverse trends likely reflect the 1) changing attitudes concerning HIV infection that have accompanied advances in HIV therapy, resulting in improved quality of life and survival for HIV-infected persons; 2) changing patterns of substance abuse; 3) demographic shifts in MSM populations; and 4) changes in sex partner networks resulting from new venues for partner acquisition (e.g., the internet). Increases in bacterial STDs are not necessarily accompanied by increases in HIV incidence; for example, oral sex may permit efficient spread of bacterial STDs but not HIV, as does serosorting (preferential selection of sex partners of the same serostatus) among HIV-infected MSM (*106,107*).

Clinicians should assess the STD-related risks for all male patients, including a routine inquiry about the sex of sex partners. MSM, including those with HIV infection, should routinely undergo nonjudgmental STD/HIV risk assessment and client-centered prevention counseling to reduce the likelihood of acquiring or transmitting HIV or other STDs. Clinicians should be familiar with the local community resources available to assist MSM at high risk in facilitating behavioral change and to enable the conduct of partner notification activities. Clinicians also should routinely ask sexually active MSM about symptoms consistent with common STDs, including urethral discharge, dysuria, genital and perianal ulcers, regional lymphadenopathy, skin rash, and anorectal symptoms consistent with proctitis, including discharge and pain on defecation or during anal intercourse. Clinicians should perform appropriate diagnostic testing on all symptomatic patients.

Routine laboratory screening for common STDs is indicated for all sexually active MSM. The following screening tests should be performed at least annually for sexually active MSM:

- HIV serology, if HIV negative or not tested within the previous year;
- syphilis serology, with a confirmatory testing to establish whether persons with reactive serologies have incident untreated syphilis, have partially treated syphilis, or are manifesting a slow serologic response to appropriate prior therapy;
- a test for urethral infection with *N. gonorrhoeae* and *C. trachomatis* in men who have had insertive intercourse[†] during the preceding year; testing of the urine using nucleic acid amplification testing (NAAT) is the preferred approach;
- a test for rectal infection[§] with *N. gonorrhoeae* and *C. trachomatis* in men who have had receptive anal intercourse[†] during the preceding year (NAAT of a rectal swab is the preferred approach); and
- a test for pharyngeal infection[§] with *N. gonorrhoeae* in men who have had receptive oral intercourse[†] during the preceding year (NAAT is the preferred approach). Testing for *C. trachomatis* pharyngeal infection is not recommended.

Evaluation for HSV-2 infection with type-specific serologic tests also can be considered if infection status is unknown; knowledge of HSV-2 serostatus might be helpful in identifying persons with previously undiagnosed genital tract infection.

[†] Regardless of history of condom use during exposure.

[§] Commercially available NAATS are not FDA cleared for these indications, but they can be used by laboratories that have met all regulatory requirements for an off-label procedure.

Because of the increased incidence of anal cancer in HIV-infected MSM, screening for anal cytologic abnormalities can be considered; however, evidence is limited concerning the natural history of anal intraepithelial neoplasias, the reliability of screening methods, the safety and response to treatments, and the programmatic support needed for such a screening activity.

More frequent STD screening (i.e., at 3–6-month intervals) is indicated for MSM who have multiple or anonymous partners. In addition, MSM who have sex in conjunction with illicit drug use (particularly methamphetamine use) or whose sex partners participate in these activities should be screened more frequently.

All MSM should be tested for HBsAg to detect HBV infection. Prompt identification of chronic infection with HBV is essential to ensure necessary care and services to prevent transmission to others (*108*). HBsAg testing should be made available in STD treatment settings. In addition, screening among past or current drug users should include HCV and HBV testing.

Vaccination against hepatitis A and B is recommended for all MSM in whom previous infection or vaccination cannot be documented (*2,3*). Preimmunization serologic testing might be considered to reduce the cost of vaccinating MSM who are already immune to these infections, but this testing should not delay vaccination. Vaccinating persons who are immune to HAV or HBV infection because of previous infection or vaccination does not increase the risk for vaccine-related adverse events (see Hepatitis B, Prevaccination Antibody Screening). Sexual transmission of hepatitis C virus infection can occur, especially among HIV-infected MSM. Serologic screening for hepatitis C infection is recommended at initial evaluation of newly diagnosed HIV-infected persons. HIV-infected MSM can also acquire HCV after initial screening; therefore, men with new and unexplained increases in alanine aminotransferase (ALT) should be tested for acute HCV infection. To detect acute HCV infection among HIV-infected MSM with high-risk sexual behaviors or concomitant ulcerative STDs, routine HCV testing of HIV-infected MSM should be considered.

Women Who Have Sex with Women

Women who have sex with women (WSW) are a diverse group with variations in sexual identity, sexual behaviors, sexual practices, and risk behaviors. Recent studies indicate that some WSW, particularly adolescents, young women, and women with both male and female partners, might be at increased risk for STDs and HIV as a result of certain reported risk behaviors (*109–112*). WSW are at risk for acquiring bacterial, viral, and protozoal infections from current and prior partners, both male and female. WSW should not be presumed to be at low or no risk for STDs based on sexual orientation. Effective screening requires that providers and their female clients engage in a comprehensive and open discussion not only about sexual identify, but sexual and behavioral risks.

Few data are available on the risk for STDs transmitted by sex between women, but risk probably varies by the specific STD and sexual practice (e.g., oral-genital sex; vaginal or anal sex using hands, fingers, or penetrative sex items; and oral-anal sex [*113,114*]). Practices involving digital-vaginal or digital-anal contact, particularly with shared penetrative sex items, present a possible means for transmission of infected cervicovaginal secretions. This possibility is most directly supported by reports of metronidazole-resistant trichomoniasis (*115*) and genotype-concordant HIV transmitted sexually between women who reported these behaviors (*116*) and by the high prevalence of BV among monogamous WSW (*117*).

Transmission of HPV can occur with skin-to-skin or skin-to-mucosa contact, which can occur during sex between women. HPV DNA has been detected through polymerase chain reaction (PCR)-based methods from the cervix, vagina, and vulva in 13%–30% of WSW, and high- and low-grade squamous intraepithelial lesions (SIL) have been detected on Pap tests in WSW who reported no previous sex with men (*118*). However, most self-identified WSW (53%–99%) report having had sex with men and indicate that they might continue this practice in the future (*119*). Therefore, routine cervical cancer screening should be offered to all women, regardless of sexual preference or sexual practices, and women should be offered HPV vaccine in accordance with current guidelines.

Limited data demonstrate that HSV-2 genital transmission between female sex partners is probably inefficient but can occur. The relatively frequent practice of orogenital sex among WSW might place them at higher risk for genital infection with herpes simplex virus type 1 (HSV-1), a hypothesis supported by the recognized association between HSV-1 seropositivity and number of female partners among WSW (*120*).

Although the rate of transmission of *C. trachomatis* between women remains largely unknown, infection also can be acquired from past or current male partners. Recent data suggest that *C. trachomatis* infection among WSW might be more common than previously thought (*121*); transmission of syphilis between female sex partners (likely through oral sex) also has been reported. Therefore, report of same-sex behavior in women should not deter providers from screening these women for STDs, including chlamydia and syphilis, as recommended.

BV is common among women in general and even more so among women with female partners. Sexual behaviors that

facilitate the transfer of vaginal fluid and/or bacteria between partners might be involved in the pathogenesis of BV. A recent study demonstrated that female sex partners frequently share identical genital *Lactobacillus* strains (*122*). Although BV is common in WSW, routine screening for BV is not recommended, nor is the treatment of partners of women with BV. Encouraging awareness of signs and symptoms of BV in women and encouraging healthy sexual practices (e.g., cleaning shared sex toys between uses) might be helpful.

HIV Infection: Detection, Counseling, and Referral

HIV infection represents a spectrum of disease that can begin with a brief acute retroviral syndrome that typically transitions to a multiyear chronic and clinically latent illness. Without treatment, this illness eventually progresses to a symptomatic, life-threatening immunodeficiency disease known as AIDS. In untreated patients, the time between HIV infection and the development of AIDS varies, ranging from a few months to many years with an estimated median time of approximately 11 years (*123*). HIV replication is present during all stages of the infection and progressively depletes CD4 lymphocytes, which are critical for maintenance of effective immune function. When the CD4 cell count falls below 200 cells/μL, patients are at high risk for life-threatening AIDS-defining opportunistic infections (e.g., *Pneumocystis pneumonia*, *Toxoplasma gondii* encephalitis, disseminated *Mycobacterium avium* complex disease, tuberculosis, and bacterial pneumonia). In the absence of treatment, virtually all HIV-infected persons will die of AIDS.

Early diagnosis of HIV infection is essential to ensuring that patients are referred promptly for evaluation, provided treatment (if indicated), and linked into counseling and related support services to help them reduce their risk for transmitting HIV to others. Diagnosing persons during acute infection is particularly important. It is during this phase that HIV-infected persons are most infectious (*124–126*), but test negative for HIV antibodies and therefore unknowingly continue to engage in those high-risk behaviors associated with HIV transmission. Providers are in a particularly good position to diagnose persons during acute HIV infection because such persons might present for assessment and treatment of a concomitantly acquired STD during this phase of the disease. Knowing that a patient is infected with HIV has important clinical implications because HIV infection alters the immune system and thereby affects the diagnosis, evaluation, treatment, and follow-up of other STDs.

Even in the era of highly effective antiretroviral therapy (HAART), HIV infection is often diagnosed in persons with advanced infection (i.e., persons with low CD4 cell counts). Nationally, the proportion of patients diagnosed with AIDS at or within 12 months of their HIV diagnosis in 2007 was 32% (*127*). Since 2006, CDC has endorsed efforts to increase HIV testing by streamlining the consent process and expanding opt-out testing to all health-care settings, especially STD clinics (*77*). However, rates of testing remain unacceptably low: in 2006, only 40% of surveyed adults had ever been tested, and <25% of high-risk adults had been tested during the preceding 12 months (*128*).

Proper management of HIV infection requires medical therapy, which for many patients should be coupled with behavioral and psychosocial services. Comprehensive HIV treatment services are usually not available in facilities focusing primarily on STD treatment (e.g., STD clinics); therefore, patients diagnosed in these settings ideally should be referred to a health-care provider or facility experienced in caring for HIV-infected patients. Nonetheless, providers working in STD-treatment facilities should be knowledgeable about the treatment options available in their communities, educate persons who test positive for HIV about the illness, and know where to refer their patients for support services and HIV care.

A detailed discussion of the complex issues required for the management of HIV infection is beyond the scope of this report; however this information is available in other published resources (*129–131*). In subsequent sections of this report, additional types of HIV-related information about the diagnosis of HIV infection, counseling of HIV-infected patients, referral of patients for support services (including medical care), and management of sex and injection-drug partners in STD-treatment facilities is provided. In addition, this report discusses HIV infection during pregnancy and among infants and children.

Detection of HIV Infection: Screening and Establishing a Diagnosis

All persons who seek evaluation and treatment for STDs should be screened for HIV infection. Screening should be routine, regardless of whether the patient is known or suspected to have specific behavioral risks for HIV infection.

Consent and Pretest Information

CDC recommends HIV screening for patients aged 13–64 years in all health-care settings (*77*). Patients should be notified that testing will be performed, but given the option to decline or defer testing (i.e., provided with opt-out testing)

(*128*). Assent is inferred unless the patient verbally declines testing. Separate written consent for HIV testing should not be required; in most facilities, general consent for medical care is considered sufficient to encompass consent for HIV testing. Providing prevention counseling along with HIV diagnostic testing or as part of HIV screening programs is not a requirement within health-care settings. In addition, routine opt-out testing (instead of traditional written informed consent with pre-and post-test counseling) might be precluded in some jurisdictions by local laws and regulations, although many state and local authorities have updated laws and regulations to facilitate adoption of routine opt-out testing. Information about regulations in specific jurisdictions is available through the National Clinicians Consultation Center at www.nccc.ucsf.edu.

Prevention Counseling

Prevention counseling should be offered and encouraged in all health-care facilities that serve patients at high risk (e.g., STD clinics), because these facilities routinely elicit information about the behaviors that place persons at high risk for HIV. Prevention counseling need not be explicitly linked to HIV testing. However, some patients might be more likely to think about HIV and consider their risk-related behavior when undergoing an HIV test. HIV testing presents an excellent opportunity to provide or arrange for prevention counseling to assist with behavior changes that can reduce risk for acquiring HIV infection.

Establishing the Diagnosis of HIV Infection

HIV infection can be diagnosed by serologic tests that detect antibodies against HIV-1 and HIV-2 and by virologic tests that can detect HIV antigens or ribonucleic acid (RNA). Antibody testing begins with a sensitive screening test (e.g., the conventional or rapid enzyme immunoassay [EIA]). Currently available serologic tests are both highly sensitive and specific and can detect all known subtypes of HIV-1. Most can also detect HIV-2 and uncommon variants of HIV-1 (e.g., Group O and Group N). The advent of HIV rapid serologic testing has enabled clinicians to make an accurate presumptive diagnosis of HIV infection within half an hour, which could potentially facilitate the identification of the approximately 250,000 persons estimated to be living with undiagnosed HIV in the United States (*127*).

Reactive screening tests must be confirmed by a supplemental antibody test (i.e., Western blot [WB] and indirect immunofluorescence assay [IFA]) or virologic test (i.e., the HIV-1 RNA assay) (*132*). A confirmed positive antibody test result indicates that a person is infected with HIV and capable of transmitting the virus to others. HIV antibody is detectable in at least 95% of patients within 3 months after infection. Although a negative antibody test result usually indicates that a person is not infected, antibody tests cannot exclude recent infection. Virologic tests for HIV-1 RNA can also be used to identify acute infection in persons who are negative for HIV antibodies.

The majority of HIV infections in the United States are caused by HIV-1. However, HIV-2 infection should be suspected in persons who have epidemiologic risk factors or an unusual clinical presentation. Epidemiologic factors associated with HIV-2 infection include having lived in or having a sex partner from an HIV-2 endemic area (e.g., West Africa and some European countries such as Portugal, where HIV-2 prevalence is increasing), having a sex partner known to be infected with HIV-2, or having received a blood transfusion or nonsterile injection in an HIV-2-endemic area. Specific testing for HIV-2 is also indicated when clinical evidence of HIV infection exists but tests for HIV-1 antibodies or HIV-1 viral load are negative, or when HIV-1 WB results exhibit the unusual indeterminate pattern of gag (p55, p24, p17) plus pol (p66, p51, p31) bands in the absence of env (gp160, gp120, gp41) bands.

Health-care providers should be knowledgeable about acute HIV infection and the symptoms and signs of acute retroviral syndrome, which develops in 50%–80% of acutely infected patients. Acute retroviral syndrome is characterized by nonspecific symptoms, including fever, malaise, lymphadenopathy, and skin rash. It frequently occurs in the first few weeks after HIV infection, before antibody test results become positive. Suspicion of acute retroviral syndrome should result in prompt nucleic acid testing (HIV plasma RNA) in addition to an HIV antibody test to detect the presence of HIV. A positive HIV nucleic acid test should be confirmed by subsequent antibody testing to document seroconversion. Acutely infected patients are highly contagious during this stage of infection because the concentration of virus in plasma and genital secretions is extremely elevated (*125,133*). Antiretroviral therapy might benefit the health of persons with recently acquired HIV infection and reduce their infectiousness to others, but evidence to support this recommendation is still inconclusive and awaits the outcomes of several clinical trials currently underway (*129*). Notwithstanding, patients with acute HIV infection should be referred immediately to an HIV clinical-care provider. Diagnosis of HIV infection should prompt efforts to reduce behaviors that could transmit HIV to others (*134*).

The following are specific recommendations that apply to testing for HIV infection:

- HIV screening is recommended for all persons who seek evaluation and treatment for STDs.

- HIV testing must be voluntary and free from coercion. Patients must not be tested without their knowledge.
- HIV screening after notifying the patient that an HIV test will be performed (unless the patient declines) is recommended in all health-care settings.
- Specific signed consent for HIV testing should not be required. In most settings, general informed consent for medical care is considered sufficient to encompass informed consent for HIV testing.
- Use of rapid HIV tests should be considered, especially in clinics where a high proportion of patients do not return for HIV test results.
- Positive screening tests for HIV antibody must be confirmed by a supplemental test before the diagnosis of HIV infection can be established.
- Providers should be alert to the possibility of acute HIV infection and perform a nucleic acid test in addition to an antibody test for HIV, if indicated. Persons suspected of recently acquired HIV infection should be referred for immediate consultation with an infectious disease specialist.

Persons with newly diagnosed HIV infection who receive care in the STD treatment setting should be informed of the importance of promptly initiating medical care, the effectiveness of HIV treatments, and about what to expect as they enter medical care for HIV infection (131). In nonemergent situations, the initial evaluation of HIV-positive patients usually includes the following:

- Detailed medical history, including sexual and substance abuse history; vaccination history; previous STDs; travel history; and assessment for specific HIV-related symptoms or diagnoses;
- physical examination, including a gynecologic examination for women;
- testing for *N. gonorrhoeae* and *C. trachomatis* (in women perform Pap test and wet mount examination or culture of vaginal secretions for *Trichomonas vaginalis*);
- complete blood and platelet counts, blood chemistry profile, and lipid profile;
- toxoplasma antibody test;
- testing for antibodies to hepatitis C virus;
- testing for previous or present infections with HAV or HBV infection (recommended if determined to be cost-effective before considering vaccination) (see Hepatitis A and Hepatitis B);
- syphilis serology;
- CD4 T-lymphocyte analysis and determination of HIV plasma viral load;
- HIV genotypic resistance testing;
- tuberculin skin test (sometimes referred to as a purified protein derivative);
- urinalysis; and
- chest radiograph.

Type-specific testing for HSV-2 infection can be considered if herpes infection status is unknown. A first dose of hepatitis A and hepatitis B vaccine should be administered at this first visit for previously unvaccinated persons for whom vaccine is recommended (see Hepatitis A and Hepatitis B). In subsequent visits, when the results of laboratory tests are available, antiretroviral therapy can be offered based on existing guidance (*129*). Recommendations for the prophylaxis of opportunistic infections and vaccinations in HIV-infected adults and adolescents are available (*130,131*).

Providers should be alert to the possibility of new or recurrent STDs and should treat such conditions aggressively. Diagnosis of an STD in an HIV-infected person indicates on-going or recurrent high-risk behavior and should prompt referral for counseling. Because many STDs are asymptomatic, routine screening for curable STDs (e.g., syphilis, gonorrhea, and chlamydia) should be performed at least annually for all sexually active, HIV-positive persons. Women should be screened annually for cervical cancer precursor lesions by cervical Pap tests. More frequent STD screening might be appropriate depending on individual risk behaviors, the local epidemiology of STDs, and whether incident STDs are detected by screening or by the presence of symptoms.

Recently identified HIV infection might not have been recently acquired; persons newly diagnosed with HIV might be at any stage of infection. Therefore, health-care providers should be alert for symptoms or signs that suggest advanced HIV infection (e.g., fever, weight loss, diarrhea, cough, shortness of breath, and oral candidiasis). The presence of any of these symptoms should prompt urgent referral to an infectious diseases provider. Similarly, providers should be alert for signs of psychological distress and be prepared to refer patients accordingly (see Counseling for Patients with HIV Infection and Referral to Support Services).

Counseling for Patients with HIV Infection and Referral to Support Services

Those persons who test positive for HIV should receive prevention counseling before leaving the testing site. Such persons should receive or be referred for a medical evaluation and, if indicated, be provided with behavioral and psychological services as determined by a thorough psychosocial evaluation, which can also be used to identify high-risk behaviors.

Providers who refer their HIV-positive patients to other professionals should establish means to ensure that these patients are linked successfully to such services, especially to on-going medical care.

Providers should expect persons to be distressed when first informed of a positive HIV test result. Such persons face multiple major adaptive challenges, including coping with the reactions of others to a stigmatizing illness, developing and adopting strategies for maintaining physical and emotional health, initiating changes in behavior to prevent HIV transmission to others, and reducing the risk for acquiring additional STDs. Many persons will require assistance with making reproductive choices, gaining access to health services, and coping with changes in personal relationships. Therefore, behavioral and psychosocial services are an integral part of health care for HIV-infected persons.

Patients testing positive for HIV have unique needs. Some patients require referral for specific behavioral interventions (e.g., a substance abuse program), mental health disorders (e.g., depression), or emotional distress. Others might require assistance with securing and maintaining employment and housing. Women should be counseled or appropriately referred regarding reproductive choices and contraceptive options, and patients with multiple psychosocial problems might be candidates for comprehensive risk-reduction counseling and services.

The following are specific recommendations for HIV counseling and referral:

- Persons who test positive for HIV antibody should be counseled, either on site or through referral, concerning the behavioral, psychosocial, and medical implications of HIV infection.
- Health-care providers should be alert for medical or psychosocial conditions that require immediate attention.
- Providers should assess the needs of newly diagnosed persons for immediate medical care or support and should link them to services provided by health-care personnel experienced in providing care for HIV-infected persons. Such persons might need medical care or services for substance abuse, mental health disorders, emotional distress, reproductive counseling, risk-reduction counseling, and case management. Providers should follow up to ensure that patients have received the needed services.
- Patients should be educated about the importance of follow-up medical care as well as what to expect.

Several successful, innovative interventions for HIV prevention have been developed for diverse at-risk populations, and these can be locally replicated or adapted (*11–14,135,136*). Involvement of nongovernment organizations and community-based organizations might complement such efforts in the clinical setting.

Management of Sex Partners and Injection-Drug Partners

Clinicians evaluating HIV-infected persons should determine whether any partners should be notified concerning possible exposure to HIV (*77,137*). In the context of HIV management, the term "partner" includes not only sex partners, but persons who share syringes or other injection equipment. Partner notification is an important component of disease management, because early diagnosis and treatment of HIV infection might reduce morbidity and provide the opportunity to encourage risk-reduction behaviors. Partner notification for HIV infection should be confidential. Specific guidance regarding spousal notification varies by jurisdiction. Detailed recommendations concerning identification, notification, diagnosis, and treatment of exposed partners are available in *Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infections* (*137*).

Two complementary notification processes, patient referral and provider referral, can be used to identify partners. With patient referral, patients directly inform their partners of their exposure to HIV infection, whereas with provider referral, trained health department personnel locate partners on the basis of information provided by the patient. During the provider referral notification process, the confidentiality of patients is protected; their names are not revealed to partners who are notified. Many state and local health departments provide these services.

The following are specific recommendations for implementing partner-notification procedures:

- HIV-infected patients should be encouraged to notify their partners and to refer them for counseling and testing. If requested by the patient, health-care providers should assist in this process, either directly or by referral to health department partner-notification programs.
- If patients are unwilling to notify their partners or if they cannot ensure that their partners will seek counseling, physicians or health department personnel should use confidential partner notification procedures.
- Partners who have been reached and were exposed to genital secretions and/or blood of an HIV-infected partner though sex or injection-drug use within the preceding 72 hours should be offered postexposure prophylaxis with combination antiretrovirals (*78*).

Special Considerations

Pregnancy

All pregnant women in the United States should be tested for HIV infection as early during pregnancy as possible. A second test during the third trimester, preferably at <36 weeks' gestation, should be considered for all pregnant women and is recommended for women known to be at high risk for acquiring HIV, those who receive health care in jurisdictions with elevated incidence of HIV or AIDS among women, and women living in facilities in which prenatal screening identifies at least one HIV-infected pregnant women per 1,000 women screened (*77*). An RNA test should be used in conjunction with an HIV antibody test for women who have signs or symptoms consistent with acute HIV infection. The patient should first be informed that she will be tested for HIV as part of the panel of prenatal tests, unless she declines, or opts-out, of screening (*77,86*). For women who decline, providers should continue to strongly encourage testing and address concerns that pose obstacles to testing. Women who decline testing because they have had a previous negative HIV test should be informed about the importance of retesting during each pregnancy. Testing pregnant women is particularly important not only to maintain the health of the patient, but because interventions (i.e., antiretroviral and obstetrical) can reduce the risk for perinatal transmission of HIV.

After a pregnant woman has been identified as being HIV-infected, she should be educated about the risk for perinatal infection. Evidence indicates that, in the absence of antiretroviral and other interventions, 15%–25% of infants born to HIV-infected mothers will become infected with HIV; such evidence also indicates that an additional 12%–14% of infants born to infected mothers who breastfeed into the second year of life will become infected (*138,139*).

The risk for perinatal HIV transmission can be reduced to <2% through the use of antiretroviral regimens and obstetrical interventions (i.e., zidovudine or nevirapine and elective cesarean section at 38 weeks of pregnancy) and by avoiding breastfeeding (*138,140*). Pregnant women who are HIV-infected should be counseled concerning their options (either on-site or by referral), given appropriate antenatal treatment, and advised not to breastfeed their infants.

HIV Infection Among Infants and Children

Diagnosis of HIV infection in a pregnant woman indicates the need to consider whether the woman's other children might be infected. Infants and young children with HIV infection differ from adults and adolescents with respect to the diagnosis, clinical presentation, and management of HIV disease. For example, because maternal HIV antibody passes through the placenta, antibody tests for HIV are expected to be positive in the sera of both infected and uninfected infants born to seropositive mothers. A definitive determination of HIV infection for an infant aged <18 months is usually based on HIV nucleic acid testing (141). Management of infants, children, and adolescents who are known or suspected to be infected with HIV requires referral to physicians familiar with the manifestations and treatment of pediatric HIV infection (*142,143*).

Diseases Characterized by Genital, Anal, or Perianal Ulcers

In the United States, most young, sexually active patients who have genital, anal, or perianal ulcers have either genital herpes or syphilis. The frequency of each condition differs by geographic area and population; however, genital herpes is the most prevalent of these diseases. More than one etiologic agent (e.g., herpes and syphilis) can be present in a genital, anal, or perianal ulcer. Less common infectious causes of genital, anal, or perianal ulcers include chancroid and donovanosis. HSV, syphilis, and chancroid have been associated with an increased risk for HIV transmission, and genital, anal, or perianal lesions might be associated with conditions that are not sexually transmitted (e.g., yeast, trauma, carcinoma, aphthae, fixed drug eruption, and psoriasis).

A diagnosis based only on the patient's medical history and physical examination frequently is inaccurate. Therefore, all patients who have genital, anal, or perianal ulcers should be evaluated with a serologic test for syphilis and a diagnostic evaluation for genital herpes; in settings where chancroid is prevalent, a test for *Haemophilus ducreyi* should also be performed. Specific tests for evaluation of genital, anal, or perianal ulcers include 1) syphilis serology and darkfield examination; 2) culture for HSV or PCR testing for HSV; and 3) serologic testing for type-specific HSV antibody.

No FDA-cleared PCR test to diagnose either herpes or syphilis is available in the United States; however, such testing can be performed by clinical laboratories that have developed their own tests and have conducted a Clinical Laboratory Improvement Amendment (CLIA) verification study. Type-specific serology for HSV-2 might be helpful in identifying persons with genital herpes (see Genital Herpes, Type-Specific Serologic Tests). In addition, biopsy of genital, anal, or perianal ulcers can help identify the cause of ulcers that are unusual or that do not respond to initial therapy. HIV testing should be performed on all persons with genital, anal, or perianal ulcers

who are not known to have HIV infection (see Diagnostic Considerations, sections on Syphilis, Chancroid, and Genital Herpes Simplex Virus).

Health-care providers frequently must treat patients before test results are available, because early treatment decreases the possibility of ongoing transmission and because successful treatment of genital herpes depends on prompt initiation of therapy. The clinician should empirically treat for the diagnosis considered most likely on the basis of clinical presentation and epidemiologic circumstances (including travel history); even after complete diagnostic evaluation, at least 25% of patients who have genital ulcers have no laboratory-confirmed diagnosis.

Chancroid

The prevalence of chancroid has declined in the United States (*93*). When infection does occur, it is usually associated with sporadic outbreaks. Worldwide, chancroid appears to have declined as well, although infection might still occur in some regions of Africa and the Caribbean. Chancroid, as well as genital herpes and syphilis, is a risk factor in the transmission of HIV infection (*144*).

A definitive diagnosis of chancroid requires the identification of *H. ducreyi* on special culture media that is not widely available from commercial sources; even when these media are used, sensitivity is <80% (*145*). No FDA-cleared PCR test for *H. ducreyi* is available in the United States, but such testing can be performed by clinical laboratories that have developed their own PCR test and have conducted a CLIA verification study.

The combination of a painful genital ulcer and tender suppurative inguinal adenopathy suggests the diagnosis of chancroid (*146*). A probable diagnosis of chancroid, for both clinical and surveillance purposes, can be made if all of the following criteria are met: 1) the patient has one or more painful genital ulcers; 2) the patient has no evidence of *T. pallidum* infection by darkfield examination of ulcer exudate or by a serologic test for syphilis performed at least 7 days after onset of ulcers; 3) the clinical presentation, appearance of genital ulcers and, if present, regional lymphadenopathy are typical for chancroid; and 4) a test for HSV performed on the ulcer exudate is negative.

Treatment

Successful treatment for chancroid cures the infection, resolves the clinical symptoms, and prevents transmission to others. In advanced cases, scarring can result, despite successful therapy.

Recommended Regimens

Azithromycin 1 g orally in a single dose

OR

Ceftriaxone 250 mg intramuscularly (IM) in a single dose

OR

Ciprofloxacin* 500 mg orally twice a day for 3 days*

OR

Erythromycin base 500 mg orally three times a day for 7 days

* Ciprofloxacin is contraindicated for pregnant and lactating women.

Azithromycin and ceftriaxone offer the advantage of single-dose therapy. Worldwide, several isolates with intermediate resistance to either ciprofloxacin or erythromycin have been reported. However, because cultures are not routinely performed, data are limited regarding the current prevalence of antimicrobial resistance.

Other Management Considerations

Men who are uncircumcised and patients with HIV infection do not respond as well to treatment as persons who are circumcised or HIV-negative. Patients should be tested for HIV infection at the time chancroid is diagnosed. If the initial test results were negative, a serologic test for syphilis and HIV infection should be performed 3 months after the diagnosis of chancroid.

Follow-Up

Patients should be re-examined 3–7 days after initiation of therapy. If treatment is successful, ulcers usually improve symptomatically within 3 days and objectively within 7 days after therapy. If no clinical improvement is evident, the clinician must consider whether 1) the diagnosis is correct, 2) the patient is coinfected with another STD, 3) the patient is infected with HIV, 4) the treatment was not used as instructed, or 5) the *H. ducreyi* strain causing the infection is resistant to the prescribed antimicrobial. The time required for complete healing depends on the size of the ulcer; large ulcers might require >2 weeks. In addition, healing is slower for some uncircumcised men who have ulcers under the foreskin. Clinical resolution of fluctuant lymphadenopathy is slower than that of ulcers and might require needle aspiration or incision and drainage, despite otherwise successful therapy. Although needle aspiration of buboes is a simpler procedure, incision and drainage might be preferred because of reduced need for subsequent drainage procedures.

Management of Sex Partners

Regardless of whether symptoms of the disease are present, sex partners of patients who have chancroid should be examined

and treated if they had sexual contact with the patient during the 10 days preceding the patient's onset of symptoms.

Special Considerations

Pregnancy

Ciprofloxacin is contraindicated during pregnancy and lactation. No adverse effects of chancroid on pregnancy outcome have been reported.

HIV Infection

HIV-infected patients who have chancroid should be monitored closely because, as a group, they are more likely to experience treatment failure and to have ulcers that heal more slowly. HIV-infected patients might require repeated or longer courses of therapy than those recommended for HIV-negative patients, and treatment failures can occur with any regimen. Because data are limited concerning the therapeutic efficacy of the recommended ceftriaxone and azithromycin regimens in HIV-infected patients, these regimens should be used for such patients only if follow-up can be ensured.

Genital HSV Infections

Genital herpes is a chronic, life-long viral infection. Two types of HSV have been identified as causing genital herpes: HSV-1 and HSV-2. Most cases of recurrent genital herpes are caused by HSV-2, and at least 50 million persons in the United States are infected with this type of genital herpes (*147*). However, an increasing proportion of anogenital herpetic infections in some populations has been attributed to HSV-1 infection.

Most persons infected with HSV-2 have not been diagnosed with genital herpes. Many such persons have mild or unrecognized infections but shed virus intermittently in the genital tract. As a result, the majority of genital herpes infections are transmitted by persons unaware that they have the infection or who are asymptomatic when transmission occurs. Management of genital HSV should address the chronic nature of the disease and go beyond the treatment of acute episodes of genital ulcers.

Diagnosis of HSV Infection

The clinical diagnosis of genital herpes is both nonsensitive and nonspecific. The classical painful multiple vesicular or ulcerative lesions are absent in many infected persons. HSV-1 is causing an increasing proportion of first episodes of anogenital herpes in some populations (e.g., young women and MSM) and might now account for most of these infections (*148,149*). Recurrences and subclinical shedding are much less frequent for genital HSV-1 infection than for genital HSV-2 infection (*150,151*). A patient's prognosis and the type of counseling needed depends on the type of genital herpes (HSV-1 or HSV-2) causing the infection; therefore, the clinical diagnosis of genital herpes should be confirmed by laboratory testing (*152*). Both virologic and type-specific serologic tests for HSV should be available in clinical settings that provide care for persons diagnosed with or at risk for STDs.

Virologic Tests

Cell culture and PCR are the preferred HSV tests for persons who seek medical treatment for genital ulcers or other mucocutaneous lesions. The sensitivity of viral culture is low, especially for recurrent lesions, and declines rapidly as lesions begin to heal. PCR assays for HSV DNA are more sensitive and are increasingly used in many settings (153,154). PCR is the test of choice for detecting HSV in spinal fluid for diagnosis of HSV infection of the central nervous system (CNS). Viral culture isolates should be typed to determine which type of HSV is causing the infection. Failure to detect HSV by culture or PCR does not indicate an absence of HSV infection, because viral shedding is intermittent. The use of cytologic detection of cellular changes of HSV infection is an insensitive and nonspecific method of diagnosis, both for genital lesions (i.e., Tzanck preparation) and for cervical Pap smears and therefore should not be relied upon.

Type-Specific Serologic Tests

Both type-specific and nontype-specific antibodies to HSV develop during the first several weeks after infection and persist indefinitely. Accurate type-specific HSV serologic assays are based on the HSV-specific glycoprotein G2 (HSV-2) and glycoprotein G1 (HSV-1). Such assays first became commercially available in 1999, but older assays that do not accurately distinguish HSV-1 from HSV-2 antibody (despite claims to the contrary) remain on the market (*155*); providers should specifically request serologic type-specific glycoprotein G (gG)-based assays when serology is performed for their patients (*156–158*).

Both laboratory-based assays and point-of-care tests that provide results for HSV-2 antibodies from capillary blood or serum during a clinic visit are available. The sensitivities of these glycoprotein G type-specific tests for the detection of HSV-2 antibody vary from 80%–98%, and false-negative results might be more frequent at early stages of infection. The specificities of these assays are ≥96%. False-positive results can occur, especially in patients with a low likelihood of HSV infection. Repeat or confirmatory testing might be indicated in some settings, especially if recent acquisition of genital herpes is suspected. IgM testing for HSV is not useful, because the

IgM tests are not type-specific and might be positive during recurrent episodes of herpes (*159*).

Because nearly all HSV-2 infections are sexually acquired, the presence of type-specific HSV-2 antibody implies anogenital infection. In this instance, education and counseling appropriate for persons with genital herpes should be provided. The presence of HSV-1 antibody alone is more difficult to interpret. Most persons with HSV-1 antibody have oral HSV infection acquired during childhood, which might be asymptomatic. However, acquisition of genital HSV-1 appears to be increasing, and genital HSV-1 also can be asymptomatic (*147–149*). Lack of symptoms in an HSV-1 seropositive person does not distinguish anogenital from orolabial or cutaneous infection, and regardless of site of infection, these persons remain at risk for acquiring HSV-2.

Type-specific HSV serologic assays might be useful in the following scenarios: 1) recurrent genital symptoms or atypical symptoms with negative HSV cultures; 2) a clinical diagnosis of genital herpes without laboratory confirmation; or 3) a partner with genital herpes. HSV serologic testing should be considered for persons presenting for an STD evaluation (especially for those persons with multiple sex partners), persons with HIV infection, and MSM at increased risk for HIV acquisition. Screening for HSV-1 and HSV-2 in the general population is not indicated.

Management of Genital Herpes

Antiviral chemotherapy offers clinical benefits to most symptomatic patients and is the mainstay of management. Counseling regarding the natural history of genital herpes, sexual and perinatal transmission, and methods to reduce transmission is integral to clinical management.

Systemic antiviral drugs can partially control the signs and symptoms of herpes episodes when used to treat first clinical and recurrent episodes, or when used as daily suppressive therapy. However, these drugs neither eradicate latent virus nor affect the risk, frequency, or severity of recurrences after the drug is discontinued. Randomized trials have indicated that three antiviral medications provide clinical benefit for genital herpes: acyclovir, valacyclovir, and famciclovir (160–168). Valacyclovir is the valine ester of acyclovir and has enhanced absorption after oral administration. Famciclovir also has high oral bioavailability. Topical therapy with antiviral drugs offers minimal clinical benefit, and its use is discouraged.

First Clinical Episode of Genital Herpes

Newly acquired genital herpes can cause a prolonged clinical illness with severe genital ulcerations and neurologic involvement. Even persons with first-episode herpes who have mild clinical manifestations initially can develop severe or prolonged symptoms. Therefore, all patients with first episodes of genital herpes should receive antiviral therapy.

Recommended Regimens*

Acyclovir 400 mg orally three times a day for 7–10 days

OR

Acyclovir 200 mg orally five times a day for 7–10 days

OR

Famciclovir 250 mg orally three times a day for 7–10 days

OR

Valacyclovir 1 g orally twice a day for 7–10 days

*Treatment can be extended if healing is incomplete after 10 days of therapy.

Established HSV-2 Infection

Almost all persons with symptomatic first-episode genital HSV-2 infection subsequently experience recurrent episodes of genital lesions; recurrences are less frequent after initial genital HSV-1 infection. Intermittent asymptomatic shedding occurs in persons with genital HSV-2 infection, even in those with longstanding or clinically silent infection. Antiviral therapy for recurrent genital herpes can be administered either as suppressive therapy to reduce the frequency of recurrences or episodically to ameliorate or shorten the duration of lesions. Some persons, including those with mild or infrequent recurrent outbreaks, benefit from antiviral therapy; therefore, options for treatment should be discussed. Many persons might prefer suppressive therapy, which has the additional advantage of decreasing the risk for genital HSV-2 transmission to susceptible partners (*169,170*).

Suppressive Therapy for Recurrent Genital Herpes

Suppressive therapy reduces the frequency of genital herpes recurrences by 70%–80% in patients who have frequent recurrences (*166–169*); many persons receiving such therapy report having experienced no symptomatic outbreaks. Treatment also is effective in patients with less frequent recurrences. Safety and efficacy have been documented among patients receiving daily therapy with acyclovir for as long as 6 years and with valacyclovir or famciclovir for 1 year (*171,172*). Quality of life is improved in many patients with frequent recurrences who receive suppressive therapy rather than episodic treatment.

The frequency of recurrent genital herpes outbreaks diminishes over time in many patients, and the patient's psychological adjustment to the disease might change. Therefore, periodically during suppressive treatment (e.g., once a year), providers should discuss the need to continue therapy with the patient.

Treatment with valacyclovir 500 mg daily decreases the rate of HSV-2 transmission in discordant, heterosexual couples in which the source partner has a history of genital HSV-2 infection (*170*). Such couples should be encouraged to consider suppressive antiviral therapy as part of a strategy to prevent transmission, in addition to consistent condom use and avoidance of sexual activity during recurrences. Suppressive antiviral therapy also is likely to reduce transmission when used by persons who have multiple partners (including MSM) and by those who are HSV-2 seropositive without a history of genital herpes.

Recommended Regimens

Acyclovir 400 mg orally twice a day

OR

Famiciclovir 250 mg orally twice a day

OR

Valacyclovir 500 mg orally once a day*

OR

Valacyclovir 1 g orally once a day

* Valacyclovir 500 mg once a day might be less effective than other valacyclovir or acyclovir dosing regimens in patients who have very frequent recurrences (i.e., ≥10 episodes per year).

Acyclovir, famciclovir, and valacyclovir appear equally effective for episodic treatment of genital herpes, but famciclovir appears somewhat less effective for suppression of viral shedding (*163–167,173*). Ease of administration and cost also are important considerations for prolonged treatment.

Episodic Therapy for Recurrent Genital Herpes

Effective episodic treatment of recurrent herpes requires initiation of therapy within 1 day of lesion onset or during the prodrome that precedes some outbreaks. The patient should be provided with a supply of drug or a prescription for the medication with instructions to initiate treatment immediately when symptoms begin.

Recommended Regimens

Acyclovir 400 mg orally three times a day for 5 days

OR

Acyclovir 800 mg orally twice a day for 5 days

OR

Acyclovir 800 mg orally three times a day for 2 days

OR

Famciclovir 125 mg orally twice daily for 5 days

OR

Famciclovir 1000 mg orally twice daily for 1 day

OR

Famciclovir 500 mg once, followed by 250 mg twice daily for 2 days

OR

Valacyclovir 500 mg orally twice a day for 3 days

OR

Valacyclovir 1 g orally once a day for 5 days

Severe Disease

Intravenous (IV) acyclovir therapy should be provided for patients who have severe HSV disease or complications that necessitate hospitalization (e.g., disseminated infection, pneumonitis, or hepatitis) or CNS complications (e.g., meningoencephalitis). The recommended regimen is acyclovir 5–10 mg/kg IV every 8 hours for 2–7 days or until clinical improvement is observed, followed by oral antiviral therapy to complete at least 10 days of total therapy. Acyclovir dose adjustment is recommended for impaired renal function.

Counseling

Counseling of infected persons and their sex partners is critical to the management of genital herpes. The goals of counseling include 1) helping patients cope with the infection and 2) preventing sexual and perinatal transmission (*174,175*). Although initial counseling can be provided at the first visit, many patients benefit from learning about the chronic aspects of the disease after the acute illness subsides. Multiple resources, including websites (http://www.ashastd.org) and printed materials, are available to assist patients, their partners, and clinicians who become involved in counseling.

Although the psychological effect of a serologic diagnosis of HSV-2 infection in a person with asymptomatic or unrecognized genital herpes appears minimal and transient (*176*), some HSV-infected persons might express anxiety concerning genital herpes that does not reflect the actual clinical severity of their disease; the psychological effect of HSV infection frequently is substantial. Common concerns regarding genital herpes include the severity of initial clinical manifestations, recurrent episodes, sexual relationships and transmission to sex partners, and ability to bear healthy children. The misconception that HSV causes cancer should be dispelled.

The following recommendations apply to counseling of persons with genital HSV infection:

- Persons who have genital herpes should be educated concerning the natural history of the disease, with emphasis on the potential for recurrent episodes, asymptomatic viral shedding, and the attendant risks of sexual transmission.
- Persons experiencing a first episode of genital herpes should be advised that suppressive therapy is available and effective in preventing symptomatic recurrent episodes

and that episodic therapy often is useful in shortening the duration of recurrent episodes.

- All persons with genital HSV infection should be encouraged to inform their current sex partners that they have genital herpes and to inform future partners before initiating a sexual relationship.
- Sexual transmission of HSV can occur during asymptomatic periods. Asymptomatic viral shedding is more frequent in genital HSV-2 infection than genital HSV-1 infection and is most frequent during the first 12 months after acquiring HSV-2.
- All persons with genital herpes should remain abstinent from sexual activity with uninfected partners when lesions or prodromal symptoms are present.
- The risk for HSV-2 sexual transmission can be decreased by the daily use of valacyclovir by the infected person. Episodic therapy does not reduce the risk for transmission and its use should be discouraged for this purpose among persons whose partners might be at risk for HSV-2 acquisition.
- Infected persons should be informed that male latex condoms, when used consistently and correctly, might reduce the risk for genital herpes transmission (*21–23*).
- Sex partners of infected persons should be advised that they might be infected even if they have no symptoms. Type-specific serologic testing of the asymptomatic partners of persons with genital herpes is recommended to determine whether such partners are already HSV seropositive or whether risk for acquiring HSV exists.
- The risk for neonatal HSV infection should be explained to all persons, including men. Pregnant women and women of childbearing age who have genital herpes should inform their providers who care for them during pregnancy and those who will care for their newborn infant about their infection. Pregnant women who are not known to be infected with HSV-2 should be advised to abstain from intercourse with men who have genital herpes during the third trimester of pregnancy. Similarly, pregnant women who are not known to be infected with HSV-1 should be counseled to avoid genital exposure to HSV-1 during the third trimester (e.g., oral sex with a partner with oral herpes and vaginal intercourse with a partner with genital HSV-1 infection).
- Asymptomatic persons diagnosed with HSV-2 infection by type-specific serologic testing should receive the same counseling messages as persons with symptomatic infection. In addition, such persons should be educated about the clinical manifestations of genital herpes.
- When exposed to HIV, HSV-2 seropositive persons are at increased risk for HIV acquisition. Patients should be informed that suppressive antiviral therapy does not reduce the increased risk for HIV acquisition associated with HSV-2 infection (*177,178*).

Management of Sex Partners

The sex partners of patients who have genital herpes can benefit from evaluation and counseling. Symptomatic sex partners should be evaluated and treated in the same manner as patients who have genital lesions. Asymptomatic sex partners of patients who have genital herpes should be questioned concerning histories of genital lesions and offered type-specific serologic testing for HSV infection.

Special Considerations

Allergy, Intolerance, and Adverse Reactions

Allergic and other adverse reactions to acyclovir, valacyclovir, and famciclovir are rare. Desensitization to acyclovir has been described (*179*).

HIV Infection

Immunocompromised patients can have prolonged or severe episodes of genital, perianal, or oral herpes. Lesions caused by HSV are common among HIV-infected patients and might be severe, painful, and atypical. HSV shedding is increased in HIV-infected persons. Whereas antiretroviral therapy reduces the severity and frequency of symptomatic genital herpes, frequent subclinical shedding still occurs (180). Clinical manifestations of genital herpes might worsen during immune reconstitution after initiation of antiretroviral therapy.

Suppressive or episodic therapy with oral antiviral agents is effective in decreasing the clinical manifestations of HSV among HIV-positive persons (*181–183*). The extent to which suppressive antiviral therapy will decrease HSV transmission from this population is unknown. HSV type-specific serologies can be offered to HIV-positive persons during their initial evaluation if infection status is unknown, and suppressive antiviral therapy can be considered in those who have HSV-2 infection.

Recommended Regimens for Daily Suppressive Therapy in Persons with HIV

Acyclovir 400–800 mg orally twice to three times a day

OR

Famciclovir 500 mg orally twice a day

OR

Valacyclovir 500 mg orally twice a day

Recommended Regimens for Episodic Infection in Persons with HIV
Acyclovir 400 mg orally three times a day for 5–10 days
OR
Famciclovir 500 mg orally twice a day for 5–10 days
OR
Valacyclovir 1 g orally twice a day for 5–10 days

Acyclovir, valacyclovir, and famciclovir are safe for use in immunocompromised patients in the doses recommended for treatment of genital herpes. For severe HSV disease, initiating therapy with acyclovir 5–10 mg/kg IV every 8 hours might be necessary.

If lesions persist or recur in a patient receiving antiviral treatment, HSV resistance should be suspected and a viral isolate should be obtained for sensitivity testing (*184*). Such persons should be managed in consultation with an HIV specialist, and alternate therapy should be administered. All acyclovir-resistant strains are resistant to valacyclovir, and the majority are resistant to famciclovir. Foscarnet, 40 mg/kg IV every 8 hours until clinical resolution is attained, is frequently effective for treatment of acyclovir-resistant genital herpes. Intravenous cidofovir 5 mg/kg once weekly might also be effective. Imiquimod is a topical alternative, as is topical cidofovir gel 1%, which is not commercially available and must be compounded at a pharmacy. These topical preparations should be applied to the lesions once daily for 5 consecutive days.

Clinical management of antiviral resistance remains challenging among HIV-infected patients, and other preventative approaches might be necessary. However, experience with another group of immunocompromised persons (hematopoietic stem-cell recipients) demonstrated that persons receiving daily suppressive antiviral therapy were less likely to develop acyclovir-resistant HSV compared with those who received episodic therapy with outbreaks (*185*).

Genital Herpes in Pregnancy

Most mothers of infants who acquire neonatal herpes lack histories of clinically evident genital herpes (*186*). The risk for transmission to the neonate from an infected mother is high (30%–50%) among women who acquire genital herpes near the time of delivery and low (<1%) among women with histories of recurrent herpes at term or who acquire genital HSV during the first half of pregnancy (*187*). However, because recurrent genital herpes is much more common than initial HSV infection during pregnancy, the proportion of neonatal HSV infections acquired from mothers with recurrent herpes is substantial. Prevention of neonatal herpes depends both on preventing acquisition of genital HSV infection during late pregnancy and avoiding exposure of the infant to herpetic lesions during delivery. Because the risk for herpes is high in infants of women who acquire genital HSV during late pregnancy, these women should be managed in consultation with an infectious disease specialist.

Women without known genital herpes should be counseled to abstain from intercourse during the third trimester with partners known or suspected of having genital herpes. In addition, pregnant women without known orolabial herpes should be advised to abstain from receptive oral sex during the third trimester with partners known or suspected to have orolabial herpes. Some specialists believe that type-specific serologic tests are useful to identify pregnant women at risk for HSV infection and to guide counseling regarding the risk for acquiring genital herpes during pregnancy and that such testing should be offered to uninfected women whose sex partner has HSV infection. However, the effectiveness of antiviral therapy to decrease the risk for HSV transmission to pregnant women by infected partners has not been studied.

All pregnant women should be asked whether they have a history of genital herpes. At the onset of labor, all women should be questioned carefully about symptoms of genital herpes, including prodromal symptoms, and all women should be examined carefully for herpetic lesions. Women without symptoms or signs of genital herpes or its prodrome can deliver vaginally. Although cesarean section does not completely eliminate the risk for HSV transmission to the infant, women with recurrent genital herpetic lesions at the onset of labor should deliver by cesarean section to prevent neonatal HSV infection.

The safety of systemic acyclovir, valacyclovir, and famciclovir therapy in pregnant women has not been definitively established. Available data do not indicate an increased risk for major birth defects compared with the general population in women treated with acyclovir during the first trimester (*188*) — findings that provide assurance to women who have had prenatal exposure to acyclovir. However, data regarding prenatal exposure to valacyclovir and famciclovir are too limited to provide useful information on pregnancy outcomes. Acyclovir can be administered orally to pregnant women with first episode genital herpes or severe recurrent herpes and should be administered IV to pregnant women with severe HSV infection. Acyclovir treatment late in pregnancy reduces the frequency of cesarean sections among women who have recurrent genital herpes by diminishing the frequency of recurrences at term (*189–191*); the effect of antiviral therapy late in pregnancy on the incidence of neonatal herpes is not known. No data support the use of antiviral therapy among HSV seropositive women without a history of genital herpes.

Neonatal Herpes

Infants exposed to HSV during birth, as documented by maternal virologic testing or presumed by observation of maternal lesions, should be followed carefully in consultation with a pediatric infectious disease specialist. Surveillance cultures of mucosal surfaces to detect HSV infection might be considered before the development of clinical signs of neonatal herpes. In addition, administration of acyclovir might be considered for infants born to women who acquired HSV near term because the risk for neonatal herpes is high for these infants. All infants who have neonatal herpes should be promptly evaluated and treated with systemic acyclovir. The recommended regimen for infants treated for known or suspected neonatal herpes is acyclovir 20 mg/kg IV every 8 hours for 21 days for disseminated and CNS disease or for 14 days for disease limited to the skin and mucous membranes.

Granuloma Inguinale (Donovanosis)

Granuloma inguinale is a genital ulcerative disease caused by the intracellular gram-negative bacterium *Klebsiella granulomatis* (formerly known as *Calymmatobacterium granulomatis*). The disease occurs rarely in the United States, although it is endemic in some tropical and developing areas, including India; Papua, New Guinea; the Caribbean; central Australia; and southern Africa (*192,193*). Clinically, the disease is commonly characterized as painless, slowly progressive ulcerative lesions on the genitals or perineum without regional lymphadenopathy; subcutaneous granulomas (pseudoboboes) might also occur. The lesions are highly vascular (i.e., beefy red appearance) and bleed easily on contact. The clinical presentation also can include hypertrophic, necrotic, or sclerotic variants. Extragenital infection can occur with extension of infection to the pelvis, or it can disseminate to intraabdominal organs, bones, or the mouth. The lesions also can develop secondary bacterial infection and can coexist with other sexually transmitted pathogens.

The causative organism is difficult to culture, and diagnosis requires visualization of dark-staining Donovan bodies on tissue crush preparation or biopsy. No FDA-cleared molecular tests for the detection of *K. granulomatis* DNA exist, but such an assay might be useful when undertaken by laboratories that have conducted a CLIA verification study.

Treatment

Several antimicrobial regimens have been effective, but only a limited number of controlled trials have been published (*192*). Treatment has been shown to halt progression of lesions, and healing typically proceeds inward from the ulcer margins; prolonged therapy is usually required to permit granulation and reepithelialization of the ulcers. Relapse can occur 6–18 months after apparently effective therapy.

Recommended Regimen

Doxycycline 100 mg orally twice a day for at least 3 weeks and until all lesions have completely healed

Alternative Regimens

Azithromycin 1 g orally once per week for at least 3 weeks and until all lesions have completely healed

OR

Ciprofloxacin 750 mg orally twice a day for at least 3 weeks and until all lesions have completely healed

OR

Erythromycin base 500 mg orally four times a day for at least 3 weeks and until all lesions have completely healed

OR

Trimethoprim-sulfamethoxazole one double-strength (160 mg/800 mg) tablet orally twice a day for at least 3 weeks and until all lesions have completely healed

The addition of an aminoglycoside (e.g., gentamicin 1 mg/kg IV every 8 hours) to these regimens can be considered if improvement is not evident within the first few days of therapy.

Follow-Up

Patients should be followed clinically until signs and symptoms have resolved.

Management of Sex Partners

Persons who have had sexual contact with a patient who has granuloma inguinale within the 60 days before onset of the patient's symptoms should be examined and offered therapy. However, the value of empiric therapy in the absence of clinical signs and symptoms has not been established.

Special Considerations

Pregnancy

Pregnancy is a relative contraindication to the use of sulfonamides. Pregnant and lactating women should be treated with the erythromycin regimen, and consideration should be given to the addition of a parenteral aminoglycoside (e.g., gentamicin). Azithromycin might prove useful for treating granuloma inguinale during pregnancy, but published data are lacking. Doxycycline and ciprofloxacin are contraindicated in pregnant women.

HIV Infection

Persons with both granuloma inguinale and HIV infection should receive the same regimens as those who are HIV

negative; however, the addition of a parenteral aminoglycoside (e.g., gentamicin) can also be considered.

Lymphogranuloma Venereum

Lymphogranuloma venereum (LGV) is caused by *C. trachomatis* serovars L1, L2, or L3 (194). The most common clinical manifestation of LGV among heterosexuals is tender inguinal and/or femoral lymphadenopathy that is typically unilateral. A self-limited genital ulcer or papule sometimes occurs at the site of inoculation. However, by the time patients seek care, the lesions have often disappeared. Rectal exposure in women or MSM can result in proctocolitis, including mucoid and/or hemorrhagic rectal discharge, anal pain, constipation, fever, and/or tenesmus (*195,196*). LGV is an invasive, systemic infection, and if it is not treated early, LGV proctocolitis can lead to chronic, colorectal fistulas and strictures. Genital and colorectal LGV lesions can also develop secondary bacterial infection or can be coinfected with other sexually and nonsexually transmitted pathogens.

Diagnosis is based on clinical suspicion, epidemiologic information, and the exclusion of other etiologies for proctocolitis, inguinal lymphadenopathy, or genital or rectal ulcers. *C. trachomatis* testing also should be conducted, if available.

Genital and lymph node specimens (i.e., lesion swab or bubo aspirate) can be tested for *C. trachomatis* by culture, direct immunofluorescence, or nucleic acid detection. NAATs for *C. trachomatis* are not FDA-cleared for testing rectal specimens, although some laboratories have performed the CLIA validation studies that are needed to provide results for clinical management. Additional molecular procedures (e.g., PCR-based genotyping) can be used to differentiate LGV from non-LGV *C. trachomatis*, but these are not widely available.

Chlamydia serology (complement fixation titers >1:64) can support the diagnosis of LGV in the appropriate clinical context. Comparative data between types of serologic tests are lacking, and the diagnostic utility of serologic methods other than complement fixation and some microimmunofluorescence procedures has not been established. Serologic test interpretation for LGV is not standardized, tests have not been validated for clinical proctitis presentations, and *C. trachomatis* serovar-specific serologic tests are not widely available.

In the absence of specific LGV diagnostic testing, patients with a clinical syndrome consistent with LGV, including proctocolitis or genital ulcer disease with lymphadenopathy, should be treated for LGV as described in this report.

Treatment

Treatment cures infection and prevents ongoing tissue damage, although tissue reaction to the infection can result in scarring. Buboes might require aspiration through intact skin or incision and drainage to prevent the formation of inguinal/femoral ulcerations. Doxycycline is the preferred treatment.

Recommended Regimen

Doxycycline 100 mg orally twice a day for 21 days

Alternative Regimen

Erythromycin base 500 mg orally four times a day for 21 days

Although clinical data are lacking, azithromycin 1 g orally once weekly for 3 weeks is probably effective based on its chlamydial antimicrobial activity. Fluoroquinolone-based treatments might also be effective, but extended treatment intervals are likely required.

Follow-Up

Patients should be followed clinically until signs and symptoms have resolved.

Management of Sex Partners

Persons who have had sexual contact with a patient who has LGV within the 60 days before onset of the patient's symptoms should be examined, tested for urethral or cervical chlamydial infection, and treated with a chlamydia regimen (azithromycin 1 gm orally single dose or doxycycline 100 mg orally twice a day for 7 days).

Special Considerations

Pregnancy

Pregnant and lactating women should be treated with erythromycin. Azithromycin might prove useful for treatment of LGV in pregnancy, but no published data are available regarding its safety and efficacy. Doxycycline is contraindicated in pregnant women.

HIV Infection

Persons with both LGV and HIV infection should receive the same regimens as those who are HIV negative. Prolonged therapy might be required, and delay in resolution of symptoms might occur.

Syphilis

Syphilis is a systemic disease caused by *Treponema pallidum*. On the basis of clinical findings, the disease has been divided into a series of overlapping stages, which are used to help guide treatment and follow-up. Persons who have syphilis might seek treatment for signs or symptoms of primary infection (i.e., ulcer

or chancre at the infection site), secondary infection (i.e., manifestations that include, but are not limited to, skin rash, mucocutaneous lesions, and lymphadenopathy), neurologic infection (i.e., cranial nerve dysfunction, meningitis, stroke, acute or chronic altered mental status, loss of vibration sense, and auditory or ophthalmic abnormalities, which might occur through the natural history of untreated infection), or tertiary infection (i.e., cardiac or gummatous lesions). Latent infections (i.e., those lacking clinical manifestations) are detected by serologic testing. Latent syphilis acquired within the preceding year is referred to as early latent syphilis; all other cases of latent syphilis are either late latent syphilis or latent syphilis of unknown duration. Treatment for both late latent syphilis and tertiary syphilis might require a longer duration of therapy because organisms might be dividing more slowly; however, the validity of this concept has not been assessed.

Diagnostic Considerations

Darkfield examinations and tests to detect *T. pallidum* in lesion exudate or tissue are the definitive methods for diagnosing early syphilis (*197*). Although no *T. pallidum* detection tests are commercially available, some laboratories provide locally developed PCR tests for the detection of *T. pallidum*. A presumptive diagnosis of syphilis is possible with the use of two types of serologic tests: 1) nontreponemal tests (e.g., Venereal Disease Research Laboratory [VDRL] and RPR) and 2) treponemal tests (e.g., fluorescent treponemal antibody absorbed [FTA-ABS] tests, the *T. pallidum* passive particle agglutination [TP-PA] assay, various EIAs, and chemiluminescence immunoassays). The use of only one type of serologic test is insufficient for diagnosis, because each type of test has limitations, including the possibility of false-positive test results in persons without syphilis. False-positive nontreponemal test results can be associated with various medical conditions unrelated to syphilis, including autoimmune conditions, older age, and injection-drug use (*198,199*); therefore, persons with a reactive nontreponemal test should receive a treponemal test to confirm the diagnosis of syphilis.

Nontreponemal test antibody titers may correlate with disease activity, and results should be reported quantitatively. A fourfold change in titer, equivalent to a change of two dilutions (e.g., from 1:16 to 1:4 or from 1:8 to 1:32), is considered necessary to demonstrate a clinically significant difference between two nontreponemal test results that were obtained using the same serologic test. Sequential serologic tests in individual patients should be performed using the same testing method (e.g., VDRL or RPR), preferably by the same laboratory. The VDRL and RPR are equally valid assays, but quantitative results from the two tests cannot be compared directly because RPR titers frequently are slightly higher than VDRL titers. Nontreponemal test titers usually decline after treatment and might become nonreactive with time; however, in some persons, nontreponemal antibodies can persist for a long period of time — a response referred to as the "serofast reaction." Most patients who have reactive treponemal tests will have reactive tests for the remainder of their lives, regardless of treatment or disease activity. However, 15%–25% of patients treated during the primary stage revert to being serologically nonreactive after 2–3 years (*200*). Treponemal test antibody titers should not be used to assess treatment response.

Some clinical laboratories and blood banks have begun to screen samples using treponemal tests, typically by EIA or chemiluminescence immunoassays (*201,202*). This strategy will identify both persons with previous treatment for syphilis and persons with untreated or incompletely treated syphilis. The positive predictive value for syphilis associated with a treponemal screening test result might be lower among populations with a low prevalence of syphilis.

Persons with a positive treponemal screening test should have a standard nontreponemal test with titer performed reflexively by the laboratory to guide patient management decisions. If the nontreponemal test is negative, then the laboratory should perform a different treponemal test (preferably one based on different antigens than the original test) to confirm the results of the initial test. If a second treponemal test is positive, persons with a history of previous treatment will require no further management unless sexual history suggests likelihood of re-exposure. Those without a history of treatment for syphilis should be offered treatment. Unless history or results of a physical examination suggest a recent infection, previously untreated persons should be treated for late latent syphilis. If the second treponemal test is negative, further evaluation or treatment is not indicated.

For most HIV-infected persons, serologic tests are accurate and reliable for the diagnosis of syphilis and for following a patient's response to treatment. However, atypical syphilis serologic test results (i.e., unusually high, unusually low, or fluctuating titers) can occur in HIV-infected persons. When serologic tests do not correspond with clinical findings suggestive of early syphilis, use of other tests (e.g., biopsy and darkfield microscopy) should be considered.

Clinical signs of neurosyphilis (i.e., cranial nerve dysfunction, meningitis, stroke, acute or chronic altered mental status, loss of vibration sense, and auditory or ophthalmic abnormalities) warrant further investigation and treatment for neurosyphilis. Laboratory testing is helpful in supporting the diagnosis of neurosyphilis; however, no single test can be used to diagnose neurosyphilis in all instances. Cerebrospinal fluid (CSF) laboratory abnormalities are common in persons with early syphilis. The VDRL in cerebrospinal fluid (CSF-VDRL),

which is highly specific but insensitive, is the standard serologic test for CSF. When reactive in the absence of substantial contamination of CSF with blood, it is considered diagnostic of neurosyphilis; however in early syphilis, it can be of unknown prognostic significance (*203*). Most other tests are both insensitive and nonspecific and must be interpreted in relation to other test results and the clinical assessment. Therefore, the laboratory diagnosis of neurosyphilis usually depends on various combinations of reactive serologic test results, CSF cell count or protein, and a reactive CSF-VDRL with or without clinical manifestations. Among persons with HIV infection, the CSF leukocyte count usually is elevated (>5 white blood cell count [WBC]/mm^3); using a higher cutoff (>20 WBC/ mm^3) might improve the specificity of neurosyphilis diagnosis (*204*). The CSF-VDRL might be nonreactive even when neurosyphilis is present; therefore, additional evaluation using FTA-ABS testing on CSF can be considered. The CSF FTA-ABS test is less specific for neurosyphilis than the CSF-VDRL but is highly sensitive; neurosyphilis is highly unlikely with a negative CSF FTA-ABS test (*205*).

Treatment

Penicillin G, administered parenterally, is the preferred drug for treating all stages of syphilis. The preparation used (i.e., benzathine, aqueous procaine, or aqueous crystalline), the dosage, and the length of treatment depend on the stage and clinical manifestations of the disease. Selection of the appropriate penicillin preparation is important, because *T. pallidum* can reside in sequestered sites (e.g., the CNS and aqueous humor) that are poorly accessed by some forms of penicillin. Combinations of benzathine penicillin, procaine penicillin, and oral penicillin preparations are not considered appropriate for the treatment of syphilis. Reports have indicated that practitioners have inadvertently prescribed combination benzathine-procaine penicillin (Bicillin C-R) instead of the standard benzathine penicillin product (Bicillin L-A) widely used in the United States. Practitioners, pharmacists, and purchasing agents should be aware of the similar names of these two products to avoid using the inappropriate combination therapy agent for treating syphilis (*206*).

The effectiveness of penicillin for the treatment of syphilis was well established through clinical experience even before the value of randomized controlled clinical trials was recognized. Therefore, nearly all the recommendations for the treatment of syphilis are based not only on clinical trials and observational studies, but approximately 50 years of clinical experience.

Parenteral penicillin G is the only therapy with documented efficacy for syphilis during pregnancy. Pregnant women with syphilis in any stage who report penicillin allergy should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy).

The Jarisch-Herxheimer reaction is an acute febrile reaction frequently accompanied by headache, myalgia, fever, and other symptoms that usually occur within the first 24 hours after the initiation of any therapy for syphilis. Patients should be informed about this possible adverse reaction. The Jarisch-Herxheimer reaction occurs most frequently among patients who have early syphilis, presumably because bacterial burdens are higher during these stages. Antipyretics can be used to manage symptoms, but they have not been proven to prevent this reaction. The Jarisch-Herxheimer reaction might induce early labor or cause fetal distress in pregnant women, but this should not prevent or delay therapy (see Syphilis During Pregnancy).

Management of Sex Partners

Sexual transmission of *T. pallidum* is thought to occur only when mucocutaneous syphilitic lesions are present. Although such manifestations are uncommon after the first year of infection, persons exposed sexually to a patient who has syphilis in any stage should be evaluated clinically and serologically and treated with a recommended regimen, according to the following recommendations:

- Persons who were exposed within the 90 days preceding the diagnosis of primary, secondary, or early latent syphilis in a sex partner might be infected even if seronegative; therefore, such persons should be treated presumptively.
- Persons who were exposed >90 days before the diagnosis of primary, secondary, or early latent syphilis in a sex partner should be treated presumptively if serologic test results are not available immediately and the opportunity for follow-up is uncertain.
- For purposes of partner notification and presumptive treatment of exposed sex partners, patients with syphilis of unknown duration who have high nontreponemal serologic test titers (i.e., >1:32) can be assumed to have early syphilis. For the purpose of determining a treatment regimen, however, serologic titers should not be used to differentiate early from late latent syphilis (see Latent Syphilis, Treatment).
- Long-term sex partners of patients who have latent syphilis should be evaluated clinically and serologically for syphilis and treated on the basis of the evaluation findings.

Sexual partners of infected patients should be considered at risk and provided treatment if they have had sexual contact with the patient within 3 months plus the duration of symptoms for patients diagnosed with primary syphilis, 6 months

plus duration of symptoms for those with secondary syphilis, and 1 year for patients with early latent syphilis.

Primary and Secondary Syphilis

Treatment

Parenteral penicillin G has been used effectively for more than 50 years to achieve clinical resolution (i.e., the healing of lesions and prevention of sexual transmission) and to prevent late sequelae. However, no comparative trials have been adequately conducted to guide the selection of an optimal penicillin regimen (i.e., the dose, duration, and preparation). Substantially fewer data are available for nonpenicillin regimens.

Recommended Regimen for Adults*
Benzathine penicillin G 2.4 million units IM in a single dose

* Recommendations for treating syphilis in HIV-infected persons and pregnant women are discussed later in this report (see Syphilis among HIV–Infected Persons and Syphilis in Pregnancy).

Available data demonstrate that additional doses of benzathine penicillin G, amoxicillin, or other antibiotics in early syphilis (primary, secondary, and early latent) do not enhance efficacy, regardless of HIV status.

Recommended Regimen for Infants and Children

Infants and children aged ≥1 month diagnosed with syphilis should have a CSF examination to detect asymptomatic neurosyphilis, and birth and maternal medical records should be reviewed to assess whether such children have congenital or acquired syphilis (see Congenital Syphilis). Children with acquired primary or secondary syphilis should be evaluated (e.g., through consultation with child-protection services) (see Sexual Assault or Abuse of Children) and treated by using the following pediatric regimen.

Recommended Regimen for Infants and Children
Benzathine penicillin G 50,000 units/kg IM, up to the adult dose of 2.4 million units in a single dose

Other Management Considerations

All persons who have syphilis should be tested for HIV infection. In geographic areas in which the prevalence of HIV is high, persons who have primary syphilis should be retested for HIV after 3 months if the first HIV test result was negative.

Patients who have syphilis and symptoms or signs suggesting neurologic disease (e.g., meningitis and hearing loss) or ophthalmic disease (e.g., uveitis, iritis, neuroretinitis, and optic neuritis) should have an evaluation that includes CSF analysis, ocular slit-lamp ophthalmologic examination, and otologic examination. Treatment should be guided by the results of this evaluation.

Invasion of CSF by *T. pallidum* accompanied by CSF laboratory abnormalities is common among adults who have primary or secondary syphilis (*203*). Therefore, in the absence of clinical neurologic findings, no evidence exists to support variation from the recommended treatment regimen for early syphilis. Symptomatic neurosyphilis develops in only a limited number of persons after treatment with the penicillin regimens recommended for primary and secondary syphilis. Therefore, unless clinical signs or symptoms of neurologic or ophthalmic involvement are present or treatment failure is documented, routine CSF analysis is not recommended for persons who have primary or secondary syphilis.

Follow-Up

Treatment failure can occur with any regimen. However, assessing response to treatment frequently is difficult, and definitive criteria for cure or failure have not been established. In addition, nontreponemal test titers might decline more slowly for persons who previously have had syphilis (*207*). Clinical and serologic evaluation should be performed 6 months and 12 months after treatment; more frequent evaluation might be prudent if follow-up is uncertain.

Patients who have signs or symptoms that persist or recur or who have a sustained fourfold increase in nontreponemal test titer (i.e., compared with the maximum or baseline titer at the time of treatment) probably failed treatment or were reinfected. These patients should be retreated and reevaluated for HIV infection. Because treatment failure usually cannot be reliably distinguished from reinfection with *T. pallidum*, a CSF analysis also should be performed.

Although failure of nontreponemal test titers to decline fourfold within 6–12 months after therapy for primary or secondary syphilis might be indicative of treatment failure, clinical trial data have demonstrated that >15% of patients with early syphilis treated with the recommended therapy will not achieve the two dilution decline in nontreponemal titer used to define response at 1 year after treatment (*208*). Persons whose titers do not decline should be reevaluated for HIV infection. Optimal management of such patients is unclear. At a minimum, these patients should receive additional clinical and serologic follow-up. If additional follow-up cannot be ensured, retreatment is recommended. Because treatment failure might be the result of unrecognized CNS infection, CSF examination can be considered in such situations.

For retreatment, weekly injections of benzathine penicillin G 2.4 million units IM for 3 weeks is recommended, unless CSF examination indicates that neurosyphilis is present (see

Neurosyphilis). In rare instances, serologic titers do not decline despite a negative CSF examination and a repeated course of therapy. In these circumstances, the need for additional therapy or repeated CSF examinations is unclear, but is not generally recommended.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy

Data to support the use of alternatives to penicillin in the treatment of early syphilis are limited. However, several therapies might be effective in nonpregnant, penicillin-allergic patients who have primary or secondary syphilis. Doxycycline 100 mg orally twice daily for 14 days (*209,210*) and tetracycline (500 mg four times daily for 14 days) are regimens that have been used for many years. Compliance is likely to be better with doxycycline than tetracycline, because tetracycline can cause gastrointestinal side effects. Although limited clinical studies, along with biologic and pharmacologic evidence, suggest that ceftriaxone (1 g daily either IM or IV for 10–14 days) is effective for treating early syphilis, the optimal dose and duration of ceftriaxone therapy have not been defined (*211*). Azithromycin as a single 2-g oral dose is effective for treating early syphilis (*212–214*). However, *T. pallidum* chromosomal mutations associated with azithromycin resistance and treatment failures have been documented in several geographical areas in the United States (*215–217*). As such, the use of azithromycin should be used with caution only when treatment with penicillin or doxycycline is not feasible. Azithromycin should not be used in MSM or pregnant women. Close follow-up of persons receiving any alternative therapies is essential.

Persons with a penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with benzathine penicillin. Skin testing for penicillin allergy might be useful in some circumstances in which the reagents and expertise are available to perform the test adequately (see Management of Patients Who Have a History of Penicillin Allergy).

Pregnancy

Pregnant patients who are allergic to penicillin should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy and Syphilis During Pregnancy).

HIV Infection

See Syphilis Among HIV-Infected Persons.

Latent Syphilis

Latent syphilis is defined as syphilis characterized by seroreactivity without other evidence of disease. Patients who have latent syphilis and who acquired syphilis during the preceding year are classified as having early latent syphilis. Patients' conditions can be diagnosed as early latent syphilis if, during the year preceding the evaluation, they had 1) a documented seroconversion or fourfold or greater increase in titer of a nontreponemal test; 2) unequivocal symptoms of primary or secondary syphilis; or 3) a sex partner documented to have primary, secondary, or early latent syphilis. In addition, for persons whose only possible exposure occurred during the previous 12 months, reactive nontreponemal and treponemal tests are indicative of early latent syphilis. In the absence of these conditions, an asymptomatic person should be considered to have late latent syphilis or syphilis of unknown duration. Nontreponemal serologic titers usually are higher during early latent syphilis than late latent syphilis. However, early latent syphilis cannot be reliably distinguished from late latent syphilis solely on the basis of nontreponemal titers. All patients with latent syphilis should have careful examination of all accessible mucosal surfaces (i.e., the oral cavity, perianal area, perineum and vagina in women, and underneath the foreskin in uncircumcised men) to evaluate for internal mucosal lesions. All patients who have syphilis should be tested for HIV infection.

Treatment

Because latent syphilis is not transmitted sexually, the objective of treating patients with this stage of disease is to prevent complications. Although clinical experience supports the effectiveness of penicillin in achieving this goal, limited evidence is available to guide choice of specific regimens.

The following regimens are recommended for penicillin nonallergic patients who have normal CSF examinations (if performed).

Recommended Regimens for Adults*
Early Latent Syphilis
Benzathine penicillin G 2.4 million units IM in a single dose
Late Latent Syphilis or Latent Syphilis of Unknown Duration
Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units IM each at 1-week intervals

* Recommendations for treating syphilis in HIV-infected persons and pregnant women are discussed later in this report (see Syphilis among HIV-Infected Persons and Syphilis in Pregnancy).

Available data demonstrate no enhanced efficacy of additional doses of penicillin G, amoxicillin, or other antibiotics in early syphilis, regardless of HIV status.

Infants and children aged ≥1 month who have been diagnosed with syphilis should have a CSF examination to exclude neurosyphilis. In addition, birth and maternal medical records should be reviewed to assess whether children have congenital or acquired syphilis (see Congenital Syphilis). Older children with acquired latent syphilis should be evaluated as described for adults and treated using the following pediatric regimens (see Sexual Assault or Abuse of Children). These regimens are for penicillin nonallergic children who have acquired syphilis and who have normal CSF examination results.

Recommended Regimens for Children
Early Latent Syphilis
Benzathine penicillin G 50,000 units/kg IM, up to the adult dose of 2.4 million units in a single dose
Late Latent Syphilis or Latent Syphilis of Unknown Duration
Benzathine penicillin G 50,000 units/kg IM, up to the adult dose of 2.4 million units, administered as 3 doses at 1-week intervals (total 150,000 units/kg up to the adult total dose of 7.2 million units)

Other Management Considerations

Patients diagnosed with latent syphilis who demonstrate any of the following criteria should have a prompt CSF examination:

- Neurologic (e.g., auditory disease, cranial nerve dysfunction, acute or chronic meningitis, stroke, acute or chronic altered mental status, and loss of vibration sense) or ophthalmic signs or symptoms (e.g., iritis and uveitis);
- evidence of active tertiary syphilis (e.g., aortitis and gumma); or
- serologic treatment failure.

If a patient misses a dose of penicillin in a course of weekly therapy for late syphilis, the appropriate course of action is unclear. Pharmacologic considerations suggest that an interval of 10–14 days between doses of benzathine penicillin for late syphilis or latent syphilis of unknown duration might be acceptable before restarting the sequence of injections. Missed doses are not acceptable for pregnant patients receiving therapy for late latent syphilis. Pregnant women who miss any dose of therapy must repeat the full course of therapy.

Follow-Up

Quantitative nontreponemal serologic tests should be repeated at 6, 12, and 24 months. A CSF examination should be performed if 1) titers increase fourfold, 2) an initially high titer (≥1:32) fails to decline at least fourfold (i.e., two dilutions) within 12–24 months of therapy, or 3) signs or symptoms attributable to syphilis develop. In such circumstances, even if the CSF examination is negative, retreatment for latent syphilis should be initiated. In rare instances, despite a negative CSF examination and a repeated course of therapy, serologic titers might fail to decline. In these circumstances, the need for additional therapy or repeated CSF examinations is unclear.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy

The effectiveness of alternatives to penicillin in the treatment of latent syphilis has not been well documented. Nonpregnant patients allergic to penicillin who have clearly defined early latent syphilis should respond to therapies recommended as alternatives to penicillin for the treatment of primary and secondary syphilis (see Primary and Secondary Syphilis, Treatment). The only acceptable alternatives for the treatment of late latent syphilis or latent syphilis of unknown duration are doxycycline (100 mg orally twice daily) or tetracycline (500 mg orally four times daily), both for 28 days. These therapies should be used only in conjunction with close serologic and clinical follow-up. Based on biologic plausibility and pharmacologic properties, ceftriaxone might be effective for treating late latent syphilis or syphilis of unknown duration. However, the optimal dose and duration of ceftriaxone therapy have not been defined, and treatment decisions should be discussed in consultation with a specialist. Some patients who are allergic to penicillin also might be allergic to ceftriaxone; in these circumstances, use of an alternative agent might be required. The efficacy of these alternative regimens in HIV-infected persons has not been well studied.

Pregnancy

Pregnant patients who are allergic to penicillin should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy and Syphilis During Pregnancy).

HIV Infection

See Syphilis Among HIV-Infected Persons.

Tertiary Syphilis

Tertiary syphilis refers to gumma and cardiovascular syphilis but not to all neurosyphilis. Patients who are not allergic to penicillin and have no evidence of neurosyphilis should be treated with the following regimen.

Recommended Regimen

Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units IM each at 1-week intervals

Other Management Considerations

Patients who have symptomatic late syphilis should be given a CSF examination before therapy is initiated. Some providers treat all patients who have cardiovascular syphilis with a neurosyphilis regimen. These patients should be managed in consultation with an infectious disease specialist.

Follow-Up

Limited information is available concerning clinical response and follow-up of patients who have tertiary syphilis.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy

Patients allergic to penicillin should be treated in consultation with an infectious disease specialist.

Pregnancy

Pregnant patients who are allergic to penicillin should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy and Syphilis During Pregnancy).

HIV Infection

See Syphilis Among HIV-Infected Persons.

Neurosyphilis

Treatment

CNS involvement can occur during any stage of syphilis. However, CSF laboratory abnormalities are common in persons with early syphilis, even in the absence of clinical neurological findings. No evidence exists to support variation from recommended treatment for early syphilis for patients found to have such abnormalities. If clinical evidence of neurologic involvement is observed (e.g., cognitive dysfunction, motor or sensory deficits, ophthalmic or auditory symptoms, cranial nerve palsies, and symptoms or signs of meningitis), a CSF examination should be performed.

Syphilitic uveitis or other ocular manifestations frequently are associated with neurosyphilis and should be managed according to the treatment recommendations for neurosyphilis. Patients who have neurosyphilis or syphilitic eye disease (e.g., uveitis, neuroretinitis, and optic neuritis) should be treated with the recommended regimen for neurosyphilis; those with eye disease should be managed in collaboration with an ophthalmologist. A CSF examination should be performed for all patients with syphilitic eye disease to identify those with abnormalities; patients found to have abnormal CSF test results should be provided follow-up CSF examinations to assess treatment response.

Recommended Regimen

Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units IV every 4 hours or continuous infusion, for 10–14 days

If compliance with therapy can be ensured, the following alternative regimen might be considered.

Alternative Regimen

Procaine penicillin 2.4 million units IM once daily

PLUS

Probenecid 500 mg orally four times a day, both for 10–14 days

The durations of the recommended and alternative regimens for neurosyphilis are shorter than the duration of the regimen used for late syphilis in the absence of neurosyphilis. Therefore, benzathine penicillin, 2.4 million units IM once per week for up to 3 weeks, can be considered after completion of these neurosyphilis treatment regimens to provide a comparable total duration of therapy.

Other Management Considerations

Other considerations in the management of patients who have neurosyphilis are as follows:

- All persons who have syphilis should be tested for HIV.
- Although systemic steroids are used frequently as adjunctive therapy for otologic syphilis, such drugs have not been proven to be beneficial.

Follow-Up

If CSF pleocytosis was present initially, a CSF examination should be repeated every 6 months until the cell count is normal. Follow-up CSF examinations also can be used to evaluate changes in the CSF-VDRL or CSF protein after therapy; however, changes in these two parameters occur more slowly than cell counts, and persistent abnormalities might be less important (*219,220*). The leukocyte count is a sensitive measure of the effectiveness of therapy. If the cell count has not decreased after 6 months or if the CSF cell count or protein is not normal after 2 years, retreatment should be considered.

Limited data suggest that in immunocompetent persons and HIV-infected persons on highly active antiretroviral therapy, normalization of the serum RPR titer predicts normalization of CSF parameters (*220*).

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy

Limited data suggest that ceftriaxone 2 g daily either IM or IV for 10–14 days can be used as an alternative treatment for patients with neurosyphilis (*221,222*). However, the possibility of cross-reactivity between ceftriaxone and penicillin exists. Other regimens have not been adequately evaluated for treatment of neurosyphilis. Therefore, if concern exists regarding the safety of ceftriaxone for a patient with neurosyphilis, skin testing should be performed (if available) to confirm penicillin allergy and, if necessary, desensitization in consultation with a specialist.

Pregnancy

Pregnant patients who are allergic to penicillin should be desensitized and treated with penicillin (see Syphilis During Pregnancy).

HIV Infection

See Syphilis Among HIV-Infected Persons.

Syphilis Among HIV-Infected Persons

Diagnostic Considerations

Although they are uncommon, unusual serologic responses have been observed among HIV-infected persons who have syphilis. Most reports have involved serologic titers that were higher than expected, but false-negative serologic test results and delayed appearance of seroreactivity also have been reported (*223*). Regardless, both treponemal and nontreponemal serologic tests for syphilis can be interpreted in the usual manner for most patients who are coinfected with *T. pallidum* and HIV.

When clinical findings are suggestive of syphilis but serologic tests are nonreactive or their interpretation is unclear, alternative tests (e.g., biopsy of a lesion, darkfield examination, and PCR of lesion material) might be useful for diagnosis. Neurosyphilis should be considered in the differential diagnosis of neurologic disease in HIV-infected persons.

Treatment

Compared with HIV-negative patients, HIV-positive patients who have early syphilis might be at increased risk for neurologic complications (*224*) and might have higher rates of serologic treatment failure with currently recommended regimens. The magnitude of these risks is not defined precisely, but is likely small. No treatment regimens for syphilis have been demonstrated to be more effective in preventing neurosyphilis in HIV-infected patients than the syphilis regimens recommended for HIV-negative patients (*208*). Careful follow-up after therapy is essential.

Primary and Secondary Syphilis Among HIV-Infected Persons

Treatment

Treatment of primary and secondary syphilis among HIV-infected persons is benzathine penicillin G, 2.4 million units IM in a single dose.

Available data demonstrate that additional doses of benzathine penicillin G, amoxicillin, or other antibiotics in early syphilis do not result in enhanced efficacy, regardless of HIV status (*208*).

Other Management Considerations

Most HIV-infected persons respond appropriately to standard benzathine penicillin for primary and secondary syphilis. CSF abnormalities (e.g., mononuclear pleocytosis and elevated protein levels) are common in HIV-infected persons, even in those without neurologic symptoms, although the clinical and prognostic significance of such CSF abnormalities with primary and secondary syphilis is unknown. Several studies have demonstrated that among persons infected with both HIV and syphilis, clinical and CSF abnormalities consistent with neurosyphilis are associated with a CD4 count of ≤350 cells/mL and/or an RPR titer of ≥1:32 (*204,225,226*); however, unless neurologic symptoms are present, CSF examination in this setting has not been associated with improved clinical outcomes.

The use of antiretroviral therapy as per current guidelines might improve clinical outcomes in HIV-infected persons with syphilis (*220,227,228*).

Follow-Up

HIV-infected persons should be evaluated clinically and serologically for treatment failure at 3, 6, 9, 12, and 24 months after therapy.

HIV-infected persons who meet the criteria for treatment failure (i.e., signs or symptoms that persist or recur or persons who have a sustained fourfold increase in nontreponemal test titer) should be managed in the same manner as HIV-negative patients (i.e., a CSF examination and retreatment). CSF examination and retreatment also should be strongly considered for persons whose nontreponemal test titers do not decrease

fourfold within 6–12 months of therapy. If CSF examination is normal, treatment with benzathine penicillin G administered as 2.4 million units IM each at weekly intervals for 3 weeks is recommended.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy. HIV-infected, penicillin-allergic patients who have primary or secondary syphilis should be managed according to the recommendations for penicillin-allergic, HIV-negative patients. Patients with penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy). The use of alternatives to penicillin has not been well studied in HIV-infected patients. These therapies should be used only in conjunction with close serologic and clinical follow-up.

Latent Syphilis Among HIV-Infected Persons

Treatment

HIV-infected persons with latent syphilis should be treated according to the stage-specific recommendations for HIV-negative persons.

- Treatment of early latent syphilis among HIV-infected persons is benzathine penicillin G, 2.4 million units IM in a single dose.
- Treatment of late latent syphilis or syphilis of unknown duration among HIV-infected persons is benzathine penicillin G, at weekly doses of 2.4 million units for 3 weeks.

Other Management Considerations

All HIV-infected persons with syphilis and neurologic symptoms should undergo immediate CSF examination. Some studies have demonstrated that clinical and CSF abnormalities consistent with neurosyphilis are most likely in HIV-infected persons who have been diagnosed with syphilis and have a CD4 count of ≤350 cells/ml and/or an RPR titer of ≥1:32 (*204,225,226*); however unless neurologic symptoms are present, CSF examination in this setting has not been associated with improved clinical outcomes.

Follow-Up

Patients should be evaluated clinically and serologically at 6, 12, 18, and 24 months after therapy. If, at any time, clinical symptoms develop or nontreponemal titers rise fourfold, a repeat CSF examination should be performed and treatment administered accordingly. If during 12–24 months the nontreponemal titer does not decline fourfold, CSF examination should be strongly considered and treatment administered accordingly.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy. The efficacy of alternative nonpenicillin regimens in HIV-infected persons has not been well studied. Patients with penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with penicillin (see Management of Patients Who Have a History of Penicillin Allergy). These therapies should be used only in conjunction with close serologic and clinical follow-up. Limited clinical studies, along with biologic and pharmacologic evidence, suggest that ceftriaxone might be effective (*229,230*). However, the optimal dose and duration of ceftriaxone therapy have not been defined.

Neurosyphilis Among HIV-Infected Persons

Treatment

HIV-infected patients with neurosyphilis should be treated according to the recommendations for HIV-negative patients with neurosyphilis (see Neurosyphilis).

Follow Up

If CSF pleocytosis was present initially, a CSF examination should be repeated every 6 months until the cell count is normal. Follow-up CSF examinations also can be used to gauge response after therapy. Limited data suggest that changes in CSF parameters might occur more slowly in HIV-infected patients, especially those with more advanced immunosuppression (*219,227*). If the cell count has not decreased after 6 months or if the CSF is not normal after 2 years, retreatment should be considered.

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy. HIV-infected, penicillin-allergic patients who have neurosyphilis should be managed according to the recommendations for penicillin-allergic, HIV-negative patients with neurosyphilis. Several small observational studies conducted in HIV-infected patients with neurosyphilis suggest that ceftriaxone 1–2 g IV daily for 10-14 days might be effective as an alternate agent (*218,229,230*).

Syphilis During Pregnancy

All women should be screened serologically for syphilis early in pregnancy. Most states mandate screening at the first prenatal visit for all women (*231*); antepartum screening by nontreponemal antibody testing is typical, but in some settings, treponemal antibody testing is being used. Pregnant women with reactive treponemal screening tests should have confirmatory testing with nontreponemal tests with titers. In populations in which use of prenatal care is not optimal, RPR test screening and treatment (if the RPR test is reactive) should be performed at the time that pregnancy is confirmed (*232*). For communities and populations in which the prevalence of syphilis is high and for patients at high risk, serologic testing should be performed twice during the third trimester (ideally at 28–32 weeks' gestation) and at delivery. Any woman who delivers a stillborn infant after 20 weeks' gestation should be tested for syphilis. No infant should leave the hospital without the maternal serologic status having been determined at least once during pregnancy.

Diagnostic Considerations

Seropositive pregnant women should be considered infected unless an adequate treatment history is documented clearly in the medical records and sequential serologic antibody titers have declined. Serofast low antibody titers might not require treatment; however, persistent higher titer antibody tests might indicate reinfection, and treatment might be required.

Treatment

Penicillin is effective for preventing maternal transmission to the fetus and for treating fetal infection (*233*). Evidence is insufficient to determine optimal, recommended penicillin regimens (*234*).

Recommended Regimen

Pregnant women should be treated with the penicillin regimen appropriate for their stage of infection.

Other Management Considerations

Some evidence suggests that additional therapy can be beneficial for pregnant women in some settings (e.g., a second dose of benzathine penicillin 2.4 million units IM administered 1 week after the initial dose for women who have primary, secondary, or early latent syphilis) (*235*). When syphilis is diagnosed during the second half of pregnancy, management should include a sonographic fetal evaluation for congenital syphilis, but this evaluation should not delay therapy. Sonographic signs of fetal or placental syphilis (i.e., hepatomegaly, ascites, hydrops, fetal anemia, or a thickened placenta) indicate a greater risk for fetal treatment failure (*231*); such cases should be managed in consultation with obstetric specialists. Evidence is insufficient to recommend specific regimens for these situations.

Women treated for syphilis during the second half of pregnancy are at risk for premature labor and/or fetal distress if the treatment precipitates the Jarisch-Herxheimer reaction (*236*). These women should be advised to seek obstetric attention after treatment if they notice any fever, contractions, or decrease in fetal movements. Stillbirth is a rare complication of treatment, but concern for this complication should not delay necessary treatment. All patients who have syphilis should be offered testing for HIV infection.

Follow-Up

Coordinated prenatal care and treatment are vital. Serologic titers should be repeated at 28–32 weeks' gestation and at delivery as recommended for the disease stage. Providers should ensure that the clinical and antibody responses are appropriate for the patient's stage of disease, although most women will deliver before their serologic response to treatment can be assessed definitively. Inadequate maternal treatment is likely if delivery occurs within 30 days of therapy, if clinical signs of infection are present at delivery, or if the maternal antibody titer at delivery is fourfold higher than the pretreatment titer. Serologic titers can be checked monthly in women at high risk for reinfection or in geographic areas in which the prevalence of syphilis is high

Management of Sex Partners

See General Principles, Management of Sex Partners.

Special Considerations

Penicillin Allergy

For treatment of syphilis during pregnancy, no proven alternatives to penicillin exist. Pregnant women who have a history of penicillin allergy should be desensitized and treated with penicillin. Oral step-wise penicillin dose challenge or skin testing might be helpful in identifying women at risk for acute allergic reactions (see Management of Patients Who Have a History of Penicillin Allergy).

Tetracycline and doxycycline usually are not used during pregnancy. Erythromycin and azithromycin should not be used, because neither reliably cures maternal infection or treats an infected fetus (*234*). Data are insufficient to recommend ceftriaxone for treatment of maternal infection and prevention of congenital syphilis.

HIV Infection

Placental inflammation from congenital infection might increase the risk for perinatal transmission of HIV. All HIV-infected women should be evaluated for syphilis and receive treatment as recommended. Data are insufficient to recommend a specific regimen for HIV-infected pregnant women (see Syphilis Among HIV-Infected Patients).

Congenital Syphilis

Effective prevention and detection of congenital syphilis depends on the identification of syphilis in pregnant women and, therefore, on the routine serologic screening of pregnant women during the first prenatal visit. In communities and populations in which the risk for congenital syphilis is high, serologic testing and a sexual history also should be obtained at 28 weeks' gestation and at delivery. Moreover, as part of the management of pregnant women who have syphilis, information concerning the treatment of sex partners should be obtained to assess the risk for reinfection.

Routine screening of newborn sera or umbilical cord blood is not recommended. Serologic testing of the mother's serum is preferred rather than testing of the infant's serum because the serologic tests performed on infant serum can be nonreactive if the mother's serologic test result is of low titer or the mother was infected late in pregnancy (see Diagnostic Considerations and Use of Serologic Tests). Screening can be performed using either a nontreponemal or treponemal test. If either screening test is positive, testing must be performed immediately using the other complimentary test (i.e., nontreponemal test followed by treponemal test or vice-versa). No infant or mother should leave the hospital unless maternal serologic status has been documented at least once during pregnancy; in communities and populations in which the risk for congenital syphilis is high, documentation should also occur at delivery.

Evaluation and Treatment of Infants During the First Month of Life

The diagnosis of congenital syphilis is complicated by the transplacental transfer of maternal nontreponemal and treponemal IgG antibodies to the fetus, which can complicate the interpretation of reactive serologic tests for syphilis in infants. Therefore, treatment decisions frequently must be made on the basis of 1) identification of syphilis in the mother; 2) adequacy of maternal treatment; 3) presence of clinical, laboratory, or radiographic evidence of syphilis in the infant; and 4) comparison of maternal (at delivery) and infant nontreponemal serologic titers using the same test conducted preferably by the same laboratory.

All infants born to mothers who have reactive nontreponemal and treponemal test results should be evaluated with a quantitative nontreponemal serologic test (RPR or VDRL) performed on infant serum, because umbilical cord blood can become contaminated with maternal blood and yield a false-positive result. Conducting a treponemal test (i.e., TP-PA, FTA-ABS, EIA, or chemiluminescence assay) on a newborn's serum is not necessary. No commercially available immunoglobulin (IgM) test can be recommended.

All infants born to women who have reactive serologic tests for syphilis should be examined thoroughly for evidence of congenital syphilis (e.g., nonimmune hydrops, jaundice, hepatosplenomegaly, rhinitis, skin rash, and pseudoparalysis of an extremity). Pathologic examination of the placenta or umbilical cord using specific fluorescent antitreponemal antibody staining is suggested. Darkfield microscopic examination of suspicious lesions or body fluids (e.g., nasal discharge) also should be performed.

The following scenarios describe the evaluation and treatment of infants for congenital syphilis.

Scenario 1

Infants with proven or highly probable disease and

1. an abnormal physical examination that is consistent with congenital syphilis;
2. a serum quantitative nontreponemal serologic titer that is fourfold higher than the mother's titer;¶ or
3. a positive darkfield test of body fluid(s).

Recommended Evaluation

- CSF analysis for VDRL, cell count, and protein**
- Complete blood count (CBC) and differential and platelet count
- Other tests as clinically indicated (e.g., long-bone radiographs, chest radiograph, liver-function tests, cranial ultrasound, ophthalmologic examination, and auditory brain stem response)

¶ The absence of a fourfold or greater titer for an infant does not exclude congenital syphilis.

** CSF test results obtained during the neonatal period can be difficult to interpret; normal values differ by gestational age and are higher in preterm infants. Values as high as 25 white blood cells (WBCs)/mm3 and/or protein of 150 mg/dL might occur among normal neonates; some specialists, however, recommend that lower values (i.e., 5 WBCs/mm3 and protein of 40 mg/dL) be considered the upper limits of normal. Other causes of elevated values should be considered when an infant is being evaluated for congenital syphilis.

Recommended Regimens

Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

OR

Procaine penicillin G 50,000 units/kg/dose IM in a single daily dose for 10 days

If more than 1 day of therapy is missed, the entire course should be restarted. Data are insufficient regarding the use of other antimicrobial agents (e.g., ampicillin). When possible, a full 10-day course of penicillin is preferred, even if ampicillin was initially provided for possible sepsis. The use of agents other than penicillin requires close serologic follow-up to assess adequacy of therapy. In all other situations, the maternal history of infection with *T. pallidum* and treatment for syphilis must be considered when evaluating and treating the infant.

Scenario 2

Infants who have a normal physical examination and a serum quantitive nontreponemal serologic titer the same or less than fourfold the maternal titer and the

1. mother was not treated, inadequately treated, or has no documentation of having received treatment;
2. mother was treated with erythromycin or another non-penicillin regimen;[††] or
3. mother received treatment <4 weeks before delivery.

Recommended Evaluation

- CSF analysis for VDRL, cell count, and protein
- CBC, differential, and platelet count
- Long-bone radiographs

A complete evaluation is not necessary if 10 days of parenteral therapy is administered, although such evaluations might be useful. For instance, a lumbar puncture might document CSF abnormalities that would prompt close follow-up. Other tests (e.g., CBC, platelet count, and bone radiographs) can be performed to further support a diagnosis of congenital syphilis. If a single dose of benzathine penicillin G is used, then the infant must be fully evaluated (i.e., by CSF examination, long-bone radiographs, and CBC with platelets), the full evaluation must be normal, and follow-up must be certain. If any part of the infant's evaluation is abnormal or not performed or if the CSF analysis is rendered uninterpretable because of contamination with blood, then a 10-day course of penicillin is required.[§§]

[††] A woman treated with a regimen other than those recommended in these guidelines for treatment should be considered untreated.

[§§] If the infant's nontreponemal test is nonreactive and the provider determines that the mother's risk for untreated syphilis is low, treatment of the infant (single IM dose of benzathine penicillin G 50,000 units/kg for possible incubating syphilis) without an evaluation can be considered.

Recommended Regimens

Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

OR

Procaine penicillin G 50,000 units/kg/dose IM in a single daily dose for 10 days

OR

Benzathine penicillin G 50,000 units/kg/dose IM in a single dose

If the mother has untreated early syphilis at delivery, 10 days of parenteral therapy can be considered.

Scenario 3

Infants who have a normal physical examination and a serum quantitative nontreponemal serologic titer the same or less than fourfold the maternal titer and the

1. mother was treated during pregnancy, treatment was appropriate for the stage of infection, and treatment was administered >4 weeks before delivery and
2. mother has no evidence of reinfection or relapse.

Recommended Evaluation

No evaluation is required.

Recommended Regimen

Benzathine penicillin G 50,000 units/kg/dose IM in a single dose*

* Another approach involves not treating the infant, but rather providing close serologic follow-up in those whose mother's nontreponemal titers decreased fourfold after appropriate therapy for early syphilis or remained stable or low for late syphilis.

Scenario 4

Infants who have a normal physical examination and a serum quantitative nontreponemal serologic titer the same or less than fourfold the maternal titer and the

1. mother's treatment was adequate before pregnancy and
2. mother's nontreponemal serologic titer remained low and stable before and during pregnancy and at delivery (VDRL <1:2; RPR <1:4).

Recommended Evaluation

No evaluation is required.

Recommended Regimen

No treatment is required; however, **benzathine penicillin G** 50,000 units/kg as a single IM injection might be considered, particularly if follow-up is uncertain.

Evaluation and Treatment of Older Infants and Children

Older infants and children aged ≥1 month who are identified as having reactive serologic tests for syphilis should have maternal serology and records reviewed to assess whether they have congenital or acquired syphilis (see Primary and Secondary Syphilis and Latent Syphilis, Sexual Assault or Abuse of Children). Any child at risk for congenital syphilis should receive a full evaluation and testing for HIV infection.

Recommended Evaluation

- CSF analysis for VDRL, cell count, and protein
- CBC, differential, and platelet count
- Other tests as clinically indicated (e.g., long-bone radiographs, chest radiograph, liver function tests, abdominal ultrasound, ophthalmologic examination, and auditory brain stem response)

Recommended Regimen

Aqueous crystalline penicillin G 200,000–300,000 units/kg/day IV, administered as 50,000 units/kg every 4–6 hours for 10 days

If the child has no clinical manifestations of disease, the CSF examination is normal, and the CSF VDRL test result is negative, treatment with up to 3 weekly doses of benzathine penicillin G, 50,000 U/kg IM can be considered.

Any child who is suspected of having congenital syphilis or who has neurologic involvement should be treated with aqueous penicillin G. A single dose of benzathine penicillin G, 50,000 units/kg IM after the 10-day course of IV aqueous penicillin can be considered. This treatment also would be adequate for children who might have other treponemal infections.

Follow-Up

All seroreactive infants (or infants whose mothers were seroreactive at delivery) should receive careful follow-up examinations and serologic testing (i.e., a nontreponemal test) every 2–3 months until the test becomes nonreactive or the titer has decreased fourfold. Nontreponemal antibody titers should decline by age 3 months and should be nonreactive by age 6 months if the infant is not infected (i.e., if the reactive test result was caused by passive transfer of maternal IgG antibody) or was infected but adequately treated. The serologic response after therapy might be slower for infants treated after the neonatal period. If these titers are stable or increase after age 6–12 months, the child should be evaluated (e.g., given a CSF examination) and treated with a 10-day course of parenteral penicillin G.

Treponemal tests should not be used to evaluate treatment response, because the results for an infected child can remain positive despite effective therapy. Passively transferred maternal treponemal antibodies can be present in an infant until age 15 months; therefore, a reactive treponemal test after age 18 months is diagnostic of congenital syphilis. If the nontreponemal test is nonreactive at this time, no further evaluation or treatment is necessary. If the nontreponemal test is reactive at age 18 months, the infant should be fully (re)evaluated and treated for congenital syphilis.

Infants whose initial CSF evaluations are abnormal should undergo a repeat lumbar puncture approximately every 6 months until the results are normal. A reactive CSF VDRL test or abnormal CSF indices that cannot be attributed to other ongoing illness requires retreatment for possible neurosyphilis.

Follow-up of children treated for congenital syphilis after the newborn period should be conducted as recommended for neonates.

Special Considerations

Penicillin Allergy

Infants and children who require treatment for syphilis but who have a history of penicillin allergy or develop an allergic reaction presumed secondary to penicillin should be desensitized, if necessary, and then treated with penicillin (see Management of Patients With a History of Penicillin Allergy). Data are insufficient regarding the use of other antimicrobial agents (e.g., ceftriaxone); if a nonpenicillin agent is used, close serologic and CSF follow-up are indicated.

Penicillin Shortage

During periods when the availability of penicillin is compromised, the following is recommended (see http://www.cdc.gov/std/treatment/misc/penicillinG.htm).

1. For infants with clinical evidence of congenital syphilis (Scenario 1), check local sources for aqueous crystalline penicillin G (potassium or sodium). If IV penicillin G is limited, substitute some or all daily doses with procaine penicillin G (50,000 U/kg/dose IM a day in a single daily dose for 10 days).

If aqueous or procaine penicillin G is not available, ceftriaxone (in doses appropriate for age and weight) can be considered with careful clinical and serologic follow-up. Ceftriaxone must be used with caution in infants with jaundice. For infants aged ≥30 days, use 75 mg/kg IV/IM a day in a single daily dose for 10–14 days; however, dose adjustment might be necessary based on current weight. For older infants, the dose should be 100 mg/kg a day in a single daily dose. Evidence is insufficient

to support the use of ceftriaxone for the treatment of congenital syphilis. Therefore, ceftriaxone should be used in consultation with a specialist in the treatment of infants with congenital syphilis. Management may include a repeat CSF examination at age 6 months if the initial examination was abnormal.

2. For infants without any clinical evidence of infection (Scenario 2 and Scenario 3), use
   a. procaine penicillin G, 50,000 U/kg/dose IM a day in a single dose for 10 days;
      or
   b. benzathine penicillin G, 50,000 U/kg IM as a single dose.

If any part of the evaluation for congenital syphilis is abnormal, CSF examination is not interpretable, CSF examination was not performed, or follow-up is uncertain, procaine penicillin G is recommended. A single dose of ceftriaxone is inadequate therapy.

3. For premature infants who have no other clinical evidence of infection (Scenario 2 and Scenario 3) and might not tolerate IM injections because of decreased muscle mass, IV ceftriaxone can be considered with careful clinical and serologic follow-up (see Penicillin Shortage, Number 1). Ceftriaxone dosing must be adjusted according to age and birth weight.

HIV Infection

Evidence is insufficient to determine whether infants who have congenital syphilis and whose mothers are coinfected with HIV require different evaluation, therapy, or follow-up for syphilis than is recommended for all infants.

Management of Persons Who Have a History of Penicillin Allergy

No proven alternatives to penicillin are available for treating neurosyphilis, congenital syphilis, or syphilis in pregnant women. Penicillin also is recommended for use, whenever possible, in HIV-infected patients. Of the adult U.S. population, 3%–10% have experienced an immunoglobulin E (IgE)-mediated allergic response to penicillin (*238,239*), such as urticaria, angioedema, or anaphylaxis (i.e., upper airway obstruction, bronchospasm, or hypotension). Readministration of penicillin to these patients can cause severe, immediate reactions. Because anaphylactic reactions to penicillin can be fatal, every effort should be made to avoid administering penicillin to penicillin-allergic patients, unless they undergo acute desensitization to eliminate anaphylactic sensitivity.

Although an estimated 10% of persons who report a history of severe allergic reactions to penicillin continue to remain allergic their entire lives, with the passage of time, most persons who have had a severe reaction to penicillin stop expressing penicillin-specific IgE (*238,239*). These persons can then be treated safely with penicillin. Penicillin skin testing with the major and minor determinants of penicillin can reliably identify persons at high risk for penicillin reactions (*238,239*). Although these reagents are easily generated and have been available for more than 30 years, only benzylpenicilloyl poly-L-lysine (Pre-Pen [i.e., the major determinant]) and penicillin G have been available commercially. These two tests identify an estimated 90%–97% of the currently allergic patients. However, because skin testing without the minor determinants would still miss 3%–10% of allergic patients and because serious or fatal reactions can occur among these minor-determinant–positive patients, caution should be exercised when the full battery of skin-test reagents is not available (Box 2). Manufacturers are working to ensure better availability of the Pre-Pen skin test reagent as well as an accompanying minor determinant mixture.

Recommendations

If the full battery of skin-test reagents is available, including both major and minor determinants (see Penicillin Allergy Skin Testing), patients who report a history of penicillin reaction and who are skin-test negative can receive conventional penicillin therapy. Skin-test–positive patients should be desensitized before initiating treatment.

If the full battery of skin-test reagents, including the minor determinants, is not available, the patient should be skin tested using benzylpenicilloyl poly-L-lysine (i.e., the major determinant) and penicillin G. Patients who have positive test results should be desensitized. One approach suggests that persons with a history of allergy who have negative test results should be regarded as possibly allergic and desensitized. Another approach in those with negative skin-test results involves test-dosing gradually with oral penicillin in a monitored setting in which treatment for anaphylactic reaction can be provided.

If the major determinant (Pre-Pen) is not available for skin testing, all patients with a history suggesting IgE-mediated reactions to penicillin (e.g., anaphylaxis, angioedema, bronchospasm, or urticaria) should be desensitized in a hospital setting. In patients with reactions not likely to be IgE-mediated, outpatient-monitored test doses can be considered.

Penicillin Allergy Skin Testing

Patients at high risk for anaphylaxis, including those who 1) have a history of penicillin-related anaphylaxis, asthma, or other diseases that would make anaphylaxis more dangerous or 2) are being treated with beta-adrenergic blocking agents,

should be tested with 100-fold dilutions of the full-strength skin-test reagents before being tested with full-strength reagents. In these situations, patients should be tested in a monitored setting in which treatment for an anaphylactic reaction is available. If possible, the patient should not have taken antihistamines recently (e.g., chlorpheniramine maleate or fexafenadine during the preceding 24 hours, diphenhydramine HCl during the preceding 4 days, or hydroxyzine or phenathiazines during the preceding 3 weeks).

Procedures

Dilute the antigens either 100-fold for preliminary testing (if the patient has had a life-threatening reaction to penicillin) or 10-fold (if the patient has had another type of immediate, generalized reaction to penicillin within the preceding year).

Epicutaneous (Prick) Tests

Duplicate drops of skin-test reagent are placed on the volar surface of the forearm. The underlying epidermis is pierced with a 26-gauge needle without drawing blood. An epicutaneous test is positive if the average wheal diameter after 15 minutes is ≥4 mm larger than that of negative controls; otherwise, the test is negative. The histamine controls should be positive to ensure that results are not falsely negative because of the effect of antihistaminic drugs.

Intradermal Test

If epicutaneous tests are negative, duplicate 0.02-mL intradermal injections of negative control and antigen solutions are made into the volar surface of the forearm by using a 26- or 27-gauge needle on a syringe. The margins of the wheals induced by the injections should be marked with a ball point pen. An intradermal test is positive if the average wheal diameter 15 minutes after injection is >2 mm larger than the initial wheal size and also is >2 mm larger than the negative controls. Otherwise, the tests are negative.

Desensitization

Patients who have a positive skin test to one of the penicillin determinants can be desensitized (Table 1). This is a straightforward, relatively safe procedure that can be performed orally or IV. Although the two approaches have not been compared, oral desensitization is regarded as safer and easier to perform. Patients should be desensitized in a hospital setting because serious IgE-mediated allergic reactions can occur. Desensitization usually can be completed in approximately 4–12 hours, after which time the first dose of penicillin is administered. After desensitization, patients must be maintained on penicillin continuously for the duration of the course of therapy.

Box 2. Skin-test reagents for identifying persons at risk for adverse reactions to penicillin*

Major Determinant
- Benzylpenicilloyl poly-L-lysine (PrePen) (AllerQuest, Plainville Connecticut) (6 x 10-5M).

Minor Determinant Precursors†
- Benzylpenicillin G (10-2M, 3.3 mg/mL, 10,000 units/mL)
- Benzylpenicilloate (10-2M, 3.3 mg/mL)
- Benzylpenicilloate (or penicilloyl propylamine) (10-2M, 3.3 mg/mL)

Positive Control
- Commercial histamine for intradermal skin testing (1.0 mg/mL)

Negative Control
- Diluent (usually saline) or allergen diluent

* Adapted from Saxon A, Beall GN, Rohr AS, Adelman DC. Immediate hypersensitivity reactions to beta-lactam antibiotics. Ann Intern Med 1987;107:204–15. Reprinted with permission from G.N. Beall and *Annals of Internal Medicine*.

† Aged penicillin is not an adequate source of minor determinants. Penicillin G should be freshly prepared or should come from a fresh-frozen source.

Diseases Characterized by Urethritis and Cervicitis

Urethritis

Urethritis, as characterized by urethral inflammation, can result from infectious and noninfectious conditions. Symptoms, if present, include discharge of mucopurulent or purulent material, dysuria, or urethral pruritis. Asymptomatic infections are common. Although *N. gonorrhoeae* and *C. trachomatis* are well established as clinically important infectious causes of urethritis, *Mycoplasma genitalium* has also been associated with urethritis (*240–243*). If clinic-based diagnostic tools (e.g., Gram-stain microscopy, first void urine with microscopy, and leukocyte esterase) are not available, patients should be treated with drug regimens effective against both gonorrhea and chlamydia. Further testing to determine the specific etiology is recommended because both chlamydia and gonorrhea are reportable to health departments and a specific diagnosis might improve partner notification and treatment. Culture, nucleic acid hybridization tests, and NAATs are available for the detection of both *N. gonorrhoeae* and *C. trachomatis*. Culture and hybridization tests require urethral swab specimens, whereas NAATs can be performed on urine specimens. Because of their

higher sensitivity, NAATs are preferred for the detection of *C. trachomatis* (*197*).

Etiology

Several organisms can cause infectious urethritis. The presence of Gram-negative intracellular diplococci (GNID) on urethral smear is indicative of gonorrhea infection, which is frequently accompanied by chlamydial infection. Nongonoccocal urethritis (NGU), which is diagnosed when examination findings or microscopy indicate inflammation without GNID, is caused by *C. trachomatis* in 15%–40% of cases; however, prevalence varies by age group, with a lower burden of disease occurring among older men (*244*). Complications of NGU among males infected with *C. trachomatis* include epididymitis and Reiter's syndrome. Documentation of chlamydial infection is essential because of the need for partner referral for evaluation and treatment.

In most cases of nonchlamydial NGU, no pathogen can be detected. *M. genitalium,* which appears to be sexually transmitted, is associated with both symptoms of urethritis and urethral inflammation and accounts for 15%–25% of NGU cases in the United States (240–243). *T. vaginalis*, HSV, and adenovirus also can cause NGU, but data supporting other *Mycoplasma* species and *Ureaplasma* as etiologic agents are inconsistent (*244–247*). Diagnostic and treatment procedures for these organisms are reserved for situations in which these infections are suspected (e.g., contact with trichomoniasis, genital lesions, or severe dysuria and meatitis, which might suggest genital herpes) or when NGU is not responsive to therapy. Enteric bacteria have been identified as an uncommon cause of NGU and might be associated with insertive anal intercourse (*244*).

Confirmed Urethritis

Clinicians should attempt to obtain objective evidence of urethral inflammation. However, if clinic-based diagnostic tools (e.g., Gram-stain microscopy) are not available, patients should be treated with drug regimens effective against both gonorrhea and chlamydia.

Urethritis can be documented on the basis of any of the following signs or laboratory tests:

- Mucopurulent or purulent discharge on examination.
- Gram stain of urethral secretions demonstrating ≥5 WBC per oil immersion field. The Gram stain is the preferred rapid diagnostic test for evaluating urethritis and is highly sensitive and specific for documenting both urethritis and the presence or absence of gonococcal infection. Gonococcal infection is established by documenting the presence of WBC containing GNID.

TABLE 1. Oral desensitization protocol for patients with a positive skin test*

Penicillin V suspension dose†	Amount§ (units/mL)	mL	Units	Cumulative dose (units)
1	1,000	0.1	100	100
2	1,000	0.2	200	300
3	1,000	0.4	400	700
4	1,000	0.8	800	1,500
5	1,000	1.6	1,600	3,100
6	1,000	3.2	3,200	6,300
7	1,000	6.4	6,400	12,700
8	10,000	1.2	12,000	24,700
9	10,000	2.4	24,000	48,700
10	10,000	4.8	48,000	96,700
11	80,000	1.0	80,000	176,700
12	80,000	2.0	160,000	336,700
13	80,000	4.0	320,000	656,700
14	80,000	8.0	640,000	1,296,700

Note: Observation period was 30 minutes before parenteral administration of penicillin.

* Reprinted with permission from the New England Journal of Medicine (Wendel GO, Jr, Stark BJ, Jamison RB, Melina RD, Sullivan TJ. Penicillin allergy and desensitization in serious infections during pregnancy. N Engl J Med 1985;312:1229–32.).

† Interval between doses, 15–30 minutes; elapsed time, 4–8 hours; cumulative dose, 1.3 million units.

§ The specific amount of drug was diluted in approximately 30 mL of water and then administered orally.

- Positive leukocyte esterase test on first-void urine or microscopic examination of first-void urine sediment demonstrating ≥10 WBC per high-power field.

If none of these criteria are present, testing for *N. gonorrhoeae* and *C. trachomatis* using NAATs might identify additional infections (*248*). If the results demonstrate infection with either of these pathogens, the appropriate treatment should be given and sex partners referred for evaluation and treatment. If none of these criteria are present, empiric treatment of symptomatic males is recommended only for men at high risk for infection who are unlikely to return for a follow-up evaluation. Such patients should be treated with drug regimens effective against gonorrhea and chlamydia. Partners of patients treated empirically should be evaluated and treated, if indicated.

Nongonococcal Urethritis

Diagnosis

All patients who have confirmed or suspected urethritis should be tested for gonorrhea and chlamydia. Testing for chlamydia is strongly recommended because of the increased utility and availability of highly sensitive and specific testing methods (e.g., NAATs) and because a specific diagnosis might enhance partner notification and improve compliance with treatment, especially in the exposed partner.

Treatment

Treatment should be initiated as soon as possible after diagnosis. Azithromycin and doxycycline are highly effective for chlamydial urethritis; however, infections with *M. genitalium* respond better to azithromycin (*249,250*). Single-dose regimens have the advantage of improved compliance and directly observed treatment. To maximize compliance with recommended therapies, medications should be dispensed on-site in the clinic, and the first dose should be directly observed.

Recommended Regimens

Azithromycin 1 g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days

Alternative Regimens

Erythromycin base 500 mg orally four times a day for 7 days

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days

OR

Levofloxacin 500 mg orally once daily for 7 days

OR

Ofloxacin 300 mg orally twice a day for 7 days

To minimize transmission, men treated for NGU should be instructed to abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen, provided their symptoms have resolved. To minimize the risk for reinfection, men should be instructed to abstain from sexual intercourse until all of their sex partners are treated.

Persons who have been diagnosed with a new STD should receive testing for other infections, including syphilis and HIV.

Follow-Up

Patients should be instructed to return for evaluation if symptoms persist or recur after completion of therapy. Symptoms alone, without documentation of signs or laboratory evidence of urethral inflammation, are not a sufficient basis for retreatment. Providers should be alert to the possibility of chronic prostatitis/chronic pelvic pain syndrome in male patients experiencing persistent pain (perineal, penile, or pelvic), discomfort, irritative voiding symptoms, pain during or after ejaculation, or new-onset premature ejaculation lasting for >3 months.

Unless a patient's symptoms persist or therapeutic noncompliance or reinfection is suspected by the provider, a test-of-cure (i.e., repeat testing 3–4 weeks after completing therapy) is not recommended for persons with documented chlamydia or gonococcal infections who have received treatment with recommended or alterative regimens. However, because men with documented chlamydial or gonococcal infections have a high rate of reinfection within 6 months after treatment (*251,252*), repeat testing of all men diagnosed with chlamydia or gonorrhea is recommended 3–6 months after treatment, regardless of whether patients believe that their sex partners were treated (*251*).

Partner Referral

A specific diagnosis might facilitate partner referral. Therefore, testing for gonorrhea and chlamydia is encouraged. Because a substantial proportion of female partners of males with nonchlamydial NGU are infected with chlamydia, partner management is recommended for males with NGU regardless of whether a specific etiology is identified. All sex partners within the preceding 60 days should be referred for evaluation, testing, and empiric treatment with a drug regimen effective against chlamydia. Expedited partner treatment and patient referral are alternative approaches to treating partners (*71*).

Recurrent and Persistent Urethritis

Objective signs of urethritis should be present before the initiation of antimicrobial therapy. In persons who have persistent symptoms after treatment without objective signs of urethritis, the value of extending the duration of antimicrobials has not been demonstrated. Persons who have persistent or recurrent urethritis can be retreated with the initial regimen if they did not comply with the treatment regimen or if they were reexposed to an untreated sex partner. Persistent urethritis after doxycycline treatment might be caused by doxycycline-resistant *U. urealyticum* or *M. genitalium*. *T. vaginalis* is also known to cause urethritis in men; a urethral swab, first void urine, or semen for culture or a NAAT (PCR or TMA) on a urethral swab or urine can be performed. If compliant with the initial regimen and re-exposure can be excluded, the following regimen is recommended while awaiting the results of the diagnostic tests.

Recommended Regimens

Metronidazole 2 g orally in a single dose

OR

Tinidazole 2 g orally in a single dose

PLUS

Azithromycin 1 g orally in a single dose (if not used for initial episode)

Studies involving a limited number of patients who experienced NGU treatment failures have demonstrated that Moxifloxacin 400 mg orally once daily for 7 days is highly effective against *M. genitalium* (*253,254*). Men with a low

probability of *T. vaginalis* (e.g., MSM) are unlikely to benefit from the addition of metronidazole or tinidazole.

Urologic examinations usually do not reveal a specific etiology for urethritis. A four-glass Meares-Stamey lower-urinary-tract localization procedure (or four-glass test) might be helpful in localizing pathogens to the prostate (*255*). A substantial proportion of men with chronic nonbacterial prostatitis/chronic pelvic pain syndrome have evidence of urethral inflammation without any identifiable microbial pathogens. Estimates vary considerably depending on the source and sensitivity of the assay, but one study demonstrated that in 50% of men with this syndrome, ≥5 WBCs per high-power field were detected in expressed prostatic secretions (*256*). Referral to a urologist should be considered for men who experience pain for more than 3 months within a 6-month period.

If men require treatment with a new antibiotic regimen for persistent urethritis and a sexually transmitted agent is the suspected cause, all partners in the past 60 days before the initial diagnosis and any interim partners should be referred for evaluation and appropriate treatment.

Special Considerations

HIV Infection

Gonococcal urethritis, chlamydial urethritis, and nongonococcal, nonchlamydial urethritis might facilitate HIV transmission. Patients who have NGU and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

Cervicitis

Two major diagnostic signs characterize cervicitis: 1) a purulent or mucopurulent endocervical exudate visible in the endocervical canal or on an endocervical swab specimen (commonly referred to as mucopurulent cervicitis or cervicitis) and 2) sustained endocervical bleeding easily induced by gentle passage of a cotton swab through the cervical os. Either or both signs might be present. Cervicitis frequently is asymptomatic, but some women complain of an abnormal vaginal discharge and intermenstrual vaginal bleeding (e.g., after sexual intercourse). A finding of leukorrhea (>10 WBC per high-power field on microscopic examination of vaginal fluid) has been associated with chlamydial and gonococcal infection of the cervix. In the absence of inflammatory vaginitis, leukorrhea might be a sensitive indicator of cervical inflammation with a high negative predictive value (*257,258*). Although some specialists consider an increased number of polymorphonuclear leukocytes on endocervical Gram stain as being useful in the diagnosis of cervicitis, this criterion has not been standardized. In addition, it has a low positive-predictive value (PPV) for infection with *C. trachomatis* and *N. gonorrhoeae* and is not available in most clinical settings. Finally, although the presence of GNID on Gram stain of endocervical fluid is specific for the diagnosis of gonococcal cervical infection, it is not a sensitive indicator, because it is observed in only 50% of women with this infection.

Etiology

When an etiologic organism is isolated in the presence of cervicitis, it is typically *C. trachomatis* or *N. gonorrhoeae*. Cervicitis also can accompany trichomoniasis and genital herpes (especially primary HSV-2 infection). However, in most cases of cervicitis, no organism is isolated, especially in women at relatively low risk for recent acquisition of these STDs (e.g., women aged >30 years). Limited data indicate that infection with *M. genitalium* and BV and frequent douching might cause cervicitis (*259–263*). For reasons that are unclear, cervicitis can persist despite repeated courses of antimicrobial therapy. Because most persistent cases of cervicitis are not caused by relapse or reinfection with *C. trachomatis* or *N. gonorrhoeae*, other factors (e.g., persistent abnormality of vaginal flora, douching [or exposure to other types of chemical irritants], or idiopathic inflammation in the zone of ectopy) might be involved.

Diagnosis

Because cervicitis might be a sign of upper-genital–tract infection (endometritis), women who seek medical treatment for a new episode of cervicitis should be assessed for signs of PID and should be tested for *C. trachomatis* and for *N. gonorrhoeae* with the most sensitive and specific test available. Women with cervicitis also should be evaluated for the presence of BV and trichomoniasis, and if these organisms are detected, they should be treated. Because the sensitivity of microscopy to detect *T. vaginalis* is relatively low (approximately 50%), symptomatic women with cervicitis and negative microscopy for trichomonads should receive further testing (i.e., culture or other FDA-cleared method). Although HSV-2 infection has been associated with cervicitis, the utility of specific testing (i.e., culture or serologic testing) for HSV-2 in this setting is unknown. Standardized diagnostic tests for *M. genitalium* are not commercially available.

As discussed, NAAT should be used for diagnosing *C. trachomatis* and *N. gonorrhoeae* in women with cervicitis; this testing can be performed on either vaginal, cervical, or urine samples (*197*). A finding of >10 WBC in vaginal fluid, in the absence of trichomoniasis, might indicate endocervical inflammation caused specifically by *C. trachomatis* or *N. gonorrhoeae* (*264,265*).

Treatment

Several factors should affect the decision to provide presumptive therapy for cervicitis or to await the results of diagnostic tests. Treatment with antibiotics for *C. trachomatis* should be provided for those women at increased risk for this common STD (e.g., those aged ≤25 years, those with new or multiple sex partners, and those who engage in unprotected sex), especially if follow-up cannot be ensured and if a relatively insensitive diagnostic test is used in place of NAAT. Concurrent therapy for *N. gonorrhoeae* is indicated if the prevalence of this infection is >5% (those in younger age groups and those living in certain facilities).

Trichomoniasis and BV should also be treated if detected. For women in whom any component of (or all) presumptive therapy is deferred, the results of sensitive tests for *C. trachomatis* and *N. gonorrhoeae* (e.g., NAATs) should determine the need for treatment subsequent to the initial evaluation.

Recommended Regimens for Presumptive Treatment*

Azithromycin 1 g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days

* Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.

Recurrent and Persistent Cervicitis

Women with persistent cervicitis should be reevaluated for possible reexposure to an STD. If relapse and/or reinfection with a specific STD has been excluded, BV is not present, and sex partners have been evaluated and treated, management options for persistent cervicitis are undefined; in addition, the utility of repeated or prolonged administration of antibiotic therapy for persistent symptomatic cervicitis remains unknown. Women who receive such therapy should return after treatment so that a determination can be made regarding whether cervicitis has resolved. Research is needed on the etiology of persistent cervicitis including the potential role of *M. genitalium* (*266*). In women with persistent symptoms that are clearly attributable to cervicitis, referral to a gynecologic specialist can be considered.

Follow-Up

Follow-up should be conducted as recommended for the infections for which a woman is treated. If symptoms persist, women should be instructed to return for re-evaluation because women with documented chlamydial or gonococcal infections have a high rate of reinfection within 6 months after treatment. Therefore, repeat testing of all women with chlamydia or gonorrhea is recommended 3-6 months after treatment, regardless of whether their sex partners were treated (*267*).

Management of Sex Partners

Management of sex partners of women treated for cervicitis should be appropriate for the identified or suspected STD. Partners should be notified and examined if chlamydia, gonorrhea, or trichomoniasis was identified or suspected in the index patient; these partners should then be treated for the STDs for which the index patient received treatment. To avoid reinfection, patients and their sex partners should abstain from sexual intercourse until therapy is completed (i.e., 7 days after a single-dose regimen or after completion of a 7-day regimen). Expedited partner treatment and patient referral (see Partner Management) are alternative approaches to treating male partners of women that have chlamydia or gonococcal infections (*68,69,71*).

Special Considerations

HIV Infection

Patients who have cervicitis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative. Treatment of cervicitis in HIV-infected women is vital because cervicitis increases cervical HIV shedding. Treatment of cervicitis in HIV-infected women reduces HIV shedding from the cervix and might reduce HIV transmission to susceptible sex partners (*268–270*).

Chlamydial Infections

Chlamydial Infections in Adolescents and Adults

Chlamydial genital infection is the most frequently reported infectious disease in the United States, and prevalence is highest in persons aged ≤25 years (*93*). Several important sequelae can result from *C. trachomatis* infection in women, the most serious of which include PID, ectopic pregnancy, and infertility. Some women who have uncomplicated cervical infection already have subclinical upper-reproductive–tract infection upon diagnosis.

Asymptomatic infection is common among both men and women. To detect chlamydial infections, health-care providers frequently rely on screening tests. Annual screening of all sexually active women aged ≤25 years is recommended, as is screening of older women with risk factors (e.g., those who have a new sex partner or multiple sex partners). In June 2007, USPSTF reviewed and updated their chlamydia screening guidance and found that the epidemiology of chlamydial

infection in the United States had not changed since the last review (*81,271*). In issuing recommendations, USPSTF made the decision to alter the age groups used to demonstrate disease incidence (i.e., from persons aged ≤25 years to those aged ≤24 years). CDC has not changed its age cutoff, and thus continues to recommend annual chlamydia screening of sexually active women aged ≤25 years.

Screening programs have been demonstrated to reduce both the prevalence of *C. trachomatis* infection and rates of PID in women (*272,273*). Although evidence is insufficient to recommend routine screening for *C. trachomatis* in sexually active young men because of several factors (including feasibility, efficacy, and cost-effectiveness) (*94*), the screening of sexually active young men should be considered in clinical settings with a high prevalence of chlamydia (e.g., adolescent clinics, correctional facilities, and STD clinics). Among women, the primary focus of chlamydia screening efforts should be to detect chlamydia and prevent complications, whereas targeted chlamydia screening in men should only be considered when resources permit and do not hinder chlamydia screening efforts in women (*274 275*). An appropriate sexual risk assessment should be conducted for all persons and might indicate more frequent screening for some women or certain men (see MSM).

Diagnostic Considerations

C. trachomatis urogenital infection in women can be diagnosed by testing urine or by collecting swab specimens from the endocervix or vagina. Diagnosis of *C. trachomatis* urethral infection in men can be made by testing a urethral swab or urine specimen. Rectal *C. trachomatis* infections in persons that engage in receptive anal intercourse can be diagnosed by testing a rectal swab specimen. NAATs, cell culture, direct immunofluorescence, EIA, and nucleic acid hybridization tests are available for the detection of *C. trachomatis* on endocervical specimens and urethral swab specimens from men (*197*). NAATs are the most sensitive tests for these specimens and are FDA-cleared for use with urine. Some NAATs are cleared for use with vaginal swab specimens, which can be collected by a provider or self-collected by a patient. Self-collected vaginal swab specimens perform at least as well as with other approved specimens using NAATs (*276,277*), and women find this screening strategy highly acceptable. Rectal and oropharyngeal *C. trachomatis* infection in persons engaging in receptive anal or oral intercourse can be diagnosed by testing at the anatomic site of exposure. Most tests, including NAAT and nucleic acid hybridization tests, are not FDA-cleared for use with rectal or oropharyngeal swab specimens, and chlamydia culture is not widely available for this purpose. However, NAATs have demonstrated improved sensitivity and specificity compared with culture for the detection of *C. trachomatis* at rectal sites (*278–280*) and at oropharyngeal sites among men (*278–281*). Some laboratories have met CLIA requirements and have validated NAAT testing on rectal swab specimens for *C. trachomatis*. Recent evidence suggests that the liquid-based cytology specimens collected for Pap smears might be acceptable specimens for NAAT testing, although test sensitivity using these specimens might be lower than those resulting from the use of cervical swab specimens (*282*); regardless, certain NAATs have been FDA-cleared for use on liquid-based cytology specimens. Persons who undergo testing and are diagnosed with chlamydia should be tested for other STDs.

Treatment

Treating infected patients prevents sexual transmission of the disease, and treating all sex partners of those testing positive for chlamydia can prevent reinfection of the index patient and infection of other partners. Treating pregnant women usually prevents transmission of *C. trachomatis* to infants during birth. Chlamydia treatment should be provided promptly for all persons testing positive for infection; delays in receiving chlamydia treatment have been associated with complications (e.g., PID) in a limited proportion of chlamydia-infected subjects (*283*). Coinfection with *C. trachomatis* frequently occurs among patients who have gonococcal infection; therefore, presumptive treatment of such patients for chlamydia is appropriate (see Gonococcal Infection, Dual Therapy for Gonococcal and Chlamydial Infections). The following recommended treatment regimens and alternative regimens cure infection and usually relieve symptoms.

Recommended Regimens

Azithromycin 1 g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days

Alternative Regimens

Erythromycin base 500 mg orally four times a day for 7 days

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days

OR

Levofloxacin 500 mg orally once daily for 7 days

OR

Ofloxacin 300 mg orally twice a day for 7 days

A meta-analysis of 12 randomized clinical trials of azithromycin versus doxycycline for the treatment of genital chlamydial infection demonstrated that the treatments were

equally efficacious, with microbial cure rates of 97% and 98%, respectively (*284*). These studies were conducted primarily in populations in which follow-up was encouraged, adherence to a 7-day regimen was effective, and culture or EIA (rather than the more sensitive NAAT) was used for determining microbiological outcome. Azithromycin should always be available to treat patients for whom compliance with multiday dosing is uncertain. The clinical significance and transmissibility of *C. trachomatis* detected at oropharyngeal sites is unclear (*285*), and the efficacy of different antibiotic regimens in resolving oropharyngeal chlamydia remains unknown.

In patients who have erratic health-care–seeking behavior, poor treatment compliance, or unpredictable follow-up, azithromycin might be more cost-effective in treating chlamydia because it enables the provision of a single-dose of directly observed therapy (*284*). Erythromycin might be less efficacious than either azithromycin or doxycycline, mainly because of the frequent occurrence of gastrointestinal side effects that can lead to noncompliance. Levofloxacin and ofloxacin are effective treatment alternatives but are more expensive and offer no advantage in the dosage regimen. Other quinolones either are not reliably effective against chlamydial infection or have not been evaluated adequately.

To maximize compliance with recommended therapies, medications for chlamydial infections should be dispensed on site, and the first dose should be directly observed. To minimize disease transmission to sex partners, persons treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen. To minimize the risk for reinfection, patients also should be instructed to abstain from sexual intercourse until all of their sex partners are treated.

Follow-Up

Except in pregnant women, test-of-cure (i.e., repeat testing 3–4 weeks after completing therapy) is not advised for persons treated with the recommended or alterative regimens, unless therapeutic compliance is in question, symptoms persist, or reinfection is suspected. Moreover, the validity of chlamydial diagnostic testing at <3 weeks after completion of therapy (to identify patients who did not respond to therapy) has not been established. False-negative results might occur in the presence of persistent infections involving limited numbers of chlamydial organisms. In addition, NAAT conducted at <3 weeks after completion of therapy in persons who were treated successfully could yield false-positive results because of the continued presence of nonviable organisms (*197*).

A high prevalence of *C. trachomatis* infection has been observed in women and men who were treated for chlamydial infection during the preceding several months (*251*,*267*,*286*–*288*). Most post-treatment infections result from reinfection caused by failure of sex partners to receive treatment or the initiation of sexual activity with a new infected partner. Repeat infections confer an elevated risk for PID and other complications. Unlike the test-of-cure, which is not recommended, repeat *C. trachomatis* testing of recently infected women or men should be a priority for providers. Chlamydia-infected women and men should be retested approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated (*251*,*267*). If retesting at 3 months is not possible, clinicians should retest whenever persons next present for medical care in the 12 months following initial treatment.

Management of Sex Partners

Patients should be instructed to refer their sex partners for evaluation, testing, and treatment if they had sexual contact with the patient during the 60 days preceding onset of the patient's symptoms or chlamydia diagnosis. Although the exposure intervals defined for the identification of at-risk sex partners are based on limited evaluation, the most recent sex partner should be evaluated and treated, even if the time of the last sexual contact was >60 days before symptom onset or diagnosis.

Among heterosexual patients, if concerns exist that sex partners who are referred to evaluation and treatment will not seek these services (or if other management strategies are impractical or unsuccessful), patient delivery of antibiotic therapy to their partners can be considered (see Partner Management). Compared with standard partner referral, this approach, which involves delivering a prescription or the medication itself, has been associated with a trend toward a decrease in rates of persistent or recurrent chlamydia (*68*,*69*,*71*). Patients must also inform their partners of their infection and provide them with written materials about the importance of seeking evaluation for any symptoms suggestive of complications (e.g., testicular pain in men and pelvic or abdominal pain in women). Patient-delivered partner therapy is not routinely recommended for MSM because of a high risk for coexisting infections, especially undiagnosed HIV infection, in their partners.

Patients should be instructed to abstain from sexual intercourse until they and their sex partners have completed treatment. Abstinence should be continued until 7 days after a single-dose regimen or after completion of a multiple-dose regimen. Timely treatment of sex partners is essential for decreasing the risk for reinfecting the index patient.

Special Considerations

Pregnancy

Doxycycline, ofloxacin, and levofloxacin are contraindicated in pregnant women. However, clinical experience and published studies suggest that azithromycin is safe and effective (*289–291*). Repeat testing to document chlamydial eradication (preferably by NAAT) 3 weeks after completion of therapy with the following regimens is recommended for all pregnant women to ensure therapeutic cure, considering the severe sequelae that might occur in mothers and neonates if the infection persists. Women aged <25 years and those at increased risk for chlamydia (i.e., women who have a new or more than one sex partner) also should be retested during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant (*81*). Pregnant women diagnosed with a chlamydial infection during the first trimester should not only receive a test to document chlamydial eradication, but be retested 3 months after treatment.

Recommended Regimens

Azithromycin 1 g orally in a single dose

OR

Amoxicillin 500 mg orally three times a day for 7 days

Alternative Regimens

Erythromycin base 500 mg orally four times a day for 7 days

OR

Erythromycin base 250 mg orally four times a day for 14 days

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days

OR

Erythromycin ethylsuccinate 400 mg orally four times a day for 14 days

The frequent gastrointestinal side effects associated with erythromycin can result in noncompliance with the alternative regimens. Although erythromycin estolate is contraindicated during pregnancy because of drug-related hepatotoxicity, the lower dose 14-day erythromycin regimens can be considered if gastrointestinal tolerance is a concern.

HIV Infection

Patients who have chlamydial infection and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

Chlamydial Infections Among Infants

Prenatal screening and treatment of pregnant women can prevent chlamydial infection among neonates. Pregnant women aged <25 years are at high risk for infection.

C. trachomatis infection of neonates results from perinatal exposure to the mother's infected cervix. Although neonatal ocular prophylaxis with silver nitrate solution or antibiotic ointments does not prevent perinatal transmission of *C. trachomatis* from mother to infant, ocular prophylaxis with these agents does prevent gonococcal ophthalmia and therefore should be administered (see Ophthalmia Neonatorum Prophylaxis).

Initial *C. trachomatis* perinatal infection involves the mucous membranes of the eye, oropharynx, urogenital tract, and rectum, although infection might be asymptomatic in these locations. Instead, *C. trachomatis* infection in neonates is most frequently recognized by conjunctivitis that develops 5–12 days after birth. *C. trachomatis* also can cause a subacute, afebrile pneumonia with onset at ages 1–3 months. Although *C. trachomatis* has been the most frequent identifiable infectious cause of ophthalmia neonatorum, perinatal chlamydial infections (including ophthalmia and pneumonia) have occurred less frequently because of the institution of widespread prenatal screening and treatment of pregnant women.

Ophthalmia Neonatorum Caused by *C. trachomatis*

A chlamydial etiology should be considered for all infants aged ≤30 days who have conjunctivitis, especially if the mother has a history of untreated chlamydia infection.

Diagnostic Considerations

Sensitive and specific methods used to diagnose chlamydial ophthalmia in the neonate include both tissue culture and nonculture tests (e.g., direct fluorescence antibody [DFA] tests, EIA, and NAAT). Most nonculture tests are not FDA-cleared for the detection of chlamydia from conjunctival swabs, and clinical laboratories must verify the procedure according to CLIA regulations. Specimens for culture isolation and nonculture tests should be obtained from the everted eyelid using a dacron-tipped swab or the swab specified by the manufacturer's test kit, and they must contain conjunctival cells, not exudate alone. Specific diagnosis of *C. trachomatis* infection confirms the need for treatment not only for the neonate, but also for the mother and her sex partner(s). Ocular specimens from infants being evaluated for chlamydial conjunctivitis also should be tested for *N. gonorrhoeae*.

Recommended Regimen

Erythromycin base or **ethylsuccinate** 50 mg/kg/day orally divided into 4 doses daily for 14 days*,†

* An association between oral erythromycin and infantile hypertrophic pyloric stenosis (IHIS) has been reported in infants aged <6 weeks who were treated with this drug. Infants treated with erythromycin should be followed for signs and symptoms of IHPS.

† Data on use of other macrolides (e.g., azithromycin and clarithromycin) for the treatment of neonatal chlamydia infection are limited. The results of one study involving a limited number of patients suggest that a short course of azithromycin, 20 mg/kg/day orally, 1 dose daily for 3 days, might be effective (292).

Topical antibiotic therapy alone is inadequate for treatment of chlamydial infection and is unnecessary when systemic treatment is administered.

Follow-Up

Because the efficacy of erythromycin treatment is only approximately 80%, a second course of therapy might be required. Therefore, follow-up of infants is recommended to determine whether initial treatment was effective. The possibility of concomitant chlamydial pneumonia should be considered.

Management of Mothers and Their Sex Partners

The mothers of infants who have chlamydial infection and the sex partners of these women should be evaluated and treated (see Chlamydial Infection in Adolescents and Adults).

Infant Pneumonia Caused by *C. trachomatis*

Characteristic signs of chlamydial pneumonia in infants include 1) a repetitive staccato cough with tachypnea and 2) hyperinflation and bilateral diffuse infiltrates on a chest radiograph. In addition, peripheral eosinophilia (≥400 cells/mm^3) occurs frequently. Wheezing is rare, and infants are typically afebrile. Because clinical presentations differ, initial treatment and diagnostic tests should include *C. trachomatis* for all infants aged 1–3 months who are suspected of having pneumonia (especially those whose mothers have untreated chlamydial infection).

Diagnostic Considerations

Specimens for chlamydial testing should be collected from the nasopharynx. Tissue culture is the definitive standard for chlamydial pneumonia. Nonculture tests (e.g., EIA, DFA, and NAAT) can be used, although nonculture tests of nasopharyngeal specimens have a lower sensitivity and specificity than nonculture tests of ocular specimens. DFA is the only FDA-cleared test for the detection of *C. trachomatis* from nasopharyngeal specimens. Tracheal aspirates and lung biopsy specimens, if collected, should be tested for *C. trachomatis*.

Because test results for chlamydia often are not available in a timely manner, the decision to provide treatment for *C. trachomatis* pneumonia must frequently be based on clinical and radiologic findings. The results of tests for chlamydial infection assist in the management of an infant's illness and can help determine the need for treating the mother and her sex partner(s).

Recommended Regimen

Erythromycin base or **ethylsuccinate** 50 mg/kg/day orally divided into 4 doses daily for 14 days

Follow-Up

The effectiveness of erythromycin in treating pneumonia caused by *C. trachomatis* is approximately 80%; a second course of therapy might be required. Follow-up of infants is recommended to determine whether the pneumonia has resolved, although some infants with chlamydial pneumonia continue to have abnormal pulmonary function tests later in childhood.

Management of Mothers and Their Sex Partners

Mothers of infants who have chlamydia pneumonia and the sex partners of these women should be evaluated and treated according to the recommended treatment of adults for chlamydial infections (see Chlamydial Infection in Adolescents and Adults).

Infants Born to Mothers Who Have Chlamydial Infection

Infants born to mothers who have untreated chlamydia are at high risk for infection; however, prophylatic antibiotic treatment is not indicated, and the efficacy of such treatment is unknown. Infants should be monitored to ensure appropriate treatment if symptoms develop.

Chlamydial Infections Among Children

Sexual abuse must be considered a cause of chlamydial infection in preadolescent children, although perinatally transmitted *C. trachomatis* infection of the nasopharynx, urogenital tract, and rectum might persist for >1 year (see Sexual Assault or Abuse of Children).

Diagnostic Considerations

Nonculture, nonamplified probe tests for chlamydia (EIA and DFA) should not be used because of the possibility of false-positive test results. With respiratory-tract specimens, false-positive results can occur because of cross-reaction of test reagents with *C. pneumoniae*; with genital and anal specimens,

false-positive results might occur as a result of cross-reaction with fecal flora.

Recommended Regimen for Children Who Weigh <45 kg
Erythromycin base or **ethylsuccinate** 50 mg/kg/day orally divided into 4 doses daily for 14 days

Recommended Regimen for Children Who Weigh ≥45 kg but Who Are Aged <8 Years
Azithromycin 1 g orally in a single dose

Recommended Regimens for Children Aged ≥8 years
Azithromycin 1 g orally in a single dose
OR
Doxycycline 100 mg orally twice a day for 7 days

Other Management Considerations

See Sexual Assault or Abuse of Children.

Follow-Up

Follow-up cultures are necessary to ensure that treatment has been effective.

Gonococcal Infections

Gonococcal Infections in Adolescents and Adults

In the United States, an estimated 700,000 new *N. gonorrhoeae* infections occur each year (*93*,*293*). Gonorrhea is the second most commonly reported bacterial STD. The majority of urethral infections caused by *N. gonorrhoeae* among men produce symptoms that cause them to seek curative treatment soon enough to prevent serious sequelae, but treatment might not be soon enough to prevent transmission to others. Among women, gonococcal infections might not produce recognizable symptoms until complications (e.g., PID) have occurred. PID can result in tubal scarring that can lead to infertility or ectopic pregnancy.

The prevalence of gonorrhea varies widely among communities and populations; health-care providers should consider local gonorrhea epidemiology when making screening decisions. Although widespread screening is not recommended because gonococcal infections among women are frequently asymptomatic, targeted screening of young women (i.e., those aged <25 years) at increased risk for infection is a primary component of gonorrhea control in the United States. For sexually active women, including those who are pregnant, USPSTF (*82*) recommends that clinicians provide gonorrhea screening only to those at increased risk for infection (e.g., women with previous gonorrhea infection, other STDs, new or multiple sex partners, and inconsistent condom use; those who engage in commercial sex work and drug use; women in certain demographic groups; and those living in communities with a high prevalence of disease). USPSTF does not recommend screening for gonorrhea in men and women who are at low risk for infection (*82*).

Diagnostic Considerations

Because of its high specificity (>99%) and sensitivity (>95%), a Gram stain of a male urethral specimen that demonstrates polymorphonuclear leukocytes with intracellular Gram-negative diplococci can be considered diagnostic for infection with *N. gonorrhoeae* in symptomatic men. However, because of lower sensitivity, a negative Gram stain should not be considered sufficient for ruling out infection in asymptomatic men. In addition, Gram stain of endocervical specimens, pharyngeal, or rectal specimens also are not sufficient to detect infection, and therefore are not recommended. Specific testing for *N. gonorrhoeae* is recommended because of the increased utility and availability of highly sensitive and specific testing methods and because a specific diagnosis might enhance partner notification.

Specific diagnosis of infection with *N. gonorrhoeae* can be performed by testing endocervical, vaginal, urethral (men only), or urine specimens. Culture, nucleic acid hybridization tests, and NAATs are available for the detection of genitourinary infection with *N. gonorrhoeae* (*197*). Culture and nucleic acid hybridization tests require female endocervical or male urethral swab specimens. NAATs allow testing of the widest variety of specimen types including endocervical swabs, vaginal swabs, urethral swabs (men), and urine (from both men and women), and they are FDA-cleared for use. However, product inserts for each NAAT vendor must be carefully examined, because specimen types that are FDA-cleared for use vary by test. NAAT tests are not FDA-cleared for use in the rectum, pharynx, and conjunctiva; however, some public and private laboratories have established performance specifications for using NAAT with rectal and pharyngeal swab specimens, thereby allowing results to be used for clinical management. Laboratories that establish performance specifications for the use of NAATs with nongenital specimens must ensure that specificity is not compromised by cross-reaction with nongonococcal *Neisseria* species. The sensitivity of NAATs for the detection of *N. gonorrhoeae* in genital and nongenital anatomic sites is superior to culture but varies by NAAT type (*197*,*278–281*).

Because nonculture tests cannot provide antimicrobial susceptibility results, in cases of suspected or documented

treatment failure, clinicians should perform both culture and antimicrobial susceptibility testing.

All persons found to have who have gonorrhea also should be tested for other STDs, including chlamydia, syphilis, and HIV.

Dual Therapy for Gonococcal and Chlamydial Infections

Patients infected with *N. gonorrhoeae* frequently are coinfected with *C. trachomatis*; this finding has led to the recommendation that patients treated for gonococcal infection also be treated routinely with a regimen that is effective against uncomplicated genital *C. trachomatis* infection (*294*). Because most gonococci in the United States are susceptible to doxycycline and azithromycin, routine cotreatment might also hinder the development of antimicrobial-resistant *N. gonorrhoeae*. Limited data suggest that dual treatment with azithromycin might enhance treatment efficacy for pharyngeal infection when using oral cephalosporins (*295*,*296*).

Antimicrobial-Resistant *N. gonorrhoeae*

Gonorrhea treatment is complicated by the ability of *N. gonorrhoeae* to develop resistance to antimicrobial therapies (*297*). Quinolone-resistant *N. gonorrhoeae* strains are now widely disseminated throughout the United States and the world (*298*). As of April 2007, quinolones are no longer recommended in the United States for the treatment of gonorrhea and associated conditions, such as PID (*299*). Consequently, only one class of antimicrobials, the cephalosporins, is recommended and available for the treatment of gonorrhea in the United States. The CDC website (http://www.cdc.gov/std/gisp) and state health departments can provide the most current information.

The proportion of isolates in CDC's Gonococcal Isolate Surveillance Project (GISP) demonstrating decreased susceptibility to ceftriaxone or cefixime has remained very low over time; during 1987–2008, only four isolates were found to have decreased susceptibility to ceftriaxone, and 48 isolates had decreased susceptibility to cefixime. In 2008, no isolates demonstrated decreased susceptibility to ceftriaxone; cefixime was not part of test panel during that year (*93*). Although only two cases of suspected treatment failure with ceftriaxone have been reported (*300*), approximately 50 patients are thought to have failed oral cephalosporin treatment (*301*–*304*).

Most of the treatment failures resulting from use of oral cephalosporins have been reported from Asian countries, although one possible case was reported in Hawaii in 2001 (*305*). To ensure appropriate antibiotic therapy, clinicians should ask patients testing positive for gonorrhea about recent travel to and sexual activity in these countries.

Decreased susceptibility of *N. gonorrhoeae* to cephalosporins and other antimicrobials is expected to continue to spread; therefore, state and local surveillance for antimicrobial resistance is crucial for guiding local therapy recommendations (*297*). GISP, which samples approximately 3% of all U.S. men who have gonococcal infections, is a mainstay of surveillance. However, surveillance by clinicians also is critical. Clinicians who diagnose *N. gonorrhoeae* infection in a patient with suspected cephalosporin treatment failure should perform culture and susceptibility testing of relevant clinical specimens, consult a specialist for guidance in clinical management, and report the case to CDC through state and local public health authorities. Health departments should prioritize partner notification and contact tracing of patients with *N. gonorrhoeae* infection thought to be associated with cephalosporin treatment failure or associated with patients whose isolates demonstrate decreased susceptibility to cephalosporin.

Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum

Recommended Regimens
Ceftriaxone 250 mg IM in a single dose
OR, IF NOT AN OPTION
Cefixime 400 mg orally in a single dose
OR
Single-dose injectible **cephalosporin** regimens
PLUS
Azithromycin 1g orally in a single dose
OR
Doxycycline 100 mg orally twice a day for 7 days

To maximize compliance with recommended therapies, medications for gonococcal infections should be dispensed on site. Ceftriaxone in a single injection of 250 mg provides sustained, high bactericidal levels in the blood. Extensive clinical experience indicates that ceftriaxone is safe and effective for the treatment of uncomplicated gonorrhea at all anatomic sites, curing 99.2% of uncomplicated urogenital and anorectal and 98.9% of pharyngeal infections in published clinical trials (*306*,*307*). A 250-mg dose of ceftriaxone is now recommended over a 125-mg dose given the 1) increasingly wide geographic distribution of isolates demonstrating decreased susceptibility to cephalosporins in vitro, 2) reports of ceftriaxone treatment failures, 3) improved efficacy of ceftriaxone 250 mg in pharyngeal infection (which is often unrecognized), and 4) the utility of having a simple and consistent recommendation for treatment regardless of the anatomic site involved.

A 400-mg oral dose of cefixime does not provide as high, nor as sustained, a bactericidal level as that provided by the 250-mg dose of ceftriaxone. In published clinical trials, the 400-mg dose cured 97.5% of uncomplicated urogenital and anorectal (95% CI = 95.4%–99.8%) and 92.3% of pharyngeal gonococcal infections (95% CI = 74.9%–99.1%) (*306*,*307*). Although cefixime can be administered orally, this advantage is offset by the limited efficacy of cefixime (as well as other oral cephalosporins) for treating gonococcal infections of the pharynx. Providers should inquire about oral sexual exposure and if reported, treat these patients with ceftriaxone because of this drug's well documented efficacy in treating pharyngeal infection.

Single-dose injectible cephalosporin regimens (other than ceftriaxone 250 mg IM) that are safe and highly effective against uncomplicated urogenital and anorectal gonococcal infections include ceftizoxime (500 mg, administered IM), cefoxitin (2 g, administered IM with probenecid 1 g orally), and cefotaxime (500 mg, administered IM). None of the injectible cephalosporins offer any advantage over ceftriaxone for urogenital infection, and efficacy for pharyngeal infection is less certain (*306*,*307*).

Alternative Regimens

Several other antimicrobials are active against *N. gonorrhoeae*, but none have substantial advantages over the recommended regimens, and they should not be used if pharyngeal infection is suspected. Some evidence suggests that cefpodoxime 400-mg orally can be considered an alternative in the treatment of uncomplicated urogenital gonorrhea; this regimen meets the minimum efficacy criteria for alternative regimens for urogenital infection (demonstrated efficacy of ≥95% in clinical trials with lower 95% CI of >90%) (*307*). In one clinical trial, cefpodoxime 400 mg orally was found to have a urogenital and rectal cure rate of 96.6% (95% CI = 93.9%), but the efficacy of cefpodoxime 400 mg orally at the pharyngeal site was poor (70.3%, 95% CI = 53.0%) (Hall, unpublished data, 2010). Gonococcal strains with decreased susceptibility to oral cephalosporins have been reported in the United States (*308*). With a cure rate of 96.5% (95% CI = 93.6%–98.3%) for urogenital and rectal infection, cefpodoxime proxetil 200 mg orally meets the criteria for an alternative regimen; however, its use is not advised because of concerns about the pharmacodynamics of cefpodoxime using this dose. Efficacy in treating pharyngeal infection with cefpodoxime 200 mg is unsatisfactory (78.9%; 95% CI = 54.5%–94%), as with cefpodoxime at the 400-mg dose.

Treatment with cefuroxime axetil 1 g orally meets the criteria for minimum efficacy as an alternative regimen for urogenital and rectal infection (95.9%; 95% CI = 94.3%–97.2%), but the pharmacodynamics of cefuroxime axetil 1 g orally are less favorable than those of cefpodoxime 400 mg, cefixime 400 mg, or ceftriaxone 125 mg (*309*). The efficacy of cefuroxime axetil 1 g orally in treating pharyngeal infection is poor (56.9%; 95% CI = 42.2%–70.7%).

Spectinomycin, which is useful in persons who cannot tolerate cephalosporins, is expensive, must be injected, and is not available in the United States (updates available at: www.cdc.gov/std/treatment) (*310*). However, it has been effective in published clinical trials, curing 98.2% of uncomplicated urogenital and anorectal gonococcal infections. Spectinomycin has poor efficacy against pharyngeal infection (51.8%; 95% CI = 38.7%–64.9%) (*306*).

Azithromycin 2 g orally is effective against uncomplicated gonococcal infection (99.2%; 95% CI = 97.3%–99.9%), but concerns over the ease with which *N. gonorrhoeae* can develop resistance to macrolides should restrict its use to limited circumstances. Although azithromycin 1 g meets alternative regimen criteria (97.6%; 95% CI = 95.7%–98.9%), it is not recommended because several studies have documented treatment failures, and concerns about possible rapid emergence of antimicrobial resistance with the 1-g dose of azithromycin are even greater than with the 2-g dose (*311*–*313*). *N. gonorrhoeae* in the United States is not adequately susceptible to penicillins, tetracyclines, and older macrolides (e.g., erythromycin) for these antimicrobials to be recommended.

Uncomplicated Gonococcal Infections of the Pharynx

Most gonococcal infections of the pharynx are asymptomatic and can be relatively common in some populations (*103*,*278*,*279*,*314*). Gonococcal infections of the pharynx are more difficult to eradicate than infections at urogenital and anorectal sites (*315*). Few antimicrobial regimens, including those involving oral cephalosporins, can reliably cure >90% of gonococcal pharyngeal infections (*306*,*307*). Providers should ask their patients about oral sexual exposure; if reported, patients should be treated with a regimen with acceptable efficacy against pharyngeal infection. Chlamydial coinfection of the pharynx is unusual; however, because coinfection at genital sites sometimes occurs, treatment for both gonorrhea and chlamydia is recommended.

Recommended Regimens

Ceftriaxone 250 mg IM in a single dose

PLUS

Azithromycin 1g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days

Follow-Up

Patients diagnosed with uncomplicated gonorrhea who are treated with any of the recommended or alternative regimens do not need a test-of-cure (i.e., repeat testing 3-4 weeks after completing therapy). Patients who have symptoms that persist after treatment should be evaluated by culture for *N. gonorrhoeae*, and any gonococci isolated should be tested for antimicrobial susceptibility. Persistent urethritis, cervicitis, or proctitis also might be caused by *C. trachomatis* or other organisms.

N. gonorrhoeae infection is prevalent among patients who have been diagnosed with and treated for gonorrhea in the preceding several months (*64,251,252,267*). Most infections result from reinfection rather than treatment failure, indicating a need for improved patient education and referral of sex partners. Clinicians should advise patients with gonorrhea to be retested 3 months after treatment. If patients do not seek medical care for retesting in 3 months, providers are encouraged to test these patients whenever they next seek medical care within the following 12 months, regardless of whether the patients believe that their sex partners were treated. Retesting is distinct from test-of-cure to detect therapeutic failure, which is not recommended.

Management of Sex Partners

Effective clinical management of patients with treatable STDs requires treatment of the patients' recent sex partners to prevent reinfection and curtail further transmission. Patients should be instructed to refer their sex partners for evaluation and treatment. Sex partners of patients with *N. gonorrhoeae* infection whose last sexual contact with the patient was within 60 days before onset of symptoms or diagnosis of infection in the patient should be evaluated and treated for *N. gonorrhoeae* and *C. trachomatis* infections. If a patient's last sexual intercourse was >60 days before onset of symptoms or diagnosis, the patient's most recent sex partner should be treated. Patients should be instructed to abstain from sexual intercourse until therapy is completed and until they and their sex partners no longer have symptoms.

For heterosexual patients with gonorrhea whose partners' treatment cannot be ensured or is unlikely, delivery of antibiotic therapy for gonorrhea (as well as for chlamydia) by the patients to their partners can be considered (see Partner Management). Use of this approach (*68,71*) should always be accompanied by efforts to educate partners about symptoms and to encourage partners to seek clinical evaluation. For male patients informing female partners, educational materials should include information about the importance of seeking medical evaluation for PID (especially if symptomatic). Possible undertreatment of PID in female partners and possible missed opportunities to diagnose other STDs are of concern and have not been evaluated in comparison with patient-delivered therapy and partner referral. This approach should not be considered a routine partner management strategy in MSM because of the high risk for coexisting undiagnosed STDs or HIV infection.

Special Considerations

Allergy, Intolerance, and Adverse Reactions

Reactions to first generation cephalosporins occur in approximately 5%–10% of persons with a history of penicillin allergy and occur less frequently with third-generation cephalosporins (*239*). In those persons with a history of penicillin allergy, the use of cephalosporins should be contraindicated only in those with a history of a severe reaction to penicillin (e.g., anaphylaxis, Stevens Johnson syndrome, and toxic epidermal necrolysis) (*316*).

Because data are limited regarding alternative regimens for treating gonorrhea among persons who have severe cephalosporin allergy, providers treating such patients should consult infectious disease specialists. Azithromycin 2 g orally is effective against uncomplicated gonococcal infection, but because of concerns over emerging antimicrobial resistance to macrolides, its use should be limited. Cephalosporin treatment following desensitization is impractical in most clinical settings.

Pregnancy

As with other patients, pregnant women infected with *N. gonorrhoeae* should be treated with a recommended or alternate cephalosporin. Because spectinomycin is not available in the United States, azithromycin 2 g orally can be considered for women who cannot tolerate a cephalosporin. Either azithromycin or amoxicillin is recommended for treatment of presumptive or diagnosed *C. trachomatis* infection during pregnancy (see Chlamydial Infections).

HIV Infection

Patients who have gonococcal infection and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

Suspected Cephalosporin Treatment Failure or Resistance

Suspected treatment failure has been reported among persons receiving oral and injectable cephalosporins (*300–304*). Therefore, clinicians of patients with suspected treatment failure or persons infected with a strain found to demonstrate in vitro resistance should consult an infectious disease specialist, conduct culture and susceptibility testing of relevant clinical

specimens, retreat with at least 250 mg of ceftriaxone IM or IV, ensure partner treatment, and report the situation to CDC through state and local public health authorities.

Gonococcal Conjunctivitis

In the only published study of the treatment of gonococcal conjunctivitis among U.S. adults, all 12 study participants responded to a single 1-g IM injection of ceftriaxone (*317*).

Recommended Regimen
Ceftriaxone 1 g IM in a single dose

Consider lavage of the infected eye with saline solution once. Persons treated for gonococcal conjunctivitis should be treated presumptively for concurrent *C. trachomatis* infection.

Management of Sex Partners

Patients should be instructed to refer their sex partners for evaluation and treatment (see Gonococcal Infections, Management of Sex Partners).

Disseminated Gonococcal Infection (DGI)

DGI frequently results in petechial or pustular acral skin lesions, asymmetrical arthralgia, tenosynovitis, or septic arthritis. The infection is complicated occasionally by perihepatitis and rarely by endocarditis or meningitis. Some strains of *N. gonorrhoeae* that cause DGI can cause minimal genital inflammation. No recent studies have been published on the treatment of DGI.

Treatment

Hospitalization is recommended for initial therapy, especially for patients who might not comply with treatment, for those in whom diagnosis is uncertain, and for those who have purulent synovial effusions or other complications. Examination for clinical evidence of endocarditis and meningitis should be performed. Persons treated for DGI should be treated presumptively for concurrent *C. trachomatis* infection.

Recommended Regimen
Ceftriaxone 1 g IM or IV every 24 hours

Alternative Regimens
Cefotaxime 1 g IV every 8 hours
OR
Ceftizoxime 1 g IV every 8 hours

All of the preceding regimens should be continued for 24–48 hours after improvement begins, at which time therapy can be switched to cefixime 400 mg orally twice daily to complete at least 1 week of antimicrobial therapy. No treatment failures have been reported with the recommended regimens.

Management of Sex Partners

Gonococcal infection frequently is asymptomatic in sex partners of patients who have DGI. As with uncomplicated gonococcal infections, patients should be instructed to refer their sex partners for evaluation and treatment (see Gonococcal Infection, Management of Sex Partners).

Gonococcal Meningitis and Endocarditis

Recommended Regimen
Ceftriaxone 1–2 g IV every 12 hours

Therapy for meningitis should be continued for 10–14 days; therapy for endocarditis should be continued for at least 4 weeks. Treatment of complicated DGI should be undertaken in consultation with an infectious disease specialist.

Management of Sex Partners

Patients should be instructed to refer their sex partners for evaluation and treatment (see Gonococcal Infection, Management of Sex Partners).

Gonococcal Infections Among Infants

Gonococcal infection among infants usually is caused by exposure to infected cervical exudate at birth. It is usually an acute illness that manifests 2–5 days after birth. The prevalence of infection among infants depends on the prevalence of infection among pregnant women, whether pregnant women are screened for gonorrhea, and whether newborns receive ophthalmia prophylaxis. The most severe manifestations of *N. gonorrhoeae* infection in newborns are ophthalmia neonatorum and sepsis, which can include arthritis and meningitis. Less severe manifestations include rhinitis, vaginitis, urethritis, and reinfection at sites of fetal monitoring.

Ophthalmia Neonatorum Caused by *N. gonorrhoeae*

Although *N. gonorrhoeae* causes ophthalmia neonatorum relatively infrequently in the United States, identifying and treating this infection is especially important because ophthalmia neonatorum can result in perforation of the globe of the eye and blindness.

Diagnostic Considerations

Infants at increased risk for gonococcal ophthalmia are those who do not receive ophthalmia prophylaxis and those whose mothers have had no prenatal care or whose mothers have a history of STDs or substance abuse. Gonococcal ophthalmia is strongly suspected when intracellular gram-negative diplococci are identified in conjunctival exudate, justifying presumptive treatment for gonorrhea after appropriate cultures for *N. gonorrhoeae* are obtained. Appropriate chlamydial testing should be done simultaneously. Presumptive treatment for *N. gonorrhoeae* might be indicated for newborns who are at increased risk for gonococcal ophthalmia and who have increased WBCs (but not gonococci) in a Gram-stained smear of conjunctival exudate.

In all cases of neonatal conjunctivitis, conjunctival exudates should be cultured for *N. gonorrhoeae* and tested for antibiotic susceptibility before a definitive diagnosis is made. A definitive diagnosis is vital because of the public health and social consequences of a diagnosis of gonorrhea. Nongonococcal causes of neonatal ophthalmia include *Moraxella catarrhalis* and other *Neisseria* species, organisms that are indistinguishable from *N. gonorrhoeae* on Gram-stained smear but can be differentiated in the microbiology laboratory.

Recommended Regimen

Ceftriaxone 25–50 mg/kg IV or IM in a single dose, not to exceed 125 mg

Topical antibiotic therapy alone is inadequate and is unnecessary if systemic treatment is administered.

Other Management Considerations

Simultaneous infection with *C. trachomatis* should be considered when a patient does not improve after treatment. Both mother and infant should be tested for chlamydial infection at the same time that gonorrhea testing is conducted (see Ophthalmia Neonatorum Caused by *C. trachomatis*). Ceftriaxone should be administered cautiously to hyperbilirubinemic infants, especially those born prematurely.

Follow-Up

Infants who have gonococcal ophthalmia should be hospitalized and evaluated for signs of disseminated infection (e.g., sepsis, arthritis, and meningitis). One dose of ceftriaxone is adequate therapy for gonococcal conjunctivitis.

Management of Mothers and Their Sex Partners

The mothers of infants who have gonococcal infection and the mothers' sex partners should be evaluated and treated according to the recommendations for treating gonococcal infections in adults (see Gonococcal Infections in Adolescents and Adults).

DGI and Gonococcal Scalp Abscesses in Newborns

Sepsis, arthritis, and meningitis (or any combination of these conditions) are rare complications of neonatal gonococcal infection. Localized gonococcal infection of the scalp can result from fetal monitoring through scalp electrodes. Detection of gonococcal infection in neonates who have sepsis, arthritis, meningitis, or scalp abscesses requires cultures of blood, CSF, and joint aspirate on chocolate agar. Specimens obtained from the conjunctiva, vagina, oropharynx, and rectum that are cultured on gonococcal selective medium are useful for identifying the primary site(s) of infection, especially if inflammation is present. Positive Gram-stained smears of exudate, CSF, or joint aspirate provide a presumptive basis for initiating treatment for *N. gonorrhoeae*. Diagnoses based on Gram-stained smears or presumptive identification of cultures should be confirmed with definitive tests on culture isolates.

Recommended Regimens

Ceftriaxone 25–50 mg/kg/day IV or IM in a single daily dose for 7 days, with a duration of 10–14 days, if meningitis is documented

OR

Cefotaxime 25 mg/kg IV or IM every 12 hours for 7 days, with a duration of 10–14 days, if meningitis is documented

Prophylactic Treatment for Infants Whose Mothers Have Gonococcal Infection

Infants born to mothers who have untreated gonorrhea are at high risk for infection.

Recommended Regimen in the Absence of Signs of Gonococcal Infection

Ceftriaxone 25–50 mg/kg IV or IM, not to exceed 125 mg, in a single dose

Other Management Considerations

Both mother and infant should be tested for chlamydial infection.

Follow-Up

Follow-up examination is not required.

Management of Mothers and Their Sex Partners

The mothers of infants who have gonococcal infection and the mothers' sex partners should be evaluated and treated according to the recommendations for treatment of gonococcal infections in adults (see Gonococcal Infections).

Gonococcal Infections Among Children

Sexual abuse is the most frequent cause of gonococcal infection in preadolescent children (see Sexual Assault or Abuse of Children). For preadolescent girls, vaginitis is the most common manifestation of this infection; gonococcal-associated PID after vaginal infection is likely less common in preadolescents than adults. Among sexually abused children, anorectal and pharyngeal infections with *N. gonorrhoeae* are common and frequently asymptomatic.

Diagnostic Considerations

Because of the legal implications of a diagnosis of *N. gonorrhoeae* infection in a child, culture remains the preferred method for diagnosis. Gram stains are inadequate for evaluating prepubertal children for gonorrhea and should not be used to diagnose or exlude gonorrhea. NAATs for the detection of *N. gonorrhoeae* can be used under certain circumstances (see Sexual Assault or Abuse of Children)

Recommended Regimen for Children Who Weigh >45 kg

Treat with one of the regimens recommended for adults (see Gonococcal Infections)

Recommended Regimen for Children Who Weigh ≤45 kg and Who Have Uncomplicated Gonococcal Vulvovaginitis, Cervicitis, Urethritis, Pharyngitis, or Proctitis

Ceftriaxone 125 mg IM in a single dose

Recommended Regimen for Children Who Weigh ≤45 kg and Who Have Bacteremia or Arthritis

Ceftriaxone 50 mg/kg (maximum dose: 1 g) IM or IV in a single dose daily for 7 days

Recommended Regimen for Children Who Weigh >45 kg and Who Have Bacteremia or Arthritis

Ceftriaxone 50 mg/kg IM or IV in a single dose daily for 7 days

Follow-Up

Follow-up cultures are unnecessary if ceftriaxone is used.

Other Management Considerations

Only parenteral cephalosporins (i.e., ceftriaxone) are recommended for use in children; cefotaxime is approved for gonococcal ophthalmia only. No data are available regarding the use of oral cefixime to treat gonococcal infections in children.

All children found to have gonococcal infections should be evaluated for coinfection with syphilis and *C. trachomatis*. (For a discussion of concerns regarding sexual assault, see Sexual Assault or Abuse of Children.)

Ophthalmia Neonatorum Prophylaxis

To prevent gonococcal ophthalmia neonatorum, a prophylactic agent should be instilled into the eyes of all newborn infants; this procedure is required by law in most states. All of the recommended prophylactic regimens in this section prevent gonococcal ophthalmia. However, the efficacy of these preparations in preventing chlamydial ophthalmia is less clear, and they do not eliminate nasopharyngeal colonization by *C. trachomatis*. The diagnosis and treatment of gonococcal and chlamydial infections in pregnant women is the best method for preventing neonatal gonococcal and chlamydial disease. Not all women, however, receive prenatal care, and therefore go untreated. Ocular prophylaxis is warranted for neonates, because it can prevent sight-threatening gonococcal ophthalmia and because it is safe, easy to administer, and inexpensive.

Recommended Regimen

Erythromycin (0.5%) ophthalmic ointment in each eye in a single application

This preparation should be instilled into both eyes of every neonate as soon as possible after delivery. Ideally, ointment should be applied using single-use tubes or ampules rather than multiple-use tubes. If prophylaxis is delayed (i.e., not administered in the delivery room), a monitoring system should be established to ensure that all infants receive prophylaxis. All infants should be administered ocular prophylaxis, regardless of whether they are delivered vaginally or by cesarean section.

Erythromycin is the only antibiotic ointment recommended for use in neonates. Silver nitrate and tetracycline ophthalmic ointment are no longer manufactured in the United States, bacitracin is not effective, and povidone iodine has not been studied adequately. If erythromycin ointment is not available, infants at risk for exposure to *N. gonorrhoeae* (especially those born to a mother with untreated gonococcal infection or who has received no prenatal care) can be administered ceftriaxone 25-50 mg/kg IV or IM, not to exceed 125 mg in a single dose.

Diseases Characterized by Vaginal Discharge

Most women will have a vaginal infection, characterized by discharge, itching, or odor, during their lifetime. With the availability of complementary and alternative therapies and over-the-counter medications for candidiasis, many symptomatic women seek these products before or in addition to an evaluation by a medical provider.

Obtaining a medical history alone has been shown to be insufficient for accurate diagnosis of vaginitis and can lead to the inappropriate administration of medication. Therefore, a careful history, examination, and laboratory testing to determine the etiology of vaginal complaints are warranted. Information on sexual behaviors and practices, gender of sex partners, menses, vaginal hygiene practices (such as douching), and other medications should be elicited. The three diseases most frequently associated with vaginal discharge are BV (caused by the replacement of the vaginal flora by an overgrowth of anaerobic bacteria including *Prevotella* sp., *Mobiluncus* sp., *G. vaginalis*, *Ureaplasma, Mycoplasma*, and numerous fastidious or uncultivated anaerobes) trichomoniasis (caused by *T. vaginalis*), and candidiasis (usually caused by *Candida albicans*). Cervicitis also can sometimes cause a vaginal discharge. Although vulvovaginal candidiasis (VVC) usually is not transmitted sexually, it is included in this section because it is frequently diagnosed in women who have vaginal complaints or who are being evaluated for STDs.

Various diagnostic methods are available to identify the etiology of an abnormal vaginal discharge. Clinical laboratory testing can identify the cause of vaginitis in most women and is discussed in detail in the sections of this report dedicated to each condition. In the clinician's office, the cause of vaginal symptoms might be determined by pH, a potassium hydroxide (KOH) test, and microscopic examination of fresh samples of the discharge. The pH of the vaginal secretions can be determined by narrow-range pH paper; an elevated pH (i.e., >4.5) is common with BV or trichomoniasis. Because pH testing is not highly specific, discharge should be further examined microscopically by first diluting one sample in one to two drops of 0.9% normal saline solution on one slide and a second sample in 10% KOH solution (samples that emit an amine odor immediately upon application of KOH suggest BV or trichomoniasis infection). Cover slips are then placed on the slides, and they are examined under a microscope at low and high power.

The saline-solution specimen might yield motile *T. vaginalis,* or clue cells (i.e., epithelial cells with borders obscured by small bacteria), which are characteristic of BV, whereas the presence of WBCs without evidence of trichomonads or yeast in this solution is suggestive of cervicitis (see Cervicitis). The KOH specimen typically is used to identify the yeast or pseudohyphae of *Candida* species. However, the absence of trichomonads or pseudohyphae in KOH samples does not rule out these infections, because the sensitivity of microscropy is approximately 50% compared with NAAT (trichomoniasis) or culture (yeast).

In settings where pH paper, KOH, and microscopy are not available, alternative commercially available point-of-care tests or clinical laboratory testing can be used to diagnose vaginitis. The presence of objective signs of vulvar inflammation in the absence of vaginal pathogens after laboratory testing, along with a minimal amount of discharge, suggests the possibility of mechanical, chemical, allergic, or other noninfectious irritation of the vulva.

Bacterial Vaginosis

BV is a polymicrobial clinical syndrome resulting from replacement of the normal hydrogen peroxide producing *Lactobacillus* sp. in the vagina with high concentrations of anaerobic bacteria (e.g., *Prevotella* sp. and *Mobiluncus* sp.), *G. vaginalis*, *Ureaplasma, Mycoplasma*, and numerous fastidious or uncultivated anaerobes. Some women experience transient vaginal microbial changes, whereas others experience them for a longer intervals of time. Among women presenting for care, BV is the most prevalent cause of vaginal discharge or malodor; however, in a nationally representative survey, most women with BV were asymptomatic (*318*).

BV is associated with having multiple male or female partners, a new sex partner, douching, lack of condom use, and lack of vaginal lactobacilli; women who have never been sexually active can also be affected. The cause of the microbial alteration that characterizes BV is not fully understood, nor is whether BV results from acquisition of a sexually transmitted pathogen. Nonetheless, women with BV are at increased risk for the acquisition of some STDs (e.g., HIV, *N. gonorrhoeae*, *C. trachomatis*, and HSV- 2), complications after gynecologic surgery, complications of pregnancy, and recurrence of BV. Treatment of male sex partners has not been beneficial in preventing the recurrence of BV.

Diagnostic Considerations

BV can be diagnosed by the use of clinical criteria (i.e., Amsel's Diagnostic Criteria) (*319*) or Gram stain. A Gram stain (considered the gold standard laboratory method for diagnosing BV) is used to determine the relative concentration of lactobacilli (i.e., long Gram-positive rods), Gram-negative and Gram-variable rods and cocci (i.e., *G. vaginalis*, *Prevotella*, *Porphyromonas*, and peptostreptococci), and curved Gram-negative rods (i.e., *Mobiluncus*) characteristic of BV. If a Gram

stain is not available, clinical criteria can be used and require three of the following symptoms or signs:

- homogeneous, thin, white discharge that smoothly coats the vaginal walls;
- presence of clue cells on microscopic examination;
- pH of vaginal fluid >4.5; or
- a fishy odor of vaginal discharge before or after addition of 10% KOH (i.e., the whiff test).

Detection of three of these criteria has been correlated with results by Gram stain (*320*). Other tests, including a DNA probe-based test for high concentrations of *G. vaginalis* (Affirm VP III, Becton Dickinson, Sparks, Maryland), a prolineaminopeptidase test card (Pip Activity TestCard, Quidel, San Diego, California), and the OSOM BVBlue test have acceptable performance characteristics compared with Gram stain. Although a card test is available for the detection of elevated pH and trimethylamine, it has low sensitivity and specificity and therefore is not recommended. PCR also has been used in research settings for the detection of a variety of organisms associated with BV, but evaluation of its clinical utility is uncertain. Detection of one organism or group of organisms might be predictive of BV by Gram stain (*321*). However, additional evaluations are needed to confirm these associations. Culture of *G. vaginalis* is not recommended as a diagnostic tool because it is not specific. Cervical Pap tests have no clinical utility for the diagnosis of BV because of their low sensitivity.

Treatment

Treatment is recommended for women with symptoms. The established benefits of therapy in nonpregnant women are to relieve vaginal symptoms and signs of infection. Other potential benefits to treatment include reduction in the risk for acquiring *C. trachomatis* or *N. gonorrhoeae* (*322*), HIV, and other viral STDs.

Recommended Regimens

Metronidazole 500 mg orally twice a day for 7 days*

OR

Metronidazole gel 0.75%, one full applicator (5 g) intravaginally, once a day for 5 days

OR

Clindamycin cream 2%, one full applicator (5 g) intravaginally at bedtime for 7 days†

* Consuming alcohol should be avoided during treatment and for 24 hours thereafter.

† Clindamycin cream is oil-based and might weaken latex condoms and diaphragms for 5 days after use (refer to clindamycin product labeling for additional information).

Providers should consider patient preference, possible side-effects, drug interactions, and other coinfections when selecting a regimen. Women should be advised to refrain from intercourse or to use condoms consistently and correctly during the treatment regimen. Douching might increase the risk for relapse, and no data support the use of douching for treatment or relief of symptoms.

Alternative Regimens

Tinidazole 2 g orally once daily for 2 days

OR

Tinidazole 1 g orally once daily for 5 days

OR

Clindamycin 300 mg orally twice daily for 7 days

OR

Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days

Alternative regimens include several tinidazole regimens (*323*) or clindamycin (oral or intravaginal) (*324*). Additional regimens include metronidazole (750-mg extended release tablets once daily for 7 days), or a single dose of clindamycin intravaginal cream, although data on the performance of these alternative regimens are limited.

Several studies have evaluated the clinical and microbiologic efficacy of using intravaginal lactobacillus formulations to treat BV and restore normal flora (*325–327*). Further research efforts to determine the role of these regimens in BV treatment and prevention are ongoing.

Follow-Up

Follow-up visits are unnecessary if symptoms resolve. Because recurrence of BV is common, women should be advised to return for evaluation if symptoms recur. Detection of certain BV-associated organisms have been associated with antimicrobial resistance and might determine risk for subsequent treatment failure (*328–333*). Limited data are available regarding optimal management strategies for women with early treatment failure. Using a different treatment regimen might be an option in patients who have a recurrence; however, re-treatment with the same topical regimen is another acceptable approach for treating recurrent BV during the early stages of infection (*334*). For women with multiple recurrences after completion of a recommended regimen, metronidazole gel twice weekly for 4-6 months has been shown to reduce recurrences, although this benefit might not persist when suppressive therapy is discontinued (*335*). Limited data suggest that oral nitroimidazole followed by intravaginal boric acid and suppressive metronidazole gel for those women in remission might be an option in women with recurrent BV (*336*). Monthly oral metronidazole administered with fluconazole has also been evaluated as suppressive therapy (*337*).

Management of Sex Partners

The results of clinical trials indicate that a woman's response to therapy and the likelihood of relapse or recurrence are not affected by treatment of her sex partner(s). Therefore, routine treatment of sex partners is not recommended.

Special Considerations

Allergy or Intolerance to the Recommended Therapy

Intravaginal clindamycin cream is preferred in case of allergy or intolerance to metronidazole or tinidazole. Intravaginal metronidazole gel can be considered for women who do not tolerate systemic metronidazole. Intravaginal metronidazole should not be administered to women allergic to metronidazole.

Pregnancy

Treatment is recommended for all pregnant women with symptoms. Although BV is associated with adverse pregnancy outcomes, including premature rupture of membranes, preterm labor, preterm birth, intra-amniotic infection, and postpartum endometritis, the only established benefit of therapy for BV in pregnant women is the reduction of symptoms and signs of vaginal infection. Additional potential benefits include reducing the risk for infectious complications associated with BV during pregnancy and reducing the risk for other infections (other STDs or HIV).

Several trials have been undertaken to determine the efficacy of BV treatment among pregnant women. Two trials demonstrated that metronidazole was efficacious during pregnancy using the 250-mg regimen (*338,339*); however, metronidazole administered at 500 mg twice daily can be used. One trial involving a limited number of participants revealed that treatment with oral metronidazole 500 mg twice daily was equally effective as metronidazole gel, with cure rates of 70% using Amsel criteria to define cure (*340*), and a recent trial demonstrated a cure rate of 85% using Gram stain criteria after 4 weeks with oral clindamycin (*341*). Multiple studies and meta-analyses have not demonstrated an association between metronidazole use during pregnancy and teratogenic or mutagenic effects in newborns (*342,343*). Regardless of the antimicrobial agent used to treat pregnant women, oral therapy is preferred because of the possibility of subclinical upper-genital–tract infection.

Recommended Regimens for Pregnant Women
Metronidazole 500 mg orally twice a day for 7 days
OR
Metronidazole 250 mg orally three times a day for 7 days
OR
Clindamycin 300 mg orally twice a day for 7 days

Treatment of asymptomatic BV among pregnant women who are at high risk for preterm delivery (i.e., those with a previous preterm birth) has been evaluated by several studies, which have yielded mixed results. Seven trials have evaluated treatment of pregnant women with asymptomatic BV at high risk for preterm delivery; one showed harm (*344*), two showed no benefit (*345,346*), and four demonstrated benefit (*338,339,347,348*). Therefore, evidence is insufficient to assess the impact of screening for BV in pregnant women at high risk for preterm delivery (*85*).

Similarly, data are inconsistent regarding whether the treatment of asymptomatic pregnant women with BV who are at low risk for preterm delivery reduces adverse outcomes of pregnancy. Although USPSTF recommends against screening these women (*85*), one trial demonstrated a 40% reduction in spontaneous preterm birth among women using oral clindamycin during weeks 13–22 of gestation (*348*). Several additional trials have shown that intravaginal clindamycin given at an average gestation of later than 20 weeks did not reduce preterm birth, and in three of these trials, intravaginal clindamycin cream administered at 16–32 weeks' gestation was associated with an increase in adverse events (e.g., low birth weight and neonatal infections) in newborns (*346,349–351*). Providers should be aware that intravaginal clindamycin cream might be associated with adverse outcomes if used in the latter half of pregnancy.

HIV Infection

BV appears to recur with higher frequency in HIV-positive women (*352*). Patients who have BV and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

Trichomoniasis

Trichomoniasis is caused by the protozoan *T. vaginalis*. Some men who are infected with *T. vaginalis* might not have symptoms; others have NGU. Some women have symptoms characterized by a diffuse, malodorous, yellow-green vaginal discharge with vulvar irritation. However, many women have minimal or no symptoms. Because of the high prevalence of trichomoniasis in clinical and nonclinical settings (*64,92,353,354*), testing for *T. vaginalis* should be performed in women seeking care for vaginal discharge. Screening for *T. vaginalis* in women can be considered in those at high risk for infection (i.e., women who have new or multiple partners, have a history of STDs, exchange sex for payment, and use injection drugs).

Diagnosis of vaginal trichomoniasis is usually performed by microscopy of vaginal secretions, but this method has a

sensitivity of only approximately 60%–70% and requires immediate evaluation of wet preparation slide for optimal results. FDA-cleared tests for trichomoniasis in women include OSOM Trichomonas Rapid Test (Genzyme Diagnostics, Cambridge, Massachusetts), an immunochromatographic capillary flow dipstick technology, and the Affirm VP III (Becton Dickenson, San Jose, California), a nucleic acid probe test that evaluates for *T. vaginalis*, *G. vaginalis*, and *C. albicans*. Each of these tests, which are performed on vaginal secretions, have a sensitivity of >83% and a specificity of >97%. Both tests are considered point-of-care diagnostics. The results of the OSOM Trichomonas Rapid Test are available in approximately 10 minutes, whereas results of the Affirm VP III are available within 45 minutes. Although these tests tend to be more sensitive than those requiring vaginal wet preparation, false positives might occur, especially in populations with a low prevalence of disease.

Culture is another sensitive and highly specific commercially available method of diagnosis. Among women in whom trichomoniasis is suspected but not confirmed by microscopy, vaginal secretions should be cultured for *T. vaginalis*. While the sensitivity of a Pap test for *T. vaginalis* diagnosis is poor, use of a liquid-based testing has demonstrated enhanced sensitivity; however, false-positive tests can occur, and confirmatory testing might be needed in some circumstances (*355*). An FDA-cleared PCR assay for detection of gonorrhea and chlamydial infection (Amplicor, manufactured by Roche Diagnostic Corp.) has been modified for *T. vaginalis* detection in vaginal or endocervical swabs and in urine from women and men; sensitivity ranges from 88%–97% and specificity from 98%–99% (*356*). APTIMA *T. vaginalis* Analyte Specific Reagents (ASR; manufactured by Gen-Probe, Inc.) also can detect *T. vaginalis* RNA by transcription-mediated amplification using the same instrumentation platforms available for the FDA-cleared APTIMA Combo2 assay for diagnosis of gonorrhea and chlamydial infection; published validation studies of *T. vaginalis* ASR found sensitivity ranging from 74%–98% and specificity of 87%–98% (*357–359*). Laboratories that use the Gen-Probe APTIMA Combo2 test for detection of *N. gonorrhoeae* and *C. trachomatis* can consider adding the *T. vaginalis* ASR to their testing armentarium, as long as the necessary CLIA verification studies have been conducted.

In men, wet preparation is not a sensitive test, and no approved point-of-care tests are available. Culture testing of urethral swab, urine, or semen is one diagnostic option; however, NAATs (i.e., PCR or transcription-mediated amplification [TMA]) have superior sensitivity for *T. vaginalis* diagnosis in men (*356,359*). *T. vaginalis* has not been found to infect oral sites, and rectal prevalence appears low in MSM (*360*). Therefore, oral and rectal testing for *T. vaginalis* is not recommended.

Recommended Regimens

Metronidazole 2 g orally in a single dose

OR

Tinidazole 2 g orally in a single dose

Alternative Regimen

Metronidazole 500 mg orally twice a day for 7 days*

* Patients should be advised to avoid consuming alcohol during treatment with metronidazole or tinidazole. Abstinence from alcohol use should continue for 24 hours after completion of metronidazole or 72 hours after completion of tinidazole.

The nitroimidazoles comprise the only class of drugs useful for the oral or parenteral therapy of trichomoniasis. Of these drugs, metronidazole and tinidazole are available in the United States and are cleared by the FDA for the treatment of trichomoniasis. In randomized clinical trials, the recommended metronidazole regimens have resulted in cure rates of approximately 90%–95%, and the recommended tinidazole regimen has resulted in cure rates of approximately 86%–100%. The appropriate treatment of sex partners might increase these reported rates. Randomized controlled trials comparing single 2-g doses of metronidazole and tinidazole suggest that tinidazole is equivalent or superior to metronidazole in achieving parasitologic cure and resolution of symptoms (*361*). Treatment of patients and sex partners results in relief of symptoms, microbiologic cure, and reduction of transmission.

Metronidazole gel is considerably less efficacious for the treatment of trichomoniasis (<50%) than oral preparations of metronidazole. Topically applied antimicrobials (e.g., metronidazole gel) are unlikely to achieve therapeutic levels in the urethra or perivaginal glands; therefore, use of this gel is not recommended. Several other topically applied antimicrobials occasionally have been used for treatment of trichomoniasis; however, these preparations likely are no more effective than metronidazole gel.

Follow-Up

Because of the high rate of reinfection among patients in whom trichomoniasis was diagnosed (17% were reinfected within 3 months in one study), rescreening for *T. vaginalis* at 3 months following initial infection can be considered for sexually active women with trichomoniasis; the benefit of this approach, however, has not been fully evaluated (*64*). No data support rescreening in men diagnosed with *T. vaginalis*. While most recurrent *T. vaginalis* infections are thought to result from having sex with an untreated partner (i.e., reinfection), some

recurrent cases can be attributed to diminished susceptibility to metronidazole. Low-level metronidazole resistance has been identified in 2%–5% of cases of vaginal trichomoniasis (*362*,*363*), but high-level resistance only rarely occurs. Fortunately, infections caused by most of these organisms respond to tinidazole or higher doses of metronidazole. Tinidazole has a longer serum half-life and reaches higher levels in genitourinary tissues than metronidazole. In addition, many *T. vaginalis* isolates have lower minimal lethal concentrations (MLCs) to tinidazole than metronidazole.

If treatment failure occurs with metronidazole 2-g single dose and reinfection is excluded, the patient can be treated with metronidazole 500 mg orally twice daily for 7 days. For patients failing this regimen, treatment with tinidazole or metronidazole at 2 g orally for 5 days should be considered. If these therapies are not effective, further management should be discussed with a specialist. The consultation should ideally include determination of the susceptibility of *T. vaginalis* to metronidazole and tinidazole. Consultation and *T. vaginalis* susceptibility testing is available from CDC (telephone: 404-718-4141; website: http://www.cdc.gov/std).

Management of Sex Partners

Sex partners of patients with *T. vaginalis* should be treated. Patients should be instructed to abstain from sex until they and their sex partners are cured (i.e., when therapy has been completed and patient and partner[s] are asymptomatic). Existing data suggest that patient-delivered partner therapy might have a role in partner management for trichomoniasis; however, no one partner management intervention has shown superiority over another in reducing reinfection rates (*72*,*73*). Although no data are available to guide treatment of the male partners of women with nitroimidazole treatment failure, on the basis of expert opinion, male partners should be evaluated and treated with either tinidazole in a single dose of 2 g orally or metronidazole twice a day at 500 mg orally for 7 days.

Special Considerations

Allergy, Intolerance, and Adverse Reactions

Metronidazole and tinidazole are both nitroimidazoles. Patients with an immediate-type allergy to a nitroimidazole can be managed by metronidazole desensitization in consultation with a specialist (*364*–*366*). Topical therapy with drugs other than nitroimidazoles can be attempted, but cure rates are low (<50%).

Pregnancy

Vaginal trichomoniasis has been associated with adverse pregnancy outcomes, particularly premature rupture of membranes, preterm delivery, and low birth weight. However, metronidazole treatment has not been shown to reduce perinatal morbidity. Although some trials suggest the possibility of increased prematurity or low birth weight after metronidazole treatment, limitations of the studies prevent definitive conclusions regarding risks for treatment (*367*,*368*). Treatment of *T. vaginalis* might relieve symptoms of vaginal discharge in pregnant women and might prevent respiratory or genital infection of the newborn and further sexual transmission. Clinicians should counsel patients regarding the potential risks and benefits of treatment and communicate the option of therapy deferral in asymptomatic pregnant women until after 37 weeks' gestation. All symptomatic pregnant women should not only be considered for treatment regardless of pregnancy stage, but be provided careful counseling regarding condom use and the continued risk of sexual transmission.

Women can be treated with 2 g metronidazole in a single dose at any stage of pregnancy. Multiple studies and meta-analyses have not demonstrated an association between metronidazole use during pregnancy and teratogenic or mutagenic effects in infants (*342*,*343*,*369*). The safety of tinidazole in pregnant women, however, has not been well evaluated.

In lactating women who are administered metronidazole, withholding breastfeeding during treatment and for 12–24 hours after the last dose will reduce the exposure of the infant to metronidazole. For women treated with tinidazole, interruption of breastfeeding is recommended during treatment and for 3 days after the last dose.

HIV Infection

There is increasing evidence for epidemiologic and biologic interaction between HIV and *T. vaginalis* (*370*–*375*). *T. vaginalis* infection in HIV-infected women might enhance HIV transmission by increasing genital shedding of the virus (*376*,*377*), and treatment for *T. vaginalis* has been shown to reduce HIV shedding (*376*,*377*). For sexually active women who are HIV-positive, screening for trichomoniasis at entry into care with subsequent screening performed at least annually is recommended based on the reported prevalence of *T. vaginalis*, the effect of treatment at reducing vaginal HIV shedding, and the potential complications of upper-genital-tract infections among women who are left untreated (*130*,*370*–*375*). Rescreening 3 months after completion of therapy should be considered among HIV-positive women with trichomoniasis, a recommendation based on the high proportion of recurrent or persistent infection and the association between HIV and *T. vaginalis* infection (*64*,*374*,*378*).

A recent randomized clinical trial involving women coinfected with trichomoniasis and HIV demonstrated that a single dose of metronidazole 2 gm orally was not as effective as 500 mg twice daily for 7 days (*379*). Therefore, a multi-

dose treatment regimen for *T. vaginalis* can be considered in HIV-infected women.

Vulvovaginal Candidiasis

VVC usually is caused by *C. albicans*, but occasionally is caused by other *Candida* sp. or yeasts. Typical symptoms of VVC include pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge. None of these symptoms is specific for VVC. An estimated 75% of women will have at least one episode of VVC, and 40%–45% will have two or more episodes within their lifetime. On the basis of clinical presentation, microbiology, host factors, and response to therapy, VVC can be classified as either uncomplicated or complicated (Box 3). Approximately 10%–20% of women will have complicated VVC that necessitates diagnostic and therapeutic considerations.

Uncomplicated VVC

Diagnostic Considerations

A diagnosis of *Candida* vaginitis is suggested clinically by the presence of external dysuria and vulvar pruritus, pain, swelling, and redness. Signs include vulvar edema, fissures, excoriations, or thick, curdy vaginal discharge. The diagnosis can be made in a woman who has signs and symptoms of vaginitis when either 1) a wet preparation (saline, 10% KOH) or Gram stain of vaginal discharge demonstrates yeasts, hyphae, or pseudohyphae or 2) a culture or other test yields a yeast species. *Candida* vaginitis is associated with a normal vaginal pH (<4.5), and therefore, pH testing is not a useful diagnostic tool. Use of 10% KOH in wet preparations improves the visualization of yeast and mycelia by disrupting cellular material that might obscure the yeast or pseudohyphae. Examination of a wet mount with KOH preparation should be performed for all women with symptoms or signs of VVC, and women with a positive result should receive treatment. For women with negative wet mounts who are symptomatic, vaginal cultures for *Candida* should be considered. If the wet mount is negative and *Candida* cultures cannot be done, empiric treatment can be considered for symptomatic women with any sign of VVC on examination. Identifying *Candida* by culture in the absence of symptoms or signs is not an indication for treatment, because approximately 10%–20% of women harbor *Candida* sp. and other yeasts in the vagina. VVC can occur concomitantly with STDs. Most healthy women with uncomplicated VVC have no identifiable precipitating factors.

Treatment

Short-course topical formulations (i.e., single dose and regimens of 1–3 days) effectively treat uncomplicated VVC. The topically applied azole drugs are more effective than nystatin. Treatment with azoles results in relief of symptoms and negative cultures in 80%–90% of patients who complete therapy.

Recommended Regimens

Over-the-Counter Intravaginal Agents:

Butoconazole 2% cream 5 g intravaginally for 3 days

OR

Clotrimazole 1% cream 5 g intravaginally for 7–14 days

OR

Clotrimazole 2% cream 5 g intravaginally for 3 days

OR

Miconazole 2% cream 5 g intravaginally for 7 days

OR

Miconazole 4% cream 5 g intravaginally for 3 days

OR

Miconazole 100 mg vaginal suppository, one suppository for 7 days

OR

Miconazole 200 mg vaginal suppository, one suppository for 3 days

OR

Miconazole 1,200 mg vaginal suppository, one suppository for 1 day

OR

Tioconazole 6.5% ointment 5 g intravaginally in a single application

Prescription Intravaginal Agents:

Butoconazole 2% cream (single dose bioadhesive product), 5 g intravaginally for 1 day

OR

Nystatin 100,000-unit vaginal tablet, one tablet for 14 days

OR

Terconazole 0.4% cream 5 g intravaginally for 7 days

OR

Terconazole 0.8% cream 5 g intravaginally for 3 days

OR

Terconazole 80 mg vaginal suppository, one suppository for 3 days

Oral Agent:

Fluconazole 150 mg oral tablet, one tablet in single dose

The creams and suppositories in this regimen are oil-based and might weaken latex condoms and diaphragms. Patients and providers should refer to condom product labeling for further information.

Intravaginal preparations of butaconazole, clotrimazole, miconazole, and tioconazole are available over-the-counter (OTC). Women whose condition has previously been diagnosed with VVC are not necessarily more capable of diagnosing themselves; therefore, any woman whose symptoms persist after using an OTC preparation or who has a recurrence of symptoms within 2 months should be evaluated with office-based testing. Unnecessary or inappropriate use of OTC preparations is common and can lead to a delay in the treatment of other

Box 3. Classification of vulvovaginal candidiasis (VVC)

Uncomplicated VVC

- Sporadic or infrequent vulvovaginal candidiasis
  OR
- Mild-to-moderate vulvovaginal candidiasis
  OR
- Likely to be *C. albicans*
  OR
- Non-immunocompromised women

Complicated VVC

- Recurrent vulvovaginal candidiasis
  OR
- Severe vulvovaginal candidiasis
  OR
- Non-albicans candidiasis
  OR
- Women with uncontrolled diabetes, debilitation, or immunosuppression

vulvovaginitis etiologies, which can result in adverse clinical outcomes.

Follow-Up

Patients should be instructed to return for follow-up visits only if symptoms persist or recur within 2 months of onset of the initial symptoms.

Management of Sex Partners

VVC is not usually acquired through sexual intercourse; no data support the treatment of sex partners. A minority of male sex partners might have balanitis, which is characterized by erythematous areas on the glans of the penis in conjunction with pruritus or irritation. These men benefit from treatment with topical antifungal agents to relieve symptoms.

Special Considerations

Allergy, Intolerance, and Adverse Reactions

Topical agents usually cause no systemic side effects, although local burning or irritation might occur. Oral agents occasionally cause nausea, abdominal pain, and headache. Therapy with the oral azoles has been associated rarely with abnormal elevations of liver enzymes. Clinically important interactions can occur when these oral agents are administered with other drugs, including astemizole, calcium channel antagonists, cisapride, cyclosporin A, oral hypoglycemic agents, phenytoin, protease inhibitors, tacrolimus, terfenadine, theophylline, trimetrexate, rifampin, and warfarin.

Complicated VVC

Recurrent Vulvovaginal Candidiasis (RVVC)

RVVC, usually defined as four or more episodes of symptomatic VVC in 1 year, affects a small percentage of women (<5%). The pathogenesis of RVVC is poorly understood, and most women with RVVC have no apparent predisposing or underlying conditions. Vaginal cultures should be obtained from patients with RVVC to confirm the clinical diagnosis and to identify unusual species (including nonalbicans species), particularly *Candida glabrata.* Although *C. glabrata* and other nonalbicans *Candidia* species are observed in 10%–20% of patients with RVVC, *C. glabrata* does not form pseudohyphae or hyphae and is not easily recognized on microscopy. Conventional antimycotic therapies are not as effective against these species as they are against *C. albicans*.

Treatment

Each individual episode of RVVC caused by *C. albicans* responds well to short-duration oral or topical azole therapy. However, to maintain clinical and mycologic control, some specialists recommend a longer duration of initial therapy (e.g., 7–14 days of topical therapy or a 100-mg, 150-mg, or 200-mg oral dose of fluconazole every third day for a total of 3 doses [day 1, 4, and 7]) to attempt mycologic remission before initiating a maintenance antifungal regimen.

Maintenance Regimens

Oral fluconazole (i.e., 100-mg, 150-mg, or 200-mg dose) weekly for 6 months is the first line of treatment. If this regimen is not feasible, topical treatments used intermittently as a maintenance regimen can be considered.

Suppressive maintenance antifungal therapies are effective in reducing RVVC. However, 30%–50% of women will have recurrent disease after maintenance therapy is discontinued. Routine treatment of sex partners is controversial. *C. albicans* azole resistance is rare in vaginal isolates, and susceptibility testing is usually not warranted for individual treatment guidance.

Severe VVC

Severe vulvovaginitis (i.e., extensive vulvar erythema, edema, excoriation, and fissure formation) is associated with lower clinical response rates in patients treated with short courses of topical or oral therapy. Either 7–14 days of topical azole or 150 mg of fluconazole in two sequential doses (second dose 72 hours after initial dose) is recommended.

Nonalbicans VVC

The optimal treatment of nonalbicans VVC remains unknown. Options include longer duration of therapy (7–14

days) with a nonfluconazole azole drug (oral or topical) as first-line therapy. If recurrence occurs, 600 mg of boric acid in a gelatin capsule is recommended, administered vaginally once daily for 2 weeks. This regimen has clinical and mycologic eradication rates of approximately 70% (*380*). If symptoms recur, referral to a specialist is advised.

Special Considerations

Compromised Host

Women with underlying debilitating medical conditions (e.g., those with uncontrolled diabetes or those receiving corticosteroid treatment) do not respond as well to short-term therapies. Efforts to correct modifiable conditions should be made, and more prolonged (i.e., 7–14 days) conventional antimycotic treatment is necessary.

Pregnancy

VVC frequently occurs during pregnancy. Only topical azole therapies, applied for 7 days, are recommended for use among pregnant women.

HIV Infection

The incidence of VVC in HIV-infected women is unknown. Vaginal *Candida* colonization rates among HIV-infected women are higher than among those for seronegative women with similar demographic characteristics and high-risk behaviors, and the colonization rates correlate with increasing severity of immunosuppression. Symptomatic VVC is more frequent in seropositive women and similarly correlates with severity of immunodeficiency. In addition, among HIV-infected women, systemic azole exposure is associated with the isolation of nonalbicans *Candida* species from the vagina.

On the basis of available data, therapy for VVC in HIV-infected women should not differ from that for seronegative women. Although long-term prophylactic therapy with fluconazole at a dose of 200 mg weekly has been effective in reducing *C. albicans* colonization and symptomatic VVC (*381*), this regimen is not recommended for routine primary prophylaxis in HIV-infected women in the absence of recurrent VVC (*129*). Given the frequency at which RVVC occurs in the immmunocompetent healthy population, the occurrence of RVVC should not be considered an indication for HIV testing among women previously testing HIV negative. Although VVC is associated with increased HIV seroconversion in HIV-negative women and increased HIV cervicovaginal levels in HIV-positive women, the effect of treatment for VVC on HIV acquisition and transmission remains unknown.

Pelvic Inflammatory Disease

PID comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis (*382*). Sexually transmitted organisms, especially *N. gonorrhoeae* and *C. trachomatis*, are implicated in many cases; however, microorganisms that comprise the vaginal flora (e.g., anaerobes, *G. vaginalis*, *Haemophilus influenzae*, enteric Gram-negative rods, and *Streptococcus agalactiae*) also have been associated with PID (*383*). In addition, cytomegalovirus (CMV), *M. hominis*, *U. urealyticum*, and *M. genitalium* might be associated with some cases of PID (*263*,*384–386*). All women who have acute PID should be tested for *N. gonorrhoeae* and *C. trachomatis* and should be screened for HIV infection.

Diagnostic Considerations

Acute PID is difficult to diagnose because of the wide variation in the symptoms and signs. Many women with PID have subtle or mild symptoms. Delay in diagnosis and treatment probably contributes to inflammatory sequelae in the upper reproductive tract. Laparoscopy can be used to obtain a more accurate diagnosis of salpingitis and a more complete bacteriologic diagnosis. However, this diagnostic tool frequently is not readily available, and its use is not easy to justify when symptoms are mild or vague. Moreover, laparoscopy will not detect endometritis and might not detect subtle inflammation of the fallopian tubes. Consequently, a diagnosis of PID usually is based on clinical findings.

The clinical diagnosis of acute PID is imprecise (*387*,*388*). Data indicate that a clinical diagnosis of symptomatic PID has a positive predictive value (PPV) for salpingitis of 65%–90% compared with laparoscopy. The PPV of a clinical diagnosis of acute PID depends on the epidemiologic characteristics of the population, with higher PPVs among sexually active young women (particularly adolescents), patients attending STD clinics, and those who live in other settings where the rates of gonorrhea or chlamydia are high. Regardlesss of PPV, however, in all settings, no single historical, physical, or laboratory finding is both sensitive and specific for the diagnosis of acute PID. Combinations of diagnostic findings that improve either sensitivity (i.e., detect more women who have PID) or specificity (i.e., exclude more women who do not have PID) do so only at the expense of the other. For example, requiring two or more findings excludes more women who do not have PID but also reduces the number of women with PID who are identified.

Many episodes of PID go unrecognized. Although some cases are asymptomatic, others are not diagnosed because the patient or the health-care provider fails to recognize the

implications of mild or nonspecific symptoms or signs (e.g., abnormal bleeding, dyspareunia, and vaginal discharge). Because of the difficulty of diagnosis and the potential for damage to the reproductive health of women (even by apparently mild or subclinical PID), health-care providers should maintain a low threshold for the diagnosis of PID (*382*).

The optimal treatment regimen and long-term outcome of early treatment of women with asymptomatic or subclinical PID are unknown. The following recommendations for diagnosing PID are intended to help health-care providers recognize when PID should be suspected and when they need to obtain additional information to increase diagnostic certainty. Diagnosis and management of other common causes of lower abdominal pain (e.g., ectopic pregnancy, acute appendicitis, and functional pain) are unlikely to be impaired by initiating empiric antimicrobial therapy for PID.

Empiric treatment for PID should be initiated in sexually active young women and other women at risk for STDs if they are experiencing pelvic or lower abdominal pain, if no cause for the illness other than PID can be identified, and if one or more of the following minimum criteria are present on pelvic examination:

- cervical motion tenderness
  or
- uterine tenderness
  or
- adnexal tenderness.

The requirement that all three minimum criteria be present before the initiation of empiric treatment could result in insufficient sensitivity for the diagnosis of PID. The presence of signs of lower-genital–tract inflammation (predominance of leukocytes in vaginal secretions, cervical exudates, or cervical friability), in addition to one of the three minimum criteria, increases the specificity of the diagnosis. Upon deciding whether to initiate empiric treatment, clinicians should also consider the risk profile of the patient for STDs.

More elaborate diagnostic evaluation frequently is needed because incorrect diagnosis and management of PID might cause unnecessary morbidity. One or more of the following additional criteria can be used to enhance the specificity of the minimum criteria and support a diagnosis of PID:

- oral temperature >101° F (>38.3° C);
- abnormal cervical or vaginal mucopurulent discharge;
- presence of abundant numbers of WBC on saline microscopy of vaginal fluid;
- elevated erythrocyte sedimentation rate;
- elevated C-reactive protein; and
- laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis*.

Most women with PID have either mucopurulent cervical discharge or evidence of WBCs on a microscopic evaluation of a saline preparation of vaginal fluid (i.e., wet prep). If the cervical discharge appears normal and no WBCs are observed on the wet prep of vaginal fluid, the diagnosis of PID is unlikely, and alternative causes of pain should be considered. A wet prep of vaginal fluid offers the ability to detect the presence of concomitant infections (e.g., BV and trichomoniasis).

The most specific criteria for diagnosing PID include:

- endometrial biopsy with histopathologic evidence of endometritis;
- transvaginal sonography or magnetic resonance imaging techniques showing thickened, fluid-filled tubes with or without free pelvic fluid or tubo-ovarian complex, or Doppler studies suggesting pelvic infection (e.g., tubal hyperemia); or
- laparoscopic abnormalities consistent with PID.

A diagnostic evaluation that includes some of these more extensive procedures might be warranted in some cases. Endometrial biopsy is warranted in women undergoing laparoscopy who do not have visual evidence of salpingitis, because endometritis is the only sign of PID for some women.

Treatment

PID treatment regimens must provide empiric, broad spectrum coverage of likely pathogens. Several antimicrobial regimens have been effective in achieving clinical and microbiologic cure in randomized clinical trials with short-term follow-up. However, only a limited number of investigations have assessed and compared these regimens with regard to elimination of infection in the endometrium and fallopian tubes or determined the incidence of long-term complications (e.g., tubal infertility and ectopic pregnancy) after antimicrobial regimens (*389–391*).

All regimens used to treat PID should also be effective against *N. gonorrhoeae* and *C. trachomatis* because negative endocervical screening for these organisms does not rule out upper-reproductive-tract infection. The need to eradicate anaerobes from women who have PID has not been determined definitively. Anaerobic bacteria have been isolated from the upper-reproductive tract of women who have PID, and data from in vitro studies have revealed that some anaerobes (e.g., *Bacteroides fragilis*) can cause tubal and epithelial destruction. BV also is present in many women who have PID (*383,391*). Until treatment regimens that do not adequately cover these microbes have been demonstrated to prevent long-term sequelae (e.g., infertility and ectopic pregnancy) as successfully as

the regimens that are effective against these microbes, the use of regimens with anaerobic activity should be considered. Treatment should be initiated as soon as the presumptive diagnosis has been made because prevention of long-term sequelae is dependent on early administration of appropriate antibiotics. When selecting a treatment regimen, health-care providers should consider availability, cost, patient acceptance, and antimicrobial susceptibility (*392*).

In women with PID of mild or moderate clinical severity, outpatient therapy yields short- and long-term clinical outcomes similar to inpatient therapy. The decision of whether hospitalization is necessary should be based on the judgment of the provider and whether the patient meets any of the following suggested criteria:

- surgical emergencies (e.g., appendicitis) cannot be excluded;
- the patient is pregnant;
- the patient does not respond clinically to oral antimicrobial therapy;
- the patient is unable to follow or tolerate an outpatient oral regimen;
- the patient has severe illness, nausea and vomiting, or high fever; or
- the patient has a tubo-ovarian abscess.

No evidence is available to suggest that adolescents benefit from hospitalization for treatment of PID. The decision to hospitalize adolescents with acute PID should be based on the same criteria used for older women. Younger women with mild-to-moderate acute PID have similar outcomes with either outpatient or inpatient therapy, and clinical response to outpatient treatment is similar among younger and older women.

Parenteral Treatment

For women with PID of mild or moderate severity, parenteral and oral therapies appear to have similar clinical efficacy. Many randomized trials have demonstrated the efficacy of both parenteral and oral regimens (*390*,*391*,*393*). Clinical experience should guide decisions regarding transition to oral therapy, which usually can be initiated within 24–48 hours of clinical improvement. In women with tubo-ovarian abscesses, at least 24 hours of direct inpatient observation is recommended.

Recommended Parenteral Regimen A

Cefotetan 2 g IV every 12 hours

OR

Cefoxitin 2 g IV every 6 hours

PLUS

Doxycycline 100 mg orally or IV every 12 hours

Because of the pain associated with intravenous infusion, doxycycline should be administered orally when possible. Oral and IV administration of doxycycline provide similar bioavailability.

Parenteral therapy can be discontinued 24 hours after clinical improvement, but oral therapy with doxycycline (100 mg twice a day) should continue to complete 14 days of therapy. When tubo-ovarian abscess is present, clindamycin or metronidazole with doxycycline can be used for continued therapy rather than doxycycline alone because this regimen provides more effective anaerobic coverage.

Limited data are available to support the use of other second- or third-generation cephalosporins (e.g., ceftizoxime, cefotaxime, and ceftriaxone), which also might be effective therapy for PID and could potentially replace cefotetan or cefoxitin. However, these cephalosporins are less active than cefotetan or cefoxitin against anaerobic bacteria.

Recommended Parenteral Regimen B

Clindamycin 900 mg IV every 8 hours

PLUS

Gentamicin loading dose IV or IM (2 mg/kg of body weight), followed by a maintenance dose (1.5 mg/kg) every 8 hours. Single daily dosing (3–5 mg/kg) can be substituted.

Although use of a single daily dose of gentamicin has not been evaluated for the treatment of PID, it is efficacious in analogous situations. Parenteral therapy can be discontinued 24 hours after clinical improvement; ongoing oral therapy should consist of doxycycline 100 mg orally twice a day, or clindamycin 450 mg orally four times a day to complete a total of 14 days of therapy. When tubo-ovarian abscess is present, clindamycin should be continued rather than doxycycline, because clindamycin provides more effective anaerobic coverage.

Alternative Parenteral Regimens

Limited data are available to support the use of other parenteral regimens. The following regimen has been investigated in at least one clinical trial and has broad-spectrum coverage (*394*).

Alternative Parenteral Regimens

Ampicillin/Sulbactam 3 g IV every 6 hours

PLUS

Doxycycline 100 mg orally or IV every 12 hours

Ampicillin/sulbactam plus doxycycline is effective against *C. trachomatis*, *N. gonorrhoeae*, and anaerobes in women with tubo-ovarian abscess. One trial demonstrated high short-term clinical cure rates with azithromycin, either as monotherapy

for 1 week (500 mg IV for 1 or 2 doses followed by 250 mg orally for 5–6 days) or combined with a 12-day course of metronidazole (*395*).

Oral Treatment

Outpatient, oral therapy can be considered for women with mild-to-moderately severe acute PID, because the clinical outcomes among women treated with oral therapy are similar to those treated with parenteral therapy (*390*). The following regimens provide coverage against the frequent etiologic agents of PID. Patients who do not respond to oral therapy within 72 hours should be reevaluated to confirm the diagnosis and should be administered parenteral therapy on either an outpatient or inpatient basis.

Recommended Regimen

Ceftriaxone 250 mg IM in a single dose

PLUS

Doxycycline 100 mg orally twice a day for 14 days

WITH or WITHOUT

Metronidazole 500 mg orally twice a day for 14 days

OR

Cefoxitin 2 g IM in a single dose and **Probenecid**, 1 g orally administered concurrently in a single dose

PLUS

Doxycycline 100 mg orally twice a day for 14 days

WITH or WITHOUT

Metronidazole 500 mg orally twice a day for 14 days

OR

Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime)

PLUS

Doxycycline 100 mg orally twice a day for 14 days

WITH or WITHOUT

Metronidazole 500 mg orally twice a day for 14 days

The optimal choice of a cephalosporin is unclear; although cefoxitin has better anaerobic coverage, ceftriaxone has better coverage against *N. gonorrhoeae*. A single dose of cefoxitin is effective in obtaining short-term clinical response in women who have PID. However, the theoretical limitations in coverage of anaerobes by recommended cephalosporin antimicrobials might require the addition of metronidazole to the treatment regimen (*393*). Adding metronidazole also will effectively treat BV, which is frequently associated with PID. No data have been published regarding the use of oral cephalosporins for the treatment of PID.

Alternative Oral Regimens

Although information regarding other outpatient regimens is limited, other regimens have undergone at least one clinical trial and have demonstrated broad spectrum coverage. In a single clinical trial, amoxicillin/clavulanic acid and doxycycline were effective together in obtaining short-term clinical response (*394*); however, gastrointestinal symptoms might limit compliance with this regimen. Azithromycin has demonstrated short-term effectiveness in one randomized trial (*395*), and in another study, it was effective when used combination with ceftriaxone 250 mg IM single dose and azithromycin 1 g orally once a week for 2 weeks (*396*). When considering alternative regimens, the addition of metronidazole should be considered because anaerobic organisms are suspected in the etiology of PID and metronidazole will also treat BV.

As a result of the emergence of quinolone-resistant *Neisseria gonorrhoeae*, regimens that include a quinolone agent are no longer recommended for the treatment of PID. If parenteral cephalosporin therapy is not feasible, use of fluoroquinolones (levofloxacin 500 mg orally once daily or ofloxacin 400 mg twice daily for 14 days) with or without metronidazole (500 mg orally twice daily for 14 days) can be considered if the community prevalence and individual risk for gonorrhea are low. Diagnostic tests for gonorrhea must be performed before instituting therapy and the patient managed as follows if the test is positive.

- If the culture for gonorrhea is positive, treatment should be based on results of antimicrobial susceptibility.
- If the isolate is determined to be quinolone-resistant *N. gonorrhoeae* (QRNG) or if antimicrobial susceptibility cannot be assessed (e.g., if only NAAT testing is available), parenteral cephalosporin is recommended. However, if cephalosporin therapy is not feasible, the addition of azithromycin 2 g orally as a single dose to a quinolone-based PID regimen is recommended.

Follow-Up

Patients should demonstrate substantial clinical improvement (e.g., defervescence; reduction in direct or rebound abdominal tenderness; and reduction in uterine, adnexal, and cervical motion tenderness) within 3 days after initiation of therapy. Patients who do not improve within this period usually require hospitalization, additional diagnostic tests, and surgical intervention.

If no clinical improvement has occurred within 72 hours after outpatient oral or parenteral therapy, further assessment should be performed. Subsequent hospitalization and an assessment of the antimicrobial regimen and diagnostics (including the consideration of diagnostic laparoscopy for alternative diagnoses) are recommended in women without clinical improvement. Women with documented chlamydial or gonococcal infections have a high rate of reinfection within

6 months of treatment. Repeat testing of all women who have been diagnosed with chlamydia or gonorrhea is recommended 3–6 months after treatment, regardless of whether their sex partners were treated (*267*). All women diagnosed with acute PID should be offered HIV testing.

Management of Sex Partners

Male sex partners of women with PID should be examined and treated if they had sexual contact with the patient during the 60 days preceding the patient's onset of symptoms. If a patient's last sexual intercourse was >60 days before onset of symptoms or diagnosis, the patient's most recent sex partner should be treated. Patients should be instructed to abstain from sexual intercourse until therapy is completed and until they and their sex partners no longer have symptoms. Evaluation and treatment are imperative because of the risk for reinfection of the patient and the strong likelihood of urethral gonococcal or chlamydial infection in the sex partner. Male partners of women who have PID caused by *C. trachomatis* and/or *N. gonorrhoeae* frequently are asymptomatic.

Sex partners should be treated empirically with regimens effective against both of these infections, regardless of the etiology of PID or pathogens isolated from the infected woman. Even in clinical settings in which only women are treated, arrangements should be made to provide care or appropriate referral for male sex partners of women who have PID (see Partner Management). Expedited partner treatment and enhanced patient referral (see Partner Management) are alternative approaches to treating male partners of women who have chlamydia or gonococcal infections (*68*,*69*).

Prevention

Screening and treating sexually active women for chlamydia reduces their risk for PID (*272*). Although BV is associated with PID, whether the incidence of PID can be reduced by identifying and treating women with BV is unclear (*383*,*391*).

Special Considerations

Pregnancy

Because of the high risk for maternal morbidity and preterm delivery, pregnant women who have suspected PID should be hospitalized and treated with parenteral antibiotics.

HIV Infection

Differences in the clinical manifestations of PID between HIV-infected women and HIV-negative women have not been well delineated. In previous observational studies, HIV-infected women with PID were more likely to require surgical intervention; more comprehensive observational and controlled studies now have demonstrated that HIV-infected women with PID have similar symptoms when compared with uninfected controls (*397*–*399*), except they were more likely to have a tubo-ovarian abscess; both groups of women responded equally well to standard parenteral and oral antibiotic regimens. The microbiologic findings for HIV-positive and HIV-negative women were similar, except HIV-infected women had higher rates of concomitant *M. hominis*, candida, streptococcal, and HPV infections and HPV-related cytologic abnormalities. Regardlesss of these data, whether the management of immunodeficient HIV-infected women with PID requires more aggressive interventions (e.g., hospitalization or parenteral antimicrobial regimens) has not been determined.

Intrauterine Contraceptive Devices

IUDs are popular contraceptive choices for women. Both levonorgestrel and copper-containing devices are marketed in the United States. The risk for PID associated with IUD use is primarily confined to the first 3 weeks after insertion and is uncommon thereafter (*400*,*401*). Given the popularity of IUDs, practitioners might encounter PID in IUD users. Evidence is insufficient to recommend that the removal of IUDs in women diagnosed with acute PID. However, caution should be exercised if the IUD remains in place, and close clinical follow-up is mandatory. The rate of treatment failure and recurrent PID in women continuing to use an IUD is unknown, and no data have been collected regarding treatment outcomes by type of IUD (e.g., copper or levonorgestrel).

Epididymitis

Acute epididymitis is a clinical syndrome consisting of pain, swelling, and inflammation of the epididymis that lasts <6 weeks (*402*). Chronic epididymitis is characterized by a ≥6 week history of symptoms of discomfort and/or pain in the scrotum, testicle, or epididymis. In most cases of acute epididymitis, the testis is also involved in the process — a condition referred to as epididymo-orchitis. Chronic epididymitis has been subcategorized into inflammatory chronic epididymitis, obstructive chronic epididymitis, and chronic epididymalgia (*403*).

Among sexually active men aged <35 years, acute epididymitis is most frequently caused by *C. trachomatis* or *N. gonorrhoeae*. Acute epididymitis caused by sexually transmitted enteric organisms (e.g., *Escherichia coli* and *Pseudomonas* spp.) also occurs among men who are the insertive partner during anal intercourse. Sexually transmitted acute epididymitis usually is accompanied by urethritis, which frequently is asymptomatic.

In men aged >35 years, sexually transmitted epididymitis is uncommon, whereas bacteriuria secondary to obstructive urinary disease (e.g., benign prostatic hyperplasia) is more common. In this older population, nonsexually transmitted epididymitis is associated with urinary tract instrumentation or surgery, systemic disease, and immunosuppression.

Chronic infectious epididymitis is most frequently seen in conditions associated with granulomatous reaction; *Mycobacterium tuberculosis* (TB) is the most common granulomatous disease affecting the epididymis. Up to 25% of patients can have bilateral disease, with ultrasound demonstrating an enlarged hyperemic epididymis with multiple cysts and calcifications. Tuberculous epididymitis should be suspected in all patients with a known history of or recent exposure to TB or in patients whose clinical status worsens despite appropriate antibiotic treatment.

Diagnostic Considerations

Men who have acute epididymitis typically have unilateral testicular pain and tenderness; hydrocele and palpable swelling of the epididymis usually are present. Although the inflammation and swelling usually begin in the tail of the epididymis, they can spread to involve the rest of the epididymis and testicle. The spermatic cord is usually tender and swollen. Testicular torsion, a surgical emergency, should be considered in all cases, but it occurs more frequently among adolescents and in men without evidence of inflammation or infection. Emergency testing for torsion might be indicated when the onset of pain is sudden, pain is severe, or the test results available during the initial examination do not support a diagnosis of urethritis or urinary-tract infection. If the diagnosis is questionable, a urologist should be consulted immediately because testicular viability might be compromised. Radionuclide scanning of the scrotum is the most accurate radiologic method of diagnosis, but it is not routinely available. Although ultrasound is primarily used for ruling out torsion of the spermatic cord in cases of acute scrotum swelling, it will often demonstrate epididymal hyperemia and swelling in men with epididymitis. However, differentiation between testicular torsion and epididymitis must be made on the basis of clinical evaluation, because partial spermatic cord torsion can mimic epididymitis on scrotal ultrasound. Ultrasound provides minimal utility for men with a clinical presentation consistent with epididymitis; a negative ultrasound does not alter physician management of clinical epididymitis. Ultrasound, therefore, should be reserved for patients with scrotal pain who cannot be diagnosed accurately by physical examination, history, and objective laboratory findings.

The evaluation of men for epididymitis should include one of the following:

- Gram stain of urethral secretions demonstrating ≥5 WBC per oil immersion field. Gram stain is the preferred rapid diagnostic test for evaluating urethritis because it is highly sensitive and specific for documenting both urethritis and the presence or absence of gonococcal infection. Gonococcal infection is established by documenting the presence of WBC containing intracellular Gram-negative diplococci on urethral Gram stain.
- Positive leukocyte esterase test on first-void urine or microscopic examination of first-void urine sediment demonstrating ≥10 WBC per high power field.

Culture, nucleic acid hybridization tests, and NAATs are available for the detection of both *N. gonorrhoeae* and *C. trachomatis*. Culture and nucleic acid hybridization tests require urethral swab specimens, whereas amplification tests can be performed on urine or urethral specimens. Because of their higher sensitivity, amplification tests are preferred for the detection of *C. trachomatis*. Depending on the risk, patients whose conditions are associated with acquiring an STD should receive testing for other STDs.

Treatment

Empiric therapy is indicated before laboratory test results are available. The goals of treatment of acute epididymitis caused by *C. trachomatis* or *N. gonorrhoeae* are 1) microbiologic cure of infection, 2) improvement of signs and symptoms, 3) prevention of transmission to others, and 4) a decrease in potential complications (e.g., infertility or chronic pain). As an adjunct to therapy, bed rest, scrotal elevation, and analgesics are recommended until fever and local inflammation have subsided. Because empiric therapy is often initiated before laboratory tests are available, all patients should receive ceftriaxone plus doxycycline for the initial therapy of epididymitis. Additional therapy can include a fluoroquinolone if acute epididymitis is not found to be caused by gonorrhea by NAAT or if the infection is most likely caused by enteric organisms. For men who are at risk for both sexually transmitted and enteric organisms (e.g., MSM who report insertive anal intercourse), ceftriaxone with a fluoroquinolone are recommended.

Recommended Regimens

Ceftriaxone 250 mg IM in a single dose

PLUS

Doxycycline 100 mg orally twice a day for 10 days

For acute epididymitis most likely caused by enteric organisms

Levofloxacin 500 mg orally once daily for 10 days

OR

Ofloxacin 300 mg orally twice a day for 10 days

Although most patients can be treated on an out-patient basis, hospitalization should be considered when severe pain suggests other diagnoses (e.g., torsion, testicular infarction, or abscess) or when patients are unable or unlikely to comply with an antimicrobial regimen. Because high fever is uncommon and indicates a complicated infection, these patients should be admitted for further evaluation.

Follow-Up

Patients should be instructed to return to their health-care providers if their symptoms fail to improve within 48 hours of the initiation of treatment. Signs and symptoms of epididymitis that do not subside within 3 days requires re-evaluation of the diagnosis and therapy. Swelling and tenderness that persist after completion of antimicrobial therapy should be evaluated comprehensively. Differential diagnoses include tumor, abscess, infarction, testicular cancer, TB, and fungal epididymitis.

Management of Sex Partners

Patients who have acute epididymitis that is confirmed or suspected to be caused by *N. gonorrhoeae* or *C. trachomatis* should be instructed to refer sex partners for evaluation and treatment if their contact with the index patient was within the 60 days preceding onset of their own symptoms.

Patients should be instructed to abstain from sexual intercourse until they and their sex partners have been adequately treated (i.e., until therapy is completed and patient and partners no longer have symptoms).

Special Considerations

HIV Infection

Patients who have uncomplicated acute epididymitis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative. Other etiologic agents have been implicated in acute epididymitis in HIV infection including CMV, salmonella, toxoplasmosis, *Ureaplasma urealyticum*, *Corynebacterium* sp., *Mycoplasma* sp., *and Mima polymorpha*. Fungi and mycobacteria are also more likely to cause acute epididymitis in immunosuppressed men than in immunocompetent men.

Human Papillomavirus (HPV) Infection

More than 100 types of HPV exist, more than 40 of which can infect the genital area. Most HPV infections are asymptomatic, unrecognized, or subclinical. Oncogenic, or high-risk HPV types (e.g., HPV types 16 and 18), are the cause of cervical cancers. These HPV types are also associated with other anogenital cancers in men and women, including penile, vulvar, vaginal, and anal cancer, as well a subset of oropharyngeal cancers (*404*). Nononcogenic, or low-risk HPV types (e.g., HPV types 6 and 11), are the cause of genital warts and recurrent respiratory papillomatosis. Asymptomatic genital HPV infection is common and usually self-limited; it is estimated that more than 50% of sexually active persons become infected at least once in their lifetime (*405*). Persistent oncogenic HPV infection is the strongest risk factor for development of precancers and cancers.

HPV Tests

HPV tests are available for women aged >30 years undergoing cervical cancer screening. These tests should not be used for men, for women <20 years of age, or as a general test for STDs. These HPV tests detect viral nucleic acid (i.e., DNA or RNA) or capsid protein. Four tests have been approved by the FDA for use in the United States: the HC II High-Risk HPV test (Qiagen), HC II Low-Risk HPV test (Qiagen), Cervista HPV 16/18 test, and Cervista HPV High-Risk test (Hologics).

Treatment

Treatment is directed to the macroscopic (i.e., genital warts) or pathologic (i.e, precancerous) lesions caused by infection. Subclinical genital HPV infection typically clears spontaneously, and therefore specific antiviral therapy is not recommended to eradicate HPV infection. In the absence of lesions, treatment is not recommended for subclinical genital HPV infection whether it is diagnosed by colposcopy, acetic acid application, or by laboratory tests for HPV DNA. Treatment also is not recommended for cervical intraepithelial neoplasia 1 (CIN1).

Prevention

Two HPV vaccines are licensed in the United States: a bivalent vaccine (Cervarix) containing HPV types 16 and 18 and a quadrivalent vaccine (Gardasil) vaccine containing HPV types 6, 11, 16, and 18. Both vaccines offer protection against the HPV types that cause 70% of cervical cancers (i.e., types 16 and 18), and the quadrivalent HPV vaccine also protects against the types that cause 90% of genital warts (i.e., types 6 and 11). Either vaccine can be administered to girls aged 11–12 years and can be administered to those as young as 9 years of age (*15,16);* girls and women ages 13–26 years who have not started or completed the vaccine series also should receive the vaccine. HPV vaccine is indicated for girls in this

age group, because benefit is greatest if it is administered before the onset of sexual activity. The quadrivalent (Gardasil) HPV vaccine can also be used in males aged 9–26 years to prevent genital warts (*17*). Administering the vaccine to boys before the onset of sexual activity is optimal. Both HPV vaccines are administered as a 3-dose series of IM injections over a 6-month period, with the second and third doses given 1–2 and then 6 months after the first dose. Ideally, the same vaccine product should be used for the entire 3-dose series. HPV vaccine is available for eligible children and adolescents aged <19 years through the Vaccines for Children (VFC) program (available by calling CDC INFO [800-232-4636]).

Women who have received HPV vaccine should continue routine cervical cancer screening because 30% of cervical cancers are caused by HPV types other than 16 or 18. In the United States, the vaccines are not licensed or recommended for use in women >26 years of age. No published data are available on the effectiveness, programmatic requirements, or cost-effectiveness of administering the HPV vaccine in STD clinic settings.

Genital Warts

Of genital warts, 90% are caused by HPV 6 or 11. HPV types 6 or 11 are commonly found before, or at the time of, detection of genital warts (*406*). HPV types 16, 18, 31, 33, and 35 are found occasionally in visible genital warts (usually as coinfections with HPV 6 or 11) and can be associated with foci of high-grade intraepithelial neoplasia, particularly in persons who are infected with HIV infection. In addition to warts on genital areas, HPV types 6 and 11 have been associated with conjunctival, nasal, oral, and laryngeal warts.

Genital warts are usually asymptomatic, but depending on the size and anatomic location, they can be painful or pruritic. Genital warts are usually flat, papular, or pedunculated growths on the genital mucosa. Genital warts occur commonly at certain anatomic sites, including around the introitus in women, under the foreskin of the uncircumcised penis, and on the shaft of the circumcised penis. Genital warts can also occur at multiple sites in the anogenital epithelium or within the anogenital tract (e.g., cervix, vagina, urethra, perineum, perianal skin, and scrotum). Intra-anal warts are observed predominantly in persons who have had receptive anal intercourse, but they can also occur in men and women who do not have a history of anal sexual contact.

Diagnosis of genital warts is usually clinical, made by visual inspection. Genital warts can be confirmed by biopsy, which might be indicated if 1) the diagnosis is uncertain; 2) the lesions do not respond to standard therapy; 3) the disease worsens during therapy; 4) the lesion is atypical; 5) the patient has comprised immunity; or 6) the warts are pigmented, indurated, fixed, bleeding, or ulcerated. Genital warts are usually asymptomatic, but depending on the size and anatomic location, they might be painful or pruritic. The use of HPV DNA testing for genital wart diagnosis is not recommended, because test results would not alter clinical management of the condition.

The application of 3%–5% acetic acid, which causes skin color to turn white, has been used by some providers to detect HPV-infected genital mucosa. However, acetic acid application is not a specific test for HPV infection. Therefore, the routine use of this procedure for screening to detect mucosal changes attributed to HPV infection is not recommended.

Treatment

The primary reason for treating genital warts is the amelioration of symptoms (including relieving cosmetic concerns) and ultimately, removal of the warts. In most patients, treatment can induce wart-free periods. If left untreated, visible genital warts can resolve on their own, remain unchanged, or increase in size or number. Available therapies for genital warts likely reduce, but probably do not eradicate, HPV infectivity. Whether the reduction in HPV viral DNA resulting from treatment reduces future transmission remains unclear. No evidence indicates that the presence of genital warts or their treatment is associated with the development of cervical cancer.

Regimens

Treatment of genital warts should be guided by the preference of the patient, available resources, and the experience of the health-care provider. No definitive evidence suggests that any of the available treatments are superior to any other, and no single treatment is ideal for all patients or all warts. The use of locally developed and monitored treatment algorithms has been associated with improved clinical outcomes and should be encouraged. Because of uncertainty regarding the effect of treatment on future transmission of HPV and the possibility of spontaneous resolution, an acceptable alternative for some persons is to forego treatment and wait for spontaneous resolution.

Factors that influence selection of treatment include wart size, wart number, anatomic site of the wart, wart morphology, patient preference, cost of treatment, convenience, adverse effects, and provider experience. Factors that might affect response to therapy include the presence of immunosuppression and compliance with therapy, which can consist of either a single treatment or complete course of treatment. In general, warts located on moist surfaces or in intertriginous areas respond best to topical treatment. The treatment modality

should be changed if a patient has not improved substantially after a complete course of treatment or if side effects are severe. Most genital warts respond within 3 months of therapy. The response to treatment and any side effects should be evaluated throughout the course of therapy.

Complications occur rarely when treatment is administered properly. Patients should be warned that persistent hypopigmentation or hyperpigmentation occurs commonly with ablative modalities and has also been described with immune modulating therapies (imiquimod). Depressed or hypertrophic scars are uncommon but can occur, especially if the patient has had insufficient time to heal between treatments. Rarely, treatment can result in disabling chronic pain syndromes (e.g., vulvodynia and hyperesthesia of the treatment site) or, in the case of anal warts, painful defecation or fistulas. A limited number of case reports of severe systemic effects resulting from treatment with podophyllin resin and interferon have been documented.

Treatment regimens are classified into patient-applied and provider-applied modalities. Patient-applied modalities are preferred by some patients because they can be administered in the privacy of the patient's home. To ensure that patient-applied modalities are effective, patients must comply with the treatment regimen and must be capable of identifying and reaching all genital warts. Follow-up visits are not required for persons using patient-applied therapy. However, follow-up visits after several weeks of therapy enable providers to answer any questions patients might have about the use of the medication and any side effects they have experienced; follow-up visits also facilitate the assessment of a patient's response to treatment.

Recommended Regimens for External Genital Warts

Patient-Applied:

Podofilox 0.5% solution or gel

OR

Imiquimod 5% cream

OR

Sinecatechins 15% ointment

Provider–Administered:

Cryotherapy with liquid nitrogen or cryoprobe. Repeat applications every 1–2 weeks.

OR

Podophyllin resin 10%–25% in a compound tincture of benzoin

OR

Trichloroacetic acid (TCA) or Bichloroacetic acid (BCA) 80%–90%

OR

Surgical removal either by tangential scissor excision, tangential shave excision, curettage, or electrosurgery.

Podofilox is an antimitotic drug that destroys warts, is relatively inexpensive, easy to use, safe, and self-applied. Podofilox solution should be applied with a cotton swab, or podofilox gel with a finger, to visible genital warts twice a day for 3 days, followed by 4 days of no therapy. This cycle can be repeated, as necessary, for up to four cycles. The total wart area treated should not exceed 10 cm^2, and the total volume of podofilox should be limited to 0.5 mL per day. If possible, the health-care provider should apply the initial treatment to demonstrate the proper application technique and identify which warts should be treated. Mild to moderate pain or local irritation might develop after treatment. The safety of podofilox during pregnancy has not been established.

Imiquimod is a topically active immune enhancer that stimulates production of interferon and other cytokines. Imiquimod cream should be applied once daily at bedtime, three times a week for up to 16 weeks (*407*). The treatment area should be washed with soap and water 6–10 hours after the application. Local inflammatory reactions, including redness, irritation, induration, ulceration/erosions, and vesicles, are common with the use of imiquimod, and hypopigmentation has also been described (*408*). Imiquimod might weaken condoms and vaginal diaphragms. The safety of imiquimod during pregnancy has not been established.

Sinecatechin ointment, a green-tea extract with an active product (catechins), should be applied three times daily (0.5-cm strand of ointment to each wart) using a finger to ensure coverage with a thin layer of ointment until complete clearance of warts. This product should not be continued for longer than 16 weeks (*409–411*). The medication should not be washed off after use. Sexual (i.e., genital, anal, or oral) contact should be avoided while the ointment is on the skin. The most common side effects of sinecatechins 15% are erythema, pruritis/burning, pain, ulceration, edema, induration, and vesicular rash. This medication may weaken condoms and diaphragms. No clinical data are available regarding the efficacy or safety of sinecatechins compared with other available anogenital wart treatment modalities. The medication is not recommended for HIV-infected persons, immunocompromised persons, or persons with clinical genital herpes because the safety and efficacy of therapy in these settings has not been established. The safety of sinecatechins during pregnancy also is unknown.

Cryotherapy destroys warts by thermal-induced cytolysis. Health-care providers must be trained on the proper use of this therapy because over- and undertreatment can result in complications or low efficacy. Pain after application of the liquid nitrogen, followed by necrosis and sometimes blistering, is common. Local anesthesia (topical or injected) might facilitate therapy if warts are present in many areas or if the area of warts is large.

Pedophyllin resin 10%–25% should be applied to each wart and allowed to air-dry before the treated area comes into contact with clothing; overapplication or failure to air dry can result in local irritation caused by spread of the compound to adjacent areas. The treatment can be repeated weekly, if necessary. To avoid the possibility of complications associated with systemic absorption and toxicity, two guidelines should be followed: 1) application should be limited to <0.5 mL of podophyllin or an area of <10 cm^2 of warts per session and 2) the area to which treatment is administered should not contain any open lesions or wounds. The preparation should be thoroughly washed off 1–4 hours after application to reduce local irritation. The safety of podophyllin during pregnancy has not been established. Podophyllin resin preparations differ in the concentration of active components and contaminants. The shelf life and stability of podophyllin preparations are unknown.

Both TCA and BCA are caustic agents that destroy warts by chemical coagulation of proteins. Although these preparations are widely used, they have not been investigated thoroughly. TCA solutions have a low viscosity comparable with that of water and can spread rapidly if applied excessively; therefore, they can damage adjacent tissues. A small amount should be applied only to the warts and allowed to dry before the patient sits or stands, at which time a white frosting develops. If pain is intense, the acid can be neutralized with soap or sodium bicarbonate. If an excess amount of acid is applied, the treated area should be powdered with talc, sodium bicarbonate (i.e., baking soda), or liquid soap preparations to remove unreacted acid. This treatment can be repeated weekly, if necessary.

Surgical therapy has the advantage of usually eliminating warts at a single visit. However, such therapy requires substantial clinical training, additional equipment, and a longer office visit. After local anesthesia is applied, the visible genital warts can be physically destroyed by electrocautery, in which case no additional hemostasis is required. Care must be taken to control the depth of electrocautery to prevent scarring. Alternatively, the warts can be removed either by tangential excision with a pair of fine scissors or a scalpel, by laser, or by curettage. Because most warts are exophytic, this procedure can be accomplished with a resulting wound that only extends into the upper dermis. Hemostasis can be achieved with an electrocautery unit or a chemical styptic (e.g., an aluminum chloride solution). Suturing is neither required nor indicated in most cases if surgical removal is performed properly. Surgical therapy is most beneficial for patients who have a large number or area of genital warts. Both carbon dioxide laser and surgery might be useful in the management of extensive warts or intraurethral warts, particularly for those persons who have not responded to other treatments.

Because all available treatments have shortcomings, some clinics employ combination therapy (simultaneous use of two or more modalities on the same wart at the same time). Data are limited regarding the efficacy or risk of complications associated with use of such combinations.

Alternative Regimens

Alternative regimens include treatment options that might be associated with more side effects and/or less data on efficacy. Alternative regimens include intralesional interferon, photodynamic therapy, and topical cidofovir.

Recommended Regimen for Cervical Warts

For women who have exophytic cervical warts, a biopsy evaluation to exclude high-grade SIL must be performed before treatment is initiated. Management of exophytic cervical warts should include consultation with a specialist.

Recommended Regimens for Vaginal Warts

Cryotherapy with liquid nitrogen. The use of a cryoprobe in the vagina is not recommended because of the risk for vaginal perforation and fistula formation.

OR

TCA or BCA 80%–90% applied to warts. A small amount should be applied only to warts and allowed to dry, at which time a white frosting develops. If an excess amount of acid is applied, the treated area should be powdered with talc, sodium bicarbonate, or liquid soap preparations to remove unreacted acid. This treatment can be repeated weekly, if necessary.

Recommended Regimens for Urethral Meatus Warts

Cryotherapy with liquid nitrogen

OR

Podophyllin 10%–25% in compound tincture of benzoin. The treatment area and adjacent normal skin must be dry before contact with podophyllin. This treatment can be repeated weekly, if necessary. The safety of podophyllin during pregnancy has not been established. Data are limited on the use of podofilox and imiquimod for treatment of distal meatal warts.

Recommended Regimens for Anal Warts

Cryotherapy with liquid nitrogen

OR

TCA or BCA 80%–90% applied to warts. A small amount should be applied only to warts and allowed to dry, at which time a white frosting develops. If an excess amount of acid is applied, the treated area should be powdered with talc, sodium bicarbonate, or liquid soap preparations to remove unreacted acid. This treatment can be repeated weekly, if necessary.

OR

Surgical removal

Intra-anal warts should be managed in consultation with a specialist. Many persons with warts on the anal mucosa also have warts on the rectal mucosa, so persons with anal and/or intra-anal warts might benefit from an inspection of the rectal mucosa by digital examination, standard anoscopy, or high-resolution anoscopy.

Counseling

The following key counseling messages should be conveyed to all patients diagnosed with HPV infection:

- Genital HPV infection is very common. Many types of HPV are passed on through genital contact, most often during vaginal and anal sexual contact. HPV can also be spread by oral sexual contact.
- Most sexually active adults will get HPV at some point in their lives, though most will never know it because HPV infection usually has no signs or symptoms.
- In most cases, HPV infection clears spontaneously, without causing any health problems. Nevertheless, some infections do progress to genital warts, precancers, and cancers.
- The types of HPV that cause genital warts are different from the types that can cause anogenital cancers.
- Within an ongoing sexual relationship, both partners are usually infected at the time one person is diagnosed with HPV infection, even though signs of infection might not be apparent.
- A diagnosis of HPV in one sex partner is not indicative of sexual infidelity in the other partner.
- Treatments are available for the conditions caused by HPV (e.g., genital warts), but not for the virus itself.
- HPV does not affect a woman's fertility or ability to carry a pregnancy to term.
- Correct and consistent male condom use might lower the chances of giving or getting genital HPV, but such use is not fully protective, because HPV can infect areas that are not covered by a condom.
- Sexually active persons can lower their chances of getting HPV by limiting their number of partners. However, HPV is common and often goes unrecognized; persons with only one lifetime sex partner can have the infection. For this reason, the only definitive method to avoid giving and getting HPV infection and genital warts is to abstain from sexual activity.
- Tests for HPV are now available to help providers screen for cervical cancer in certain women. These tests are not useful for screening adolescent females for cervical cancer, nor are they useful for screening for other HPV-related cancers or genital warts in men or women. HPV tests should not be used to screen:
  - men;
  - partners of women with HPV;
  - adolescent females; or
  - for health conditions other than cervical cancer.
- Two HPV vaccines are available, both of which offer protection against the HPV types that cause 70% of cervical cancers (i.e., types 16 and 18); the quadrivalent vaccine (Gardasil) also protects against the types that cause 90% of genital warts (i.e., types 6 and 11). These vaccines are most effective when all doses are administered before sexual contact. Either vaccine is recommended for 11- and 12-year-old girls and for females aged 13–26 years who did not receive or complete the vaccine series when they were younger. The quadrivalent HPV vaccine can be used in males aged 9–26 years to prevent genital warts.

The following are specific counseling messages for those persons diagnosed with genital warts and their partners:

- Genital warts are not life threatening. If left untreated, genital warts might go away, stay the same, or grow in size or number. Except in very rare and unusual cases, genital warts will not turn into cancer.
- It is difficult to determine how or when a person became infected with HPV; genital warts can be transmitted to others even when no visible signs of warts are present, even after warts are treated.
- It is not known how long a person remains contagious after warts are treated. It is also unclear whether informing subsequent sex partners about a past diagnosis of genital warts is beneficial to the health of those partners.
- Genital warts commonly recur after treatment, especially in the first 3 months.
- Women should get regular Pap tests as recommended, regardless of vaccination or genital wart history. Women with genital warts do not need to get Pap tests more often than recommended.
- HPV testing is unnecessary in sexual partners of persons with genital warts.
- If one sex partner has genital warts, both sex partners benefit from getting screened for other STDs.
- Persons with genital warts should inform current sex partner(s) because the warts can be transmitted to other partners. In addition, they should refrain from sexual activity until the warts are gone or removed.
- Correct and consistent male condom use can lower the chances of giving or getting genital warts, but such use is not fully protective because HPV can infect areas that are not covered by a condom.

- The Gardasil vaccine, which has been approved for use in males and females aged 9–26 years, protects against the HPV types that cause 90% of genital warts (i.e., types 6 and 11).

Special Considerations

Pregnancy

Imiquimod, sinecatechins, podophyllin, and podofilox should not be used during pregnancy. Genital warts can proliferate and become friable during pregnancy. Although removal of warts during pregnancy can be considered, resolution might be incomplete or poor until pregnancy is complete. Rarely, HPV types 6 and 11 can cause respiratory papillomatosis in infants and children, although the route of transmission (i.e., transplacental, perinatal, or postnatal) is not completely understood. Whether cesarean section prevents respiratory papillomatosis in infants and children also is unclear (*412*); therefore, cesarean delivery should not be performed solely to prevent transmission of HPV infection to the newborn. Cesarean delivery is indicated for women with genital warts if the pelvic outlet is obstructed or if vaginal delivery would result in excessive bleeding. Pregnant women with genital warts should be counseled concerning the low risk for warts on the larynx (recurrent respiratory papillomatosis) in their infants or children.

HIV Infection

Persons who are HIV-infected are more likely to develop genital warts then persons who are not HIV-infected (*413*); moreover, lesions are more recalcitrant to treatment due to depressed cell-mediated immunity. No data suggest that treatment modalities for external genital warts should be different for HIV-infected persons. However, persons who are immunosuppressed because of HIV or other reasons might have larger or more numerous warts, might not respond as well as immunocompetent persons to therapy for genital warts, and might have more frequent recurrences after treatment (*414–416*). Squamous cell carcinomas arising in or resembling genital warts might occur more frequently among immunosuppressed persons, therefore requiring biopsy for confirmation of diagnosis for suspicious cases. Because of the increased incidence of anal cancer in HIV-infected MSM, screening for anal intraepithelial neoplasia by cytology can be considered (*417*). However, evidence is limited concerning the natural history of anal intraepithelial neoplasias, the reliability of screening methods, the safety and response to treatments, and the programmatic considerations that would support this screening approach.

Squamous Cell Carcinoma in Situ

Persons in whom squamous cell carcinoma in situ of the genitalia is diagnosed should be referred to a specialist for treatment. Ablative modalities usually are effective, but careful follow-up is essential for patient management.

Cervical Cancer Screening for Women Who Attend STD Clinics or Have a History of STDs

Women attending STD clinics for the treatment of genital infection with high-risk types of Human Papillomavirus (HR-HPV) might be at increased risk for cervical cancer; persistence of HR-HPV can cause cervical cancer and its precancerous lesions. One study demonstrated an HR-HPV prevalence of 27% among women receiving treatment in an STD clinic setting; prevalence was highest among persons aged 14–19 and decreased with increasing age (*418*). In an evaluation of women attending STD clinics, over half of women were at increased risk for cervical cancer as a result of HPV infection, cervical disease, or history of cervical disease compared with women without these characteristics (*419*).

Cervical cytology (i.e., a Pap test) is an effective, low-cost screening test for preventing invasive cervical cancer. In a 2004 survey, 49% of all STD clinics in the United States reported providing cervical screening services, and 20% reported use of HPV DNA testing (*419*).

Current guidelines from USPSTF and ACOG recommend that cervical screening begin at age 21 years (*96*,*97*). This recommendation is based on the low incidence of cervical cancer and limited utility of screening in younger women (*98*). ACS recommends that women start cervical screening with Pap tests after 3 years of initiating sexual activity but by no later than age 21 years (*98*). Recommended screening intervals (http://www.cdc.gov/cancer/cervical/pdf/guidelines.pdf) should continue through 65 years according to USPSTF (http://www.ahrq.gov/clinic/uspstf/uspscerv.htm) or 70 years according to ACS (http://cancer.org/docroot/ped/content/ped_2_3x_acs_cancerdetection_guidelines_36.asp).

Screening Recommendations

STD clinics that provide routine cervical screening services should follow the available guidelines. However, to ensure the provision of adequate care, follow-up and referral sources must be in place. Cervical screening should be performed using either conventional or liquid-based cytologic tests (i.e., Pap tests) and can include HR-HPV DNA tests in specific circumstances (*420*). For cythopathologic and HPV/DNA

testing, STD clinics should use CLIA certified laboratories (*421*) and those that report cytopathology findings according to the following Bethesda 2001 terminology (*422*): atypical squamous cells (ASC), low-grade squamous intraepithelial lesions (LSIL), and high-grade intraepithelial lesions (HSIL). The ASC category is subdivided into atypical squamous cells of undetermined significance (ASC-US) and atypical squamous cells—cannot exclude HSIL (ASC-H).

During appointments in which a pelvic examination for STD screening is performed, the health-care provider should inquire about the result of the patient's most recent Pap test and discuss the following information with the patient:

- the purpose and importance of a Pap test;
- the need for regularly scheduled Pap tests between 21–65 years of age;
- whether a Pap test will be obtained during this clinic visit; and
- if a Pap test will not be obtained during this examination, the names of local providers or referral clinics that can perform Pap tests and adequately follow up results.

If a woman has not had a Pap test during the previous 12 months (2-year intervals for women aged 21–29 years and 3-year intervals for women aged ≥30 years with a history of three normal Pap tests) and cervical screening is indicated, a Pap test should be obtained as part of the routine pelvic examination. Health-care providers should be aware that many women frequently equate having a pelvic examination with having a Pap test; they erroneously believe that a sample for Pap testing was taken, when in reality, only a pelvic examination was performed. Because self-reports of Pap tests often are not accurate, STD clinics should have a protocol for conducting cervical cancer screening and obtaining a Pap test during the routine clinical evaluation of women who do not have clinical-record documentation of a normal Pap test within the preceding 12 months and do not have another provider for screening services.

HPV Tests

HPV tests are available for clinical use and are recommended for the triage of women aged ≥21 years who have abnormal Pap test results (ASC-US). Additionally, these tests can be used in conjunction with a Pap test (adjunct testing) for cervical cancer screening of women aged ≥30 years. These tests should not be used for women aged <20 years for screening or management of abnormal Pap tests or for STD screening. Current FDA-approved HPV tests detect viral nucleic acid (DNA). Several FDA-approved tests for high-risk HPV testing are available for use in the United States. The Hybrid Capture 2 High-Risk HPV DNA test (Qiagen, Gaithersburg, Maryland) and the Cervista HPV High-Risk test (Hologics, Beford, Massachusetts) detect any of 13–14 high-risk HPV types, whereas the Cervista HPV 16/18 test detects type-specific infection with HPV types 16 and 18. The Digene HC2 HPV DNA test (Qiagen, Gaithersburg, Maryland) detects any of 13 high-risk or five low-risk HPV types, although use of this test is not indicated in the STD clinic setting (i.e., only high-risk HPV DNA testing is necessary) (*423*).

High-risk HPV DNA tests are recommended for the triage of women aged ≥21 years who have ASC-US cytology results. In addition, these tests are recommended for routine adjunctive testing (along with cervical cytology) used to screen women aged ≥30 years (*424*).

HPV DNA testing (including HR HPV and HPV 16/18 tests) is not recommended for the following situations (*425–427*):

- deciding whether to vaccinate for HPV;
- conducting STD screening for HPV;
- triaging LSIL;
- testing adolescents aged <21 years; and
- screening for primary cervical cancer as a stand-alone test (i.e., without a Pap test).

Women might benefit from receiving printed information about the value of and indication for cervical cancer screening (i.e., Pap testing), and they should be provided a clinic visit report that states whether a Pap test was obtained during the clinic visit. When available, a copy of the Pap test result should be provided. Women with abnormal screening or diagnostic tests should be referred to clinic settings that employ providers who are experienced in managing these cases (see Follow-Up). Cervical screening programs should screen women who have received HPV vaccination in the same manner as unvaccinated women.

Follow-Up

Among women aged ≥30 years with normal Pap tests and negative tests for HR-HPV, the screening interval can be increased to 3 years. At that time, routine testing with either a Pap test or a Pap and HR-HPV testing can resume (*428*).

If the results of the Pap test are abnormal, follow-up care should be provided according to the *ASCCP 2006 Consensus Guidelines for Management of Abnormal Cervical Cytology* (*429*) (information regarding management and follow-up care is available at http://www.asccp.org). If resources in STD clinics do not allow for follow-up of women with abnormal results, protocols for referral for follow-up and case management should be in place.

- According to American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines, women with Pap tests results indicating ASC-H, low- or high-grade

squamous intraepithelial lesion should be referred to a clinician who can perform a colposcopic examination of the lower genital tract and, if indicated, conduct a colposcopically directed biopsy. For women aged <21 years, referral to colposcopy for ASC-US and LSIL is not recommended, because rates of spontaneous clearance are high in this population; repeat Pap testing at 12 and 24 months is recommended for these women.

- For women aged ≥21 years with a Pap test report of ASC-US, three options are available for follow-up management: 1) prompt colposcopy, 2) repeat Pap tests at 6 and 12 months, and 3) a high-risk HR HPV DNA test. Colposcopy is appropriate if the provider has concerns about adherence with recommended follow-up or concerns about other clinical indications. High-grade histological changes (i.e., CIN 2 or higher) after colposcopic evaluation for ASC-US Pap test reports is typically detected in <12% of cases. If repeat Pap tests are used (instead of prompt colposcopy) to follow ASC-US results, tests should be performed at 6- and 12-month intervals until two consecutive negative results are noted, at which time cervical cancer screening at a normal interval for age can be resumed. If subsequent Pap tests demonstrate ASC or a more serious condition, follow-up should be conducted according to ASCCP 2006 Consensus Guidelines (*424*). A third strategy for managing patients with ASC-US Pap test results involves testing for high-risk HPV DNA (*423*,*424*,*430*,*431*). Whereas conducting high-risk HPV testing might not be possible in some STD clinics because of resource limitations, such testing might be appropriate in other public health clinic settings. HPV tests that detect low-risk HPV types are not recommended for use in STD clinics, because they are not beneficial in this setting.
- If indicated, high-risk HPV DNA testing can be performed by 1) collecting a specimen for Pap test and HPV DNA on the same swab, 2) using a supplied swab at the time of the Pap test, if conventional cytology is used, 3) reflex testing (if liquid-based cytology is used and enough residual material is available in the cytology test vial), or 4) scheduling a separate follow-up appointment when the Pap test report results are known. If the high-risk HPV DNA test is negative, a repeat Pap test should be performed at 12 months. If the test is positive, the patient should be referred immediately for colposcopy, and if indicated, directed cervical biopsy.

Because many public health clinics (including most STD clinics) cannot provide clinical follow-up of abnormal Pap tests, women with Pap tests demonstrating low- or high-grade SIL or ASC-US usually need a referral to other local health-care providers or clinics for colposcopy and biopsy. Clinics and health-care providers who offer cervical screening services but cannot provide appropriate colposcopic follow-up of abnormal Pap tests should arrange referral to health-care facilities that will promptly evaluate and treat patients and report evaluation results to the referring clinic or health-care provider. Clinics and health-care providers should develop protocols that identify women who miss follow-up appointments so that these women can be located and scheduled for needed studies and management, and they should reevaluate these protocols routinely. Pap-test results, type and location of follow-up appointments, and results of follow-up appointment should be clearly documented in the clinic record. The establishment of colposcopy and biopsy services in local health departments, especially in circumstances in which referrals are difficult and follow-up is unlikely, should be considered if resources are available.

Other Management Considerations

The following additional considerations are associated with performing Pap tests:

- The Pap test should not be considered a screening test for STDs.
- All women receiving care in an STD-clinic setting should be considered for cervical cancer screening, regardless of sexual orientation (i.e., heterosexual women and those who identify themselves as lesbian or bisexual).
- If a woman is menstruating, a conventional cytology Pap test should be postponed, and the woman should be advised to have a Pap test at the earliest opportunity.
- If specific infections other than HPV are identified, the patient might need to have a repeat Pap test after appropriate treatment for those infections. However, in most instances (even in the presence of some severe infections), Pap tests will be reported as satisfactory for evaluation, and reliable final reports can be produced without the need to repeat the Pap test after treatment is received.
- When it is necessary to repeat the Pap test because the report was interpreted as unsatisfactory, the repeat test must be determined by the laboratory to be satisfactory and negative before screening can be resumed at regularly scheduled intervals.
- The presence of a mucopurulent discharge should not delay the Pap test. The test can be performed after careful removal of the discharge with a saline-soaked cotton swab.

- In the absence of other indications, women who have external genital warts do not need Pap tests more frequently than women who do not have warts.
- The sequence of Pap testing in relation to collection of other cervicovaginal specimens has not been shown to influence Pap test results or their interpretation (*432*).
- Women who have had a total hysterectomy do not require a routine Pap test unless the hysterectomy was performed because of cervical cancer or its precursor lesions. As recommended by ACOG, for women with hysterectomy resulting from CIN 2 or higher, cervical or vaginal cuff screening can be discontinued once three normal Pap tests have been documented. In these situations, women should be advised to continue follow-up with the physician(s) who provided health care at the time of the hysterectomy, if possible. In women whose cervix remains intact after a hysterectomy, regularly scheduled Pap tests should be performed as indicated (*433–435*).
- Health-care providers who receive basic retraining on Pap-test collection and clinics that use simple quality assurance measures are more likely to obtain satisfactory test results as determined by the laboratory. The use of cytobrushes and brooms also improves the number of satisfactory Pap tests.
- Although evidence supports the option of HPV testing for the triage of women with ASC-US Pap test results, this option might not be feasible in an STD clinic because of limited resources.
- Liquid-based cytology is an acceptable alternative to conventional Pap tests, as it has similar test-performance characteristics.

Special Considerations

Pregnancy

Pregnant women should be screened at the same frequency as nonpregnant women; however, recommendations for management differ in this population (*83*,*84*,*424*). A swab and an Ayre's spatula can be used for obtaining Pap tests in pregnant women, but cytobrushes are not recommended.

HIV Infection

Several studies have documented an increased prevalence of SIL in HIV-infected women (*416*,*436*). The following recommendations for Pap test screening among HIV-infected women are consistent with most of the guidelines published by the U.S. Department of Health and Human Services (HHS) (*129*) and are based partially on the opinions of professionals knowledgeable about the care and management of cervical cancer and HIV infection in women.

HIV-positive women should be provided cervical cytology screening twice (every 6 months) within the first year after initial HIV diagnosis and, if both tests are normal, annual screening can be resumed thereafter. HIV-positive women with ASC-H, LSIL, or HSIL on cytologic screening should undergo colposcopic evaluation. Recommendations for management of HIV-positive women with ASC-US vary. HHS recommends a more conservative management approach (i.e., immediate colposcopy), whereas ASCCP recommends that these women be managed like HIV-negative women with ASC-US (i.e., tested for HR HPV DNA) (*424*,*429*).

Adolescents

Prevalence of HR HPV is high among adolescents aged <21 years (*425*). Infections in adolescent patients tend to clear rapidly, and lesions caused by these infections also have high rates of regression to normal. Therefore, ASCCP and ACOG recommend that adolescents with ASC-US or low-grade SIL be managed with repeat cytologic testing at 12 months and 24 months. Only those with HSIL at either follow-up visit or persistence of ASC-US or LSIL at 24 months should be referred for colposcopic evaluation.

Counseling Messages for Women Receiving Cervical Cancer Screening and HPV Testing

When a woman receives abnormal cervical cytology test results, she might experience considerable anxiety, distress, fear, and confusion, which can serve as barriers to follow-up care. Furthermore, a positive HPV DNA test result might exacerbate these feelings and might also elicit partner concerns, worry about disclosure, and feelings of guilt, anger, and stigmatization.

Health-care providers are the most trusted source of information about HPV and abnormal cervical cytology test results. Therefore, they have an important role to play in educating women about high-risk HPV and moderating the psychosocial impact of the diagnosis.

STD clinic providers should offer patients counseling and information both verbally and in print when delivering HPV and Pap test results. Print materials are available at several websites (http://www.cdc.gov/std/hpv/common/; http://www.ashastd.org/hpv/hpv_publications.cfm). The manner in which this information is communicated to patients can influence the psychological effect of this diagnosis, as well as a woman's likelihood of following up with necessary testing or treatment. Providers should frame high-risk HPV in a neutral, nonstigmatizing context and emphasize its common, asymptomatic, and transient nature. Also, the provider should emphasize that

HPV is often shared between partners and can lie dormant for many years; having HPV does not imply infidelity, nor should it necessarily raise concerns about a partner's health.

In counseling women with high-risk HPV infections about partner management, messages should be tailored to the individual woman's circumstances. While no evidence supports either partner notification (PN) or clinical-evaluation referral for partners of patients with high-risk HPV, some women might benefit from having an informed discussion about their diagnosis with their partners. This type of communication can foster partner support and ensure the sharing of information that can inform decision-making (e.g., decisions regarding condom use).

The following specific key messages should be communicated to patients receiving cervical screening:

- The purpose of regular, lifelong cervical cancer screening is to identify cervical cancer precursors, which can be treated before progression to cervical cancer.
- A positive high-risk HPV DNA test or an abnormal cervical cytology test is not indicative of cervical cancer. Appropriate follow-up is necessary to ensure that cervical abnormalities do not progress.
- Some women might have a normal Pap test and a positive high-risk HPV test. A positive high risk HPV DNA test indicates a HPV infection of the cervix, but does not indicate cervical cancer. A normal cervical cytology test indicates that no cellular abnormalities were detected at the time of testing, but women who have HPV infection of the cervix have a higher likelihood of developing cell changes, which could lead to cervical cancer over time. Follow-up evaluation is essential to monitor cervical cytology.
- A Pap test that reveals ASC-US indicates some abnormal areas on the cervix that may require close follow-up or treatment so that they do not progress. Additional testing might be required to confirm these results. It is essential that patients return for all follow-up appointments and recommended tests.

Discussion concerning disclosure of a positive high-risk HPV test to sex partners might be appropriate and can include the following information:

- HPV is very common. It can infect the genital areas of both men and women. It usually has no signs or symptoms.
- Most sexually active persons get HPV at some time in their lives, though most will never know it. Even persons with only one lifetime sex partner can get HPV if their partner was infected.
- While the immune system clears HPV infection most of the time, in some persons, HPV infection does not resolve.
- No clinically validated test exists for men to determine if they have HPV infection. The most common manifestation of HPV infection in men is genital warts. High-risk HPV types seldom cause genital warts.
- Partners who are in a long-term relationship tend to share HPV. Sexual partners of HPV-infected patients also likely have HPV, even though they might have no signs or symptoms of infection.
- Detection of high-risk HPV infection in a woman does not mean that the woman or her partner is engaging in sexual activity outside of a relationship. HPV infection can be present for many years before it is detected, and no method can accurately confirm when HPV infection was acquired.

Prevention measures for current and subsequent sex partners and risk reduction should be discussed. Providers should counsel women about condom use depending on their current circumstances. Consistent condom use by male partners of sexually active women can reduce the risk for cervical and vulvovaginal HPV infection (*25*), and condom use by couples in long-term partnerships might decrease the time required to clear HPV in the infected woman. Skin not covered by a condom remains vulnerable to HPV infection. HPV vaccines are available and recommended for girls and young women aged 9–26 years, even those who have been diagnosed with HPV infection. Male partners can be vaccinated with the quadrivalent vaccine (Gardasil) to prevent genital warts.

Vaccine-Preventable STDs

Several STDs can be effectively prevented through preexposure vaccination with widely available vaccines, including HAV, HBV, and HPV. Vaccines for other STDs (e.g., HIV and HSV) are under development or are undergoing clinical trials. This guidance focuses largely on integrating the use of available vaccines into STD prevention and treatment activities.

Every person being evaluated or treated for an STD should receive hepatitis B vaccination unless already vaccinated. In addition, some persons (e.g., MSM and IDUs) should receive hepatitis A vaccination.

Hepatitis A

Hepatitis A, caused by infection with HAV, has an incubation period of approximately 28 days (range: 15–50 days). HAV replicates in the liver and is shed in high concentrations in feces from 2 weeks before to 1 week after the onset of clini-

cal illness. HAV infection produces a self-limited disease that does not result in chronic infection or chronic liver disease (CLD). However, 10%–15% of patients experience a relapse of symptoms during the 6 months after acute illness. Acute liver failure from hepatitis A is rare (overall case-fatality rate: 0.5%). The risk for symptomatic infection is directly related to age, with >80% of adults having symptoms compatible with acute viral hepatitis and most children having either asymptomatic or unrecognized infection. Antibody produced in response to HAV infection persists for life and confers protection against reinfection.

HAV infection is primarily transmitted by the fecal-oral route, by either person-to-person contact or through consumption of contaminated food or water. Although viremia occurs early in infection and can persist for several weeks after onset of symptoms, bloodborne transmission of HAV is uncommon. HAV occasionally is detected in saliva in experimentally infected animals, but transmission by saliva has not been demonstrated.

In the United States, almost half of all persons with hepatitis A report having no risk factor for the disease. Among adults with identified risk factors, most cases occur among international travelers, household or sexual contacts, nonhousehold contacts (e.g., those encountered through play and daycare), and IDUs (*437*). Because transmission of HAV during sexual activity probably results from fecal-oral contact, measures typically used to prevent the transmission of other STDs (e.g., use of condoms) do not prevent HAV transmission. In addition, efforts to promote good personal hygiene have not been successful in interrupting outbreaks of hepatitis A. Vaccination is the most effective means of preventing HAV transmission among persons at risk for infection (e.g., MSM, illegal drug users, and persons with CLD), many of whom might seek services in STD clinics.

Diagnosis

The diagnosis of hepatitis A cannot be made on clinical grounds alone; serologic testing also is required. The presence of IgM antibody to HAV is diagnostic of acute HAV infection. A positive test for total anti-HAV indicates immunity to HAV infection but does not differentiate current from previous HAV infection. Although usually not sensitive enough to detect the low level of protective antibody after vaccination, anti-HAV tests also might be positive after hepatitis A vaccination.

Treatment

Patients with acute hepatitis A usually require only supportive care, with no restrictions in diet or activity. Hospitalization might be necessary for patients who become dehydrated because of nausea and vomiting and is critical for patients with signs or symptoms of acute liver failure. Medications that might cause liver damage or are metabolized by the liver should be used with caution among persons with hepatitis A.

Prevention

Two products are available for the prevention of HAV infection: hepatitis A vaccine (Table 2) and immune globulin (IG) for IM administration. Hepatitis A vaccines are prepared from formalin-inactivated, cell-culture–derived HAV and have been available in the United States since 1995, initially for persons aged ≥2 years. In 2005, the vaccines were approved by FDA for persons aged ≥12 months, and the vaccine is available for eligible children and adolescents aged <19 years through the VFC program (telephone: 800-232-4636).

Administered IM in a 2-dose series at 0 and 6–12 months, these vaccines induce protective antibody levels in virtually all adults. By 1 month after the first dose, 94%–100% of adults have protective antibody levels; 100% of adults develop protective antibody after a second dose. In randomized controlled trials, the equivalent of 1 dose of hepatitis A vaccine administered before exposure has been 94%–100% effective in preventing clinical hepatitis A (*2*). Kinetic models of antibody decline indicate that protective levels of antibody persist for at least 20 years.

IG is a sterile solution of concentrated immunoglobulins prepared from pooled human plasma processed by cold ethanol fractionation. In the United States, IG is produced only from plasma that has tested negative for hepatitis B surface antigen, antibodies to HIV and HCV, and HCV RNA. In addition, the process used to manufacture IG inactivates viruses (e.g., HBV, HCV, and HIV). When administered IM before or within 2 weeks after exposure to HAV, IG is >85% effective in preventing HAV infections.

A combined hepatitis A and hepatitis B vaccine has been developed and licensed for use as a 3-dose series in adults aged ≥18 years (Table 3). When administered IM on a 0-, 1-, and 6-month schedule, the vaccine has equivalent immunogenicity to that of the monovalent vaccines.

Pre-exposure Vaccination

Persons in the following groups who are likely to be treated in STD clinic settings should be offered hepatitis A vaccine: 1) all MSM; 2) illegal drug users (of both injection and noninjection drugs); and 3) persons with CLD, including persons with chronic HBV and HCV infection who have evidence of CLD.

Prevaccination Serologic Testing for Susceptibility

Approximately one third of the U.S. population has serologic evidence of previous HAV infection, which increases

TABLE 2. Recommended regimens: dose and schedule for hepatitis A vaccines

Vaccine	Age (yrs)	Dose	Volume (mL)	Two-dose schedule (months)*
HAVRIX†	1–18	720 (EL.U.)	0.5	0 (6–12)
	>18	1,440 (EL.U.)	1.0	0 (6–12)
VAQTA§	1–18	25 (U)	0.5	0 (6–18)
	>18	50 (U)	1.0	0 (6–18)

Source: CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(No. RR-7).
Abbreviations: EL.U = Enzyme-linked immunosorbent assay (ELISA) units; U = units.
* 0 months represents timing of the initial dose; subsequent numbers represent months after the initial dose.
† Hepatitis A vaccine, inactivated, GlaxoSmithKline Biologicals; this vaccine is also licensed for a 3-dose series in children aged 2–18 years, with 360 EL.U, 0.5 mL doses at 0, 1, and 6–12 months.
§ Hepatitis A vaccine, inactivated, Merck & Co., Inc.

with age and reaches 75% among persons aged >70 years. Screening for HAV infection might be cost-effective in populations where the prevalence of infection is likely to be high (e.g., persons aged >40 years and persons born in areas of high HAV endemicity). The potential cost-savings of testing should be weighed against the cost and the likelihood that testing will interfere with initiating vaccination. Vaccination of a person who is already immune is not harmful.

Postvaccination Serologic Testing

Postvaccination serologic testing is not indicated because most persons respond to the vaccine. In addition, the commercially available serologic test is not sensitive enough to detect the low, but protective, levels of antibody produced by vaccination.

Postexposure Prophylaxis

Persons who recently have been exposed to HAV and who previously have not received hepatitis A vaccine should be administered a single dose of single-antigen vaccine or IG (0.02 mL/kg) as soon as possible. Information about the relative efficacy of vaccine compared with IG postexposure is limited, and no data are available for persons aged >40 years or those with underlying medical conditions. Therefore, decisions to use vaccine or IG should take into account patient characteristics associated with more severe manifestations of hepatitis A, including older age and CLD.

For healthy persons aged 12 months to 40 years, single-antigen hepatitis A vaccine at the age-appropriate dose is preferred over IG because of vaccine advantages, including long-term protection and ease of administration. For persons aged >40 years, IG is preferred because of the absence of information regarding vaccine performance and the more severe manifestations of hepatitis A in this age group; vaccine can be used if IG cannot be obtained. The magnitude of the risk for HAV transmission from the exposure should be considered in decisions to use IG or vaccine. IG should be used for children aged <12 months, immunocompromised persons, persons who have had diagnosed CLD, and persons for whom vaccine is contraindicated.

If IG is administered to persons for whom hepatitis A vaccine also is recommended, a dose of vaccine should be provided simultaneously with IG. The second vaccine dose should be administered according to the licensed schedule to complete the series. The efficacy of IG or vaccine when administered >2 weeks after exposure has not been established (*438*).

Special Considerations

Limited data indicate that vaccination of persons with CLD and of persons with advanced HIV infection results in lower seroprotection rates and antibody concentrations (*4*). In HIV-infected persons, antibody response might be directly related to CD4+ levels.

Hepatitis B

Hepatitis B is caused by infection with the hepatitis B virus (HBV). The incubation period from the time of exposure to onset of symptoms is 6 weeks to 6 months. The highest concentrations of HBV are found in blood, with lower concentrations found in other body fluids including wound exudates, semen, vaginal secretions, and saliva (*439*,*440*). HBV is more infectious and relatively more stable in the environment than other bloodborne pathogens like HCV and HIV.

HBV infection can be self-limited or chronic. In adults, only approximately half of newly acquired HBV infections are symptomatic, and approximately 1% of reported cases result in acute liver failure and death. Risk for chronic infection is inversely related to age at acquisition; approximately 90% of infected infants and 30% of infected children aged <5 years become chronically infected, compared with 2%–6% of persons who become infected as adults. Among persons with chronic HBV infection, the risk for premature death from cirrhosis or hepatocellular carcinoma (HCC) is 15%–25%.

HBV is efficiently transmitted by percutaneous or mucous membrane exposure to blood or body fluids that contain blood. The primary risk factors associated with infection among adolescents and adults are unprotected sex with an infected partner, unprotected sex with more than one partner, MSM, history of other STDs, and illegal injection-drug use. In addition, several studies have demonstrated the horizontal transmission of HBV, including through premastication, as a less common source of transmission (*441*,*442*).

TABLE 3. Recommended doses of currently licensed formulations of adolescent and adult hepatitis B vaccines

	Single-antigen vaccine				Combination vaccine	
	Recombivax HB		Engerix-B		Twinrix*	
Group	Dose (μg)†	Volume (mL)	Dose (μg)†	Volume (mL)	Dose (μg)†	Volume (mL)
Adolescents aged 11–19 years§	5	0.5	10	0.5	NA	NA
Adolescents aged 11–15 years¶	10	1.0	NA	NA	NA	NA
Adults (aged ≥20 years)	10	1.0	20	1.0	20	1.0
Hemodialysis patients and other immunocompromised persons aged < 20 years§	5	0.5	10	0.5	NA	NA
Hemodialysis patients and other immunocompromised persons aged ≥20 years	40**	1.0	40††	2.0	NA	NA

Sources: CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: immunization of infants, children, and adolescents. MMWR 2005;54(No. RR-16). CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: immunization of adults. MMWR 2006;55(No. RR-16).

* Combined hepatitis A and hepatitis B vaccine. This vaccine is recommended for persons aged ≥18 years who are at increased risk for both hepatitis B and hepatitis A virus infections.

† Recombinant hepatitis B surface antigen protein dose, in micrograms.

§ Pediatric formulation administered on a 3-dose schedule; higher doses might be more immunogenic, but no specific recommendations have been made.

¶ Adult formulation administered on a 2-dose schedule.

** Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.

†† Two 1.0-mL doses of the adult formulation administered at one site on a 4-dose schedule at 0, 1, 2, and 6 months.

CDC's national strategy to eliminate transmission of HBV infection includes 1) prevention of perinatal infection through routine screening of all pregnant women for HBsAg and immunoprophylaxis of infants born to HBsAg-positive mothers or mothers whose HBsAg status is unknown, 2) routine infant vaccination, 3) vaccination of previously unvaccinated children and adolescents through age 18 years, and 4) vaccination of previously unvaccinated adults at increased risk for infection (*3*,*4*). High vaccination coverage rates, with subsequent declines in acute hepatitis B incidence, have been achieved among infants and adolescents (*4*,*437*,*443*). In contrast, vaccination coverage among most high-risk adult groups (e.g., persons with more than one sex partner in the previous 6 months, MSM, and IDUs) has remained low, and most new infections occur in these high-risk groups (*3*,*108*,*444–446*). STD clinics and other settings that provide services to high-risk adults are ideal sites in which to provide hepatitis B vaccination to adults at risk for HBV infection. All unvaccinated adults seeking services in these settings should be assumed to be at risk for hepatitis B and should be offered hepatitis B vaccination.

Diagnosis

Diagnosis of acute or chronic HBV infection requires serologic testing (Table 4). Because HBsAg is present in both acute and chronic infection, the presence of IgM antibody to hepatitis B core antigen (IgM anti-HBc) is diagnostic of acute or recently acquired HBV infection. Antibody to HBsAg (anti-HBs) is produced after a resolved infection and is the only HBV antibody marker present after vaccination. The presence of HBsAg and total anti-HBc, with a negative test for IgM anti-HBc, indicates chronic HBV infection. The presence of anti-HBc alone might indicate a false-positive result or acute, resolved, or chronic infection.

Treatment

No specific therapy is available for persons with acute hepatitis B; treatment is supportive. Persons with chronic HBV infection should be referred for evaluation to a physician experienced in the management of CLD. Therapeutic agents cleared by FDA for treatment of chronic hepatitis B can achieve sustained suppression of HBV replication and remission of liver disease in some persons. In addition, patients with chronic hepatitis B might benefit from screening to detect HCC at an early stage.

Prevention

Two products have been approved for hepatitis B prevention: hepatitis B immune globulin (HBIG) and hepatitis B vaccine (*3*,*4*). HBIG provides temporary (i.e., 3–6 months) protection from HBV infection and is typically used as PEP either as an adjunct to hepatitis B vaccination in previously unvaccinated persons or alone in persons who have not responded to vaccination. HBIG is prepared from plasma known to contain high concentrations of anti-HBs. The recommended dose of HBIG is 0.06 mL/kg.

Hepatitis B vaccine contains HBsAg produced in yeast by recombinant DNA technology and provides protection from HBV infection when used for both pre-exposure vaccination and PEP. The two available monovalent hepatitis B vaccines for use in adolescents and adults are Recombivax HB (Merck and Co., Inc., Whitehouse Station, New Jersey) and Engerix-B (GlaxoSmithKline Biologicals, Pittsburgh, Pennsylvania). A combination vaccine (hepatitis A and hepatitis B) for use in

TABLE 4. Interpretation of serologic test results* for HBV infection

Serologic marker				
HBsAg†	Total anti-HBc§	IgM¶ anti-HBc	Anti-HBs**	Interpretation
–	–	–	–	Never infected
+††	–	–	–	Early acute infection; transient (up to 18 days) after vaccination
+	+	+	–	Acute infection
–	+	+	–	Acute resolving infection
–	+	–	+	Recovered from past infection and immune
+	+	–	–	Chronic infection
–	+	–	–	False positive (i.e., susceptible); past infection; "low-level" chronic infection§§; passive transfer to infant born to HBsAg-positive mother
–	–	–	+	Immune if concentration is >10 mIU/mL,¶¶ passive transfer after HBIG administration

* Symbol for negative test result, "–"; symbol for positive test result, "+".
† Hepatitis B surface antigen.
§ Antibody to hepatitis B core antigen.
¶ Immunoglobulin M.
** Antibody to HBsAg.
†† To ensure that an HBsAg-positive test result is not a false positive, samples with repeatedly reactive HBsAg results should be tested with an FDA-cleared (and, if appropriate, neutralizing confirmatory) test.
§§ Persons positive for only anti-HBc are unlikely to be infectious except under unusual circumstances involving direct percutaneous exposure to large quantities of blood (e.g., blood transfusion and organ transplantation).
¶¶ Milli-International Units per milliliter.

adults, Twinrix (GlaxoSmithKline Biologicals, Pittsburgh, Pennsylvania), also is available. The recommended HBV dose varies by product and age of recipient (Table 3).

When selecting a hepatitis B vaccination schedule, the health-care provider should consider the need to achieve completion of the vaccine series. Approved adolescent and adult schedules for both monovalent hepatitis B vaccine (i.e., Engerix-B and Recombivax HB) include the following: 0, 1, and 6 months; 0, 1, and 4 months; and 0, 2, and 4 months. A 4-dose schedule of Engerix-B at 0, 1, 2, and 12 months is licensed for all age groups. A 2-dose schedule of Recombivax HB adult formulation (10 μg) is licensed for adolescents aged 11–15 years. When scheduled to receive the second dose, adolescents aged >15 years should be switched to a 3-dose series, with doses two and three consisting of the pediatric formulation (5 μg) administered on an appropriate schedule. Twinrix can be administered to persons aged ≥18 years at risk for both HAV and HBV infections at 0, 1, and 6 months.

Hepatitis B vaccine should be administered IM in the deltoid muscle and can be administered simultaneously with other vaccines. For adolescents and adults, the needle length should be 1–2 inches, depending on the recipient's weight (1 inch for females weighing <70 kg, 1.5 inches for males weighing <120 kg, and 2 inches for males and females weighing >120 kg and >100 kg, respectively). A 22- to 25-gauge needle is recommended. If the vaccine series is interrupted after the first or second dose of vaccine, the missed dose should be administered as soon as possible. The series does not need to be restarted after a missed dose.

In adolescents and healthy adults aged <40 years, approximately 30%–55% acquire a protective antibody response (anti-HBs ≥10 mIU/mL) after the first vaccine dose, 75% after the second, and >90% after the third. Vaccine-induced immune memory has been demonstrated to persist for at least 15–20 years. Periodic testing to determine antibody levels after routine vaccination in immunocompetent persons is not necessary, and booster doses of vaccine are not currently recommended.

Hepatitis B vaccination is generally well-tolerated by most recipients. Pain at the injection site and low-grade fever are reported by a minority of recipients. For children and adolescents, a causal association exists between receipt of hepatitis B vaccination and anaphylaxis: for each 1.1 million doses of vaccine administered, approximately one vaccinee will experience this type of reaction. No deaths have been reported in these patients (*3,4,447*). Vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of hepatitis B vaccine and in persons with a known anaphylactic reaction to any vaccine component. No evidence for a causal association has been demonstrated for other adverse events after administration of hepatitis B vaccine.

Pre-exposure Vaccination

Hepatitis B vaccination is recommended for all unvaccinated adolescents, all unvaccinated adults at risk for HBV infection, and all adults seeking protection from HBV infection. For adults, acknowledgement of a specific risk factor is not a requirement for vaccination.

Hepatitis B vaccine should be routinely offered to all unvaccinated persons attending STD clinics and to all unvaccinated persons seeking treatment for STDs in other settings. Other settings where all unvaccinated adults should be assumed to be at risk for hepatitis B and should receive hepatitis B vaccination

include correctional facilities, facilities providing drug abuse treatment and prevention services, health-care settings serving MSM, and HIV testing and treatment facilities. All persons who receive clinical services in these settings should be offered hepatitis B vaccine unless they have a reliable vaccination history (i.e., a written, dated record of each dose of a complete series). In all settings, vaccination should be initiated even when completion of the vaccine series cannot be ensured.

Prevaccination Antibody Screening

Prevaccination serologic testing for susceptibility might be considered to reduce the cost of vaccinating adult populations that have an expected high prevalence (20%–30%) of HBV infection (e.g., IDUs and MSM, especially those in older age groups). In addition, prevaccination testing for susceptibility is recommended for unvaccinated household, sexual, and needle-sharing contacts of HBsAg-positive persons (*108*).

Anti-HBc is the test of choice for prevaccination testing; persons who are anti-HBc–positive should be tested for HBsAg. If persons are determined to be HBsAg negative, no further action is required. If persons are determined to be HBsAg positive, the person should be referred for medical follow-up to include counseling and evaluation for antiviral treatment (see Management of HBsAg-Positive Persons). In addition, all household members, sex partners, and needle-sharing partners of HBsAg-positive persons should be vaccinated.

Serologic testing should not be a barrier to vaccination of susceptible persons, especially in populations that are difficult to access. In most cases, the first vaccine dose should be administered immediately after collection of the blood sample for serologic testing. Vaccination of persons who are immune to HBV infection because of current or previous infection or vaccination does not increase the risk for adverse events.

Postvaccination Testing for Serologic Response

Serologic testing for immunity is not necessary after routine vaccination of adolescents or adults. However, such testing is recommended for persons whose subsequent clinical management depends on knowledge of their immune status (e.g., health-care workers or public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids). In addition, postvaccination testing is recommended for 1) HIV-infected persons and other immunocompromised persons to determine the need for revaccination and the type of follow-up testing and 2) sex and needle-sharing partners of HBsAg-positive persons to determine the need for revaccination and for other methods to protect themselves from HBV infection.

If indicated, testing should be performed 1–2 months after administration of the last dose of the vaccine series by using a method that allows determination of a protective level of anti-HBs (i.e., ≥10 mIU/mL). Persons determined to have anti-HBs levels of <10 mIU/mL after the primary vaccine series should be revaccinated with a 3-dose series and provided with anti-HBs testing 1–2 months after the third dose. Persons who do not respond to revaccination should be tested for HBsAg. If HBsAg positive, the person should receive appropriate management (see Management of HBsAg-Positive Persons); if HBsAg negative, the person should be considered susceptible to HBV infection and counseled concerning precautions to prevent HBV infection and the need for HBIG PEP for any known exposure (see Postexposure Prophylaxis).

Postexposure Prophylaxis

Both passive-active PEP (the administration of HBIG and hepatitis B vaccine at separate sites) and active PEP (the administration of hepatitis B vaccination alone) have been demonstrated to be highly effective in preventing transmission after exposure to HBV (*4*). HBIG alone also has been demonstrated to be effective in preventing HBV transmission, but with the availability of hepatitis B vaccine, HBIG typically is used as an adjunct to vaccination.

Exposure to HBsAg-Positive Source

Unvaccinated persons or persons known not to have responded to a complete hepatitis B vaccine series should receive both HBIG and hepatitis vaccine as soon as possible (preferably ≤24 hours) after a discrete, identifiable exposure to blood or body fluids that contain blood from an HBsAg-positive source (Table 5). Hepatitis B vaccine should be administered simultaneously with HBIG at a separate injection site, and the vaccine series should be completed by using the age-appropriate vaccine dose and schedule (Table 3). Exposed persons who are in the process of being vaccinated but who have not completed the vaccine series should receive the appropriate dose of HBIG (i.e., 0.06 mL/kg) and should complete the vaccine series. Exposed persons who are known to have responded to vaccination are considered protected; therefore, they need no additional doses of vaccine. Persons who have written documentation of a complete hepatitis B vaccine series who did not receive postvaccination testing should receive a single vaccine booster dose. Alternatively, these persons can be managed according to guidelines for management of persons with occupational exposure to blood or body fluids that contain blood (*446*).

Exposure to Source with Unknown HBsAg Status

Unvaccinated persons who have a discrete, identifiable exposure to blood or body fluids containing blood from a source with unknown HBsAg status should receive the hepatitis

TABLE 5. Guidelines for postexposure immunoprophylaxis of unvaccinated persons who have an identifiable exposure to blood or body fluids that contain blood

Cause	Action
Exposure to an HBsAg*-positive source	
Percutaneous (e.g., bite or needlestick) or mucosal exposure to HBsAg-positive blood or body fluids that contain blood	Administer hepatitis B vaccine & HBIG†
Sexual or needle-sharing contact of an HBsAg-positive person	Administer hepatitis B vaccine & HBIG†
Victim of sexual assault/abuse by a perpetrator who is HBsAg positive	Administer hepatitis B vaccine & HBIG†
Exposure to a source with unknown HBsAg status	
Victim of sexual assault/abuse by a perpetrator with unknown HBsAg status	Administer hepatitis B vaccine†
Percutaneous (e.g., bite or needlestick) or mucosal exposure to blood or body fluids that contain blood from a source with unknown HBsAg status	Administer hepatitis B vaccine†

* Hepatitis B surface antigen.
† Immunoprophylaxis should be administered as soon as possible, preferably ≤24 hours. Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposures and 14 days for sexual exposures. The complete, 3-dose hepatitis B vaccine series should be administered.

B vaccine series, with the first dose initiated as soon as possible after exposure (preferably within 24 hours) and the series completed by using the age-appropriate dose and schedule. Exposed persons who are not fully vaccinated should complete the vaccine series. Exposed persons with written documentation of a complete hepatitis B vaccine series require no further treatment.

Special Considerations

Pregnancy

All pregnant women receiving STD services should be tested for HBsAg, regardless of whether they have been previously tested or vaccinated. All HBsAg-positive pregnant women should be reported to state and local perinatal hepatitis B prevention programs. HBsAg-negative pregnant women seeking STD treatment who have not been previously vaccinated should receive hepatitis B vaccination. Additional information regarding management of HBsAg-positive pregnant women and their infants is available at http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

HIV Infection

HIV infection can impair the response to hepatitis B vaccination. HIV-infected persons should be tested for anti-HBs 1–2 months after the third vaccine dose (see Postvaccination Testing for Serologic Response). Modified dosing regimens, including a doubling of the standard antigen dose and administration of additional doses, might increase the response rate (*130*).

Management of HBsAg-Positive Persons

This section provides recommendations for management of all HBsAg-positive persons. Additional recommendations for management of HBsAg-positive persons who are coinfected with HIV are available (*130*).

- All persons with HBsAg-positive laboratory results should be reported to the state or local health department.
- To verify the presence of chronic HBV infection, HBsAg-positive persons should be retested. The absence of IgM anti-HBc or the persistence of HBsAg for 6 months indicates chronic HBV infection.
- Persons with chronic HBV infection should be referred for evaluation to a physician experienced in the management of CLD. Some patients with chronic hepatitis B will benefit from early intervention with antiviral treatment or screening to detect HCC at an early stage.
- Household, sexual, and needle-sharing contacts of chronically infected persons should be identified. Unvaccinated sex partners and household and needle-sharing contacts should be tested for susceptibility to HBV infection (see Prevaccination Antibody Screening) and should receive the first dose of hepatitis B vaccine immediately after collection of the blood sample for serologic testing. Susceptible persons should complete the vaccine series by using an age-appropriate vaccine dose and schedule.
- Sex partners of HBsAg-positive persons should be counseled to use latex condoms (*448*) to protect themselves from sexual exposure to infectious body fluids (e.g., semen and vaginal secretions), unless they have been demonstrated to be immune after vaccination (anti-HBs ≥10 mIU/mL) or previously infected (anti-HBc positive).
- To prevent or reduce the risk for transmission to others, HBsAg-positive persons should be advised about the risk for transmission to household, sexual, and needle-sharing contacts and the need for such contacts to receive hepatitis B vaccination. HBsAg-positive persons also should be advised to:
  - use methods (e.g., condoms) to protect nonimmune sex partners from acquiring HBV infection from sexual activity until the partner can be vaccinated and immunity documented;
  - cover cuts and skin lesions to prevent spread by infectious secretions or blood;

  - refrain from donating blood, plasma, body organs, other tissue, or semen; and
  - refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could become contaminated with blood. In addition, HBsAg-positive persons should refrain from premasticating food provided to susceptible persons.
- To protect the liver from further harm, HBsAg-positive persons should be advised to:
  - avoid or limit alcohol consumption because of the effects of alcohol on the liver;
  - refrain from starting any new medicines, including OTC and herbal medicines, without checking with their health-care provider; and
  - obtain vaccination against hepatitis A if liver disease is determined to be present.

When seeking medical or dental care, HBsAg-positive persons should be advised to inform their health-care providers of their HBsAg status so that they can be appropriately evaluated and managed. The following counseling messages should be considered for HBsAg-positive persons:

- HBV is not usually spread by hugging, coughing, food or water, sharing eating utensils or drinking glasses, or casual contact.
- Persons should not be excluded from work, school, play, child care, or other settings because they are infected with HBV.
- Involvement with a support group might help patients cope with chronic HBV infection.

Hepatitis C

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States; an estimated 3.2 million persons are chronically infected (*449*). Although HCV is not efficiently transmitted sexually, persons at risk for infection through injection-drug use might seek care in STD treatment facilities, HIV counseling and testing facilities, correctional facilities, drug treatment facilities, and other public health settings where STD and HIV prevention and control services are available.

Persons newly infected with HCV typically are either asymptomatic or have a mild clinical illness. HCV RNA can be detected in blood within 1–3 weeks after exposure. The average time from exposure to antibody to HCV (anti-HCV) seroconversion is 8–9 weeks, and anti-HCV can be detected in >97% of persons by 6 months after exposure. Chronic HCV infection develops in 70%–85% of HCV-infected persons; 60%–70% of chronically infected persons develop evidence of active liver disease. Most infected persons remain unaware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for CLD and other HCV-related chronic diseases for decades after infection.

HCV is transmitted through parenteral exposures to contaminated blood, usually through use of injection drugs (sharing of needles or works) and to a lesser extent through exposures in health-care settings as a consequence of inadequate infection-control practices. Transmission rarely follows receipt of blood, tissues, and organs from HCV-infected donors who were not identified during routine screening activities, which have been mandated in the United States since 1992. Occupational and perinatal exposures, although less efficient, also can result in transmission of HCV.

Sexual transmission of HCV had been considered to occur rarely. However, recent data indicate that sexual transmission of HCV can occur, especially among HIV-infected persons. CDC surveillance data demonstrate that 10% of persons with acute HCV infection report contact with a known HCV-infected sex partner as their only risk for infection (*437*). Specific studies of HCV transmission between heterosexual or homosexual couples have yielded mixed results, but generally have found low but increased rates of HCV infection in partners of persons with HCV infection compared with those whose partners are not HCV-infected (*450–455*). Several studies have revealed that risk increases commensurate with increasing numbers of sex partners among heterosexual persons (*450*,*451*,*456–458*) and MSM (*459–462*), especially if those partners are coinfected with HIV (*459–465*).

Apparent sexual transmission of HCV has recently been reported among HIV-infected MSM in multiple European cities (*464*,*465*) and New York City (*466*). Common practices associated with these clusters of infection include serosorting (i.e., HIV-infected men having sex with one another), group sex, and the use of cocaine and other nonintravenous drugs during sex.

All persons with HIV infection should undergo serologic testing for HCV at initial evaluation (*130*,*131*). HIV-infected MSM can also acquire HCV after initial screening. Liver function tests should be serially monitored for abnormalities that could be caused by acute viral hepatitis or medication toxicity. HIV-infected persons with new and unexplained increases in ALT should be tested for acute HCV infection. To ensure the detection of acute HCV infection among HIV-infected MSM with high-risk sexual behaviors or concomitant ulcerative STDs, routine HCV testing of HIV-infected MSM should be considered. Acute hepatitis C is a reportable condition in 49 states, and matching viral hepatitis and HIV surveillance registries can facilitate early detection of social networks of HCV transmission among HIV-infected MSM. Suspected

clusters of acute infection should be reported to the appropriate public health authorities. Unprotected sexual contact between HIV-infected partners can facilitate spread of HCV, as the virus can be recovered from the semen of men coinfected with HIV (*467*). Specific prevention practices (e.g., barrier precautions that limit contact with body fluids during sexual contact with other MSM) should be discussed with patients.

Diagnosis and Treatment

Anti-HCV testing is recommended for routine screening of asymptomatic persons based on their risk for infection or based on a recognized exposure (see Hepatitis C, Prevention). For such persons, testing for HCV infection should include the use of an FDA-cleared test for antibody to HCV (i.e., immunoassay, EIA, or enhanced chemiluminescence imunoassay and, if recommended, a supplemental antibody test) (*468*).

Persons counseled and tested for HCV infection and determined to be anti-HCV positive should be evaluated (by referral or consultation, if appropriate) for the presence of active infection, presence or development of CLD, and possible treatment. Nucleic acid testing, including reverse transcriptase polymerase chain reaction (RT-PCR) to detect HCV RNA, is necessary to confirm the diagnosis of current HCV infection, and an elevated ALT level is biochemical evidence of CLD. Combination therapy with pegylated interferon and ribavirin is the treatment of choice for patients with chronic hepatitis C. Providers should consult with specialists knowledgeable about management of hepatitis C infection because these experts remain cognizant of the latest advances in the field of antiviral therapy for acute and chronic hepatitis C.

Prevention

No vaccine for hepatitis C is available, and prophylaxis with immune globulin is not effective in preventing HCV infection after exposure. Reducing the burden of HCV infection and disease in the United States requires implementation of both primary and secondary prevention activities. Primary prevention reduces or eliminates HCV transmission, whereas secondary prevention activities are aimed at reducing CLD and other chronic diseases in HCV-infected persons by first identifying them and then providing medical management and antiviral therapy, if appropriate.

Most scientific evidence demonstrates that although HCV can be transmitted sexually, such transmission happens rarely. Because incident HCV has not been demonstrated to occur in heterosexual partner-pairs followed over time (*452–454*), condom use might not be necessary in such circumstances. However, heterosexual and homosexual persons, especially those with concurrent HIV infection or with more than one partner, should protect themselves and their partners against transmission of HCV, HBV, HIV, and other pathogens by use of male latex condoms. Condom use is especially important for HIV-infected men, who might spread HCV to other men though unprotected sexual activity (*464–466*).

Providers in STD clinics and other primary-care settings should identify those persons who should be offered HCV counseling and testing. In STD clinics and other settings that serve large numbers of persons at high risk for bloodborne infections (e.g., correctional settings), the major risk factor necessitating screening for HCV infection is past or current injection of illegal drugs. Because both HCV and HIV are transmitted through injection-drug use, about one fourth of all HIV patients are also coinfected with HCV. For this reason, all persons with HIV infection should be offered HCV counseling and testing. Other risk factors for which routine HCV testing is recommended include:

- having had a blood transfusion or solid organ transplant before July 1992;
- having received clotting factor concentrates produced before 1987;
- having been on long-term dialysis; and
- having signs and symptoms of liver disease (e.g., abnormal ALT).

Persons who test negative for anti-HCV who had an exposure previously should be reassured that they are not infected. Those who test positive for anti-HCV (see Diagnosis and Treatment) should be provided information regarding how to protect their liver from further harm; for instance, HCV-positive persons should be advised to avoid drinking alcohol and taking any new medicines (including OTC and herbals) without checking with their clinician.

To reduce the risk for transmission to others, HCV-positive persons should be advised to 1) not donate blood, body organs, other tissue, or semen; 2) not share any personal items that might have blood on them (e.g., toothbrushes and razors); and 3) cover cuts and sores on the skin to keep the virus from spreading by blood or secretions. HCV-positive persons with one long-term, steady sex partner do not need to change their sexual practices. They should discuss the low but present risk for transmission with their partner and discuss the need for counseling and testing. HCV-positive women do not need to avoid pregnancy or breastfeeding.

HCV-positive persons should be evaluated (by referral or consultation, if appropriate) to detect active HCV infection and the presence of CLD. Evaluation should involve testing for liver function, additional assessment of the severity of liver

disease, possible treatment, and the determination for the need of hepatitis A and B vaccination.

Regardless of test results, persons who use or inject illegal drugs should be counseled to stop using and injecting drugs and to enter and complete substance abuse treatment (including relapse prevention). Persons who continue to inject drugs despite counseling should be encouraged to take the following steps to reduce personal and public health risks:

- never reuse or share syringes, water, or drug preparation equipment;
- only use syringes obtained from a reliable source (e.g., pharmacies);
- use a new, sterile syringe to prepare and inject drugs;
- if possible, use sterile water to prepare drugs; otherwise, use clean water from a reliable source (e.g., fresh tap water);
- use a new or disinfected container (i.e., cooker) and a new filter (i.e., cotton) to prepare drugs;
- clean the injection site before injection with a new alcohol swab;
- safely dispose of syringes after one use;
- get vaccinated for hepatitis A and B if nonimmune; and
- get tested for HIV infection.

Postexposure Follow-Up

No PEP has been demonstrated to be effective against HCV. Testing to determine whether HCV infection has developed is recommended for health-care workers after percutaneous or permucosal exposures to HCV-positive blood. Children born to HCV-positive women also should be tested for HCV. Prompt identification of acute infection is important, because outcomes are improved when treatment is initiated earlier in the course of illness.

Special Considerations

Pregnancy

Routine testing for HCV infection is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Patients should be advised that approximately six of every 100 infants born to HCV-infected woman become infected; this infection occurs predominantly during or near delivery, and no treatment or delivery method—such as caesarian section—has been demonstrated to decrease this risk. The risk is increased, however, by the presence of maternal HCV viremia at delivery and also is greater (2–3 times) if the woman is coinfected with HIV. HCV has not been shown to be transmitted through breast milk, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding. Infants born to HCV-positive mothers should be tested for HCV infection and, if positive, evaluated for the presence of CLD.

HIV Infection

Because of the high prevalence of HIV/HCV coinfection and because of critical clinical management issues for coinfected persons, all persons with HIV infection should undergo serologic testing for HCV. Providers should be aware of the likelihood that HIV-infected MSM will acquire HCV after initial screening. Liver function tests should be serially monitored, and those persons with new and unexplained increases in ALT should be tested for acute HCV infection. To detect acute HCV infection among HIV-infected MSM with high-risk sexual behaviors or concomitant ulcerative STDs, routine HCV testing of HIV-infected MSM should be considered. Because a small percentage of coinfected persons fail to acquire HCV antibodies, HCV RNA should be tested in HIV-positive persons with unexplained liver disease who are anti-HCV negative. The course of liver disease is more rapid in HIV/HCV coinfected persons, and the risk for cirrhosis is nearly twice that of persons with HCV infection alone. Coinfected persons receiving HIV antiviral regimens are now being treated for HCV after their CD4+ cell counts increase, optimizing their immune response.

Proctitis, Proctocolitis, and Enteritis

Sexually transmitted gastrointestinal syndromes include proctitis, proctocolitis, and enteritis. Evaluation for these syndromes should include appropriate diagnostic procedures (e.g., anoscopy or sigmoidoscopy, stool examination, and culture).

Proctitis is inflammation of the rectum (i.e., the distal 10–12 cm) that can be associated with anorectal pain, tenesmus, or rectal discharge. *N. gonorrhoeae*, *C. trachomatis* (including LGV serovars), *T. pallidum*, and HSV are the most common sexually transmitted pathogens involved. In patients coinfected with HIV, herpes proctitis can be especially severe. Proctitis occurs predominantly among persons who participate in receptive anal intercourse.

Proctocolitis is associated with symptoms of proctitis, diarrhea or abdominal cramps, and inflammation of the colonic mucosa extending to 12 cm above the anus. Fecal leukocytes might be detected on stool examination, depending on the pathogen. Pathogenic organisms include *Campylobacter* sp., *Shigella* sp., *Entamoeba histolytica*, and LGV serovars of *C. trachomatis*. CMV or other opportunistic agents can be involved in immunosuppressed HIV-infected patients.

Proctocolitis can be acquired by the oral route or by oral-anal contact, depending on the pathogen.

Enteritis usually results in diarrhea and abdominal cramping without signs of proctitis or proctocolitis; it occurs among persons whose sexual practices include oral-anal contact. In otherwise healthy persons, *Giardia lamblia* is most frequently implicated. When outbreaks of gastrointestinal illness occur among social or sexual networks of MSM, clinicians should consider sexual transmission as a mode of spread and provide counseling accordingly. Among HIV-infected patients, gastrointestinal illness can be caused by other infections that usually are not sexually transmitted, including CMV, *Mycobacterium avium–intracellulare*, *Salmonella* sp., *Campylobacter* sp., *Shigella* sp., *Cryptosporidium*, *Microsporidium*, and *Isospora*. Multiple stool examinations might be necessary to detect *Giardia*, and special stool preparations are required to diagnose cryptosporidiosis and microsporidiosis. In addition, enteritis can be directly caused by HIV infection.

When laboratory diagnostic capabilities are available, treatment decisions should be based on the specific diagnosis. Diagnostic and treatment recommendations for all enteric infections are beyond the scope of these guidelines.

Treatment for Proctitis

Acute proctitis of recent onset among persons who have recently practiced receptive anal intercourse is usually sexually acquired (*469*,*470*). Such patients should be examined by anoscopy and should be evaluated for infection with HSV, *N. gonorrhoeae*, *C. trachomatis*, and *T. pallidum*. If an anorectal exudate is detected on examination or if polymorphonuclear leukocytes are detected on a Gram-stained smear of anorectal secretions, the following therapy should be prescribed while awaiting additional laboratory tests.

Recommended Regimen

Ceftriaxone 250 mg IM

PLUS

Doxycycline 100 mg orally twice a day for 7 days

Patients with suspected or documented herpes proctitis should be managed in the same manner as those with genital herpes (see Genital HSV Infections). If painful perianal ulcers are present or mucosal ulcers are detected on anoscopy, presumptive therapy should include a regimen for genital herpes and LGV. Appropriate diagnostic testing for LGV should be conducted in accordance with state or federal guidelines, and doxycycline therapy should be administered 100 mg orally twice daily for 3 weeks.

For MSM, treatment for LGV proctitis/proctocolitis with 3 weeks of doxycycline in those with anorectal chlamydia and either 1) proctitis (as detected by proctoscopic examination and the presence of >10 white-blood cells upon high-power field examination of an anorectal smear specimen) or 2) HIV infection can be considered.

Follow-Up

Follow-up should be based on specific etiology and severity of clinical symptoms. Reinfection might be difficult to distinguish from treatment failure.

Management of Sex Partners

Partners of persons with sexually transmitted enteric infections should be evaluated for any diseases diagnosed in the index patient.

Ectoparasitic Infections

Pediculosis Pubis

Persons who have pediculosis pubis (i.e., pubic lice) usually seek medical attention because of pruritus or because they notice lice or nits on their pubic hair. Pediculosis pubis is usually transmitted by sexual contact.

Recommended Regimens

Permethrin 1% cream rinse applied to affected areas and washed off after 10 minutes

OR

Pyrethrins with piperonyl butoxide applied to the affected area and washed off after 10 minutes

Alternative Regimens

Malathion 0.5% lotion applied for 8–12 hours and washed off

OR

Ivermectin 250 μg/kg orally, repeated in 2 weeks

Reported resistance to pediculicides has been increasing and is widespread (*471–473*). Malathion can be used when treatment failure is believed to have resulted from drug resistance. The odor and long duration of application for malathion make it a less attractive alternative than the recommended pediculcides. Ivermectin has been successfully used to treat lice, but it has only been evaluated in studies involving a limited number of participants.

Other Management Considerations

The recommended regimens should not be applied to the eyes. Pediculosis of the eyelashes should be treated by applying occlusive ophthalmic ointment to the eyelid margins twice a day for 10 days. Bedding and clothing should be decontaminated (i.e., either dry cleaned or machine-washed and dried using the heat cycle) or removed from body contact for at least 72 hours. Fumigation of living areas is not necessary.

Patients with pediculosis pubis should be evaluated for other STDs.

Follow-Up

Patients should be evaluated after 1 week if symptoms persist. Retreatment might be necessary if lice are found or if eggs are observed at the hair-skin junction. Patients who do not respond to one of the recommended regimens should be retreated with an alternative regimen.

Management of Sex Partners

Sex partners that have had sexual contact with the patient within the previous month should be treated. Patients should abstain from sexual contact with their sex partner(s) until patients and partners have been treated and reevaluated to rule out persistent disease.

Special Considerations

Pregnancy

Pregnant and lactating women should be treated with either permethrin or pyrethrins with piperonyl butoxide; lindane and ivermectin are contraindicated in pregnancy and lactating women.

HIV Infection

Patients who have pediculosis pubis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

Scabies

The predominant symptom of scabies is pruritus, but sensitization to *Sarcoptes scabiei* occurs before pruritus begins. The first time a person is infested with *S. scabiei*, sensitization can take several weeks to develop. However, pruritus might occur within 24 hours after a subsequent reinfestation. Scabies in adults frequently is sexually acquired, although scabies in children usually is not.

Recommended Regimens

Permethrin cream (5%) applied to all areas of the body from the neck down and washed off after 8–14 hours

OR

Ivermectin 200 µg/kg orally, repeated in 2 weeks

Alternative Regimen

Lindane (1%) 1 oz. of lotion (or 30 g of cream) applied in a thin layer to all areas of the body from the neck down and thoroughly washed off after 8 hours

Lindane is not recommended as first-line therapy because of toxicity (*471*). It should only be used as an alternative if the patient cannot tolerate other therapies or if other therapies have failed.

Lindane should not be used immediately after a bath or shower, and it should not be used by persons who have extensive dermatitis, women who are pregnant or lactating, or children aged <2 years. Lindane resistance has been reported in some areas of the world, including parts of the United States (*474*). Seizures have occurred when lindane was applied after a bath or used by patients who had extensive dermatitis. Aplastic anemia after lindane use also has been reported (*471, 474*).

Permethrin is effective and safe and less expensive than ivermectin (*471, 474*). One study demonstrated increased mortality among elderly, debilitated persons who received ivermectin, but this observation has not been confirmed in subsequent studies (*475*).

Other Management Considerations

Bedding and clothing should be decontaminated (i.e., either dry cleaned or machine-washed and dried using the hot cycle) or removed from body contact for at least 72 hours. Fumigation of living areas is unnecessary.

Crusted Scabies

Crusted scabies (i.e., Norwegian scabies) is an aggressive infestation that usually occurs in immunodeficient, debilitated, or malnourished persons (*476*). Patients who are receiving systemic or potent topical glucocorticoids, organ transplant recipients, mentally retarded or physically incapacitated persons, HIV-infected or human T-lymphotrophic virus-1-infected persons, and persons with various hematologic malignancies are at risk for developing crusted scabies. Crusted scabies is associated with greater transmissibility than scabies. No controlled therapeutic studies for crusted scabies have been conducted, and the appropriate treatment remains

unclear. Substantial risk for treatment failure might exist with a single topical scabicide or with oral ivermectin treatment. Combined treatment with a topical scabicide and repeated treatment with oral ivermectin 200 µg/kg on days 1, 2, 8, 9, and 15 are suggested. Additional treatment on days 22 and 29 might be required for severe cases. Ivermectin should be combined with the application of either 5% topical benzyl benzoate or 5% topical permethrin (full body application to be repeated daily for 7 days then 2 times weekly until release from care or cure). Lindane should be avoided because of the risks for neurotoxicity associated with both heavy applications and denuded skin. Fingernails should be closely trimmed to reduce injury from excessive scratching.

Follow-Up

Patients should be informed that the rash and pruritus of scabies might persist for up to 2 weeks after treatment. Symptoms or signs that persist for >2 weeks can be attributed to several factors. Treatment failure can be caused by resistance to medication, although faulty application of topical scabicides also can contribute to persistence — patients with crusted scabies might have poor penetration into thick scaly skin and harbor mites in these difficult-to-penetrate layers. Particular attention must be given to the fingernails of these patients. Reinfection from family members or fomites can occur in the absence of appropriate contact treatment and washing of bedding and clothing. Even when treatment is successful and reinfection is avoided, symptoms can persist or worsen as a result of allergic dermatitis. Finally, the presence of household mites can cause symptoms to persist as a result of cross reactivity between antigens. Retreatment can be considered after 1–2 weeks for patients who are still symptomatic or if live mites are present. Treatment with an alternative regimen is recommended for persons who do not respond to the recommended treatment.

Management of Sex Partners and Household Contacts

Sexual contacts and those that have had close personal or household contact with the patient within the preceding month should be examined and treated.

Management of Outbreaks in Communities, Nursing Homes, and Other Institutional Settings

Scabies outbreaks frequently occur in nursing homes, hospitals, residential facilities, and other communities. Control of an epidemic can only be achieved by treatment of the entire population at risk. Ivermectin can be considered in this setting, especially if treatment with topical scabicides fails. Epidemics should be managed in consultation with an infectious disease specialist.

Special Considerations

Infants, Young Children, and Pregnant or Lactating Women

Infants, young children, and pregnant or lactating women should not be treated with lindane; however, they can be treated with permethrin. Ivermectin is not recommended for pregnant or lactating patients, and the safety of ivermectin in children who weigh <15 kg has not been determined.

HIV Infection

Patients who have uncomplicated scabies and also are infected with HIV should receive the same treatment regimens as those who are HIV negative. HIV-infected patients and others who are immunosuppressed are at increased risk for crusted scabies, for which ivermectin has been reported to be effective in noncontrolled studies involving only a limited number of participants. HIV-infected patients with crusted scabies should be managed in consultation with an infectious disease specialist.

Sexual Assault and STDs

Adults and Adolescents

The recommendations in this report are limited to the identification, prophylaxis, and treatment of STDs and conditions commonly identified in the management of such infections. The documentation of findings, collection of nonmicrobiologic specimens for forensic purposes, and management of potential pregnancy or physical and psychological trauma are beyond the scope of this report.

Examinations of survivors of sexual assault should be conducted by an experienced clinician in a way that minimizes further trauma to the survivor. The decision to obtain genital or other specimens for STD diagnosis should be made on an individual basis. Care systems for survivors should be designed to ensure continuity (including timely review of test results), support adherence, and monitor for adverse reactions to any therapeutic or prophylactic regimens prescribed at initial examination. Laws in all 50 states strictly limit the evidentiary use of a survivor's previous sexual history, including evidence of previously acquired STDs, as part of an effort to undermine the credibility of the survivor's testimony. Evidentiary privilege against revealing any aspect of the examination or treatment also is enforced in most states. Although it rarely occurs, STD diagnoses might later be accessed, and the survivor and clinician

might opt to defer testing for this reason. While collection of specimens at initial examination for laboratory STD diagnosis gives the survivor and clinician the option to defer empiric prophylactic antimicrobial treatment, compliance with follow up visits is traditionally poor (*477*,*478*). Among sexually active adults, the identification of an STD might represent an infection acquired prior to the assault, and therefore might be more important for the psychological and medical management of the patient than for legal purposes.

Trichomoniasis, BV, gonorrhea, and chlamydial infection are the most frequently diagnosed infections among women who have been sexually assaulted. Such conditions are relatively prevalent, and the presence after an assault does not necessarily imply acquisition during the assault. However, a postassault examination presents an important opportunity to identify or prevent STDs. Chlamydial and gonococcal infections in women are of particular concern because of the possibility of ascending infection. In addition, HBV infection can be prevented by postexposure administration of hepatitis B vaccine. Reproductive-aged female survivors should be evaluated for pregnancy, if appropriate.

Evaluating Adults and Adolescents for Sexually Transmitted Diseases

Initial Examination

An initial examination might include the following procedures:

- NAATs for *C. trachomatis* and *N. gonorrhoeae*. These tests are preferred for the diagnostic evaluation of sexual assault victims, regardless of the sites of penetration or attempted penetration (197).
- Wet mount and culture or point-of-care testing of a vaginal-swab specimen for *T. vaginalis* infection. The wet mount also should be examined for evidence of BV and candidiasis, especially if vaginal discharge, malodor, or itching is evident.
- A serum sample for immediate evaluation for HIV infection, hepatitis B, and syphilis. Decisions to perform these tests should be made on an individual basis.

Follow-Up Examinations

After the initial postassault examination, follow-up examinations provide an opportunity to 1) detect new infections acquired during or after the assault; 2) complete hepatitis B vaccination, if indicated; 3) complete counseling and treatment for other STDs; and 4) monitor side effects and adherence to postexposure prophylactic medication, if prescribed.

Examination for STDs can be repeated within 1–2 weeks of the assault. Because infectious agents acquired through assault might not have produced sufficient concentrations of organisms to result in positive test results at the initial examination, testing can be repeated during the follow-up visit, unless prophylactic treatment was provided. If treatment was provided, testing should be conducted only if the survivor reports having symptoms. If treatment was not provided, follow-up examination should be conducted within 1 week to ensure that results of positive tests can be discussed promptly with the survivor and that treatment is provided. Serologic tests for syphilis and HIV infection can be repeated 6 weeks, 3 months, and 6 months after the assault if initial test results were negative and infection in the assailant could not be ruled out (see Sexual Assault and STDs, Risk for Acquiring HIV Infection).

Prophylaxis

Compliance with follow-up visits is poor among survivors of sexual assault (*477*,*478*). As a result, routine preventive therapy after a sexual assault should be encouraged. The following prophylactic regimen is suggested as preventive therapy:

- Postexposure hepatitis B vaccination, without HBIG. This vaccine should be administered to sexual assault survivors at the time of the initial examination if they have not been previously vaccinated. Follow-up doses of vaccine should be administered 1–2 and 4–6 months after the first dose.
- An empiric antimicrobial regimen for chlamydia, gonorrhea, and trichomonas.
- Emergency contraception. (This measure is necessary only when the assault could result in pregnancy in the survivor.)

Recommended Regimens

Ceftriaxone 250 mg IM in a single dose

OR

Cefixime 400 mg orally in a single dose

PLUS

Metronidazole 2 g orally in a single dose

PLUS

Azithromycin 1 g orally in a single dose OR Doxycycline 100 mg orally twice a day for 7 days

For those requiring alternative treatments, refer to the specific sections in this report relevant to the specific agent. The efficacy of these regimens in preventing infections after sexual assault has not been evaluated. Clinicians should counsel patients regarding the possible benefits and toxicities associated with these treatment regimens; gastrointestinal side effects can occur with this combination.

Other Management Considerations

At the initial examination and, if indicated, at follow-up examinations, patients should be counseled regarding 1) symptoms of STDs and the need for immediate examination if symptoms occur and 2) abstinence from sexual intercourse until STD prophylactic treatment is completed.

Risk for Acquiring HIV Infection

HIV seroconversion has occurred in persons whose only known risk factor was sexual assault or sexual abuse, but the frequency of this occurrence is probably low. In consensual sex, the risk for HIV transmission from vaginal intercourse is 0.1%–0.2% and for receptive rectal intercourse, 0.5%–3% (*479*). The risk for HIV transmission from oral sex is substantially lower. Specific circumstances of an assault (e.g., bleeding, which often accompanies trauma) might increase risk for HIV transmission in cases involving vaginal, anal, or oral penetration. Site of exposure to ejaculate, viral load in ejaculate, and the presence of an STD or genital lesions in the assailant or survivor also might increase the risk for HIV.

Children might be at higher risk for transmission, because the sexual abuse of children is frequently associated with multiple episodes of assault and might result in mucosal trauma (see Sexual Assault or Abuse of Children).

Postexposure therapy with zidovudine was associated with a reduced risk for acquiring HIV in a study of health-care workers who had percutaneous exposures to HIV-infected blood (*480*). On the basis of these results and the results of animal studies, PEP has been recommended for health-care workers who have occupational exposures to HIV (*446*). These findings have been extrapolated to other types of HIV exposure, including sexual assault (*78*). If HIV exposure has occurred, initiation of PEP as soon as possible after the exposure likely increases benefit. Although a definitive statement of benefit cannot be made regarding PEP after sexual assault, the possibility of HIV exposure from the assault should be assessed at the time of the postassault examination. The possible benefit of PEP in preventing HIV infection also should be discussed with the assault survivor if the assault poses a risk for HIV exposure.

Several factors impact the medical recommendation for PEP and affect the assault survivor's acceptance of that recommendation, including 1) the likelihood of the assailant having HIV, 2) any exposure characteristics that might increase the risk for HIV transmission, 3) the time elapsed after the event, and 4) the potential benefits and risks associated with the PEP (*78*). Determination of the assailant's HIV status at the time of the assault examination usually in not possible. Therefore, the health-care provider should assess any available information concerning 1) characteristics and HIV risk behaviors of the assailant(s) (e.g., a man who has sex with other men and persons who use injection drugs or crack cocaine), 2) local epidemiology of HIV/AIDS, and 3) exposure characteristics of the assault. When an assailant's HIV status is unknown, factors that should be considered in determining whether an increased risk for HIV transmission exists include 1) whether vaginal or anal penetration occurred; 2) whether ejaculation occurred on mucous membranes; 3) whether multiple assailants were involved; 4) whether mucosal lesions are present in the assailant or survivor; and 5) any other characteristics of the assault, survivor, or assailant that might increase risk for HIV transmission.

If PEP is offered, the following information should be discussed with the patient: 1) the unproven benefit and known toxicities of antiretrovirals; 2) the importance of close follow-up; 3) the benefit of adherence to recommended dosing; and 4) the necessity of early initiation of PEP to optimize potential benefits (i.e., as soon as possible after and up to 72 hours after the assault). Providers should emphasize that PEP appears to be well-tolerated in both adults and children and that severe adverse effects are rare (*481–483*). Clinical management of the survivor should be implemented according to the following guidelines (*78*). Specialist consultation on PEP regimens is recommended if HIV exposure during the assault was possible and if PEP is being considered. The sooner PEP is initiated after the exposure, the higher the likelihood that it will prevent HIV transmission if HIV exposure occurred; however, distress after an assault also might prevent the survivor from accurately weighing exposure risks and benefits of PEP and from making an informed decision to start such therapy. If use of PEP is judged to be warranted, the survivor should be offered a 3–5-day supply of PEP, and a follow-up visit should be scheduled several days later to allow for additional counseling.

Recommendations for Postexposure Assessment of Adolescent and Adult Survivors Within 72 Hours of Sexual Assault[§§]

- Assess risk for HIV infection in the assailant.
- Evaluate characteristics of the assault event that might increase risk for HIV transmission.
- Consult with a specialist in HIV treatment, if PEP is being considered.
- If the survivor appears to be at risk for HIV transmission from the assault, discuss antiretroviral prophylaxis, including toxicity and lack of proven benefit.

[§§] Assistance with PEP-related decisions can be obtained by calling the National Clinician's Post-Exposure Prophylaxis Hotline (PEP Line) (telephone: 888-448-4911).

- If the survivor chooses to start antiretroviral PEP (*78*), provide enough medication to last until the next return visit; reevaluate the survivor 3–7 days after initial assessment and assess tolerance of medications.
- If PEP is started, perform CBC and serum chemistry at baseline (initiation of PEP should not be delayed, pending results).
- Perform HIV antibody test at original assessment; repeat at 6 weeks, 3 months, and 6 months.

Sexual Assault or Abuse of Children

Recommendations in this report are limited to the identification and treatment of STDs. Management of the psychosocial aspects of the sexual assault or abuse of children is beyond the scope of these recommendations.

The identification of sexually transmissible agents in children beyond the neonatal period suggests sexual abuse. The significance of the identification of a sexually transmitted agent in such children as evidence of possible child sexual abuse varies by pathogen. Postnatally acquired gonorrhea; syphilis; and nontransfusion, nonperinatally acquired HIV are usually diagnostic of sexual abuse. Sexual abuse should be suspected when genital herpes is diagnosed. The investigation of sexual abuse among children who have an infection that could have been transmitted sexually should be conducted in compliance with recommendations by clinicians who have experience and training in all elements of the evaluation of child abuse, neglect, and assault. The social significance of an infection that might have been acquired sexually and the recommended action regarding reporting of suspected child sexual abuse varies by the specific organism, as do the recommendations regarding reporting of suspected child sexual abuse (Table 6). In all cases in which an STD has been diagnosed in a child, efforts should be made to detect evidence of sexual abuse, including conducting diagnostic testing for other commonly occurring STDs (*484–486*).

The general rule that sexually transmissible infections beyond the neonatal period are evidence of sexual abuse has exceptions. For example, rectal or genital infection with *C. trachomatis* among young children might be the result of perinatally acquired infection and has, in some cases, persisted for as long as 2–3 years. Genital warts have been diagnosed in children who have been sexually abused, but also in children who have no other evidence of sexual abuse (*487*,*488*). BV has been diagnosed in children who have been abused, but its presence alone does not prove sexual abuse. In addition, most HBV infections in children result from household exposure to persons who have chronic HBV infection.

TABLE 6. Implications of commonly encountered sexually transmitted (ST) or sexually associated (SA) infections for diagnosis and reporting of sexual abuse among infants and pre-pubertal children

ST/SA confirmed	Evidence for sexual abuse	Suggested action
Gonorrhea*	Diagnostic	Report†
Syphilis*	Diagnostic	Report†
Human immunodeficiency virus§	Diagnostic	Report†
*Chlamydia trachomatis**	Diagnostic	Report†
Trichomonas vaginalis	Highly suspicious	Report†
Condylomata acuminata (anogenital warts)*	Suspicious	Report†
Genital herpes*	Suspicious	Report†¶
Bacterial vaginosis	Inconclusive	Medical follow-up

Source: Adapted from Kellogg N, American Academy of Pediatrics Committee on Child Abuse and Neglect. The evaluation of child abuse in children. Pediatrics 2005;116(2):506–12.

* If not likely to be perinatally acquired and rare nonsexual, vertical transmission is excluded.

† Reports should be made to the agency in the community mandated to receive reports of suspected child abuse or neglect.

§ If not likely to be acquired perinatally or through transfusion.

¶ Unless there is a clear history of autoinoculation.

The possibility of sexual abuse should be strongly considered if no conclusive explanation for nonsexual transmission of an STD can be identified.

Reporting

All U.S. states and territories have laws that require the reporting of child abuse. Although the exact requirements differ by state, if a health-care provider has reasonable cause to suspect child abuse, a report must be made. Health-care providers should contact their state or local child-protection service agency regarding child-abuse reporting requirements in their states.

Evaluating Children for Sexually Transmitted Diseases

Examinations of children for sexual assault or abuse should be conducted in a manner designed to minimize pain and trauma to the child. Collection of vaginal specimens in prepubertal children can be very uncomfortable and should be performed by an experienced clinician to avoid psychological and physical trauma to the child. The decision to obtain genital or other specimens from a child to conduct an STD evaluation must be made on an individual basis. The following situations place children at high-risk for STDs and constitute a strong indication for testing.

- The child has or has had symptoms or signs of an STD or of an infection that can be sexually transmitted, even in the absence of suspicion of sexual abuse. Among the signs that are associated with a confirmed STD diagnosis are vaginal discharge or pain, genital itching or odor, urinary symptoms, and genital ulcers or lesions.

- A suspected assailant is known to have an STD or to be at high risk for STDs (e.g., has multiple sex partners or a history of STDs).
- A sibling or another child or adult in the household or child's immediate environment has an STD.
- The patient or parent requests testing.
- Evidence of genital, oral, or anal penetration or ejaculation is present.

If a child has symptoms, signs, or evidence of an infection that might be sexually transmitted, the child should be tested for other common STDs before the initiation of any treatment that could interfere with the diagnosis of those other STDs. Because of the legal and psychosocial consequences of a false-positive diagnosis, only tests with high specificities should be used. The potential benefit to the child of a reliable diagnosis of an STD justifies deferring presumptive treatment until specimens for highly specific tests are obtained by providers with experience in the evaluation of sexually abused and assaulted children.

The scheduling of an examination should depend on the history of assault or abuse. If the initial exposure was recent, the infectious agents acquired through the exposure might not have produced sufficient concentrations of organisms to result in positive test results. A follow-up visit approximately 2 weeks after the most recent sexual exposure can include a repeat physical examination and collection of additional specimens. To allow sufficient time for antibodies to develop, another follow-up visit approximately 12 weeks after the most recent sexual exposure might be necessary to collect sera. A single examination might be sufficient if the child was abused for an extended period and if a substantial amount of time elapsed between the last suspected episode of abuse and the medical evaluation.

The following recommendations for scheduling examinations serve as a general guide. The exact timing and nature of follow-up examinations should be determined on an individual basis and should be performed to minimize the possibility for psychological trauma and social stigma. Compliance with follow-up appointments might be improved when law enforcement personnel or child protective services are involved.

Initial and 2-Week Follow-Up Examinations

During the initial examination and 2-week follow-up examination (if indicated), the following should be performed.

- Visual inspection of the genital, perianal, and oral areas for genital discharge, odor, bleeding, irritation, warts, and ulcerative lesions. The clinical manifestations of some STDs are different in children than in adults. For example, typical vesicular lesions might not be present in the presence of HSV infection. Because this infection can be indicative of sexual abuse, specimens should be obtained from all vesicular or ulcerative genital or perianal lesions compatible with genital herpes and then sent for viral culture.
- Specimen collection for *N. gonorrhoeae* culture from the pharynx and anus in boys and girls, the vagina in girls, and the urethra in boys. Cervical specimens are not recommended for prepubertal girls. For boys with a urethral discharge, a meatal specimen discharge is an adequate substitute for an intraurethral swab specimen. Because of the legal implications of a diagnosis of *N. gonorrhoeae* infection in a child, if culture for the isolation of *N. gonorrhoeae* is done, only standard culture procedures should be performed. Gram stains are inadequate to evaluate prepubertal children for gonorrhea and should not be used to diagnose or exclude gonorrhea. Specimens from the vagina, urethra, pharynx, or rectum should be streaked onto selective media for isolation of *N. gonorrhoeae*, and all presumptive isolates of *N. gonorrhoeae* should be identified definitively by at least two tests that involve different principles (e.g., biochemical, enzyme substrate, or serologic). Isolates should be preserved to enable additional or repeated testing.
- Cultures for *C. trachomatis* from specimens collected from the anus in both boys and girls and from the vagina in girls. The likelihood of recovering *C. trachomatis* from the urethra of prepubertal boys is too low to justify the trauma involved in obtaining an intraurethral specimen. However, a meatal specimen should be obtained if urethral discharge is present. Pharyngeal specimens for *C. trachomatis* are not recommended for children of either sex because the yield is low, perinatally acquired infection might persist beyond infancy, and culture systems in some laboratories do not distinguish between *C. trachomatis* and *C. pneumoniae*. Only standard culture systems for the isolation of *C. trachomatis* should be used. The isolation of *C. trachomatis* should be confirmed by microscopic identification of inclusions by staining with fluorescein-conjugated monoclonal antibody specific for *C. trachomatis*; EIAs are not acceptable confirmatory methods. Isolates should be preserved. Nonculture tests for chlamydia (e.g., nonamplified probes, EIAs, and DFA) are not sufficiently specific for use in circumstances involving possible child abuse or assault. NAATs can be used for detection of *C. trachomatis* in vaginal specimens

or urine from girls. All specimens should be retained for additional testing if necessary. No data are available regarding the use of NAATs in boys or for extragenital specimens (e.g., those obtained from the rectum) in boys and girls. Culture remains the preferred method for extragenital sites.

- Culture and wet mount of a vaginal swab specimen for *T. vaginalis* infection and BV.
- Collection of serum samples to be evaluated immediately, preserved for subsequent analysis, and used as a baseline for comparison with follow-up serologic tests. Sera should be tested immediately for antibodies to sexually transmitted agents. Agents for which suitable tests are available include *T. pallidum*, HIV, and HBV. Decisions regarding the agents for which to perform serologic tests should be made on a case-by-case basis.

Data on use of NAATs for detection of *N. gonorrhoeae* in children are limited, and performance is test dependent (*197*,*486*). Consultation with an expert is necessary before using NAATs in this context to minimize the possibility of cross-reaction with nongonococcal *Neisseria* species and other commensals (e.g., *N. meningitidis*, *N. sicca*, *N. lactamica*, *N. cinerea,* and *Moraxella catarrhalis*). NAATs can be used as an alternative to culture with vaginal specimens or urine from girls, whereas culture remains the preferred method for urethral specimens or urine from boys and for extragenital specimens (pharynx and rectum) from all children. All positive specimens should be retained for additional testing.

HIV infection has been reported in children whose only known risk factor was sexual abuse. Serologic testing for HIV infection should be considered for abused children. The decision to test for HIV infection should be made on a case-by-case basis, depending on the likelihood of infection among assailant(s). Although data are insufficient concerning the efficacy and safety of PEP among both children and adults, treatment is well tolerated by infants and children (with and without HIV infection), and children have a minimal risk for serious adverse reactions because of the short period recommended for prohylaxis. (*78*,*138*). In considering whether to offer antiretroviral PEP, health-care providers should consider whether the child can be treated soon after the sexual exposure (i.e., within 72 hours), the likelihood that the assailant is infected with HIV, and the likelihood of high compliance with the prophylactic regimen. The potential benefit of treating a sexually abused child should be weighed against the risk for adverse reactions. If antiretroviral PEP is being considered, a provider specializing in evaluating or treating HIV-infected children should be consulted.

Recommendations for HIV-Related Postexposure Assessment of Children within 72 Hours of Sexual Assault

- Review HIV/AIDS local epidemiology and assess risk for HIV infection in the assailant.
- Evaluate circumstances of assault that might affect risk for HIV transmission.
- Consult with a specialist in treating HIV-infected children if PEP is considered.
- If the child appears to be at risk for HIV transmission from the assault, discuss PEP with the caregiver(s), including its toxicity and unknown efficacy.
- If caregivers choose for the child to receive antiretroviral PEP (*78,142,489*), provide enough medication to last until the return visit at 3–7 days after the initial assessment, at which time the child should be reevaluated and tolerance of medication assessed; dosages should not exceed those for adults.
- Perform HIV antibody test at original assessment, 6 weeks, 3 months, and 6 months.

Follow-Up Examination After Assault

In circumstances in which transmission of syphilis, HIV, or hepatitis B is a concern but baseline tests are negative, an examination approximately 6 weeks, 3 months, and 6 months after the last suspected sexual exposure is recommended to allow time for antibodies to infectious agents to develop. In addition, results of HBsAg testing must be interpreted carefully, because HBV can be transmitted nonsexually. Decisions regarding which tests should be performed must be made on an individual basis.

Presumptive Treatment

The risk of a child acquiring an STD as a result of sexual abuse or assault has not been well studied. Presumptive treatment for children who have been sexually assaulted or abused is not recommended because 1) the incidence of most STDs in children is low after abuse/assault, 2) prepubertal girls appear to be at lower risk for ascending infection than adolescent or adult women, and 3) regular follow-up of children usually can be ensured. However, some children or their parent(s) or guardian(s) might be concerned about the possibility of infection with an STD, even if the risk is perceived to be low by the health-care provider. Such concerns might be an appropriate indication for presumptive treatment in some settings and might be considered after all specimens for diagnostic tests relevant to the investigation have been collected.

References

1. CDC. Sexually transmitted diseases treatment guidelines, 2006. MMWR 2006;55(No. RR-11).
2. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(No. RR-7).
3. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: immunization of adults. MMWR 2006;55(No. RR-16).
4. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: immunization of infants, children, and adolescents. MMWR 2005;54(No. RR-16).
5. Lin JS, Whitlock E, O'Connor E, et al. Behavioral counseling to prevent sexually transmitted infections: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med 2008; 149:497–9.
6. U.S. Preventive Services Task Force. Behavioral counseling to prevent sexually transmitted infections: recommendation statement. Ann Intern Med 2008;149:491–6.
7. Hatcher RA, Trussell J, Nelson AL, et al. Contraceptive technology. 19th ed. New York: Ardent Media; 2007.
8. Kamb ML, Fishbein M, Douglas JM, Jr., et al. Project RESPECT Study Group. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. JAMA 1998;280:1161–7.
9. Gottlieb SL, Douglas JM, Jr., Foster M, et al. Incidence of herpes simplex virus type 2 infection in 5 sexually transmitted disease (STD) clinics and the effect of HIV/STD risk-reduction counseling. J Infect Dis 2004;190:1059–67.
10. Warner L, Klausner JD, Rietmeijer CA, et al. Effect of a brief video intervention on incident infection among patients attending sexually transmitted disease clinics. PLoS Med 2008;5:e135.
11. CDC, Health Resources and Services Administration, National Institutes of Health, NIV Medicine Association of the Infectious Diseases Society of American, HIV Prevention in Clinical Care Working Group. Recommendations for incorporating human immunodeficiency virus (HIV) prevention into the medical care of persons living with HIV. Clin Infect Dis 2004;38:104–21.
12. Wingood GM, DiClemente RJ, Mikhail I, et al. A randomized controlled trial to reduce HIV transmission risk behaviors and sexually transmitted diseases among women living with HIV: The WiLLOW Program. J Acquir Immune Defic Syndr 2004;37(Suppl 2):S58–67.
13. Richardson JL, Milam J, Stoyanoff S, et al. Using patient risk indicators to plan prevention strategies in the clinical care setting. J Acquir Immune Defic Syndr 2004;37(Suppl 2):S88–94.
14. Fisher JD, Cornman DH, Osborn CY, et al. Clinician-initiated HIV risk reduction intervention for HIV-positive persons: Formative Research, Acceptability, and Fidelity of the Options Project. J Acquir Immune Defic Syndr 2004;37(Suppl 2):S78–87.
15. CDC. Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007;56(No. RR-2).
16. CDC. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59:626–9.
17. CDC. FDA licensure of quadrivalent human papillomavirus vaccine (HPV4, Gardasil) for use in males and guidance from the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59:630–2.
18. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. Cochrane Database Syst Rev 2002;(1):CD003255.
19. Ness RB, Randall H, Richter HE, et al. Condom use and the risk of recurrent pelvic inflammatory disease, chronic pelvic pain, or infertility following an episode of pelvic inflammatory disease. Am J Public Health 2004;94:1327–9.
20. Holmes KK, Levine R, Weaver M. Effectiveness of condoms in preventing sexually transmitted infections. Bull World Health Organ 2004;82:454–61.
21. Wald A, Langenberg AG, Krantz E, et al. The relationship between condom use and herpes simplex virus acquisition. Ann Intern Med 2005;143:707–13.
22. Martin ET, Krantz E, Gottlieb SL, et al. A pooled analysis of the effect of condoms in preventing HSV-2 acquisition. Arch Intern Med 2009;169:1233–40.
23. Wald A, Langenberg AG, Link K, et al. Effect of condoms on reducing the transmission of herpes simplex virus type 2 from men to women. JAMA 2001;285:3100–6.
24. Koss CA, Dunne EF, Warner L. A systematic review of epidemiologic studies assessing condom use and risk of syphilis. Sex Transm Dis 2009;36:401–5.
25. Winer RL, Hughes JP, Feng Q, et al. Condom use and the risk of genital human papillomavirus infection in young women. N Engl J Med 2006;354:2645–54.
26. Hogewoning CJ, Bleeker MC, van den Brule AJ, et al. Condom use promotes regression of cervical intraepithelial neoplasia and clearance of human papillomavirus: a randomized clinical trial. Int J Cancer 2003;107:811–6.
27. Bleeker MC, Hogewoning CJ, Voorhorst FJ, et al. Condom use promotes regression of human papillomavirus-associated penile lesions in male sexual partners of women with cervical intraepithelial neoplasia. Int J Cancer 2003;107:804–10.
28. Steiner MJ, Cates W Jr, Warner L. The real problem with male condoms is nonuse. Sex Transm Dis 1999;26:459–62.
29. NIAID. Workshop summary: scientific evidence on condom effectiveness for sexually transmitted disease (STD) prevention. 2001. Available at www.niaid.nih.gov/about/organization/dmid/documents/condomreport.pdf.
30. Gallo MF, Grimes DA, Lopez LM, Schulz KF. Non-latex versus latex male condoms for contraception. Cochrane Database Syst Rev 2006;1:CD003550.
31. Macaluso M, Blackwell R, Jamieson DJ, et al. Efficacy of the male latex condom and of the female polyurethane condom as barriers to semen during intercourse: a randomized clinical trial. Am J Epidemiol 2007;166:88–96.
32. French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. Sex Transm Dis 2003;30:433–9.
33. Gross M, Buchbinder SP, Holte S, et al. Use of reality "female condoms" for anal sex by US men who have sex with men. HIVNET Vaccine Preparedness Study Protocol Team. Am J Public Health 1999;89:1739–41.
34. Minnis AM, Padian NS. Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: current evidence and future research directions. Sex Transm Infect 2005;81:193–200.
35. Padian NS, van der SA, Ramjee G, et al. Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: a randomised controlled trial. Lancet 2007;370:251–61.
36. Ramjee G, van der SA, Chipato T, et al. The diaphragm and lubricant gel for prevention of cervical sexually transmitted infections: results of a randomized controlled trial. PLoS One 2008;3:e3488.
37. Fihn SD, Boyko EJ, Normand EH, et al. Association between use of spermicide-coated condoms and *Escherichia coli* urinary tract infection in young women. Am J Epidemiol 1996;144:512–20.
38. Padian NS, Buve A, Balkus J, et al. Biomedical interventions to prevent HIV infection: evidence, challenges, and way forward. Lancet 2008;372:585–99.

39. Cates W, Feldblum P. HIV prevention research: the ecstasy and the agony. Lancet 2008;372:1932–3.
40. Wilkinson D, Tholandi M, Ramjee G, et al. Nonoxynol-9 spermicide for prevention of vaginally acquired HIV and other sexually transmitted infections: systematic review and meta-analysis of randomised controlled trials including more than 5000 women. Lancet Infect Dis 2002;2:613–7.
41. Skoler-Karpoff S, Ramjee G, Ahmed K, et al. Efficacy of Carraguard for prevention of HIV infection in women in South Africa: a randomised, double-blind, placebo-controlled trial. Lancet 2008;372:1977–87.
42. Van DL, Govinden R, Mirembe FM, et al. Lack of effectiveness of cellulose sulfate gel for the prevention of vaginal HIV transmission. N Engl J Med 2008;359:463–72.
43. Feldblum PJ, Adeiga A, Bakare R, et al. SAVVY vaginal gel (C31G) for prevention of HIV infection: a randomized controlled trial in Nigeria. PLoS One 2008;3:e1474.
44. Peterson L, Nanda K, Opoku BK, et al. SAVVY (C31G) gel for prevention of HIV infection in women: a phase 3, double-blind, randomized, placebo-controlled trial in Ghana. PLoS One 2007;2:e1312.
45. Karim SA, Coletti A, Richardson BS. Safety and effectiveness of vaginal microbicides BufferGel and 0.5% PRO 2000/5 gel for the prevention of HIV infection in women: results of the HPTN 035 trial. In: 16th Conference on Retroviruses and Opportunistic Infections, Montreal, Canada, 2009.
46. Microbicides Development Programme. Technical fact sheet for scientists (MDP 301). London, 2009. Available at http://www.mdp.mrc.ac.uk.
47. Karim QA, Karim SS, Frohlich JA, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. Science 2010;329:1168–74.
48. Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet 2007;369:643–6.
49. Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. Lancet 2007;369:657–66.
50. Auvert B, Taljaard D, Lagarde E, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. PLoS Med 2005;2:e298.
51. Auvert B, Sobngwi-Tambekou J, Cutler E, et al. Effect of male circumcision on the prevalence of high-risk human papillomavirus in young men: results of a randomized controlled trial conducted in Orange Farm, South Africa. J Infect Dis 2009;199:14–9.
52. Sobngwi-Tambekou J, Taljaard D, Lissouba P, et al. Effect of HSV-2 serostatus on acquisition of HIV by young men: results of a longitudinal study in Orange Farm, South Africa. J Infect Dis 2009;199:958–64.
53. Sobngwi-Tambekou J, Taljaard D, Nieuwoudt M, et al. Male circumcision and *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Trichomonas vaginalis*: observations after a randomised controlled trial for HIV prevention. Sex Transm Infect 2009;85:116–20.
54. Tobian AA, Serwadda D, Quinn TC, et al. Male circumcision for the prevention of HSV-2 and HPV infections and syphilis. N Engl J Med 2009;360:1298–309.
55. Millett GA, Flores SA, Marks G, et al. Circumcision status and risk of HIV and sexually transmitted infections among men who have sex with men: a meta-analysis. JAMA 2008;300:1674–84.
56. UNAIDS, WHO. New data on male circumcision and HIV prevention: policy and programme implications: WHO/UNAIDS technical consultation male circumcision and HIV prevention—research implications for policy and programming. Geneva: Joint United Nations Programme on HIV/AIDS and World Health Organization; 2007.
57. Smith DK, Taylor A, Kilmarx PH, et al. Male circumcision in the United States for the prevention of HIV infection and other adverse health outcomes: report from a CDC consultation. Public Health Rep 2010;125(Suppl 1):72–82.
58. Cheng L, Gulmezoglu AM, Piaggio G, et al. Interventions for emergency contraception (update of 2004 document). Cochrane Database Syst Rev 2008;(2):CD001324.
59. Myer L, Kuhn L, Stein ZA, et al. Intravaginal practices, bacterial vaginosis, and women's susceptibility to HIV infection: epidemiological evidence and biological mechanisms. Lancet Infect Dis 2005;5:786–94.
60. Cohen MS, Gay C, Kashuba AD, et al. Narrative review: antiretroviral therapy to prevent the sexual transmission of HIV-1. Ann Intern Med 2007;146:591–601.
61. Peterson L, Taylor D, Roddy R, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. PLoS Clin Trials 2007;2:e27.
62. Cohen MS, Kashuba AD. Antiretroviral therapy for prevention of HIV infection: new clues from an animal model. PLoS Med 2008;5:e30.
63. Karim QA, Karim SS, Frohlich JA, et al; The CAPRISA 004 Trial Group. Available at Science express/www.sciencexpress.org/19 July 2010/10.1126/science.1193748.
64. Peterman TA, Tian LH, Metcalf CA, et al. High incidence of new sexually transmitted infections in the year following a sexually transmitted infection: a case for rescreening. Ann Intern Med 2006;145:564–72.
65. Hogben M. Partner notification for sexually transmitted diseases. Clin Infect Dis 2007;44(Suppl 3):S160–74.
66. Wilson TE, Hogben M, Malka ES, et al. A randomized controlled trial for reducing risks for sexually transmitted infections through enhanced patient-based partner notification. Am J Public Health 2009;99(Suppl 1):S104–10.
67. Hodge JG, Jr., Pulver A, Hogben M, et al. Expedited partner therapy for sexually transmitted diseases: assessing the legal environment. Am J Public Health 2008;98:238–43.
68. Golden MR, Whittington WL, Handsfield HH, et al. Effect of expedited treatment of sex partners on recurrent or persistent gonorrhea or chlamydial infection. N Engl J Med 2005;352:676–85.
69. Schillinger JA, Kissinger P, Calvet H, et al. Patient-delivered partner treatment with azithromycin to prevent repeated *Chlamydia trachomatis* infection among women: a randomized, controlled trial. Sex Transm Dis 2003;30:49–56.
70. Trelle S, Shang A, Nartey L, et al. Improved effectiveness of partner notification for patients with sexually transmitted infections: systematic review. BMJ 2007;334(7589):354.
71. Kissinger P, Mohammed H, Richardson-Alston G, et al. Patient-delivered partner treatment for male urethritis: a randomized, controlled trial. Clin Infect Dis 2005;41:623–9.
72. Kissinger P, Schmidt N, Mohammed H, et al. Patient-delivered partner treatment for *Trichomonas vaginalis* infection: a randomized controlled trial. Sex Transm Dis 2006;33:445–50.
73. Schwebke JR, Desmond RA. A randomized controlled trial of partner notification methods for prevention of trichomoniasis in women. Sex Transm Dis 2010;37:392–6.
74. Rothenberg R, Kimbrough L, Lewis-Hardy R, et al. Social network methods for endemic foci of syphilis: a pilot project. Sex Transm Dis 2000;27:12–8.
75. Ogilvie G, Knowles L, Wong E, et al. Incorporating a social networking approach to enhance contact tracing in a heterosexual outbreak of syphilis. Sex Transm Inf 2005;81:124–7.
76. Vest JR, Valadez AM, Hanner A, et al. Using e-mail to notify pseudonymous e-mail sexual partners. Sex Transm Dis 2007;34:840–5.
77. CDC. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR 2006;55(No. RR-14).
78. CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the US Department of Health and Human Services. MMWR 2005;54(No. RR-2).

79. U.S. Preventive Services Task Force. Screening for syphilis infection in pregnancy: reaffirmation recommendation statement. Ann Intern Med 2009;150:705–9.
80. U.S. Prevention Task Force. Screening for hepatitis B virus infection in pregnancy: reaffirmation recommendation statement. Ann Intern Med 2009;150:869–73.
81. U.S. Preventive Services Task Force. Screening for chlamydial infection: recommendation statement. Ann Intern Med 2007;147:128–34.
82. U.S. Preventive Services Task Force. Screening for gonorrhea: recommendation statement. Ann Fam Med 2005;3:263–7.
83. Sadler L, Saftlas A, Wang W, et al. Treatment for cervical intraepithelial neoplasia and risk of preterm delivery. JAMA 2004;291:2100–6.
84. Serati M, Uccella S, Laterza RM, et al. Natural history of cervical intraepithelial neoplasia during pregnancy. Acta Obstet Gynecol Scand 2008;87:1296–1300.
85. U.S. Preventive Services Task Force. Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: recommendation statement. Ann Intern Med 2008;148:214–9.
86. Chou R, Smits AK, Huffman LH, et al. Prenatal screening for HIV: A review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2005;143:38–54.
87. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Guidelines for perinatal care, 6th ed. Washington, DC: American College of Obstetricians and Gynecologists; 2007.
88. CDC. Rapid HIV antibody testing during labor and delivery for women of unknown HIV status: a practical guide and model protocol, 2004. Atlanta, GA: CDC, National Center for HIV, STD, and TB Prevention; 2004.
89. American College of Obstetricians and Gynecologists. Viral hepatitis in pregnancy. ACOG Practice Bulletin No. 86. Obstet Gynecol 2007;110:941–56.
90. Public Health Agency of Canada. Canadian guidelines on sexually transmitted infections. 2006 ed. Centre for Communicable Diseases and Infection Control; 2010. Available at http://www.phac-aspc.gc.ca/std-mts/sti-its/.
91. Meyers D, Wolff T, Gregory K, et al. USPSTF recommendations for STI screening. Am Fam Physician 2008;77:819–24.
92. Forhan SE, Gottlieb SL, Sternberg MR, et al. Prevalence of sexually transmitted infections among female adolescents aged 14 to 19 in the United States. Pediatrics 2009;124:1505–12.
93. CDC. Sexually Transmitted Disease Surveillance, 2008. Atlanta, GA: US Department of Health and Human Services, CDC; 2009.
94. CDC. Male Chlamydia Screening Consultation, Atlanta, Georgia. March 28 – 29, 2006. Meeting Report, May 2007. Available at http://www.cdc.gov/std/chlamydia/ChlamydiaScreening-males.pdf.
95. U.S. Preventive Services Task Force. Human immunodeficiency virus infection. Rockville, MD: Agency for Healthcare Research and Quality; 2007. Available at http://www.ahrq.gov/clinic/uspstf/uspshivi.htm.
96. American College of Obstetricians and Gynecologists (ACOG). Cervical cytology screening. ACOG Practice Bulletin No. 109. Obstet Gynecol 2009;114:1409–20.
97. U.S. Preventive Services Task Force. Screening for cervical cancer: recommendations. In press 2011.
98. Sasieni P, Castanon A, Cuzick J. Effectiveness of cervical screening with age: population based case-control study of prospectively recorded data. BMJ 2009;339:b2968.
99. Saslow D, Runowicz CD, Solomon D, et al. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. J Low Genit Tract Dis 2003;7:67–86.
100. Chow JM, Joesoef MR, Kent C, et al. Responding to the burden of STD, HIV, and viral hepatitis in correctional populations through program collaboration and integration. Sex Transm Dis 2009;36(2 Suppl):S1–2.
101. Joesoef MR, Weinstock HS, Kent CK, et al. Sex and age correlates of Chlamydia prevalence in adolescents and adults entering correctional facilities, 2005: implications for screening policy. Sex Transm Dis 2009;36(2 Suppl):S67–71.
102. Kahn RH, Voigt RF, Swint E, et al. Early syphilis in the United States identified in corrections facilities, 1999–2002. Sex Transm Dis 2004;31:360–4.
103. Mayer KH, Klausner JD, Handsfield HH. Intersecting epidemics and educable moments: sexually transmitted disease risk assessment and screening in men who have sex with men. Sex Transm Dis 2001;28:464–7.
104. Kent CK, Chaw JK, Wong W, et al. Prevalence of rectal, urethral, and pharyngeal chlamydia and gonorrhea detected in 2 clinical settings among men who have sex with men: San Francisco, California, 2003. Clin Infect Dis 2005;41:67–74.
105. Millett GA, Peterson JL, Wolitski RJ, et al. Greater risk for HIV infection of black men who have sex with men: a critical literature review. Am J Public Health 2006;96:1007–19.
106. Klausner JD, Wong W. Sexually transmitted diseases in men who have sex with men: a clinical review. Curr Infect Dis Rep 2003;5:135–44.
107. Golden MR, Stekler J, Hughes JP, et al. HIV serosorting in men who have sex with men: is it safe? J Acquir Immune Defic Syndr 2008;49:212–8.
108. CDC. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR 2008;57(No. RR-8).
109. Goodenow C, Szalacha LA, Robin LE, et al. Dimensions of sexual orientation and HIV-related risk among adolescent females: evidence from a statewide survey. Am J Public Health 2008;98:1051–8.
110. Eisenberg M. Differences in sexual risk behaviors between college students with same-sex and opposite-sex experience: results from a national survey. Arch Sex Behav 2001;30:575–89.
111. Koh AS, Gomez CA, Shade S, et al. Sexual risk factors among self-identified lesbians, bisexual women, and heterosexual women accessing primary care settings. Sex Transm Dis 2005;32:563–9.
112. Lindley L, Barnett TL, Brandt HM, et al. STDs among sexually active college students: does sexual orientation make a difference? Perspect Sex Reprod Health 2008;40(4):212–17.
113. Fethers K, Marks C, Mindel A, et al. Sexually transmitted infections and risk behaviours in women who have sex with women. Sex Transm Infect 2000;76:345–9.
114. Marrazzo JM, Koutsky LA, Eschenbach DA, et al. Characterization of vaginal flora and bacterial vaginosis in women who have sex with women. J Infect Dis 2002;185:1307–13.
115. Kellock D, O'Mahony CP. Sexually acquired metronidazole-resistant trichomoniasis in a lesbian couple. Genitourin Med. 1996;72:60–61.
116. Kwakwa HA, Ghobrial MW. Female-to-Female Transmission of Human Immunodeficiency Virus. Clin Infect Dis. 2003;36:e40–e41.
117. Berger BJ, Kolton S, Zenilman JM, Cummings MC, Feldman J, McCormack WM. Bacterial vaginosis in lesbians: a sexually transmitted disease. Clin Infect Dis. Dec 1995;21:1402–1405.
118. Marrazzo JM, Koutsky LA, Kiviat NB, et al. Papanicolaou test screening and prevalence of genital human papillomavirus among women who have sex with women. Am J Public Health 2001;91:947–52.

119. Diamant AL, Schuster MA, McGuigan K, et al. Lesbians' sexual history with men: implications for taking a sexual history. Arch Intern Med 1999;159:2730–6.
120. Marrazzo JM, Stine K, Wald A. Prevalence and risk factors for infection with herpes simplex virus type-1 and -2 among lesbians. Sex Transm Dis 2003;30:890–5.
121. Singh D, Fine D, Marrazzo JM. *Chlamydia trachomatis* infection among women reporting sexual activity with women screened in family planning clinics in the Pacific Northwest, 1997 to 2005. Am J Public Health 2010; Aug 19[epub].
122. Marrazzo JM, Antonio M, Agnew K, et al. Distribution of genital Lactobacillus strains shared by female sex partners. J Infect Dis 2009;199:680–3.
123. Smit C, Geskus R, Walker S, et al. Effective therapy has altered the spectrum of cause-specific mortality following HIV seroconversion. AIDS 2006;20:741–9.
124. Hollingsworth TD, Anderson RM, Fraser C. HIV-1 transmission, by stage of infection. J Infect Dis 2008;198:687–3.
125. Wawer MJ, Gray RH, Sewankambo NK, et al. Rates of HIV-1 transmission per coital act, by stage of HIV-1 infection, in Rakai, Uganda. J Infect Dis 2005;191:1403–9.
126. Pilcher CD, Tien HC, Eron JJ Jr., et al. Brief but efficient: acute HIV infection and the sexual transmission of HIV. J Infect Dis 2004;189:1785–92.
127. CDC. HIV/AIDS Surveillance Report, 2008. Vol. 20. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2010. Available at http://www.cdc.gov/hiv/topics/surveillance/resources/reports/.
128. CDC. Persons tested for HIV—United States, 2006. MMWR 2008;57:845–9.
129. DHHS. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2010. Available at http://AIDSinfo.nih.gov.
130. CDC. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents. MMWR 2009;58(No. RR-4).
131. Aberg JA, Kaplan JE, Libman H, et al. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. Clin Infect Dis 2009;49:651–81.
132. CDC. Protocols for the confirmation of reactive rapid HIV tests. MMWR 2004;53:221–2.
133. Pilcher CD, Eron JJ Jr., Vemazza PL, et al. Sexual transmission during the incubation period of primary HIV infection. JAMA 2001;286:1713–4.
134. Marks G, Crepaz N, Senterfitt JW, et al. Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs. J Acquir Immune Defic Syndr 2005;39:446–53.
135. Myers JJ, Shade SB, Rose CD, et al. Interventions delivered in clinical settings are effective in reducing risk of HIV transmission among people living with HIV: results from the Health Resources and Services Administration (HRSA)'s Special Projects of National Significance Initiative. AIDS Behav 2010;14:483–92.
136. CDC. Incorporating HIV prevention into the medical care of persons living with HIV: recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR 2003;52(No. RR-12).
137. CDC. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. MMWR 2008;57(No. RR-9).
138. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. 2010. Available at www.aidsinfo.nih.gov.
139. Bulterys M, Weidle PJ, Abrams EJ, et al. Combination antiretroviral therapy in African nursing mothers and drug exposure in their infants: new pharmacokinetic and virologic findings. J Infect Dis 2005;192:709–12.
140. Public Health Service Task Force. Recommendations for use of antiretroviral drugs in pregnant HIV-1 infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville, MD: US Department of Health and Human Services, National Institutes of Health, Health Resources and Services Administration; 2010. Available at http://www.aidsinfo.nih.gov.
141. Read JS. Diagnosis of HIV-1 infection in children younger than 18 months in the United States. Pediatrics 2007;120:e1547–62.
142. Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection. 2009. Available at http://aidsinfo.nih.gov/ContentFiles/PediatricGuidelines.pdf.
143. CDC. Guidelines for prevention and treatment of opportunistic infections in HIV-exposed and HIV-infected children. MMWR 2009;58(No. RR-11).
144. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect 1999;75:3–17.
145. Lockett AE, Dance DA, Mabey DC, Drasar BS. Serum free media for the isolation of *Haemophilus ducreyi*. Lancet 1991; 338:326.
146. Lewis D. Chancroid: clinical manifestations, diagnosis and management. Sex Transm Infect 2002;79:68.
147. Xu F, Sternberg MR, Kottiri BJ, et al. Trends in herpes simplex virus type 1 and type 2 seroprevalence in the United States. JAMA 2006;296:964–73.
148. Ryder N, Jin F, McNulty AM, et al. Increasing role of herpes simplex virus type 1 in first-episode anogenital herpes in heterosexual women and younger men who have sex with men, 1992–2006. Sex Transm Infect 2009;85:416–9.
149. Roberts CM, Pfister JR, Spear SJ. Increasing proportion of herpes simplex virus type 1 as a cause of genital herpes infection in college students. Sex Transm Dis 2003;30:797–800.
150. Benedetti J, Corey L, Ashley R. Recurrence rates in genital herpes after symptomatic first-episode infection. Ann Intern Med 1994;121:847–54.
151. Engelberg R, Carrell D, Krantz E, et al. Natural history of genital herpes simplex virus type 1 infection. Sex Transm Dis 2003;30:174–7.
152. Scoular A. Using the evidence base on genital herpes: optimising the use of diagnostic tests and information provision. Sex Transm Infect 2002;78:160–5.
153. Scoular A, Gillespie G, Carman WF. Polymerase chain reaction for diagnosis of genital herpes in a genitourinary medicine clinic. Sex Transm Infect 2002;78:21–5.

154. Wald A, Huang ML, Carrell D, et al. Polymerase chain reaction for detection of herpes simplex virus (HSV) DNA on mucosal surfaces: comparison with HSV isolation in cell culture. J Infect Dis 2003;188:1345–51.
155. Ashley R, Cent A, Maggs V, et al. Inability of enzyme immunoassays to discriminate between infections with herpes simplex virus types 1 and 2. Ann Intern Med 1991;115:520–6.
156. Song B, Dwyer DE, Mindel A. HSV type specific serology in sexual health clinics: use, benefits, and who gets tested. Sex Transm Infect 2004;80:113–7.
157. Whittington WL, Celum CL, Cent A, et al. Use of a glycoprotein G-based type-specific assay to detect antibodies to herpes simplex virus type 2 among persons attending sexually transmitted disease clinics. Sex Transm Dis 2001;28:99–104.
158. Zimet GD, Rosenthal SL, Fortenberry JD, et al. Factors predicting the acceptance of herpes simplex virus type 2 antibody testing among adolescents and young adults. Sex Transm Dis 2004;31:665–69.
159. Morrow R, Friedrich D. Performance of a novel test for IgM and IgG antibodies in subjects with culture-documented genital herpes simplex virus-1 or -2 infection. Clin Microbiol Infect 2006;12:463–9.
160. Leone PA, Trottier S, Miller JM. Valacyclovir for episodic treatment of genital herpes: a shorter 3-day treatment course compared with 5-day treatment. Clin Infect Dis 2002;34:958–62.
161. Wald A, Carrell D, Remington M, et al. Two-day regimen of acyclovir for treatment of recurrent genital herpes simplex virus type 2 infection. Clin Infect Dis 2002;34:944–8.
162. Aoki FY, Tyring S, az-Mitoma F, et al. Single-day, patient-initiated famciclovir therapy for recurrent genital herpes: a randomized, double-blind, placebo-controlled trial. Clin Infect Dis 2006;42:8–13.
163. Chosidow O, Drouault Y, Leconte-Veyriac F, et al. Famciclovir vs. aciclovir in immunocompetent patients with recurrent genital herpes infections: a parallel-groups, randomized, double-blind clinical trial. Br J Dermatol 2001;144:818–24.
164. Bodsworth NJ, Crooks RJ, Borelli S, et al. Valaciclovir versus aciclovir in patient initiated treatment of recurrent genital herpes: a randomised, double blind clinical trial. International Valaciclovir HSV Study Group. Genitourin Med 1997;73:110–6.
165. Fife KH, Barbarash RA, Rudolph T, et al. Valaciclovir versus acyclovir in the treatment of first-episode genital herpes infection. Results of an international, multicenter, double-blind, randomized clinical trial. The Valaciclovir International Herpes Simplex Virus Study Group. Sex Transm Dis 1997;24:481–6.
166. Diaz-Mitoma F, Sibbald RG, Shafran SD, et al. Oral famciclovir for the suppression of recurrent genital herpes: a randomized controlled trial. Collaborative Famciclovir Genital Herpes Research Group. JAMA 1998;280:887–92.
167. Mertz GJ, Loveless MO, Levin MJ, et al; Collaborative Famciclovir Genital Herpes Research Group. Oral famciclovir for suppression of recurrent genital herpes simplex virus infection in women: a multicenter, double-blind, placebo-controlled trial. Arch Intern Med 1997;157:343–49.
168. Reitano M, Tyring S, Lang W, et al; International Valaciclovir HSV Study Group. Valaciclovir for the suppression of recurrent genital herpes simplex virus infection: a large-scale dose range-finding study. J Infect Dis 1998;178:603–10.
169. Romanowski B, Marina RB, Roberts JN. Patients‘ preference of valacyclovir once-daily suppressive therapy versus twice-daily episodic therapy for recurrent genital herpes: a randomized study. Sex Transm Dis 2003;30:226–231.
170. Corey L, Wald A, Patel R, et al. Once-daily valacyclovir to reduce the risk of transmission of genital herpes. N Engl J Med 2004;350:11–20.
171. Goldberg LH, Kaufman R, Kurtz TO, et al; Acyclovir Study Group. Long-term suppression of recurrent genital herpes with acyclovir: a 5-year benchmark. Arch Dermatol 1993;129:582–7.
172. Fife KH, Crumpacker CS, Mertz GJ, et al; Acyclovir Study Group. Recurrence and resistance patterns of herpes simplex virus following cessation of ≥6 years of chronic suppression with acyclovir. J Infect Dis 1994;169:1338–41.
173. Wald A, Selke S, Warren T, et al. Comparative efficacy of famciclovir and valacyclovir for suppression of recurrent genital herpes and viral shedding. Sex Transm Dis 2006;33:529–33.
174. Gilbert LK, Wyand F. Genital herpes education and counseling: testing a one-page, FAQ intervention. Herpes 2009;15:51–6.
175. Rosenthal SL, Zimet GD, Leichliter JS, et al. The psychosocial impact of serological diagnosis of asymptomatic herpes simplex virus type 2 infection. Sex Transm Infect 2006;82:154–7.
176. Miyai T, Turner KR, Kent CK, et al. The psychosocial impact of testing individuals with no history of genital herpes for herpes simplex virus type 2. Sex Transm Dis 2004;31:517–21.
177. Watson-Jones D, Weiss HA, Rusizoka M, et al. Effect of herpes simplex suppression on incidence of HIV among women in Tanzania. N Engl J Med 2008;358:1560–71.
178. Celum C, Wald A, Hughes J, et al. Effect of aciclovir on HIV-1 acquisition in herpes simplex virus 2 seropositive women and men who have sex with men: a randomised, double-blind, placebo-controlled trial. Lancet 2008;371(9630):2109–19.
179. Henry RE, Wegmann JA, Hartle JE, et al. Successful oral acyclovir desensitization. Ann Allergy 1993;70:386–8.
180. Posavad CM, Wald A, Kuntz S, et al. Frequent reactivation of herpes simplex virus among HIV-1-infected patients treated with highly active antiretroviral therapy. J Infect Dis 2004;190:693–6.
181. Conant MA, Schacker TW, Murphy RL, et al. Valaciclovir versus aciclovir for herpes simplex virus infection in HIV-infected individuals: two randomized trials. Int J STD AIDS 2002;13:12–21.
182. Romanowski B, Aoki FY, Martel AY, et al. Efficacy and safety of famciclovir for treating mucocutaneous herpes simplex infection in HIV-infected individuals. Collaborative Famciclovir HIV Study Group. AIDS 2000;14:1211–7.
183. DeJesus E, Wald A, Warren T, et al. Valacyclovir for the suppression of recurrent genital herpes in human immunodeficiency virus-infected subjects. J Infect Dis 2003;188:1009–16.
184. Reyes M, Shaik NS, Graber JM, et al. Acyclovir-resistant genital herpes among persons attending sexually transmitted disease and human immunodeficiency virus clinics. Arch Intern Med 2003;163:76–80.
185. Erard V, Wald A, Corey L, et al. Use of long-term suppressive acyclovir after hematopoietic stem-cell transplantation: impact on herpes simplex virus (HSV) disease and drug-resistant HSV disease. J Infect Dis 2007;196:266–70.
186. Brown ZA, Selke S, Zeh, et al. Acquisition of herpes simplex virus during pregnancy. N Engl J Med 1997;337:509–15.
187. Brown ZA, Wald A, Morrow RA, et al. Effect of serologic status and cesarean delivery on transmission rates of herpes simplex virus from mother to infant. JAMA 2003;289:203–9.
188. Stone KM, Reiff-Eldridge R, White AD, et al. Pregnancy outcomes following systemic prenatal acyclovir exposure: conclusions from the international acyclovir pregnancy registry, 1984–1999. Birth Defects Res A Clin Mol Teratol 2004;70:201–7.

189. Sheffield JS, Hollier LM, Hill JB, et al. Acyclovir prophylaxis to prevent herpes simplex virus recurrence at delivery: a systematic review. Obstet Gynecol 2003;102:1396–1403.
190. Watts DH, Brown ZA, Money D, et al. A double-blind, randomized, placebo-controlled trial of acyclovir in late pregnancy for the reduction of herpes simplex virus shedding and cesarean delivery. Am J Obstet Gynecol 2003;188:836–43.
191. Scott LL, Hollier LM, McIntire D, et al. Acyclovir suppression to prevent recurrent genital herpes at delivery. Infect Dis Obstet Gynecol 2002;10:71–7.
192. O'Farrell N. Donovanosis. Sex Transm Infect 2002;78:452–7.
193. Bowden FJ. Donovanosis in Australia: going, going. Sex Transm Infect 2005;81:365–6.
194. Mabey D, Peeling RW. Lymphogranuloma venereum. Sex Transm Infect 2002;78:90–2.
195. Nieuwenhuis RF, Ossewaarde JM, Gotz HM, et al. Resurgence of lymphogranuloma venereum in Western Europe: an outbreak of *Chlamydia trachomatis* serovar l2 proctitis in the Netherlands among men who have sex with men. Clin Infect Dis 2004;39:996–1003.
196. Ward H, Martin I, Macdonald N, et al. Lymphogranuloma venereum in the United Kingdom. Clin Infect Dis 2007;44:26–32.
197. CDC. Guidelines for the laboratory diagnosis of gonorrhea, chlamydia and syphilis. Available at http://www.aphl.org/aphlprograms/infectious/std/Pages/stdtestingguidelines.aspx.
198. Nandwani R, Evans DT. Are you sure it's syphilis? A review of false positive serology. Int J STD AIDS 1995;6:241–8.
199. Association of Public Health Laboratories (APHL). Laboratory Diagnostic Testing for Treponema pallidum. Expert Consultation Meeting Summary Report, January 13–15, 2009, Atlanta, GA. Available at http://www.aphl.org/aphlprograms/infectious/std/Documents/LaboratoryGuidelinesTreponemapallidumMeetingReport.pdf.
200. Romanowski B, Sutherland R, Fick GH, et al. Serologic response to treatment of infectious syphilis. Ann Intern Med 1991;114:1005–9.
201. CDC. Syphilis testing algorithms using treponemal tests for initial screening–four laboratories, New York City, 2005–2006. MMWR 2008;57:872–5.
202. Pope V. Use of treponemal tests to screen for syphilis. Infect Med 2004;21:399–402.
203. Lukehart SA, Hook EW, III, Baker-Zander SA, et al. Invasion of the central nervous system by *Treponema pallidum*: implications for diagnosis and treatment. Ann Intern Med 1988;109:855–62.
204. Marra CM, Maxwell CL, Smith SL, et al. Cerebrospinal fluid abnormalities in patients with syphilis: association with clinical and laboratory features. J Infect Dis 2004;189:369–76.
205. Jaffe HW, Larsen SA, Peters M, et al. Tests for treponemal antibody in CSF. Arch Intern Med 1978;138:252–5.
206. CDC. Inadvertent use of Bicillin® C-R to treat syphilis infection — Los Angeles, California, 1999–2004. MMWR 2005;54:217–9.
207. Ghanem KG, Erbelding EJ, Wiener ZS, et al. Serological response to syphilis treatment in HIV-positive and HIV-negative patients attending sexually transmitted diseases clinics. Sex Transm Infect 2007;83:97–101.
208. Rolfs RT, Joesoef MR, Hendershot EF, et al; The Syphilis and HIV Study Group. A randomized trial of enhanced therapy for early syphilis in patients with and without human immunodeficiency virus infection. N Engl J Med 1997;337:307–14.
209. Ghanem KG, Erbelding EJ, Cheng WW, et al. Doxycycline compared with benzathine penicillin for the treatment of early syphilis. Clin Infect Dis 2006;42:e45–9.
210. Wong T, Singh AE, De P. Primary syphilis: serological treatment response to doxycycline/tetracycline versus benzathine penicillin. Am J Med 2008;121:903–8.
211. Hook EW, III, Roddy RE, Handsfield HH. Ceftriaxone therapy for incubating and early syphilis. J Infect Dis 1988;158:881–4.
212. Riedner G, Rusizoka M, Todd J, et al. Single-dose azithromycin versus penicillin G benzathine for the treatment of early syphilis. N Engl J Med 2005;353:1236–44.
213. Hook EW, III, Martin DH, Stephens J, et al. A randomized, comparative pilot study of azithromycin versus benzathine penicillin G for treatment of early syphilis. Sex Transm Dis 2002;29:486–90.
214. Hook EW, III, Behets F, Van DK, et al. A phase III equivalence trial of azithromycin versus benzathine penicillin for treatment of early syphilis. J Infect Dis 2010;201:1729–35.
215. Lukehart SA, Godornes C, Molini BJ, et al. Macrolide resistance in *Treponema pallidum* in the United States and Ireland. N Engl J Med 2004;351:154–8.
216. Mitchell SJ, Engelman J, Kent CK, et al. Azithromycin-resistant syphilis infection: San Francisco, California, 2000–2004. Clin Infect Dis 2006;42:337–45.
217. Su JR, Hook E, Kenney K, et al. Prevalence of the 23S rRNA point mutation in *Treponema pallidum* in the United States and Associated Factors, 2006–2008. 18th International Society for Sexually Transmitted Diseases Research, #OS1.11.03. London, England: June 2009.
218. Marra CM, Boutin P, McArthur JC, et al. A pilot study evaluating ceftriaxone and penicillin G as treatment agents for neurosyphilis in human immunodeficiency virus-infected individuals. Clin Infect Dis 2000;30:540–4.
219. Marra CM, Maxwell CL, Tantalo L, et al. Normalization of cerebrospinal fluid abnormalities after neurosyphilis therapy: does HIV status matter? Clin Infect Dis 2004;38:1001–6.
220. Marra CM, Maxwell CL, Tantalo LC, et al. Normalization of serum rapid plasma reagin titer predicts normalization of cerebrospinal fluid and clinical abnormalities after treatment of neurosyphilis. Clin Infect Dis 2008;47:893–9.
221. Hook EW, III, Baker-Zander SA, Moskovitz BL, et al. Ceftriaxone therapy for asymptomatic neurosyphilis. Case report and Western blot analysis of serum and cerebrospinal fluid IgG response to therapy. Sex Transm Dis 1986;13(3 Suppl):S185–8.
222. Shann S, Wilson J. Treatment of neurosyphilis with ceftriaxone. Sex Transm Infect 2003;79:415–6.
223. Kingston AA, Vujevich J, Shapiro M, et al. Seronegative secondary syphilis in 2 patients coinfected with human immunodeficiency virus. Arch Dermatol 2005;141:431–3.
224. CDC. Symptomatic early neurosyphilis among HIV-positive men who have sex with men: four cities, United States, January 2002–June 2004. MMWR 2007;56:625–8.
225. Libois A, De WS, Poll B, et al. HIV and syphilis: when to perform a lumbar puncture. Sex Transm Dis 2007;34:141–4.
226. Ghanem KG. Sensitivity and specificity of lumbar puncture in HIV-infected patients with syphilis and no neurologic symptoms reply. Clin Infect Dis 2009;49:162–3.
227. Ghanem KG, Moore RD, Rompalo AM, et al. Neurosyphilis in a clinical cohort of HIV-1-infected patients. AIDS 2008;22:1145–51.
228. Ghanem KG, Moore RD, Rompalo AM, et al. Antiretroviral therapy is associated with reduced serologic failure rates for syphilis among HIV-infected patients. Clin Infect Dis 2008;47:258–65.

229. Dowell ME, Ross PG, Musher DM, et al. Response of latent syphilis or neurosyphilis to ceftriaxone therapy in persons infected with human immunodeficiency virus. Am J Med 1992;93:481–8.
230. Smith NH, Musher DM, Huang DB, et al. Response of HIV-infected patients with asymptomatic syphilis to intensive intramuscular therapy with ceftriaxone or procaine penicillin. Int J STD AIDS 2004;15:328–32.
231. Hollier LM, Harstad TW, Sanchez PJ, et al. Fetal syphilis: clinical and laboratory characteristics. Obstet Gynecol 2001;97:947–53.
232. World Health Organization. The global elimination of congenital syphilis: rationale and strategy for action. Geneva: WHO Department of Reproductive Health and Research; 2005.
233. Alexander JM, Sheffield JS, Sanchez PJ, et al. Efficacy of treatment for syphilis in pregnancy. Obstet Gynecol 1999;93:5–8.
234. Walker GJ. Antibiotics for syphilis diagnosed during pregnancy. Cochrane Database Syst Rev 2001;CD001143.
235. Wendel GD, Jr., Sheffield JS, Hollier LM, et al. Treatment of syphilis in pregnancy and prevention of congenital syphilis. Clin Infect Dis 2002;35(Suppl 2):S200–9.
236. Klein VR, Cox SM, Mitchell MD, et al. The Jarisch-Herxheimer reaction complicating syphilotherapy in pregnancy. Obstet Gynecol 1990;75(3 Pt 1):375–80.
237. Katz KA, Klausner JD. Azithromycin resistance in *Treponema pallidum*. Curr Opin Infect Dis 2008;21:83–91.
238. Saxon A, Beall GN, Rohr AS, et al. Immediate hypersensitivity reactions to beta-lactam antibiotics. Ann Intern Med 1987;107:204–15.
239. Yates AB. Management of patients with a history of allergy to beta-lactam antibiotics. Am J Med 2008;121:572–6.
240. Manhart LE, Holmes KK, Hughes JP, et al. *Mycoplasma genitalium* among young adults in the United States: an emerging sexually transmitted infection. Am J Public Health 2007;97:1118–25.
241. Ross JD, Jensen JS. *Mycoplasma genitalium* as a sexually transmitted infection: implications for screening, testing, and treatment. Sex Transm Infect 2006;82:269–71.
242. Taylor-Robinson D, Gilroy CB, Thomas BJ, et al. *Mycoplasma genitalium* in chronic non-gonococcal urethritis. Int J STD AIDS 2004;15:21–5.
243. Dupin N, Bijaoui G, Schwarzinger M, et al. Detection and quantification of *Mycoplasma genitalium* in male patients with urethritis. Clin Infect Dis 2003;37:602–5.
244. Bradshaw CS, Tabrizi SN, Read TR, et al. Etiologies of nongonococcal urethritis: bacteria, viruses, and the association with orogenital exposure. J Infect Dis 2006;193:336–45.
245. Madeb R, Nativ O, Benilevi D, et al. Need for diagnostic screening of herpes simplex virus in patients with nongonococcal urethritis. Clin Infect Dis 2000;30:982–3.
246. Martin DH. Nongonococcal urethritis: new views through the prism of modern molecular microbiology. Curr Infect Dis Rep 2008;10:128–32.
247. Schwebke JR, Hook EW, III. High rates of *Trichomonas vaginalis* among men attending a sexually transmitted diseases clinic: implications for screening and urethritis management. J Infect Dis 2003;188:465–8.
248. Geisler WM, Yu S, Hook EW, III. Chlamydial and gonococcal infection in men without polymorphonuclear leukocytes on gram stain: implications for diagnostic approach and management. Sex Transm Dis 2005;32:630–4.
249. Falk L, Fredlund H, Jensen JS. Tetracycline treatment does not eradicate *Mycoplasma genitalium*. Sex Transm Infect 2003;79:318–9.
250. Mena LA, Mroczkowski TF, Nsuami M, et al. A randomized comparison of azithromycin and doxycycline for the treatment of *Mycoplasma genitalium*-positive urethritis in men. Clin Infect Dis 2009;48:1649–54.
251. Fung M, Scott KC, Kent CK, et al. Chlamydial and gonococcal reinfection among men: a systematic review of data to evaluate the need for retesting. Sex Transm Infect 2007;83:304–9.
252. Kissinger PJ, Reilly K, Taylor SN, et al. Early repeat *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections among heterosexual men. Sex Transm Dis 2009;36:498–500.
253. Jernberg E, Moghaddam A, Moi H. Azithromycin and moxifloxacin for microbiological cure of *Mycoplasma genitalium* infection: an open study. Int J STD AIDS 2008;19:676–9.
254. Bradshaw CS, Chen MY, Fairley CK. Persistence of *Mycoplasma genitalium* following azithromycin therapy. PLoS One 2008;3:e3618.
255. Meares EM, Stamey TA. Bacteriologic localization patterns in bacterial prostatitis and urethritis. Invest Urol 1968;5:492–518.
256. Nickel JC, Alexander RB, Schaeffer AJ, et al. Leukocytes and bacteria in men with chronic prostatitis/chronic pelvic pain syndrome compared to asymptomatic controls. J Urol 2003;170:818–22.
257. Lusk MJ, Konecny P. Cervicitis: a review. Curr Opin Infect Dis 2008;21:49–55.
258. Marrazzo JM, Martin DH. Management of women with cervicitis. Clin Infect Dis 2007;44 (Suppl 3):S102–10.
259. Korte JE, Baseman JB, Cagle MP, et al. Cervicitis and genitourinary symptoms in women culture positive for *Mycoplasma genitalium*. Am J Reprod Immunol 2006;55:265–75.
260. Gaydos C, Maldeis NE, Hardick A, et al. *Mycoplasma genitalium* as a contributor to the multiple etiologies of cervicitis in women attending sexually transmitted disease clinics. Sex Transm Dis 2009;36:598–606.
261. Schwebke JR, Weiss HL. Interrelationships of bacterial vaginosis and cervical inflammation. Sex Transm Dis 2002;29:59–64.
262. Marrazzo JM, Wiesenfeld HC, Murray PJ, et al. Risk factors for cervicitis among women with bacterial vaginosis. J Infect Dis 2006;193:617–24.
263. Haggerty CL, Totten PA, Astete SG, et al. *Mycoplasma genitalium* among women with nongonococcal, nonchlamydial pelvic inflammatory disease. Infect Dis Obstet Gynecol 2006; Article ID 30184:1–5.
264. Steinhandler L, Peipert JF, Heber W, et al. Combination of bacterial vaginosis and leukorrhea as a predictor of cervical chlamydial or gonococcal infection. Obstet Gynecol 2002;99:603–7.
265. Geisler WM, Yu S, Venglarik M, et al. Vaginal leucocyte counts in women with bacterial vaginosis: relation to vaginal and cervical infections. Sex Transm Infect 2004;80:401–5.
266. Manhart LE. Has the time come to systematically test for *Mycoplasma genitalium*? Sex Transm Dis 2009;36:607–8.
267. Hosenfeld CB, Workowski KA, Berman S, et al. Repeat infection with chlamydia and gonorrhea among females: a systematic review of the literature. Sex Transm Dis 2009;36:478–89.
268. Coleman JS, Hitti J, Bukusi EA, et al. Infectious correlates of HIV-1 shedding in the female upper and lower genital tracts. AIDS 2007;21:755–9.
269. Johnson LF, Lewis DA. The effect of genital tract infections on HIV-1 shedding in the genital tract: a systematic review and meta-analysis. Sex Transm Dis 2008;35:946–59.
270. Mcclelland RS, Wang CC, Mandaliya K, et al. Treatment of cervicitis is associated with decreased cervical shedding of HIV-1. AIDS 2001;15:105–10.

271. Meyers DS, Halvorson H, Luckhaupt S. Screening for chlamydial infection: an evidence update for the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:135–42.
272. Scholes D, Stergachis A, Heidrich FE, et al. Prevention of pelvic inflammatory disease by screening for cervical chlamydial infection. N Engl J Med 1996;334:1362–6.
273. Kamwendo F, Forslin L, Bodin L, et al. Decreasing incidences of gonorrhea- and chlamydia-associated acute pelvic inflammatory disease: a 25-year study from an urban area of central Sweden. Sex Transm Dis 1996;23:384–91.
274. Gift TL, Blake DR, Gaydos CA, et al. The cost-effectiveness of screening men for *Chlamydia trachomatis*: a review of the literature. Sex Transm Dis 2008;35(11 Suppl):S51–60.
275. Gift TL, Gaydos CA, Kent CK, et al. The program cost and cost-effectiveness of screening men for chlamydia to prevent pelvic inflammatory disease in women. Sex Transm Dis 2008;35(11 Suppl):S66–75.
276. Schachter J, Chernesky MA, Willis DE, et al. Vaginal swabs are the specimens of choice when screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: results from a multicenter evaluation of the APTIMA assays for both infections. Sex Transm Dis 2005;32:725–8.
277. Doshi JS, Power J, Allen E. Acceptability of chlamydia screening using self-taken vaginal swabs. Int J STD AIDS 2008;19:507–9.
278. Schachter J, Moncada J, Liska S, et al. Nucleic acid amplification tests in the diagnosis of chlamydial and gonococcal infections of the oropharynx and rectum in men who have sex with men. Sex Transm Dis 2008;35:637–42.
279. Mimiaga MJ, Mayer KH, Reisner SL, et al. Asymptomatic gonorrhea and chlamydial infections detected by nucleic acid amplification tests among Boston area men who have sex with men. Sex Transm Dis 2008;35:495–8.
280. Bachmann LH, Johnson RE, Cheng H, et al. Nucleic acid amplification tests for diagnosis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* rectal infections. J Clin Microbiol 2010;48:1827–32.
281. Bachmann LH, Johnson RE, Cheng H, et al. Nucleic acid amplification tests for diagnosis of *Neisseria gonorrhoeae* oropharyngeal infections. J Clin Microbiol 2009;47:902–7.
282. Chernesky M, Freund GG, Hook E, III, et al. Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in North American women by testing SurePath liquid-based Pap specimens in APTIMA assays. J Clin Microbiol 2007;45:2434–8.
283. Geisler WM, Wang C, Morrison SG, et al. The natural history of untreated *Chlamydia trachomatis* infection in the interval between screening and returning for treatment. Sex Transm Dis 2008;35:119–23.
284. Lau CY, Qureshi AK. Azithromycin versus doxycycline for genital chlamydial infections: a meta-analysis of randomized clinical trials. Sex Transm Dis 2002;29:497–502.
285. Bernstein KT, Stephens SC, Barry PM, et al. *Chlamydia trachomatis* and *Neisseria gonorrhoeae* transmission from the oropharynx to the urethra among men who have sex with men. Clin Infect Dis 2009;49:1793–7.
286. Dunne EF, Chapin JB, Rietmeijer CA, et al. Rate and predictors of repeat *Chlamydia trachomatis* infection among men. Sex Transm Dis 2008;35(11 Suppl):S40–4.
287. Kjaer HO, Dimcevski G, Hoff G, et al. Recurrence of urogenital *Chlamydia trachomatis* infection evaluated by mailed samples obtained at home: 24 weeks' prospective follow up study. Sex Transm Infect 2000;76:169–72.
288. Whittington WL, Kent C, Kissinger P, et al. Determinants of persistent and recurrent *Chlamydia trachomatis* infection in young women: results of a multicenter cohort study. Sex Transm Dis 2001;28:117–123.
289. Jacobson GF, Autry AM, Kirby RS, et al. A randomized controlled trial comparing amoxicillin and azithromycin for the treatment of *Chlamydia trachomatis* in pregnancy. Am J Obstet Gynecol 2001;184:1352–4.
290. Kacmar J, Cheh E, Montagno A, et al. A randomized trial of azithromycin versus amoxicillin for the treatment of *Chlamydia trachomatis* in pregnancy. Infect Dis Obstet Gynecol 2001;9:197–202.
291. Rahangdale L, Guerry S, Bauer HM, et al. An observational cohort study of *Chlamydia trachomatis* treatment in pregnancy. Sex Transm Dis 2006;33:106–110.
292. Hammerschlag MR, Gelling M, Roblin PM, et al. Treatment of neonatal chlamydial conjunctivitis with azithromycin. Pediatr Infect Dis J 1998;17:1049–50.
293. Weinstock H, Berman S, Cates W, Jr. Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000. Perspect Sex Reprod Health 2004;36:6–10.
294. Lyss SB, Kamb ML, Peterman TA, et al. *Chlamydia trachomatis* among patients infected with and treated for *Neisseria gonorrhoeae* in sexually transmitted disease clinics in the United States. Ann Intern Med 2003;139:178–85.
295. Sathia L, Ellis B, Phillip S, et al. Pharyngeal gonorrhoea—is dual therapy the way forward? Int J STD AIDS 2007;18:647–8.
296. Golden M, Kerani R, Shafii T, Whittington W, Holmes K. Does azithromycin co-treatment enhance the efficacy of oral cephalosporins for pharyngeal gonorrhea? Presented at: 18th International Society for STD Research (ISSTDR) Conference, London, UK, June 2009.
297. Workowski KA, Berman SM, Douglas JM, Jr. Emerging antimicrobial resistance in *Neisseria gonorrhoeae*: urgent need to strengthen prevention strategies. Ann Intern Med 2008;148:606–13.
298. Tapsall JW. What management is there for gonorrhea in the postquinolone era? Sex Transm Dis 2006;33:8–10.
299. CDC. Update to CDC's sexually transmitted diseases treatment guidelines, 2006: fluoroquinolones no longer recommended for treatment of gonococcal infections. MMWR 2007;56:332–6.
300. Tapsall J, Read P, Carmody C, et al. Two cases of failed ceftriaxone treatment in pharyngeal gonorrhoea verified by molecular microbiological methods. J Med Microbiol 2009;58(Pt 5):683–7.
301. Lo JY, Ho KM, Leung AO, et al. Ceftibuten resistance and treatment failure of *Neisseria gonorrhoeae* infection. Antimicrob Agents Chemother 2008;52:3564–7.
302. Deguchi T, Yasuda M, Yokoi S, et al. Treatment of uncomplicated gonococcal urethritis by double-dosing of 200 mg cefixime at a 6-h interval. J Infect Chemother 2003;9:35–9.
303. Yokoi S, Deguchi T, Ozawa T, et al. Threat to cefixime treatment for gonorrhea. Emerg Infect Dis 2007;13:1275–7.
304. Muratani T, Akasaka S, Kobayashi T, et al. Outbreak of cefozopran (penicillin, oral cephems, and aztreonam)-resistant *Neisseria gonorrhoeae* in Japan. Antimicrob Agents Chemother 2001;45:3603–6.
305. Wang SA, Lee MV, O'Connor N, et al. Multidrug-resistant *Neisseria gonorrhoeae* with decreased susceptibility to cefixime-Hawaii, 2001. Clin Infect Dis 2003;37:84952.
306. Moran JS, Levine WC. Drugs of choice for the treatment of uncomplicated gonococcal infections. Clin Infect Dis 1995;20 Suppl 1:S47–S65.
307. Newman LM, Moran JS, Workowski KA. Update on the management of gonorrhea in adults in the United States. Clin Infect Dis 2007;44 Suppl 3:S84–101.

308. Pandori M, Barry PM, Wu A, et al. Mosaic penicillin-binding protein 2 in *Neisseria gonorrhoeae* isolates collected in 2008 in San Francisco, California. Antimicrob Agents Chemother 2009;53:4032–4.
309. Ison CA, Mouton JW, Jones K, et al. Which cephalosporin for gonorrhoea? Sex Transm Infect 2004;80:386–8.
310. CDC. Notice to Readers: Discontinuation of Spectinomycin. MMWR 2006;55:370.
311. Waters LJ, Boag FC, Betournay R. Efficacy of azithromycin 1 g single dose in the management of uncomplicated gonorrhoea. Int J STD AIDS 2005;16:84.
312. McLean CA, Wang SA, Hoff GL, et al. The emergence of *Neisseria gonorrhoeae* with decreased susceptibility to azithromycin in Kansas City, Missouri, 1999 to 2000. Sex Transm Dis 2004;31:73–8.
313. Chisholm SA, Neal TJ, Alawattegama AB, et al. Emergence of high-level azithromycin resistance in *Neisseria gonorrhoeae* in England and Wales. J Antimicrob Chemother 2009;64:353–8.
314. Linhart Y, Shohat T, Amitai Z, et al. Sexually transmitted infections among brothel-based sex workers in Tel-Aviv area, Israel: high prevalence of pharyngeal gonorrhoea. Int J STD AIDS 2008;19:656–9.
315. Ota KV, Fisman DN, Tamari IE, et al. Incidence and treatment outcomes of pharyngeal *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infections in men who have sex with men: a 13-year retrospective cohort study. Clin Infect Dis 2009;48:1237–43.
316. Pichichero ME. A review of evidence supporting the American Academy of Pediatrics recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. Pediatrics 2005;115:1048–57.
317. Haimovici R, Roussel TJ. Treatment of gonococcal conjunctivitis with single-dose intramuscular ceftriaxone. Am J Ophthalmol 1989;107:511–4.
318. Koumans EH, Sternberg M, Bruce C, et al. The prevalence of bacterial vaginosis in the United States, 2001–2004: associations with symptoms, sexual behaviors, and reproductive health. Sex Transm Dis 2007;34:864–9.
319. Amsel R, Totten PA, Spiegel CA, et al. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. Am J Med 1983;74:14–22.
320. Schwebke JR, Hillier SL, Sobel JD, et al. Validity of the vaginal gram stain for the diagnosis of bacterial vaginosis. Obstet Gynecol 1996;88(4 Pt 1):573–6.
321. Fredricks DN, Fiedler TL, Thomas KK, et al. Targeted PCR for detection of vaginal bacteria associated with bacterial vaginosis. J Clin Microbiol 2007;45:3270–6.
322. Schwebke JR, Desmond R. A randomized trial of metronidazole in asymptomatic bacterial vaginosis to prevent the acquisition of sexually transmitted diseases. Am J Obstet Gynecol 2007;196:517–6.
323. Livengood CH, III, Ferris DG, Wiesenfeld HC, et al. Effectiveness of two tinidazole regimens in treatment of bacterial vaginosis: a randomized controlled trial. Obstet Gynecol 2007;110(2 Pt 1):302–9.
324. Sobel J, Peipert JF, McGregor JA, et al. Efficacy of clindamycin vaginal ovule (3-day treatment) vs. clindamycin vaginal cream (7-day treatment) in bacterial vaginosis. Infect Dis Obstet Gynecol 2001;9:9–15.
325. Antonio MA, Meyn LA, Murray PJ, et al. Vaginal colonization by probiotic *Lactobacillus crispatus* CTV-05 is decreased by sexual activity and endogenous Lactobacilli. J Infect Dis 2009;199:1506–13.
326. Mastromarino P, Macchia S, Meggiorini L, et al. Effectiveness of Lactobacillus-containing vaginal tablets in the treatment of symptomatic bacterial vaginosis. Clin Microbiol Infect 2009;15:67–74.
327. Hemmerling A, Harrison W, Schroeder A, et al. Phase 1 dose-ranging safety trial of *Lactobacillus crispatus* CTV-05 for the prevention of bacterial vaginosis. Sex Transm Dis 2009;36:564–9.
328. Ferris MJ, Masztal A, Aldridge KE, et al. Association of Atopobium vaginae, a recently described metronidazole resistant anaerobe, with bacterial vaginosis. BMC Infect Dis 2004;4:5.
329. Bradshaw CS, Tabrizi SN, Fairley CK, et al. The association of *Atopobium vaginae* and *Gardnerella vaginalis* with bacterial vaginosis and recurrence after oral metronidazole therapy. J Infect Dis 2006;194:828–36.
330. Marrazzo JM, Thomas KK, Fiedler TL, et al. Relationship of specific vaginal bacteria and bacterial vaginosis treatment failure in women who have sex with women. Ann Intern Med 2008;149:20–8.
331. Meltzer MC, Desmond RA, Schwebke JR. Association of Mobiluncus curtisii with recurrence of bacterial vaginosis. Sex Transm Dis 2008;35:611–3.
332. Beigi RH, Austin MN, Meyn LA, et al. Antimicrobial resistance associated with the treatment of bacterial vaginosis. Am J Obstet Gynecol 2004;191:1124–9.
333. Nyirjesy P, McIntosh MJ, Steinmetz JI, et al. The effects of intravaginal clindamycin and metronidazole therapy on vaginal mobiluncus morphotypes in patients with bacterial vaginosis. Sex Transm Dis 2007;34:197–202.
334. Bunge KE, Beigi RH, Meyn LA, et al. The efficacy of retreatment with the same medication for early treatment failure of bacterial vaginosis. Sex Transm Dis 2009;36:711–3.
335. Sobel JD, Ferris D, Schwebke J, et al. Suppressive antibacterial therapy with 0.75% metronidazole vaginal gel to prevent recurrent bacterial vaginosis. Am J Obstet Gynecol 2006;194:1283–9.
336. Reichman O, Akins R, Sobel JD. Boric acid addition to suppressive antimicrobial therapy for recurrent bacterial vaginosis. Sex Transm Dis 2009;36:732–4.
337. Mcclelland RS, Richardson BA, Hassan WM, et al. Improvement of vaginal health for Kenyan women at risk for acquisition of human immunodeficiency virus type 1: results of a randomized trial. J Infect Dis 2008;197:1361–8.
338. Hauth JC, Goldenberg RL, Andrews WW, et al. Reduced incidence of preterm delivery with metronidazole and erythromycin in women with bacterial vaginosis. N Engl J Med 1995;333:1732–6.
339. Morales WJ, Schorr S, Albritton J. Effect of metronidazole in patients with preterm birth in preceding pregnancy and bacterial vaginosis: a placebo-controlled, double-blind study. Am J Obstet Gynecol 1994;171:345–7.
340. Yudin MH, Landers DV, Meyn L, et al. Clinical and cervical cytokine response to treatment with oral or vaginal metronidazole for bacterial vaginosis during pregnancy: a randomized trial. Obstet Gynecol 2003;102:527–34.
341. Ugwumadu A, Reid F, Hay P, et al. Natural history of bacterial vaginosis and intermediate flora in pregnancy and effect of oral clindamycin. Obstet Gynecol 2004;104:114–9.
342. Burtin P, Taddio A, Ariburnu O, et al. Safety of metronidazole in pregnancy: a meta-analysis. Am J Obstet Gynecol 1995;172(2 Pt 1):525–9.
343. Piper JM, Mitchel EF, Ray WA. Prenatal use of metronidazole and birth defects: no association. Obstet Gynecol 1993;82:348–52.
344. Odendaal HJ, Popov I, Schoeman J, et al. Preterm labour—is bacterial vaginosis involved? S Afr Med J 2002;92:231–4.

345. Carey JC, Klebanoff MA, Hauth JC, et al. Metronidazole to prevent preterm delivery in pregnant women with asymptomatic bacterial vaginosis. National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units. N Engl J Med 2000;342:534–40.
346. Vermeulen GM, Bruinse HW. Prophylactic administration of clindamycin 2% vaginal cream to reduce the incidence of spontaneous preterm birth in women with an increased recurrence risk: a randomised placebo-controlled double-blind trial. Br J Obstet Gynaecol 1999;106:652–7.
347. McDonald HM, O'Loughlin JA, Vigneswaran R, et al. Impact of metronidazole therapy on preterm birth in women with bacterial vaginosis flora (*Gardnerella vaginalis*): a randomised, placebo controlled trial. Br J Obstet Gynaecol 1997;104:1391–7.
348. Hay P, Ugwumadu AHN, Manyonda IT. Oral clindamycin prevents spontaneous preterm birth and mid trimester miscarriage in pregnant women with bacterial vaginosis. Int J STD AIDS 2001;12(Suppl 2):70–1.
349. Lamont RF, Duncan SL, Mandal D, et al. Intravaginal clindamycin to reduce preterm birth in women with abnormal genital tract flora. Obstet Gynecol 2003;101:516–22.
350. McGregor JA, French JI, Jones W, et al. Bacterial vaginosis is associated with prematurity and vaginal fluid mucinase and sialidase: results of a controlled trial of topical clindamycin cream. Am J Obstet Gynecol 1994;170:1048–59.
351. Joesoef MR, Hillier SL, Wiknjosastro G, et al. Intravaginal clindamycin treatment for bacterial vaginosis: effects on preterm delivery and low birth weight. Am J Obstet Gynecol 1995;173:1527–31.
352. Jamieson DJ, Duerr A, Klein RS, et al. Longitudinal analysis of bacterial vaginosis: findings from the HIV epidemiology research study. Obstet Gynecol 2001;98:656–63.
353. Van Der PB, Williams JA, Orr DP, et al. Prevalence, incidence, natural history, and response to treatment of *Trichomonas vaginalis* infection among adolescent women. J Infect Dis 2005;192:2039–44.
354. Sutton M, Sternberg M, Koumans EH, et al. The prevalence of *Trichomonas vaginalis* infection among reproductive-age women in the United States, 2001–2004. Clin Infect Dis 2007;45:1319–26.
355. Lara-Torre E, Pinkerton JS. Accuracy of detection of *Trichomonas vaginalis* organisms on a liquid-based papanicolaou smear. Am J Obstet Gynecol 2003;188:354–6.
356. Van Der PB, Kraft CS, Williams JA. Use of an adaptation of a commercially available PCR assay aimed at diagnosis of chlamydia and gonorrhea to detect *Trichomonas vaginalis* in urogenital specimens. J Clin Microbiol 2006;44:366–73.
357. Hardick A, Hardick J, Wood BJ, et al. Comparison between the Gen-Probe transcription-mediated amplification *Trichomonas vaginalis* research assay and real-time PCR for *Trichomonas vaginalis* detection using a Roche LightCycler instrument with female self-obtained vaginal swab samples and male urine samples. J Clin Microbiol 2006;44:4197–9.
358. Huppert JS, Mortensen JE, Reed JL, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of *Trichomonas vaginalis* in young women. Clin Infect Dis 2007;45:194–8.
359. Nye MB, Schwebke JR, Body BA. Comparison of APTIMA *Trichomonas vaginalis* transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. Am J Obstet Gynecol 2009;200:188–97.
360. Francis SC, Kent CK, Klausner JD, et al. Prevalence of rectal *Trichomonas vaginalis* and *Mycoplasma genitalium* in male patients at the San Francisco STD clinic, 2005–2006. Sex Transm Dis 2008;35:797–800.
361. Forna F, Gulmezoglu AM. Interventions for treating trichomoniasis in women. Cochrane Database Syst Rev 2003;(2):CD000218.
362. Schmid G, Narcisi E, Mosure D, et al. Prevalence of metronidazole-resistant *Trichomonas vaginalis* in a gynecology clinic. J Reprod Med 2001;46:545–9.
363. Schwebke JR, Barrientes FJ. Prevalence of *Trichomonas vaginalis* isolates with resistance to metronidazole and tinidazole. Antimicrob Agents Chemother 2006;50:4209–10.
364. Pearlman MD, Yashar C, Ernst S, et al. An incremental dosing protocol for women with severe vaginal trichomoniasis and adverse reaction to metronidazole. Am J Obstet Gynecol 1996;174:934–6.
365. Kurohara ML, Kwong FK, Lebherz TB, et al. Metronidazole hypersensitivity and oral desensitization. J Allergy Clin Immunol 1991;88:279–80.
366. Helms DJ, Mosure DJ, Secor WE, et al. Management of *Trichomonas vaginalis* in women with suspected metronidazole hypersensitivity. Am J Obstet Gynecol 2008;198:370–7.
367. Klebanoff MA, Carey JC, Hauth JC, et al. Failure of metronidazole to prevent preterm delivery among pregnant women with asymptomatic *Trichomonas vaginalis* infection. N Engl J Med 2001;345:487–93.
368. Kigozi GG, Brahmbhatt H, Wabwire-Mangen F, et al. Treatment of Trichomonas in pregnancy and adverse outcomes of pregnancy: a subanalysis of a randomized trial in Rakai, Uganda. Am J Obstet Gynecol 2003;189:1398–1400.
369. Caro-Paton T, Carvajal A, Martin dD, I, et al. Is metronidazole teratogenic? A meta-analysis. Br J Clin Pharmacol 1997;44:179–82.
370. Van Der PB, Kwok C, Pierre-Louis B, et al. *Trichomonas vaginalis* infection and human immunodeficiency virus acquisition in African women. J Infect Dis 2008;197:548–54.
371. Moodley P, Wilkinson D, Connolly C, et al. Influence of HIV-1 coinfection on effective management of abnormal vaginal discharge. Sex Transm Dis 2003;30:1–5.
372. Moodley P, Wilkinson D, Connolly C, et al. *Trichomonas vaginalis* is associated with pelvic inflammatory disease in women infected with human immunodeficiency virus. Clin Infect Dis 2002;34:519–22.
373. McClelland RS, Sangare L, Hassan WM, et al. Infection with *Trichomonas vaginalis* increases the risk of HIV-1 acquisition. J Infect Dis 2007;195:698–702.
374. Kissinger P, Secor WE, Leichliter JS, et al. Early repeated infections with *Trichomonas vaginalis* among HIV-positive and HIV-negative women. Clin Infect Dis 2008;46:994–9.
375. Kissinger P, Amedee A, Clark RA, et al. *Trichomonas vaginalis* treatment reduces vaginal HIV-1 shedding. Sex Transm Dis 2009;36:11–6.
376. Tuomala RE, O'Driscoll PT, Bremer JW, et al. Cell-associated genital tract virus and vertical transmission of human immunodeficiency virus type 1 in antiretroviral-experienced women. J Infect Dis 2003;187:375–84.
377. Wang CC, Mcclelland RS, Reilly M, et al. The effect of treatment of vaginal infections on shedding of human immunodeficiency virus type 1. J Infect Dis 2001;183:1017–22.
378. Niccolai LM, Kopicko JJ, Kassie A, et al. Incidence and predictors of reinfection with *Trichomonas vaginalis* in HIV-infected women. Sex Transm Dis 2000;27:284–8.

379. Kissinger P, Mena L, Levison J, et al. A randomized treatment trial: single versus 7-day dose of metronidazole for the treatment of *Trichomonas vaginalis* among HIV-infected women. J Acquir Immune Defic Syndr 2010;55:565-71.
380. Sobel JD, Chaim W, Nagappan V, et al. Treatment of vaginitis caused by *Candida glabrata*: use of topical boric acid and flucytosine. Am J Obstet Gynecol 2003;189:1297–1300.
381. Vazquez JA, Peng G, Sobel JD, et al. Evolution of antifungal susceptibility among Candida species isolates recovered from human immunodeficiency virus-infected women receiving fluconazole prophylaxis. Clin Infect Dis 2001;33:1069–75.
382. Wiesenfeld HC, Sweet RL, Ness RB, et al. Comparison of acute and subclinical pelvic inflammatory disease. Sex Transm Dis 2005;32:400–5.
383. Ness RB, Kip KE, Hillier SL, et al. A cluster analysis of bacterial vaginosis-associated microflora and pelvic inflammatory disease. Am J Epidemiol 2005;162:585–90.
384. Cohen CR, Mugo NR, Astete SG, et al. Detection of *Mycoplasma genitalium* in women with laparoscopically diagnosed acute salpingitis. Sex Transm Infect 2005;81:463–66.
385. Jurstrand M, Jensen JS, Magnuson A, et al. A serological study of the role of *Mycoplasma genitalium* in pelvic inflammatory disease and ectopic pregnancy. Sex Transm Infect 2007;83:319–23.
386. Short VL, Totten PA, Ness RB, et al. Clinical presentation of *Mycoplasma genitalium* infection versus *Neisseria gonorrhoeae* infection among women with pelvic inflammatory disease. Clin Infect Dis 2009;48:41–7.
387. Peipert JF, Ness RB, Blume J, et al. Clinical predictors of endometritis in women with symptoms and signs of pelvic inflammatory disease. Am J Obstet Gynecol 2001;184:856–63.
388. Gaitan H, Angel E, Diaz R, et al. Accuracy of five different diagnostic techniques in mild-to-moderate pelvic inflammatory disease. Infect Dis Obstet Gynecol 2002;10:171–80.
389. Haggerty CL, Ness RB, Amortegui A, et al. Endometritis does not predict reproductive morbidity after pelvic inflammatory disease. Am J Obstet Gynecol 2003;188:141–8.
390. Ness RB, Soper DE, Holley RL, et al. Effectiveness of inpatient and outpatient treatment strategies for women with pelvic inflammatory disease: results from the Pelvic Inflammatory Disease Evaluation and Clinical Health (PEACH) Randomized Trial. Am J Obstet Gynecol 2002;186:929–37.
391. Ness RB, Hillier SL, Kip KE ea. Bacterial vaginosis and risk of pelvic inflammatory disease. Obstet Gynecol 2004;44 (Supp 3):S111–22.
392. Smith KJ, Ness RB, Wiesenfeld HC, et al. Cost-effectiveness of alternative outpatient pelvic inflammatory disease treatment strategies. Sex Transm Dis 2007;34:960–6.
393. Walker CK, Wiesenfeld H. Antibiotic Therapy for Acute Pelvic Inflammatory Disease: The 2006 Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines. Clin Infect Dis 2007;28(Supp 1):S29–S36.
394. McGregor JA, Crombleholme WR, Newton E, et al. Randomized comparison of ampicillin-sulbactam to cefoxitin and doxycycline or clindamycin and gentamicin in the treatment of pelvic inflammatory disease or endometritis. Obstet Gynecol 1994;83:998–1004.
395. Bevan CD, Ridgway GL, Rothermel CD. Efficacy and safety of azithromycin as monotherapy or combined with metronidazole compared with two standard multidrug regimens for the treatment of acute pelvic inflammatory disease. J Int Med Res 2003;31:45–54.
396. Savaris RF, Teixeira LM, Torres TG, et al. Comparing ceftriaxone plus azithromycin or doxycycline for pelvic inflammatory disease: a randomized controlled trial. Obstet Gynecol 2007;110:53–60.
397. Bukusi EA, Cohen CR, Stevens CE, et al. Effects of human immunodeficiency virus 1 infection on microbial origins of pelvic inflammatory disease and on efficacy of ambulatory oral therapy. Am J Obstet Gynecol 1999;181:1374–81.
398. Irwin KL, Moorman AC, O'Sullivan MJ, et al. Influence of human immunodeficiency virus infection on pelvic inflammatory disease. Obstet Gynecol 2000;95:525–34.
399. Mugo NR, Kiehlbauch JA, Nguti R, et al. Effect of human immunodeficiency virus-1 infection on treatment outcome of acute salpingitis. Obstet Gynecol 2006;107:807–12.
400. Viberga I, Odlind V, Lazdane G, et al. Microbiology profile in women with pelvic inflammatory disease in relation to IUD use. Infect Dis Obstet Gynecol 2005;13:183–90.
401. Grimes DA. Intrauterine device and upper-genital-tract infection. Lancet 2000;356(9234):1013–19.
402. Tracy CR, Steers WD, Costabile R. Diagnosis and management of epididymitis. Urol Clin North Am 2008;35:101–8.
403. Nickel JC, Siemens DR, Nickel KR, et al. The patient with chronic epididymitis: characterization of an enigmatic syndrome. J Urol 2002;167:1701–4.
404. Cogliano V, Baan R, Straif K, et al. Carcinogenicity of human papillomaviruses. Lancet Oncol 2005;6:204.
405. Myers ER, McCrory DC, Nanda K, et al. Mathematical model for the natural history of human papillomavirus infection and cervical carcinogenesis. Am J Epidemiol 2000;151:1158–71.
406. Garland SM, Steben M, Sings HL, et al. Natural history of genital warts: analysis of the placebo arm of 2 randomized phase III trials of a quadrivalent human papillomavirus (types 6, 11, 16, and 18) vaccine. J Infect Dis 2009;199:805–14.
407. Gotovtseva EP, Kapadia AS, Smolensky MH, et al. Optimal frequency of imiquimod (aldara) 5% cream for the treatment of external genital warts in immunocompetent adults: a meta-analysis. Sex Transm Dis 2008;35:346–51.
408. Mashiah J, Brenner S. Possible mechanisms in the induction of vitiligo-like hypopigmentation by topical imiquimod. Clin Exp Dermatol 2008;33:74–6.
409. Tatti S, Swinehart JM, Thielert C, et al. Sinecatechins, a defined green tea extract, in the treatment of external anogenital warts: a randomized controlled trial. Obstet Gynecol 2008;111:1371–9.
410. Stockfleth E, Beti H, Orasan R, et al. Topical Polyphenon E in the treatment of external genital and perianal warts: a randomized controlled trial. Br J Dermatol 2008;158:1329–38.
411. Gross G, Meyer KG, Pres H, et al. A randomized, double-blind, four-arm parallel-group, placebo-controlled Phase II/III study to investigate the clinical efficacy of two galenic formulations of Polyphenon E in the treatment of external genital warts. J Eur Acad Dermatol Venereol 2007;21:1404–12.
412. Silverberg MJ, Thorsen P, Lindeberg H, et al. Condyloma in pregnancy is strongly predictive of juvenile-onset recurrent respiratory papillomatosis. Obstet Gynecol 2003;101:645–52.
413. Dolev JC, Maurer T, Springer G, et al. Incidence and risk factors for verrucae in women. AIDS 2008;22:1213–19.
414. Silverberg MJ, Ahdieh L, Munoz A, et al. The impact of HIV infection and immunodeficiency on human papillomavirus type 6 or 11 infection and on genital warts. Sex Transm Dis 2002;29:427–35.

415. De Panfilis G., Melzani G, Mori G, et al. Relapses after treatment of external genital warts are more frequent in HIV-positive patients than in HIV-negative controls. Sex Transm Dis 2002;29:121–5.
416. Conley LJ, Ellerbrock TV, Bush TJ, et al. HIV-1 infection and risk of vulvovaginal and perianal condylomata acuminata and intraepithelial neoplasia: a prospective cohort study. Lancet 2002;359(9301):108–13.
417. Chiao EY, Giordano TP, Palefsky JM, et al. Screening HIV-infected individuals for anal cancer precursor lesions: a systematic review. Clin Infect Dis 2006;43:223–33.
418. Datta SD, Koutsky LA, Ratelle S, et al. Human papillomavirus infection and cervical cytology in women screened for cervical cancer in the United States, 2003–2005. Ann Intern Med 2008;148:493–500.
419. Selvam N, Barrow R, Shlay J, et al. Should STD clinics participate in cervical cancer screening: (1) Measurement of pap test abnormalities and HPV infection among women attending STD clinics and (2) A survey of cervical cancer screening practices, ISSTDR, Seattle, WA 2007.
420. Arbyn M, Bergeron C, Klinkhamer P, et al. Liquid compared with conventional cervical cytology: a systematic review and meta-analysis. Obstet Gynecol 2008;111:167–77.
421. Stoler MH, Castle PE, Solomon D, et al. The expanded use of HPV testing in gynecologic practice per ASCCP-guided management requires the use of well-validated assays. Am J Clin Pathol 2007;127:335–7.
422. Solomon D, Davey D, Kurman R, et al; Bethesda 2001 Workshop. The 2001 Bethesda System: terminology for reporting results of cervical cytology. JAMA 2002;287:2114–9.
423. Naucler P, Ryd W, Tornberg S, et al. Human papillomavirus and Papanicolaou tests to screen for cervical cancer. N Engl J Med 2007;357:1589–97.
424. Wright TC, Jr., Massad LS, Dunton CJ, et al. 2006 consensus guidelines for the management of women with abnormal cervical screening tests. J Low Genit Tract Dis 2007;11:201–22.
425. Widdice LE, Moscicki AB. Updated guidelines for Papanicolaou tests, colposcopy, and human papillomavirus testing in adolescents. J Adolesc Health 2008;43(4 Suppl):S41–S51.
426. Solomon D, Schiffman M, Tarone R. Comparison of three management strategies for patients with atypical squamous cells of undetermined significance: baseline results from a randomized trial. J Natl Cancer Inst 2001;93:293–9.
427. American Society for Colposcopy and Cervical Pathology (ASCCP). HPV Genotyping Clinical Update. Available at: http://www.asccp.org/pdfs/consensus/clinical_update_20090408.pdf.
428. American Society for Colposcopy and Cervical Pathology (ASCCP) Clinical Update for HPV Genotyping, 2009.
429. Wright TC, Jr., Massad LS, Dunton CJ, et al. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. J Low Genit Tract Dis 2007;11:223–39.
430. Ronco G, Giorgi-Rossi P, Carozzi F, et al. Results at recruitment from a randomized controlled trial comparing human papillomavirus testing alone with conventional cytology as the primary cervical cancer screening test. J Natl Cancer Inst 2008;100:492–501.
431. Mayrand MH, Duarte-Franco E, Rodrigues I, et al. Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. N Engl J Med 2007;357:1579–88.
432. Ghanem KG, Koumans EH, Johnson RE, et al. Effect of specimen order on *Chlamydia trachomatis* and *Neisseria gonorrhoeae* test performance and adequacy of Papanicolaou smear. J Pediatr Adolesc Gynecol 2006;19:23–30.
433. Saraiya M, Lee NC, Blackman D, et al. Self-reported Papanicolaou smears and hysterectomies among women in the United States. Obstet Gynecol 2001;98:269–78.
434. Sirovich BE, Welch HG. Cervical cancer screening among women without a cervix. JAMA 2004;291:2990–3.
435. Stokes-Lampard H, Wilson S, Waddell C, et al. Vaginal vault smears after hysterectomy for reasons other than malignancy: a systematic review of the literature. BJOG 2006;113:1354–65.
436. Delmas MC, Larsen C, van BB, et al. Cervical squamous intraepithelial lesions in HIV-infected women: prevalence, incidence and regression. European Study Group on Natural History of HIV Infection in Women. AIDS 2000;14:1775–84.
437. CDC. Surveillance for acute viral hepatitis. MMWR 2008;57(No. SS-2):1-24.
438. CDC. Update: Prevention of hepatitis A after exposure to hepatitis A virus and in international travelers. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007;56:1080–4.
439. Alter HJ, Purcell RH, Gerin JL, et al. Transmission of hepatitis B to chimpanzees by hepatitis B surface antigen-positive saliva and semen. Infect Immun 1977;16:928–33.
440. Villarejos VM, Visona KA, Gutierrez A, et al. Role of saliva, urine and feces in the transmission of type B hepatitis. N Engl J Med 1974;291:1375–1378.
441. Davis LG, Weber DJ, Lemon SM. Horizontal transmission of hepatitis B virus. Lancet 1989;1(8643):889–93.
442. Martinson FE, Weigle KA, Royce RA, et al. Risk factors for horizontal transmission of hepatitis B virus in a rural district in Ghana. Am J Epidemiol 1998;147:478–87.
443. CDC. National, state, and urban area vaccination coverage among children aged 19–35 months—United States, 2004. MMWR 2005;54:717–21.
444. CDC. Hepatitis B vaccination among high-risk adolescents and adults–San Diego, California, 1998–2001. MMWR 2002;51:618–21.
445. MacKellar DA, Valleroy LA, Secura GM, et al. Two decades after vaccine license: hepatitis B immunization and infection among young men who have sex with men. Am J Public Health 2001;91:965–71.
446. CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11).
447. Bohlke K, Davis RL, Marcy SM, et al. Risk of anaphylaxis after vaccination of children and adolescents. Pediatrics 2003;112:815–20.
448. Minuk GY, Bohme CE, Bowen TJ, et al. Efficacy of commercial condoms in the prevention of hepatitis B virus infection. Gastroenterology 1987;93:710–4.
449. Armstrong GL, Wasley A, Simard EP, et al. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med 2006;144:705–14.
450. Brettler DB, Mannucci PM, Gringeri A, et al. The low risk of hepatitis C virus transmission among sexual partners of hepatitis C-infected hemophilic males: an international, multicenter study. Blood 1992;80:540–3.
451. Kao JH, Hwang YT, Chen PJ, et al. Transmission of hepatitis C virus between spouses: the important role of exposure duration. Am J Gastroenterol 1996;91:2087–90.
452. Marincovich B, Castilla J, del RJ, et al. Absence of hepatitis C virus transmission in a prospective cohort of heterosexual serodiscordant couples. Sex Transm Infect 2003;79:160–2.

453. Tahan V, Karaca C, Yildirim B, et al. Sexual transmission of HCV between spouses. Am J Gastroenterol 2005;100:821–4.
454. Vandelli C, Renzo F, Romano L, et al. Lack of evidence of sexual transmission of hepatitis C among monogamous couples: results of a 10-year prospective follow-up study. Am J Gastroenterol 2004;99:855–9.
455. Feldman JG, Minkoff H, Landesman S, et al. Heterosexual transmission of hepatitis C, hepatitis B, and HIV-1 in a sample of inner city women. Sex Transm Dis 2000;27:338–42.
456. Hammer GP, Kellogg TA, McFarland WC, et al. Low incidence and prevalence of hepatitis C virus infection among sexually active non-intravenous drug-using adults, San Francisco, 1997–2000. Sex Transm Dis 2003;30:919–24.
457. Roy KM, Goldberg DJ, Hutchinson S, et al. Hepatitis C virus among self declared non-injecting sexual partners of injecting drug users. J Med Virol 2004;74:62–6.
458. Mele A, Stroffolini T, Tosti ME, et al. Heterosexual transmission of hepatitis C in Italy. J Med Virol 1999;57:111–3.
459. Rauch A, Rickenbach M, Weber R, et al. Unsafe sex and increased incidence of hepatitis C virus infection among HIV-infected men who have sex with men: the Swiss HIV Cohort Study. Clin Infect Dis 2005;41:395–402.
460. van de Laar TJ, van der Bij AK, Prins M, et al. Increase in HCV incidence among men who have sex with men in Amsterdam most likely caused by sexual transmission. J Infect Dis 2007;196:230–8.
461. Browne R, Asboe D, Gilleece Y, et al. Increased numbers of acute hepatitis C infections in HIV positive homosexual men: is sexual transmission feeding the increase? Sex Transm Infect 2004;80:326–7.
462. Danta M, Brown D, Bhagani S, et al. Recent epidemic of acute hepatitis C virus in HIV-positive men who have sex with men linked to high-risk sexual behaviours. AIDS 2007;21:983–91.
463. Ghosn J, Pierre-Francois S, Thibault V, et al. Acute hepatitis C in HIV-infected men who have sex with men. HIV Med 2004;5:303–6.
464. van de LT, Pybus O, Bruisten S, et al. Evidence of a large, international network of HCV transmission in HIV-positive men who have sex with men. Gastroenterology 2009;136:1609–17.
465. Urbanus AT, van de Laar TJ, Stolte IG, et al. Hepatitis C virus infections among HIV-infected men who have sex with men: an expanding epidemic. AIDS 2009;23:F1–F7.
466. Fierer DS, Uriel AJ, Carriero DC, et al. Liver fibrosis during an outbreak of acute hepatitis C virus infection in HIV-infected men: a prospective cohort study. J Infect Dis 2008;198:683–6.
467. Briat A, Dulioust E, Galimand J, et al. Hepatitis C virus in the semen of men coinfected with HIV-1: prevalence and origin. AIDS 2005;19:1827–35.
468. CDC. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. MMWR 2003;52(No. RR-3).
469. Klausner JD, Kohn R, Kent C. Etiology of clinical proctitis among men who have sex with men. Clin Infect Dis 2004;38:300–2.
470. Rompalo AM. Diagnosis and treatment of sexually acquired proctitis and proctocolitis: an update. Clin Infect Dis 1999;28(Suppl 1):S84–S90.
471. Chosidow O. Scabies and pediculosis. Lancet 2000;355 (9206):819–26.
472. Meinking TL, Serrano L, Hard B, et al. Comparative in vitro pediculicidal efficacy of treatments in a resistant head lice population in the United States. Arch Dermatol 2002;138:220–4.
473. Yoon KS, Gao JR, Lee SH, et al. Permethrin-resistant human head lice, Pediculus capitis, and their treatment. Arch Dermatol 2003;139:994–1000.
474. Mounsey KE, Holt DC, McCarthy J, et al. Scabies: molecular perspectives and therapeutic implications in the face of emerging drug resistance. Future Microbiol 2008;3:57–66.
475. Barkwell R, Shields S. Deaths associated with ivermectin treatment of scabies. Lancet 1997;349(9059):1144–5.
476. Roberts LJ, Huffam SE, Walton SF, et al. Crusted scabies: clinical and immunological findings in seventy-eight patients and a review of the literature. J Infect 2005;50:375–81.
477. Ackerman DR, Sugar NF, Fine DN, et al. Sexual assault victims: factors associated with follow-up care. Am J Obstet Gynecol 2006;194:1653–9.
478. Parekh V, Brown CB. Follow up of patients who have been recently sexually assaulted. Sex Transm Infect 2003;79:349.
479. Varghese B, Maher JE, Peterman TA, et al. Reducing the risk of sexual HIV transmission: quantifying the per-act risk for HIV on the basis of choice of partner, sex act, and condom use. Sex Transm Dis 2002;29:38–43.
480. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. N Engl J Med 1997;337:1485–90.
481. Du Mont J., Myhr TL, Husson H, et al. HIV postexposure prophylaxis use among Ontario female adolescent sexual assault victims: a prospective analysis. Sex Transm Dis 2008;35:973–8.
482. Neu N, Heffernan-Vacca S, Millery M, et al. Postexposure prophylaxis for HIV in children and adolescents after sexual assault: a prospective observational study in an urban medical center. Sex Transm Dis 2007;34:65–8.
483. Loutfy MR, Macdonald S, Myhr T, et al. Prospective cohort study of HIV post-exposure prophylaxis for sexual assault survivors. Antivir Ther 2008;13:87–95.
484. Kellogg N. The evaluation of sexual abuse in children. Pediatrics 2005;116:506–12.
485. Girardet RG, Lahoti S, Howard LA, et al. Epidemiology of sexually transmitted infections in suspected child victims of sexual assault. Pediatrics 2009;124:79–86.
486. Black CM, Driebe EM, Howard LA, et al. Multicenter study of nucleic acid amplification tests for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in children being evaluated for sexual abuse. Pediatr Infect Dis J 2009;28:608–13.
487. Jones V, Smith SJ, Omar HA. Nonsexual transmission of anogenital warts in children: a retrospective analysis. ScientificWorldJournal 2007;7:1896–9.
488. Smith EM, Swarnavel S, Ritchie JM, et al. Prevalence of human papillomavirus in the oral cavity/oropharynx in a large population of children and adolescents. Pediatr Infect Dis J 2007;26:836–40.
489. Havens PL. Postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus. Pediatrics 2003;111(6 Pt 1):1475–89.

Terms and Abbreviations Used in This Report

AIDS	Acquired immunodeficiency syndrome
ALT	Alanine aminotransferase
anti-HBc	Antibody to hepatitis B core antigen
anti-HCV	Hepatitis C antibodies
ASC-US	Atypical squamous cells of undetermined significance
BCA	Bichloroacetic acid
BV	Bacterial vaginosis
CBC	Complete blood count
CI	Confidence interval
CIN	Cervical intraepithelial neoplasia
CLD	Chronic liver disease
CLIA	Clinical Laboratory Improvement Amendments
CNS	Central nervous system
CSF	Cerebrospinal fluid
DFA	Direct fluorescent antibody
DGI	Disseminated gonococcal infection
dL	Deciliter
DNA	Deoxyribonucleic acid
EC	Emergency contraception
EIA	Enzyme immunoassay
ELISA	Enzyme-linked immunosorbent assay
EPT	Expedited partner therapy
FDA	Food and Drug Administration
FTA-ABS	Fluorescent treponemal antibody absorbed
gG	Glycoprotein G
GNID	Gram-negative intracellular diplococci
HAART	Highly active antiretroviral therapy
HAV	Hepatitis A virus
HBIG	Hepatitis B immune globulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCC	hepatocellular carcinoma
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
HSV	Herpes simplex virus
IFA	Immunofluorescence assay
IgE	Immunoglobulin E
Ig	Immune globulin
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IM	Intramuscularly
IUD	Intrauterine device
IV	Intravenous or intravenously
KOH	Potassium hydroxide
LGV	Lymphogranuloma venereum
MAC	*Mycobacterium avium* complex
MIC	Minimum inhibitory concentration
MSM	Men who have sex with men
N-9	Nonoxynol-9
NAAT	Nucleic acid amplification test
NGU	Nongonococcal urethritis
Pap	Papanicolaou
PCR	Polymerase chain reaction
PEP	Postexposure prophylaxis
PID	Pelvic inflammatory disease
PO	By mouth
PPV	Positive predictive value
QRNG	Quinolone-resistant *Neisseria gonorrhoeae*
RNA	Ribonucleic acid
RPR	Rapid plasma reagin
RT-PCR	Reverse transcriptase polymerase chain reaction
RVVC	Recurrent vulvovaginal candidiasis
SIL	Squamous intraepithelial lesion
STD	Sexually transmitted disease
TCA	Trichloroacetic acid
TE	Toxoplasmic encephalitis
TP-PA	*Treponema pallidum* particle agglutation
VDRL	Venereal Disease Research Laboratory
VVC	Vulvovaginal candidiasis
WB	Western blot
WBC	White blood count
WSW	Women who have sex with women

Sexually Transmitted Diseases Treatment Guidelines, 2010

Consultants

Chairperson: Kimberly A. Workowski, MD, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC and Emory University, Atlanta, Georgia.

Presenters: Heidi Bauer, MD, California Sexually Transmitted Disease Control Branch, Oakland, California; Laura Bachman, MD, Wake Forest University; Gale Burstein, MD, MPH, Erie County Department of Health; Linda Eckert, MD, University of Washington; William M. Geisler, MD, University of Alabama, Birmingham, Alabama; Khalil Ghanem, MD, Johns Hopkins University; Matt Golden, MD, MPH, University of Washington; Linda Gorgos, MD, New Mexico Department of Health; Margaret Hammerschlag, MD, State University of New York, Downstate Medical Center, Brooklyn, New York; Lisa Hollier, MD, University of Texas at Houston; Peter Leone, MD, University of North Carolina School of Medicine, Chapel Hill, North Carolina; Jeanne Marrazzo, MD, University of Washington, Seattle, Washington; Kenneth Hugh Mayer, MD, Brown University Medical School, Providence, Rhode Island; Paul Nyirjesy, MD, Drexel University College of Medicine, Philadelphia, Pennsylvania; Anne Rompalo, MD, Johns Hopkins School of Medicine, Baltimore, Maryland; Pablo Sanchez, MD, University of Texas Southwestern Medical Center, Dallas, Texas; Bradley Stoner, MD, PhD, Washington University, St. Louis, Missouri; Anna Wald, MD, University of Washington, Seattle, Washington; George Wendel, MD, University of Texas Southwestern Medical School, Dallas, Texas; Harold C. Wiesenfeld, MD, University of Pittsburgh, Pittsburgh, Pennsylvania.

Moderators: Willard Cates, Jr., MD, MPH, Family Health International, Durham, North Carolina; King K. Holmes, MD, PhD, University of Washington, Seattle, Washington; David Martin, MD, Louisiana State University Medical Center, New Orleans, Louisiana.

Rapporteurs: Hunter Handsfield, MD, University of Washington, Seattle, Washington; William McCormack, MD, State University of New York Health Science Center, Brooklyn, New York; William M. Geisler, MD, University of Alabama, Birmingham, Alabama.

Consultants: N. Franklin Adkinson, MD, Johns Hopkins University; William Andrews, MD, PhD, University of Alabama, Birmingham; Michael Augenbraun, MD, State University of New York Health Science Center, Brooklyn, New York; Bryon Batteiger, MD, University of Indiana; Gail Bolan, MD, California Department of Health, Oakland, California; Bruce Coles, DO, New York Department of Health; Carolyn Deal, PhD, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland; J. Dennis Fortenberry, MD, Indiana University School of Medicine, Indianapolis, Indiana; Edward Hook, III, MD, University of Alabama, Birmingham, Alabama; Jane R. Schwebke, MD, University of Alabama, Birmingham, Alabama; Joann Schulte, DO, National Institutes of Health, Bethesda, Maryland; David Soper, MD, Medical University of South Carolina, Charleston, South Carolina; Lawrence Stanberry, MD, PhD, University of Texas Medical Branch, Galveston, Texas; Bruce Trigg, MD, New Mexico Department of Health; Yolanda Wimberly, MD, Morehouse School of Medicine; Jonathan M. Zenilman, MD, Johns Hopkins Bayview Medical Center, Baltimore, Maryland.

Liaison Participants: Kaytura Aaron MD, HRSA; Laura Bachman, MD, HIV Association of America; Lynn Barclay, MD, American Social Health Association; Margaret J. Blythe, MD, American Academy of Pediatrics; Carolyn D. Deal, PhD, National Institutes of Health; Jordon Dimitrakov, MD, PhD, American Urological Association; Mark FitzGerald, MD, British Association for Sexual Health and HIV, Southampton, United Kingdom; Dennis Fortenberry, MD, Society of Adolescent Medicine; Edward W. Hook, III, MD, Infectious Disease Society of America; Noreen Jack, MD, Pan American Health Association; Peter Kerndt, MD, National Coalition of STD Directors; Jeanne Marrazzo, MD, American Sexually Transmitted Diseases Association; Francis J. Ndowa, MD, World Health Organization, Geneva, Switzerland; Michael Parkinson, MD, American College of Preventative Medicine; Jeffrey Piepert, MD, American College of Obstetrics and Gynecology; Patricia Reams, MD, National Commission on Correctional Health Care; Bisan Salhi, MD, American College of Emergency Physicians; Karen Shea, MSN, Planned Parenthood Federation of America; David Soper, MD, Infectious Diseases Society for Obstetrics and Gynecology; Bradley Stoner, MD, PhD, CDC STD Prevention Training Centers; Amy Swann, Assoication of Reproductive Health Professionals; Litjen Tan, PhD, American Medical Association; Tom Wong, MD, Public Health Agency of Canada, Ottawa, Ontario, Canada.

CDC, Division of Sexually Transmitted Disease Prevention Treatment Guidelines 2010 Project Coordinator: Kimberly A. Workowski, MD, NCHHSTP, CDC and Emory University, Atlanta, Georgia.

Project Manager: Richard Voigt, NCHHSTP, CDC, Atlanta, Georgia.

NCHHSTP/CDC Presenters: Deblina Datta, MD; Eileen Dunne, MD; Matthew Hogben, PhD; Scott Holmberg, MD; Emily Koumans, MD; Lori Newman, MD.

CDC Consultants: Sevgi O. Aral, PhD; Ronald Ballard, PhD; Bernard Branson, MD; John Brooks, MD, MPH; John Douglas, MD; Alison Friedman; Dale Hu, MD; Peter Kilmarx, MD; John Papp, PhD; Phil Spradling, MD.

Support Staff: Brenda Kelley, Valerie Barner, and Deborah McElroy, NCHHSTP, CDC, Atlanta, Georgia.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR*'s free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Data presented by the Notifiable Disease Data Team and 122 Cities Mortality Data Team in the weekly *MMWR* are provisional, based on weekly reports to CDC by state health departments. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30333 or to *mmwrq@cdc.gov.*

All material in the *MMWR* Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

☆U.S. Government Printing Office: 2010-623-026/21014 Region IV ISSN: 1057-5987

Iowa Code 622.10 (5)(a)

5. At any time, upon a written request from a patient, a patient's legal representative or attorney, or an adverse party pursuant to subsection 3, any provider shall provide copies of the requested records or images to the requester within thirty days of receipt of the written request. The written request shall be accompanied by a legally sufficient patient's waiver unless the request is made by the patient or the patient's legal representative or attorney.

a. The fee charged for the cost of producing the requested records or images shall be based upon the actual cost of production. If the written request and accompanying patient's waiver, if required, authorizes the release of all of the patient's records for the requested time period, including records relating to the patient's mental health, substance abuse, and acquired immune deficiency syndrome-related conditions, the amount charged shall not exceed the rates established by the workers' compensation commissioner for copies of records in workers' compensation cases. If requested, the provider shall include an affidavit certifying that the records or images produced are true and accurate copies of the originals for an additional fee not to exceed ten dollars.

Iowa Administrative Code
Agency 876 Workers' Compensation Division
876-8.9(85,86)

Fees:

$20 for 1 to 20 pages;
$20 plus $1 per page for 21-30 pages;
$30 plus $.50 per page for 31 – 100 pages;
$65 plus $.25 per page for 101-200 pages
$90 plus $.10 per page for more than 200 pages;

Checklist

Family planning and related preventive health services

for women

FPNTC FAMILY PLANNING NATIONAL TRAINING CENTER

		Family planning services (provide services in accordance with the appropriate clinical recommendation)					
	Screening components	Contraceptive services[1]	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services[2]	Related preventive health services
History	Reproductive life plan	✔	✔	✔	✔	✔	
	Medical history	✔	✔	✔	✔	✔	✔
	Current pregnancy status	✔					
	Sexual health assessment	✔		✔	✔	✔	
	Intimate partner violence				✔		
	Alcohol & other drug use				✔		
	Tobacco use	✔ *(combined hormonal methods for clients ≥35 years)*			✔		
	Immunizations				✔	✔ [4] *(HPV & HBV)*	
	Depression				✔		
	Folic acid				✔		
Physical examination	Height, weight & BMI	✔ *(hormonal methods)*[3]		✔	✔		
	Blood pressure	✔ *(combined hormonal methods)*			✔ [4]		
	Clinical breast exam			✔			✔ [4]
	Pelvic exam	✔ *(initiating diaphragm or IUD)*	✔ *(if clinically indicated)*	✔			
	Signs of androgen excess			✔			
	Thyroid exam			✔			
Laboratory testing	Pregnancy test	✔ *(if clinically indicated)*	✔				
	Chlamydia	✔ [5]				✔ [4]	
	Gonorrhea	✔ [5]				✔ [4]	
	Syphilis					✔ [4]	
	HIV/AIDS					✔ [4]	
	Hepatitis C					✔ [4]	
	Diabetes				✔ [4]		
	Cervical cytology						✔ [4]
	Mammography						✔ [4]

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

[1] This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC, U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]).

[2] STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

[3] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (US Medical Eligibility Criteria 1) or generally can be used (US Medical Eligibility Criteria 2) among obese women. (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[4] Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

[5] Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Checklist

Family planning and related preventive health services

for men

FPNTC
FAMILY PLANNING
NATIONAL TRAINING CENTER

		Family planning services (provide services in accordance with the appropriate clinical recommendation)				
	Screening components	Contraceptive services[1]	Basic infertility services	Preconception health services[2]	STD services[3]	Related preventive health services
History	Reproductive life plan	✔	✔	✔	✔	
	Medical history	✔	✔	✔	✔	
	Sexual health assessment	✔	✔	✔	✔	
	Alcohol & other drug use			✔		
	Tobacco use			✔		
	Immunizations			✔	✔ *(HPV & HBV)*[4]	
	Depression			✔		
Physical examination	Height, weight & BMI			✔		
	Blood pressure			✔ [4]		
	Genital exam		✔ *(if clinically indicated)*		✔ *(if clinically indicated)*	✔ [4]
Laboratory testing	Chlamydia				✔ [4]	
	Gonorrhea				✔ [4]	
	Syphilis				✔ [4]	
	HIV/AIDS				✔ [4]	
	Hepatitis C				✔ [4]	
	Diabetes			✔ [4]		

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from **http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf**

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

1 No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

2 The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2]:S389-95).

3 STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

4 Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

Contraceptive Counseling and Education Checklist

Counselor Name: _____ **Date:** _____

Observer Name: _____

Purpose: Use this checklist to note and provide feedback to a contraceptive counselor after observing their counseling session. You can also use this checklist to self-assess your own counseling and education skills.

How to Use: When observing a counseling session, notice how the counselor performs the bulleted skills or practices. Mark the level of competence you perceive (1 for needs improvement, 2 for satisfactory, or 3 for excellent). If an item is not done, but should have been, leave it blank. If an item is not applicable, mark N/A. Some items may not be necessary for a particular session. Write comments in the space available. Then, after the visit, share your observations with the counselor in a private place and discuss.

Process	Assessment
Beginning (and throughout)	
Establish and maintain rapport with the client	1 Needs Improvement / 2 Satisfactory / 3 Excellent
• Warmly greet the client, introduce yourself. . . . . 1 2 3 N/A • Discuss the reason(s) for the visit . . . . . 1 2 3 N/A • Explain confidential services. . . . . 1 2 3 N/A • Ask open-ended questions . . . . . 1 2 3 N/A • Actively listen and share your perceptions . . . . . 1 2 3 N/A • Affirm client responses . . . . . 1 2 3 N/A • Summarize key points . . . . . 1 2 3 N/A Other practices observed: _____ _____	Comments
Middle	
Assess the client's needs and personalize discussions accordingly	1 Needs Improvement / 2 Satisfactory / 3 Excellent
• Review and update the client's medical, sexual and social history . . . . . 1 2 3 N/A • Ask about the client's thoughts and desires regarding future pregnancy. . . . . 1 2 3 N/A • Explore client preferences regarding method characteristics. . . . . 1 2 3 N/A (risk of pregnancy, how method is used, menstrual side effects, other side effects, and other considerations) • Ask about client knowledge and experience with birth control . . . . . 1 2 3 N/A • Respectfully explore factors that may influence method preference . . . . . 1 2 3 N/A (past experiences, beliefs, cultural and religious considerations, and feelings about the methods) Other practices observed: _____ _____	Comments

Over to Continue >>

Middle continued

Work with the client interactively to establish a birth control method plan	1 Needs Improvement	2 Satisfactory	3 Excellent
• Help the client identify the method that matches their preferences ..... 1 2 3 N/A • Ask open-ended questions about concerns related to method choice..... 1 2 3 N/A • Discuss partners and others who may influence decision making and method use ..... 1 2 3 N/A • Help the client make a plan for correct use of their selected method ..... 1 2 3 N/A • Include information about STD/HIV protection and emergency contraception, as appropriate ..... 1 2 3 N/A Other practices observed: _____ _____	Comments		

Provide information that can be understood and retained by the client	1 Needs Improvement	2 Satisfactory	3 Excellent
• Actively engage the client in conversation (not a presentation) ..... 1 2 3 N/A • Provide accurate information ..... 1 2 3 N/A (correct use, effectiveness, benefits, side effects, potential risks, STD/HIV prevention) • Use clear, understandable words, images, models and/or sample methods... 1 2 3 N/A • Use numbers and comparisons that are easy to understandd ..... 1 2 3 N/A • Provide balanced, unbiased, tailored information ..... 1 2 3 N/A • Assess and address myths and misinformation in a respectful and affirming way..... 1 2 3 N/A Other practices observed: _____ _____	Comments		

Closing

Confirm client understanding	1 Needs Improvement	2 Satisfactory	3 Excellent
• Ask the client to tell and show the main things they learned (teach-back) and provide additional information as needed ..... 1 2 3 N/A • Address possible barriers to method use, specific to the client and their method ..... 1 2 3 N/A • Confirm the client's plan for correct method use and follow up ..... 1 2 3 N/A (including what to do if dissatisfied with the method, back-up method, STD/HIV protection, and emergency contraception, as needed) • Provide contact information and future opportunities for follow up, other methods or services..... 1 2 3 N/A • Summarize key points and end with a friendly close..... 1 2 3 N/A Other practices observed: _____ _____	Comments		

Improvement Plan:

_____

_____

_____

_____

Centers for Disease Control and Prevention

MMWR

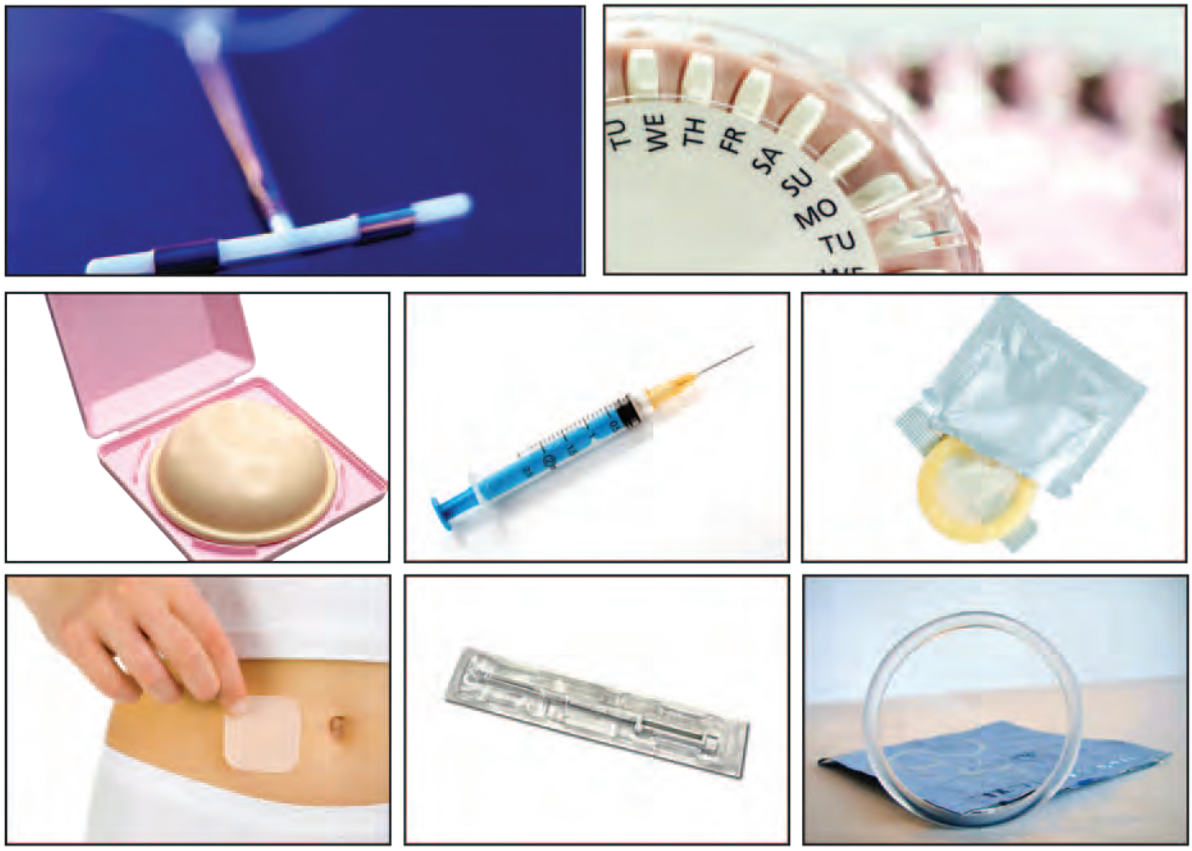
Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 62 / No. 5

June 21, 2013

U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition



Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONTENTS

Introduction 1
Methods 2
How To Use This Document 3
Summary of Changes from WHO SPR 4
Contraceptive Method Choice 4
Maintaining Updated Guidance 4
How To Be Reasonably Certain that a Woman Is Not Pregnant 5
Intrauterine Contraception 7
Implants 14
Injectables 17
Combined Hormonal Contraceptives 22
Progestin-Only Pills 29
Standard Days Method 33
Emergency Contraception 34
Female Sterilization 35
Male Sterilization 36
When Women Can Stop Using Contraceptives 37
Conclusion 37
Acknowledgment 38
References 38

CONTENTS (*Continued*)

Appendix A: Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* 47
Appendix B: When To Start Using Specific Contraceptive Methods 55
Appendix C: Examinations and Tests Needed Before Initiation of Contraceptive Methods 56
Appendix D: Routine Follow-Up After Contraceptive Initiation 57
Appendix E: Management of Women with Bleeding Irregularities While Using Contraception 58
Appendix F: Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have Pelvic Inflammatory Disease 59

Disclosure of Relationship

CDC, our planners, and our content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling. CDC does not accept commercial support.

Front cover photos, *left to right:* intrauterine device, oral contraceptive pills, diaphragm, syringe for injectable contraceptives, male condom, transdermal contraceptive patch, etonogestrel implant, vaginal ring.

The *MMWR* series of publications is published by the Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

Suggested Citation: Centers for Disease Control and Prevention. [Title]. MMWR 2013;62(No. RR-#):[inclusive page numbers].

Centers for Disease Control and Prevention
Thomas R. Frieden, MD, MPH, *Director*
Harold W. Jaffe, MD, MA, *Associate Director for Science*
James W. Stephens, PhD, *Director, Office of Science Quality*
Denise M. Cardo, MD, *Acting Deputy Director for Surveillance, Epidemiology, and Laboratory Services*
Stephanie Zaza, MD, MPH, *Director, Epidemiology and Analysis Program Office*

MMWR Editorial and Production Staff
Ronald L. Moolenaar, MD, MPH, *Editor,* MMWR *Series*
Christine G. Casey, MD, *Deputy Editor,* MMWR *Series*
Teresa F. Rutledge, *Managing Editor,* MMWR *Series*
David C. Johnson, *Lead Technical Writer-Editor*
Catherine B. Lansdowne, MS, *Project Editor*
Martha F. Boyd, *Lead Visual Information Specialist*
Maureen A. Leahy, Julia C. Martinroe,
Stephen R. Spriggs, Terraye M. Starr
Visual Information Specialists
Quang M. Doan, MBA, Phyllis H. King
Information Technology Specialists

MMWR Editorial Board
William L. Roper, MD, MPH, Chapel Hill, NC, Chairman
Matthew L. Boulton, MD, MPH, Ann Arbor, MI
Virginia A. Caine, MD, Indianapolis, IN
Barbara A. Ellis, PhD, MS, Atlanta, GA
Jonathan E. Fielding, MD, MPH, MBA, Los Angeles, CA
David W. Fleming, MD, Seattle, WA
William E. Halperin, MD, DrPH, MPH, Newark, NJ
King K. Holmes, MD, PhD, Seattle, WA
Timothy F. Jones, MD, Nashville, TN
Rima F. Khabbaz, MD, Atlanta, GA
Dennis G. Maki, MD, Madison, WI
Patricia Quinlisk, MD, MPH, Des Moines, IA
Patrick L. Remington, MD, MPH, Madison, WI
John V. Rullan, MD, MPH, San Juan, PR
William Schaffner, MD, Nashville, TN

U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition

Prepared by
Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion

Summary

The U. S. Selected Practice Recommendations for Contraceptive Use 2013 *(U.S. SPR), comprises recommendations that address a select group of common, yet sometimes controversial or complex, issues regarding initiation and use of specific contraceptive methods. These recommendations are a companion document to the previously published CDC recommendations* U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 *(U.S. MEC). U.S. MEC describes who can use various methods of contraception, whereas this report describes how contraceptive methods can be used. CDC based these U.S. SPR guidelines on the global family planning guidance provided by the World Health Organization (WHO). Although many of the recommendations are the same as those provided by WHO, they have been adapted to be more specific to U.S. practices or have been modified because of new evidence. In addition, four new topics are addressed, including the effectiveness of female sterilization, extended use of combined hormonal methods and bleeding problems, starting regular contraception after use of emergency contraception, and determining when contraception is no longer needed. The recommendations in this report are intended to serve as a source of clinical guidance for health-care providers; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients. Persons should seek advice from their health-care providers when considering family planning options.*

Introduction

Unintended pregnancy rates remain high in the United States; approximately 50% of all pregnancies are unintended, with higher proportions among adolescent and young women, women who are racial/ethnic minorities, and women with lower levels of education and income (*1*). Unintended pregnancies increase the risk for poor maternal and infant outcomes (*2*) and in 2002, resulted in $5 billion in direct medical costs in the United States (*3*). Approximately half of unintended pregnancies are among women who were not using contraception at the time they became pregnant; the other half are among women who became pregnant despite reported use of contraception (*4*). Therefore, strategies to prevent unintended pregnancy include assisting women at risk for unintended pregnancy and their partners with choosing appropriate contraceptive methods and helping women use methods correctly and consistently to prevent pregnancy. In 2010, CDC first adapted global guidance from the World Health Organization (WHO) to help health-care providers counsel women, men, and couples about contraceptive method choice. The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (U.S. MEC), focuses on who can safely use specific methods of contraception and provides recommendations for the safety of contraceptive methods for women with various medical conditions (e.g., hypertension and diabetes) and characteristics (e.g., age, parity, and smoking status) (Appendix A) (*5*). The recommendations in this new guide, *U.S. Selected Practice Recommendations for Contraceptive Use, 2013* (U.S. SPR), focuses on how contraceptive methods can be used and provides recommendations on optimal use of contraceptive methods for persons of all ages, including adolescents.

During the past 15 years, CDC has contributed to the development and updating of the WHO global family planning guidance. CDC has supported WHO by coordinating the identification, critical appraisal, and synthesis of the scientific evidence on which the WHO guidance is based. In 2002, WHO published the first edition of the *Selected Practice Recommendations for Contraceptive Use* (WHO SPR), which presented evidence-based global guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. Since then, WHO has regularly updated its guidance on the basis of new evidence, and the document is now in its second edition (*6*), with an additional update in 2008 (*7*). The WHO global guidance is not intended for use directly by health-care providers; rather, WHO intends for the guidance to be used by local or national policy makers, family planning program managers, and the

The material in this report originated in the National Center for Chronic Disease Prevention and Health Promotion, Ursula Bauer, PhD, Director; Division of Reproductive Health, Wanda Barfield, MD, Director.
Corresponding preparer: Kathryn M. Curtis, PhD, Division of Reproductive Health. Telephone: 770-488-5200; E-mail: kmc6@cdc.gov.

scientific community as a reference when they develop family planning guidance at the country or program level (*6*). For example, the United Kingdom adapted WHO SPR and in 2002 published the *U.K. Selected Practice Recommendations for Contraceptive Use* for use by U.K. health-care providers (*8*).

CDC initiated a formal adaptation process to create U.S. SPR, using both the second edition of WHO SPR (*6*) and the 2008 update (*7*) as the basis for the U.S. version. Although much of the guidance is the same as the WHO guidance, the recommendations are specific to U.S. family planning practice. In addition, guidance on contraceptive methods not available in the United States has been removed, and four new topics for guidance have been added (the effectiveness of female sterilization, extended use of combined hormonal methods and bleeding problems, starting regular contraception after use of emergency contraception, and determining when contraception is no longer needed). This document contains recommendations for health-care providers for the safe and effective use of contraceptive methods and addresses provision of contraceptive methods and management of side effects and other problems with contraceptive method use. Although the term woman is used throughout this report, these recommendations refer to all females of reproductive age, including adolescents. Adolescents are identified throughout this document as a special population that might benefit from more frequent follow-up. These recommendations are meant to serve as a source of clinical guidance for health-care providers; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients; persons should seek advice from their health-care providers when considering family planning options.

Methods

CDC initiated a process to adapt WHO SPR for the United States. This adaptation process included four steps: 1) determining the scope of and process for the adaptation, including an October 2010 meeting in which individual feedback was solicited from a small group of partners and experts; 2) preparing the systematic reviews of the evidence during October 2010–September 2011 to be used for the adaptation, including peer review; 3) convening a larger meeting of experts in October 2011 to examine the evidence and receive input on the recommendations; and 4) finalizing recommendations by CDC.

During October 21–22, 2010, CDC convened a meeting of 10 partners and U.S. family planning experts in Atlanta, Georgia, to discuss the scope of and process for a U.S. adaptation of WHO SPR. A list of participants is provided at the end of this report. CDC identified the specific WHO recommendations that might benefit from modification for the United States. Criteria used to modify the WHO recommendations included the availability of new scientific evidence or the context in which family planning services are provided in the United States. CDC also identified several WHO recommendations that needed additional specificity to be useful for U.S. health-care providers, as well as the need for additional recommendations not currently included in WHO SPR. In addition, the meeting members discussed removing recommendations that provide information about contraceptive methods that are not available in the United States.

Representatives from CDC and WHO conducted systematic reviews of the scientific evidence for each of the WHO recommendations being considered for adaptation and for each new topic being considered for addition to the guidance. The purpose of these systematic reviews was to identify evidence related to the common clinical challenges associated with the recommendations. When no direct evidence was available, indirect evidence and theoretical issues were considered. Standard guidelines were followed for reporting systematic reviews (*9,10*), and strength and quality of the evidence were graded using the system of the U.S. Preventive Services Task Force (*11*). Each complete systematic review was peer reviewed by two or three experts before its use in the adaptation process. Peer reviewers, who were identified from the list of persons scheduled to participate in the October 2011 meeting, were asked to comment on the search strategy, list of articles included in the reviews, and the summary of findings. The systematic reviews were finalized and provided to participants before the October 2011 meeting and were published in May 2013 (*12–30*).

During October 4–7, 2011, CDC convened a meeting in Atlanta, Georgia, of 36 experts who were invited to assist in guideline development and provide their perspective on the scientific evidence presented and the discussions on potential recommendations that followed. The group included obstetrician/gynecologists, pediatricians, family physicians, nurse-midwives, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management. All participants received all of the systematic reviews before the meeting. During the meeting, the evidence from the systematic review for each topic was presented, and participants discussed the evidence and the translation of the scientific evidence into recommendations that would meet the needs of U.S. health-care providers. In particular, participants discussed whether and how the U.S. context might be different from the global context and whether these differences suggested any need for modifications to the global guidance. CDC gathered the input from the experts during the meeting and finalized the recommendations in this

report. The document was peer reviewed by meeting participants, who were asked to comment on specific issues that were raised during the meeting. Feedback also was received from an external review panel, composed of health-care providers who had not participated in the adaptation meetings. These providers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations, as well as to provide other comments. Areas of research that need additional investigation also were considered during the meeting (*31*).

How To Use This Document

The recommendations in this report are intended to help health-care providers address issues related to use of contraceptives, such as how to help a woman initiate use of a contraceptive method, which examinations and tests are needed before initiating use of a contraceptive method, what regular follow-up is needed, and how to address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding. Each recommendation addresses what a woman or health-care provider can do in specific situations. For situations in which certain groups of women might be medically ineligible to follow the recommendations, comments and reference to U.S. MEC are provided (*5*). The full U.S. MEC recommendations and the evidence supporting those recommendations were published in 2010 (*5*).

The information in this document is organized by contraceptive method, and the methods generally are presented in order of effectiveness, from highest to lowest. However, the recommendations are not intended to provide guidance on every aspect of provision and management of contraceptive method use. Instead, they use the best available evidence to address specific issues regarding common, yet sometimes complex, clinical issues. Each contraceptive method section generally includes information about initiation of the method, regular follow-up, and management of problems with use (e.g., usage errors and side effects). Each section first provides the recommendation and then includes a comments and evidence section, which includes comments about the recommendations and a brief summary of the scientific evidence on which the recommendation is based.

Recommendations in this document are provided for permanent methods of contraception, such as vasectomy and female sterilization, as well as for reversible methods of contraception, including the copper-containing intrauterine device (Cu-IUD); levonorgestrel-releasing IUD (LNG-IUD); the etonogestrel implant; progestin-only injectables; progestin-only pills (POPs); combined hormonal contraceptive methods that contain both estrogen and a progestin, including combined oral contraceptives (COCs), a transdermal contraceptive patch, and a vaginal contraceptive ring; and the standard days method (SDM). Recommendations also are provided for emergency use of the Cu-IUD and emergency contraceptive pills (ECPs).

For each contraceptive method, recommendations are provided on the timing for initiation of the method and indications for when and for how long additional contraception, or a back-up method, is needed. Many of these recommendations include guidance that a woman can start a contraceptive method at any time during her menstrual cycle if it is reasonably certain that the woman is not pregnant. Guidance for health-care providers on how to be reasonably certain that a woman is not pregnant is provided.

For each contraceptive method, recommendations include the examinations and tests needed before initiation of the method. These recommendations apply to persons who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*). Most women need no or very few examinations or tests before initiating a contraceptive method. The following classification system was developed by WHO and adopted by CDC to categorize the applicability of the various examinations or tests before initiation of contraceptive methods (*6*):

Class A: These tests and examinations are essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B: These tests and examinations contribute substantially to safe and effective use, although implementation can be considered within the public health context, service context, or both. The risk for not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

Class C: These tests and examinations do not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relation of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions. Systematic reviews were conducted for several different types of examinations and tests to assess whether a screening test was associated with safe use of contraceptive methods. Because no single convention exists for screening panels for certain diseases, including diabetes,

lipid disorders, and liver diseases, the search strategies included broad terms for the tests and diseases of interest.

Summary charts and clinical algorithms that summarize the guidance for the various contraceptive methods have been developed for many of the recommendations, including when to start using specific contraceptive methods (Appendix B), examinations and tests needed before initiating the various contraceptive methods (Appendix C), routine follow-up after initiating contraception (Appendix D), management of bleeding irregularities (Appendix E), and management of IUDs when users are found to have pelvic inflammatory disease (PID) (Appendix F). These summaries might be helpful to health-care providers when managing family planning patients. Additional tools are available on the U.S. SPR website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm).

Summary of Changes from WHO SPR

Much of the guidance in U.S. SPR is the same or very similar to the WHO SPR guidance. U.S. SPR includes new guidance on the use of the combined contraceptive patch and vaginal ring, as well as recommendations for four new topics:

- how to start regular contraception after taking ECPs
- management of bleeding irregularities among women using extended or continuous combined hormonal contraceptives (including pills, the patch, and the ring)
- when a woman can rely on female sterilization for contraception
- when a woman can stop using contraceptives and not be at risk for unintended pregnancy

Adaptations to the WHO SPR recommendations include 1) changes to the length of the grace period for depot medroxyprogesterone acetate (DMPA) reinjection, 2) differences in some of the examinations and tests recommended before contraceptive method initiation, 3) differences in some of the recommendations for management of bleeding irregularities because of new data and drug availability in the United States, and 4) a modified missed pill algorithm to respond to concerns of the CDC expert group and other reviewers that simplified algorithms are preferable.

Contraceptive Method Choice

Many elements need to be considered individually by a woman, man, or couple when choosing the most appropriate contraceptive method. Some of these elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability.

Contraceptive method effectiveness is critically important in minimizing the risk for unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (Table 1). Both consistent and correct use can vary greatly with characteristics such as age, income, desire to prevent or delay pregnancy, and culture. Methods that depend on consistent and correct use by clients have a wide range of effectiveness between typical and perfect users. IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method (Figure 1).

In choosing a method of contraception, the risk for human immunodeficiency virus (HIV) infection and other sexually transmitted diseases (STDs) also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs and HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonorrhea, and trichomoniasis (*32*). On the basis of a limited number of clinical studies, when a male condom cannot be used properly to prevent infection, a female condom should be considered (*32*). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (*32*). Additional information about prevention and treatment of STDs is available from the CDC *Sexually Transmitted Diseases Treatment Guidelines* (*32*).

Maintaining Updated Guidance

As with any evidence-based guidance document, a key challenge is keeping the recommendations up to date as new scientific evidence becomes available. Working with WHO, CDC uses the continuous identification of research evidence (CIRE) system to ensure that WHO and CDC guidance is based on the best available evidence and that a mechanism is in place to update guidance when new evidence becomes available (*33*). CDC will continue to work with WHO to identify and assess all new relevant evidence and determine whether changes in the recommendations are warranted. In

TABLE 1. Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year — United States

Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at 1 year[§]
	Typical use*	Perfect use[†]	
No method[¶]	85	85	—
Spermicides**	28	18	42
Fertility awareness–based methods[††]	24	—	47
Standard days method	—	5	—
Two day method	—	4	—
Ovulation method	—	3	—
Symptothermal method	—	0.4	—
Withdrawal	22	4	46
Sponge			
Parous women	24	20	36
Nulliparous women	12	9	—
Condom[§§]			
Female	21	5	41
Male	18	2	43
Diaphragm***	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Evra patch	9	0.3	67
NuvaRing	9	0.3	67
Depo-Provera	6	0.2	56
Intrauterine devices			
Paragard (copper containing)	0.8	0.6	78
Mirena (levenorgestrel releasing)	0.2	0.2	80
Implanon	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100
Lactational amenorrhea method[†††]	—	—	—

Source: Adapted from Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth (NSFG) corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill and Depo-Provera are taken from the 1995 and 2002 NSFG corrected for underreporting of abortion.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

§ Among couples attempting to avoid pregnancy, the percentage who continues to use a method for 1 year.

¶ The percentage becoming pregnant in the second and third columns are based on data from populations where contraception is not used and from women who cease using contraception to become pregnant. Among such populations, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women not relying on reversible methods of contraception if they abandoned contraception altogether.

** Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The ovulation and two day methods are based on evaluation of cervical mucus. The standard days method avoids intercourse on cycle days 8–19. The symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

§§ Without spermicides.

*** With spermicidal cream or jelly.

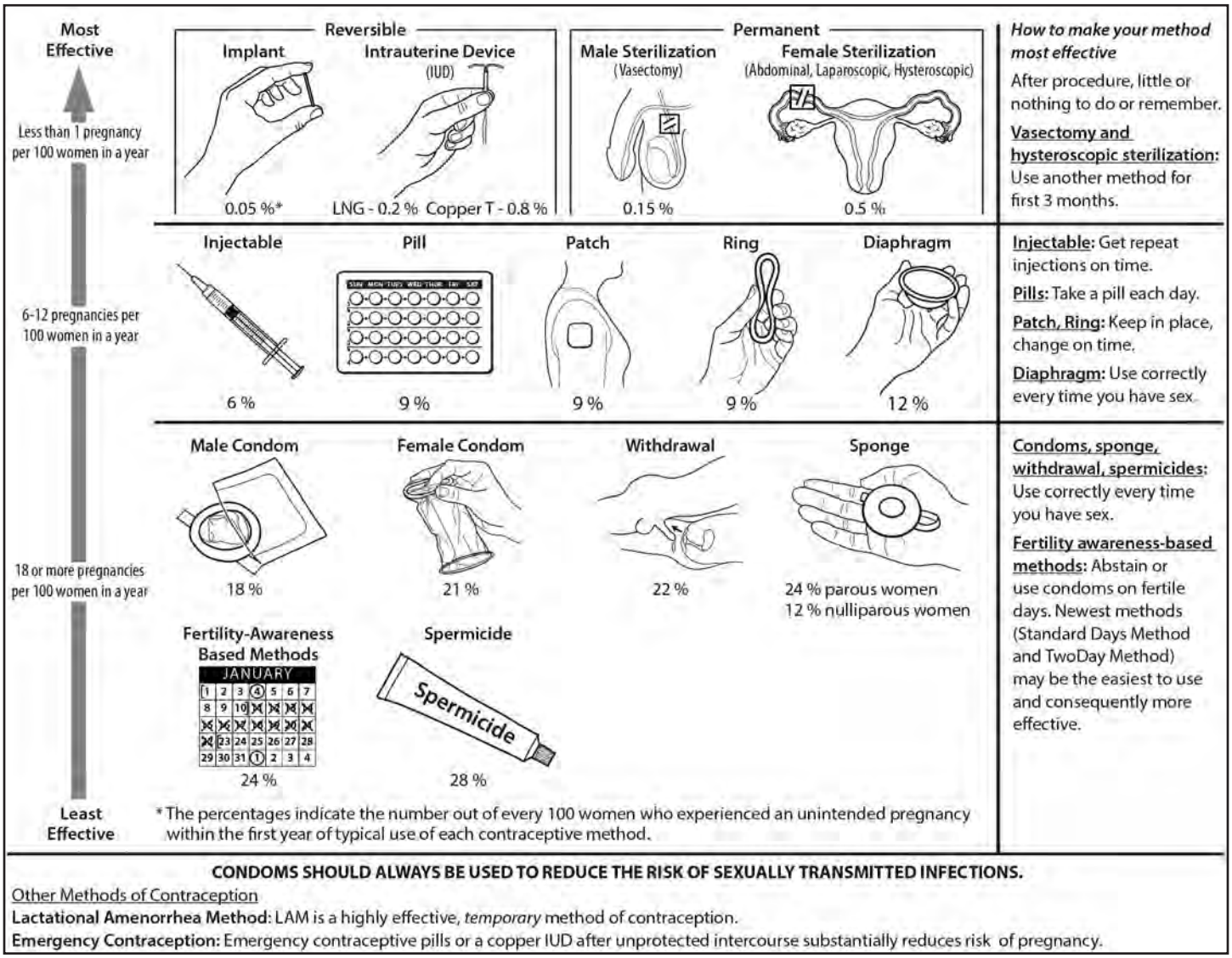
††† This is a highly effective, temporary method of contraception. However, to maintain in effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency of duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches age 6 months.

most cases, U.S. SPR will follow any updates in the WHO guidance, which typically occurs every 3–4 years (or sooner if warranted by new data). In addition, CDC will review any interim WHO updates for their application in the United States. CDC also will identify and assess any new literature for the recommendations that are not included in the WHO guidance and will completely review U.S. SPR every 3–4 years. Updates to the guidance can be found on the U.S. SPR website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm).

How To Be Reasonably Certain that a Woman Is Not Pregnant

In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman who is about to start using a contraceptive method. Several criteria for assessing pregnancy risk are listed in the recommendation that follows. These criteria are highly accurate (i.e., a negative predictive value of 99%–100%) in ruling out pregnancy among women who are not pregnant (*34–37*). Therefore, CDC recommends that health-care providers use these criteria to assess pregnancy

FIGURE 1. Effectiveness of family planning methods



Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/ Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

status in a woman who is about to start using contraceptives (Box 1). If a woman meets one of these criteria (and therefore the health-care provider can be reasonably certain that she is not pregnant), a urine pregnancy test might be considered in addition to these criteria (based on clinical judgment), bearing in mind the limitations of the accuracy of pregnancy testing. If a woman does not meet any of these criteria, then the health-care provider cannot be reasonably certain that she is not pregnant, even with a negative pregnancy test. Routine pregnancy testing for every woman is not necessary.

On the basis of clinical judgment, health-care providers might consider the addition of a urine pregnancy test; however, they should be aware of the limitations, including accuracy of the test relative to the time of last sexual intercourse, recent delivery, or spontaneous or induced abortion. Routine pregnancy testing for every woman is not necessary. If a woman has had recent (i.e., within the last 5 days) unprotected sexual intercourse, consider offering emergency contraception (either a Cu-IUD or ECPs), if pregnancy is not desired.

Comments and Evidence Summary. The criteria for determining whether a woman is pregnant depend on the assurance that she has not ovulated within a certain amount of time after her last menses, spontaneous or induced abortion, or delivery. Among menstruating women, the timing of ovulation can vary widely. During an average 28-day cycle, ovulation generally occurs during days 9–20 (*38*). In addition, the

BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds),* amenorrheic, and <6 months postpartum

*Source: Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. Adv Contracept 1994;10:93–109.

likelihood of ovulation is low from days 1–7 of the menstrual cycle (*39*). After a spontaneous or an induced abortion, ovulation can occur within 2–3 weeks and has been found to occur as early as 8–13 days after the end of the pregnancy. Therefore, the likelihood of ovulation is low ≤7 days after an abortion (*40–42*). A recent systematic review reported that the mean day of first ovulation among postpartum nonlactating women occurred 45–94 days after delivery (*43*). In one study, the earliest ovulation was reported at 25 days after delivery. Among women who are within 6 months postpartum, are fully or nearly fully breastfeeding, and are amenorrheic, the risk for pregnancy is <2% (*44*).

Although pregnancy tests often are performed before initiating contraception, the accuracy of qualitative urine pregnancy tests varies depending on the timing of the test relative to missed menses, recent sexual intercourse, or recent pregnancy. The sensitivity of a pregnancy test is defined as the concentration of human chorionic gonadotropin (hCG) at which 95% of tests are positive. Most qualitative pregnancy tests approved by the U.S. Food and Drug Administration (FDA) report a sensitivity of 20–25 mIU/mL in urine (*45–48*) However, pregnancy detection rates can vary widely because of differences in test sensitivity and the timing of testing relative to missed menses (*47*,*49*). Some studies have shown that an additional 11 days past the day of expected menses are needed to detect 100% of pregnancies using qualitative tests (*46*). In addition, pregnancy tests cannot detect a pregnancy resulting from recent sexual intercourse. Qualitative tests also might have positive results for several weeks after termination of pregnancy because hCG can be present for several weeks after delivery or abortion (spontaneous or induced) (*50–52*).

For contraceptive methods other than IUDs, the benefits of starting to use a contraceptive method likely exceed any risk, even in situations in which the health-care provider is uncertain whether the woman is pregnant. Therefore, the health-care provider can consider having patients start using contraceptive methods other than IUDs at any time, with a follow-up pregnancy test in 2–4 weeks. The risks of not starting to use contraception should be weighed against the risks of initiating contraception use in a woman who might be already pregnant. Most studies have shown no increased risk for adverse outcomes, including congenital anomalies or neonatal or infant death, among infants exposed in utero to COCs (*53–55*). Studies also have shown no increased risk for neonatal or infant death or developmental abnormalities among infants exposed in utero to DMPA (*54*,*56*,*57*).

In contrast, for women who want to begin using an IUD (Cu-IUD or LNG-IUD), in situations in which the health-care provider is uncertain whether the woman is pregnant, the woman should be provided with another contraceptive method to use until the health-care provider is reasonably certain that she is not pregnant and can insert the IUD. Pregnancies among women with IUDs are at higher risk for complications such as spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis (*58*).

A systematic review identified four analyses of data from three diagnostic accuracy studies that evaluated the performance of the criteria listed above through use of a pregnancy checklist compared with a urine pregnancy test conducted concurrently (*12*). The performance of the checklist to diagnose or exclude pregnancy varied, with sensitivity of 55%–100% and specificity of 39%–89%. The negative predictive value was consistent across studies at 99%–100%; the pregnancy checklist correctly ruled out women who were not pregnant. One of the studies assessed the added usefulness of signs and symptoms of pregnancy and found that these criteria did not substantially improve the performance of the pregnancy checklist, although the number of women with signs and symptoms was small (*34*) (Level of evidence: Diagnostic accuracy studies, fair, direct).

Intrauterine Contraception

Three IUDs are available in the United States, the Cu-IUD and two LNG-IUDs (containing a total of either 13.5 mg or 52 mg levonorgestrel). Fewer than 1 woman out of 100 becomes pregnant in the first year of using IUDs (with typical use) (*59*). IUDs are long acting, are reversible, and can be

used by women of all ages, including adolescents, and both by parous and nulliparous women. IUDs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Initiation of Cu-IUDs

Timing

- The Cu-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- The Cu-IUD also can be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive. If the day of ovulation can be estimated, the Cu-IUD also can be inserted >5 days after sexual intercourse as long as insertion does not occur >5 days after ovulation.

Need for Back-Up Contraception

- No additional contraceptive protection is needed after Cu-IUD insertion.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** The Cu-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

Postpartum (Including After Cesarean Section)

- **Timing:** The Cu-IUD can be inserted at any time postpartum, including immediately postpartum (U.S. MEC 1 or 2) (Box 2), if it is reasonably certain that the woman is not pregnant (Box 1). The Cu-IUD should not be inserted in a woman with puerperal sepsis (U.S. MEC 4).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

Postabortion (Spontaneous or Induced)

- **Timing:** The Cu-IUD can be inserted within the first 7 days, including immediately postabortion (U.S. MEC 1 for first trimester abortion and U.S. MEC 2 for second trimester abortion). The Cu-IUD should not be inserted immediately after septic abortion (U.S. MEC 4).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

Switching from Another Contraceptive Method

- **Timing:** The Cu-IUD can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** No additional contraceptive protection is needed.

Comments and Evidence Summary. In situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the Cu-IUD.

A systematic review identified eight studies that suggested that timing of Cu-IUD insertion in relation to the menstrual cycle in nonpostpartum women had little effect on long-term outcomes (rates of continuation, removal, expulsion, or pregnancy) or on short-term outcomes (pain at insertion, bleeding at insertion, or immediate expulsion) (*13*) (Level of evidence: II-2, fair, direct).

BOX 2. Categories of medical eligibility criteria for contraceptive use

U.S. MEC 1 = A condition for which there is no restriction for the use of the contraceptive method.

U.S. MEC 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

U.S. MEC 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

U.S. MEC 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

Abbreviations: U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.*
Source: CDC. U.S. medical eligibility criteria for contraceptive use. MMWR 2010;59(No. RR-4).

Initiation of LNG-IUDs

Timing of LNG-IUD Insertion

- The LNG-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).

Need for Back-Up Contraception

- If the LNG-IUD is inserted within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the LNG-IUD is inserted >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** The LNG-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Including After Cesarean Section)

- **Timing:** The LNG-IUD can be inserted at any time, including immediately postpartum (U.S. MEC 1 or 2) if it is reasonably certain that the woman is not pregnant (Box 1). The LNG-IUD should not be inserted in a woman with puerperal sepsis (U.S. MEC 4).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (*60*), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding began, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postabortion (Spontaneous or Induced)

- **Timing:** The LNG-IUD can be inserted within the first 7 days, including immediately postabortion (U.S. MEC 1 for first-trimester abortion and U.S. MEC 2 for second-trimester abortion). The LNG-IUD should not be inserted immediately after a septic abortion (U.S. MEC 4).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the IUD is placed at the time of a surgical abortion.

Switching from Another Contraceptive Method

- **Timing:** The LNG-IUD can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >7 days since menstrual bleeding began, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from a Cu-IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider can consider providing ECPs at the time of LNG-IUD insertion.

Comments and Evidence Summary. In situations in which the health-care provider is uncertain whether the woman might be pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the LNG-IUD. If a woman needs to use additional contraceptive protection when switching to an LNG-IUD from another contraceptive method, consider continuing her previous method for 7 days after LNG-IUD insertion. No direct evidence was found regarding the effects of inserting LNG-IUDs on different days of the cycle on short- or long-term outcomes (*13*).

Examinations and Tests Needed Before Initiation of a Cu-IUD or an LNG-IUD

Among healthy women, few examinations or tests are needed before initiation of an IUD (Table 2). Bimanual examination and cervical inspection are necessary before IUD insertion. A baseline weight and BMI measurement might be useful for monitoring IUD users over time. If a woman has not been screened for STDs according to STD screening guidelines, screening can be performed at the time of insertion. Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*).

Comments and Evidence Summary. Weight (BMI): Obese women can use IUDs (U.S. MEC 1) (*5*); therefore, screening for obesity is not necessary for the safe initiation of IUDs. However, measuring weight and calculating BMI (weight [kg] / height [m]^2) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Bimanual examination and cervical inspection: Bimanual examination and cervical inspection are necessary before IUD insertion to assess uterine size and position and to detect any cervical or uterine abnormalities that might indicate infection or otherwise prevent IUD insertion (*61*,*62*).

STDs: Women should be routinely screened for chlamydial infection and gonorrhea according to national screening guidelines. The CDC *Sexually Transmitted Diseases Treatment Guidelines* provide information on screening eligibility, timing, and frequency of screening and on screening for persons

TABLE 2. Classification of examinations and tests needed before IUD insertion

Examination or test	Class*	
	Copper-containing IUD	Levonorgestrel-releasing IUD
Examinations		
Blood pressure	C	C
Weight (BMI) (weight [kg]/ height [m]^2)	—†	—†
Clinical breast examination	C	C
Bimanual examination and cervical inspection	A	A
Laboratory tests		
Glucose	C	C
Lipids	C	C
Liver enzymes	C	C
Hemoglobin	C	C
Thrombogenic mutations	C	C
Cervical cytology (Papanicolaou smear)	C	C
STD screening with laboratory tests	—§	—§
HIV screening with laboratory tests	C	C

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occur.

with risk factors (*32*). If STD screening guidelines have been followed, most women do not need additional STD screening at the time of IUD insertion. If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (*5*). For these women, IUD insertion should be delayed until appropriate testing and treatment occur. A systematic review did not identify any evidence regarding women who were screened versus not screened for STDs before IUD insertion (*14*). Although women with STDs at the time of IUD insertion have a higher risk for PID, the overall rate of PID among all IUD users is low (*63*,*64*).

Hemoglobin: Women with iron-deficiency anemia can use the LNG-IUD (U.S. MEC 1) (*5*); therefore, screening for anemia is not necessary for safe initiation of the LNG-IUD. Women with iron-deficiency anemia generally can use the Cu-IUD (U.S. MEC 2). Measurement of hemoglobin before initiation of Cu-IUDs is not necessary because of the minimal change in hemoglobin among women with and without anemia using Cu-IUDs. A systematic review identified four studies that provided direct evidence for changes in hemoglobin among women with anemia who received Cu-IUDs (*30*). Evidence from one randomized trial (*65*) and one prospective cohort study (*66*) showed no significant changes in hemoglobin among Cu-IUD users with anemia, whereas two prospective cohort studies (*67*,*68*) showed a statistically significant decrease in hemoglobin levels during 12 months of follow-up; however, the magnitude of the decrease was small and most likely not clinically significant. The systematic review also identified 21 studies that provided indirect evidence by examining changes in hemoglobin among healthy women receiving Cu-IUDs (*69*–*89*), which generally showed no clinically significant changes in hemoglobin levels with up to 5 years of follow-up (Level of evidence: I to II-2, fair, direct).

Liver enzymes: Women with liver disease can use the Cu-IUD (U.S. MEC 1) (*5*); therefore, screening for liver disease is not necessary for the safe initiation of the Cu-IUD. Although women with certain liver diseases generally should not use the LNG-IUD (U.S. MEC 3) (*5*), screening for liver disease before initiation of the LNG-IUD is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptive use (*14*). The prevalence of liver disorders among women of reproductive age is low. In 2008, among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (*90*). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (*91*). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (*92*). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease

might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (*93*,*94*), although evidence is limited, and no evidence exists for the LNG-IUD.

Clinical breast examination: Women with breast disease can use the Cu-IUD (U.S. MEC 1) (*5*); therefore, screening for breast disease is not necessary for the safe initiation of the Cu-IUD. Although women with current breast cancer should not use the LNG-IUD (U.S. MEC 4) (*5*), screening asymptomatic women with a clinical breast examination before inserting an IUD is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (*15*). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (*95*).

Cervical cytology: Although women with cervical cancer should not undergo IUD insertion (U.S. MEC 4) (*5*), screening asymptomatic women with cervical cytology before IUD insertion is not necessary because of the high rates of cervical screening, low incidence of cervical cancer in the United States, and high likelihood that a woman with cervical cancer already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with cervical cytology before initiation of IUDs (*14*). Cervical cancer is rare in the United States, with an incidence rate of 8.1 per 100,000 women per year during 2004–2008 (*95*). The incidence and mortality rates from cervical cancer have declined dramatically in the United States, largely because of cervical cytology screening (*96*). Overall screening rates for cervical cancer in the United States are high; among women aged 22–30 years, approximately 87% reported having cervical cytology screening within the last 3 years (*97*).

HIV screening: Although women with acquired immunodeficiency syndrome (AIDS) who are not clinically well should generally not undergo IUD insertion (U.S. MEC 3) (*5*), HIV screening is not necessary before IUD insertion because of the high likelihood that a woman in the United States with such an advanced stage of disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened for HIV infection before IUD insertion (*14*). Limited evidence suggests that IUDs are not associated with disease progression, increased infection, or other adverse health effects among women with HIV infection (*98*).

Other screening: Women with hypertension, diabetes, hyperlipidemia, or thrombogenic mutations can use (U.S. MEC 1) or generally can use (U.S. MEC 2) IUDs (*5*). Therefore, screening for these conditions is not necessary for the safe initiation of IUDs.

Provision of Prophylactic Antibiotics at the Time of IUD Insertion

- Prophylactic antibiotics are generally not recommended for Cu-IUD or LNG-IUD insertion.

Comments and Evidence Summary. Theoretically, IUD insertion could induce bacterial spread and lead to complications such as PID or infective endocarditis. A metaanalysis was conducted of randomized controlled trials examining antibiotic prophylaxis versus placebo or no treatment for IUD insertion (*99*). Use of prophylaxis reduced the frequency of unscheduled return visits but did not significantly reduce the incidence of PID or premature IUD discontinuation. Although the risk for PID was higher within the first 20 days after insertion, the incidence of PID was low among all women who had IUDs inserted (*63*). In addition, the American Heart Association recommends that the use of prophylactic antibiotics solely to prevent infective endocarditis is not needed for genitourinary procedures (*100*). Studies have not demonstrated a conclusive link between genitourinary procedures and infective endocarditis or a preventive benefit of prophylactic antibiotics during such procedures (*100*).

Routine Follow-Up After IUD Insertion

These recommendations address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, persons with certain medical conditions or characteristics, and persons with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time to remove or replace the contraceptive method. No routine follow-up visit is required.
- At other routine visits, health-care providers who see IUD users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.

- Assess any changes in health status, including medications, that would change the appropriateness of the IUD for safe and effective continued use on the basis of U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
- Consider performing an examination to check for the presence of the IUD strings.
- Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

Comments and Evidence Summary. Evidence from a systematic review about the effect of a specific follow-up visit schedule on IUD continuation is very limited and of poor quality. The evidence did not suggest that greater frequency of visits or earlier timing of the first follow-up visit after insertion improves continuation of use (*16*) (Level of evidence: II-2, poor, direct). Evidence from four studies from a systematic review on the incidence of PID among IUD initiators, or IUD removal as a result of PID, suggested that the incidence of PID did not differ between women using Cu-IUDs and those using DMPA, COCs, or LNG-IUDs (*17*) (Level of evidence: I to II-2, good, indirect). Evidence on the timing of PID after IUD insertion is mixed. Although the rate of PID was generally low, the largest study suggested that the rate of PID was significantly higher in the first 20 days after insertion (*63*) (Level of evidence: I to II-3, good to poor, indirect).

Bleeding Irregularities with Cu-IUD Use

- Before Cu-IUD insertion, provide counseling about potential changes in bleeding patterns during Cu-IUD use. Unscheduled spotting or light bleeding, as well as heavy or prolonged bleeding, is common during the first 3–6 months of Cu-IUD use, is generally not harmful, and decreases with continued Cu-IUD use.
- If clinically indicated, consider an underlying gynecological problem, such as Cu-IUD displacement, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids), especially in women who have already been using the Cu-IUD for a few months or longer and who have developed a new onset of heavy or prolonged bleeding. If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecological problem is not found and the woman requests treatment, the following treatment option can be considered during days of bleeding:
  - Nonsteroidal antiinflammatory drugs (NSAIDs) for short-term treatment (5–7 days)
- If bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Comments and Evidence Summary. During contraceptive counseling and before insertion of the Cu-IUD, information about common side effects such as unscheduled spotting or light bleeding or heavy or prolonged menstrual bleeding, especially during the first 3–6 months of use, should be discussed (*70*). These bleeding irregularities are generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce method discontinuation in clinical trials with other contraceptives (i.e., DMPA) (*101*,*102*).

Evidence is limited on specific drugs, doses, and durations of use for effective treatments for bleeding irregularities with Cu-IUD use; therefore, although this document includes general recommendations for treatments to consider, evidence for specific regimens is lacking.

A systematic review identified 11 articles that examined various therapeutic treatments for heavy menstrual bleeding, prolonged menstrual bleeding, or both among women using Cu-IUDs (*18*). Nine studies examined the use of various oral NSAIDs for the treatment of heavy or prolonged menstrual bleeding among Cu-IUD users and compared them to either a placebo or a baseline cycle. Three of these trials examined the use of indomethacin (*103*–*105*), another three examined mefenamic acid (*106*–*108*), and another three examined flufenamic acid (*103*,*104*,*109*). Other NSAIDs used in the reported trials included alclofenac (*103*,*104*), suprofen (*110*), and diclofenac sodium (*111*). All but one NSAID study (*107*) demonstrated statistically significant or notable reductions in mean total menstrual blood loss with NSAID use. One study among 19 Cu-IUD users with heavy bleeding suggested that treatment with oral tranexamic acid can significantly reduce mean blood loss during treatment compared with placebo (*111*). Data regarding the overall safety of tranexamic acid are limited; an FDA warning states that tranexamic acid is contraindicated in women with active thromboembolic disease or with a history or intrinsic risk for thrombosis or thromboembolism (*112*,*113*). Treatment with aspirin demonstrated no statistically significant change in mean blood loss among women whose pretreatment menstrual blood loss was >80 mL or 60–80 mL; treatment resulted in a significant increase among women whose pretreatment menstrual blood loss was <60 mL (*114*). One study examined the use of a synthetic form of vasopressin, intranasal desmopressin (300 μg/day), for the first 5 days of menses for three treatment cycles and found a significant reduction in mean blood loss

compared with baseline (*106*) (Level of evidence: I to II-3, poor to fair, direct). Only one small study examined treatment of spotting with three separate NSAIDs and did not observe improvements in spotting in any of the groups (*103*) (Level of evidence: I, poor, direct).

Bleeding Irregularities (Including Amenorrhea) with LNG-IUD Use

- Before LNG-IUD insertion, provide counseling about potential changes in bleeding patterns during LNG-IUD use. Unscheduled spotting or light bleeding is expected during the first 3–6 months of LNG-IUD use, is generally not harmful, and decreases with continued LNG-IUD use. Over time, bleeding generally decreases with LNG-IUD use, and many women experience only light menstrual bleeding or amenorrhea. Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon during LNG-IUD use.

Irregular Bleeding (Spotting, Light Bleeding, or Heavy or Prolonged Bleeding)

- If clinically indicated, consider an underlying gynecological problem, such as LNG-IUD displacement, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired

Comments and Evidence Summary. During contraceptive counseling and before insertion of the LNG-IUD, information about common side effects such as unscheduled spotting or light bleeding, especially during the first 3–6 months of use, should be discussed. Approximately half of LNG-IUD users are likely to experience amenorrhea or oligomenorrhea by 2 years of use (*115*). These bleeding irregularities are generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce method discontinuation in clinical trials with other hormonal contraceptives (i.e., DMPA) (*101*,*102*). No direct evidence was found regarding therapeutic treatments for bleeding irregularities during LNG-IUD use.

Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have PID

- Treat the PID according to the CDC *Sexually Transmitted Diseases Treatment Guidelines* (*32*).
- Provide comprehensive management for STDs, including counseling about condom use.
- The IUD does not need to be removed immediately if the woman needs ongoing contraception.
- Reassess the woman in 48–72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of the IUD.
- If the woman wants to discontinue use, remove the IUD sometime after antibiotics have been started to avoid the potential risk for bacterial spread resulting from the removal procedure.
- If the IUD is removed, consider ECPs if appropriate. Counsel the woman on alternative contraceptive methods, and offer another method if it is desired.
- A summary of IUD management in women with PID is provided (Appendix F).

Comments and Evidence Summary. Treatment outcomes do not generally differ between women with PID who retain the IUD and those who have the IUD removed; however, appropriate antibiotic treatment and close clinical follow-up are necessary.

A systematic review identified four studies that included women using copper or nonhormonal IUDs who developed PID and compared outcomes between women who had the IUD removed or did not (*19*). One randomized trial showed that women with IUDs removed had longer hospitalizations than those who did not, although no differences in PID recurrences or subsequent pregnancies were observed (*116*). Another randomized trial showed no differences in laboratory findings among women who removed the IUD compared with those who did not (*117*). One prospective cohort study showed no differences in clinical or laboratory findings during hospitalization; however, the IUD removal group had longer hospitalizations (*118*). One randomized trial showed that the rate of recovery for most clinical signs and symptoms was higher among women who had the IUD removed than among women who did not (*119*). No evidence was found regarding women using LNG-IUDs (Level of evidence: I to II-2, fair, direct).

Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Be Pregnant

- Evaluate for possible ectopic pregnancy.
- Advise the woman that she has an increased risk for spontaneous abortion (including septic abortion that might be life threatening) and of preterm delivery if the IUD is left in place. The removal of the IUD reduces these risks but might not decrease the risk to the baseline level of a pregnancy without an IUD.
  - If she does not want to continue the pregnancy, counsel her about options.
  - If she wants continue the pregnancy, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

IUD Strings Are Visible or Can Be Retrieved Safely from the Cervical Canal

- Advise the woman that the IUD should be removed as soon as possible.
  - If the IUD is to be removed, remove it by pulling on the strings gently.
  - Advise the woman that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.
- If she chooses to keep the IUD, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

IUD Strings Are Not Visible and Cannot Be Retrieved Safely

- If ultrasonography is available, consider performing or referring for ultrasound examination to determine the location of the IUD. If the IUD cannot be located, it might have been expelled or have perforated the uterine wall.
- If ultrasonography is not possible or the IUD is determined by ultrasound to be inside the uterus, advise the woman to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

Comments and Evidence Summary. Removing the IUD improves the pregnancy outcome if the IUD strings are visible or the device can be retrieved safely from the cervical canal. Risks for spontaneous abortion, preterm delivery, and infection are substantial if the IUD is left in place.

Theoretically, the fetus might be affected by hormonal exposure from an LNG-IUD; however, whether this exposure increases the risk for fetal abnormalities is unknown.

A systematic review identified nine studies suggesting that women who did not remove their IUDs during pregnancy were at greater risk for adverse pregnancy outcomes (including spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis) compared with women who had their IUDs removed or who did not have an IUD (*58*). Cu-IUD removal decreased risks but not to the baseline risk for pregnancies without an IUD. One case series examined LNG-IUDs. When they were not removed, eight in 10 pregnancies ended in spontaneous abortions (Level of evidence: II-2, fair, direct).

Implants

The etonogestrel implant, a single rod with 68 mg of etonogestrel, is available in the United States. Fewer than 1 woman out of 100 become pregnant in the first year of use of the etonogestrel implant with typical use (*59*). The implant is long acting, is reversible, and can be used by women of all ages, including adolescents. The implant does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Initiation of Implants

Timing

- The implant can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).

Need for Back-Up Contraception

- If the implant is inserted within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the implant is inserted >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** The implant can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Breastfeeding)

- **Timing:** The implant can be inserted at any time (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds

are breastfeeds) (*60*), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Not Breastfeeding)

- **Timing:** The implant can be inserted at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** A woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postabortion (Spontaneous or Induced)

- **Timing:** The implant can be inserted within the first 7 days, including immediately after the abortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the implant is placed at the time of a surgical abortion.

Switching from Another Contraceptive Method

- **Timing:** The implant can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days after insertion.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the woman to retain the IUD for at least 7 days after the implant is inserted and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

Comments and Evidence Summary. In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant likely exceed any risk; therefore, starting the implant should be considered at any time, with a follow-up pregnancy test in 2–4 weeks.

If a woman needs to use additional contraceptive protection when switching to an implant from another contraceptive method, consider continuing her previous method for 7 days after implant insertion. No direct evidence was found regarding the effects of starting the etonogestrel implant at different times of the cycle.

Examinations and Tests Needed Before Implant Insertion

Among healthy women, no examinations or tests are needed before initiation of an implant, although a baseline weight and BMI measurement might be useful for monitoring implant users over time (Table 3). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*).

TABLE 3. Classification of examinations and tests needed before implant insertion

Examination or test	Class*
Examination	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m]^2)	—†
Clinical breast examination	C
Bimanual examination and cervical inspection	C
Laboratory test	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Comments and Evidence Summary. Weight (BMI): Obese women can use implants (U.S. MEC 1) (*5*); therefore, screening for obesity is not necessary for the safe initiation of implants. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Bimanual examination and cervical inspection: A pelvic examination is not necessary before initiation of implants because it would not facilitate detection of conditions for which implant use would be unsafe. Women with current breast cancer should not use implants (U.S. MEC 4); women with certain liver diseases generally should not use implants (U.S. MEC 3) (*5*). However, none of these conditions are likely to be detected by pelvic examination (*120*). A systematic review identified two case-control studies that compared delayed and immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (*15*). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed. No evidence was found regarding implants (Level of evidence: II-2 fair, direct).

Liver enzymes: Although women with certain liver diseases generally should not use implants (U.S. MEC 3) (*5*), screening for liver disease before initiation of implants is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (*14*). The prevalence of liver disorders among women of reproductive age is low. In 2008, the percentage of adults aged 18–44 years with liver disease (not further specified) was 1.0% (*90*). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (*91*). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (*92*). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (*93*,*94*), although evidence is limited and no evidence exists for implants.

Clinical breast examination: Although women with current breast cancer should not use implants (U.S. MEC 4) (*5*), screening asymptomatic women with a clinical breast examination before initiating an implant is not necessary because of the low prevalence of breast cancer among women of reproductive age (15–49 years). A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (*15*). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (*95*).

Other screening: Women with hypertension, diabetes, hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, STDs, or HIV infection can use (U.S. MEC 1) or generally can use (U.S. MEC 2) implants (*5*); therefore, screening for these conditions is not necessary for the safe initiation of implants.

Routine Follow-Up After Implant Insertion

These recommendations address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time to remove or replace the contraceptive method. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing implant users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of the implant for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

Comments and Evidence Summary. A systematic review did not identify any evidence regarding whether a routine follow-up visit after initiating an implant improves correct or continued use (*16*).

Bleeding Irregularities (Including Amenorrhea) During Implant Use

- Before implant insertion, provide counseling about potential changes in bleeding patterns during implant use. Unscheduled spotting or light bleeding is common with implant use, and some women experience amenorrhea. These bleeding changes are generally not harmful and might or might not decrease with continued implant use. Heavy or prolonged bleeding, unscheduled or menstrual, is uncommon during implant use.

Irregular Bleeding (Spotting, Light Bleeding, or Heavy or Prolonged Bleeding)

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment options during days of bleeding can be considered:
  - NSAIDS for short-term treatment (5–7 days)
  - Hormonal treatment (if medically eligible) with low-dose COCs or estrogen for short-term treatment (10–20 days)
- If irregular bleeding persists and the woman finds it unacceptable, counsel her on alternative methods, and offer another method if it is desired.

Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Comments and Evidence Summary. During contraceptive counseling and before insertion of the implant, information about common side effects, such as unscheduled spotting or light bleeding and amenorrhea, especially during the first year of use should be discussed. A pooled analysis of data from 11 clinical trials indicate that a significant proportion of etonogestrel implant users had relatively little bleeding: 22% of women experienced amenorrhea and 34% experienced infrequent spotting, although 7% reported frequent bleeding and 18% reported prolonged bleeding (*121*). Unscheduled bleeding or amenorrhea is generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce discontinuation in clinical trials with other hormonal contraceptives (i.e., DMPA) (*101*,*102*).

A systematic review and four newly published studies examined several medications for the treatment of bleeding irregularities with primarily LNG contraceptive implants (*122*–*126*). Two small studies found significant cessation of bleeding within 7 days of start of treatment among women taking oral celecoxib (200 mg) daily for 5 days or oral mefenamic acid (500 mg) 3 times daily for 5 days compared with placebo (*124*,*125*). Differences in bleeding cessation were not found among women with etonogestrel implants taking mifepristone but were found when women with the implants combined mifepristone with either ethinyl estradiol or doxycycline (*126*,*127*). Doxycycline alone or in combination with ethinyl estradiol did not improve bleeding cessation among etonogestrel implant users (*126*). Among LNG implant users, mifepristone reduced the number of bleeding or spotting days but only after 6 months of treatment (*128*). Evidence also suggests that estrogen (*129*–*131*), daily COCs (*129*), levonorgestrel pills (*130*), tamoxifen (*132*), or tranexamic acid (*133*) can reduce the number of bleeding or spotting days during treatment among levonorgestrel implant users. In one small study, vitamin E was found to significantly reduce the mean number of bleeding days after the first treatment cycle; however, another larger study reported no significant differences in length of bleeding and spotting episodes with vitamin E treatment (*134*,*135*). Use of aspirin did not result in a significant difference in median length of bleeding or bleeding and spotting episodes after treatment (*134*). One study among implant users reported a reduction in number of bleeding days after initiating ibuprofen; however, another trial did not demonstrate any significant differences in the number of spotting and bleeding episodes with ibuprofen compared with placebo (*123*,*130*).

Injectables

Progestin-only injectable contraceptives (DMPA, 150 mg intramuscularly or 104 mg subcutaneously) are available in the United States; the only difference between these two formulations is the route of administration. Approximately 6 out of 100 women will become pregnant in the first year of use of DMPA with typical use (*59*). DMPA is reversible and can be used by women of all ages, including adolescents. DMPA does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Initiation of Injectables

Timing

- The first DMPA injection can be given at any time if it is reasonably certain that the woman is not pregnant (Box 1).

Need for Back-Up Contraception

- If DMPA is started within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If DMPA is started >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** The first DMPA injection can be given at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Breastfeeding)

- **Timing:** The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (*60*), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Not Breastfeeding)

- **Timing:** The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** A woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postabortion (Spontaneous or Induced)

- **Timing:** The first DMPA injection can be given within the first 7 days, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the injection is given at the time of a surgical abortion.

Switching from Another Contraceptive Method

- **Timing:** The first DMPA injection can be given immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 7 days after the injection and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

Comments and Evidence Summary. In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting DMPA likely exceed any risk; therefore, starting DMPA should be considered at any time, with a follow-up pregnancy test in 2–4 weeks. If a woman needs to use additional contraceptive protection when switching to DMPA from another contraceptive method, consider continuing her previous method for 7 days after DMPA injection.

A systematic review identified eight articles examining DMPA initiation on different days of the menstrual cycle (*20*). Evidence from two studies with small samples indicated that DMPA injections given up to day 7 of the menstrual cycle inhibited ovulation; when DMPA was administered after

day 7, ovulation occurred in some women. Cervical mucus was of poor quality (i.e., not favorable for sperm penetration) in 90% of women within 24 hours of the injection (Level of evidence: II-2, fair) (*136–138*). Studies found that use of another contraceptive method until DMPA could be initiated (bridging option) did not help women initiate DMPA and was associated with more unintended pregnancies than immediate receipt of DMPA (*139–143*) (Level of evidence: I to II-3, fair to poor, indirect).

Examinations and Tests Needed Before Initiation of an Injectable

Among healthy women, no examinations or tests are needed before initiation of DMPA, although a baseline weight and BMI measurement might be useful for monitoring DMPA users over time (Table 4). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*).

Comments and Evidence Summary. Weight (BMI): Obese women can use (U.S. MEC 1) or generally can use (U.S. MEC 2) DMPA (*5*); therefore, screening for obesity is not necessary for the safe initiation of DMPA. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method. (See guidance on follow-up for DMPA users for evidence on weight gain with DMPA use.)

TABLE 4. Classification of examinations and tests needed before DMPA initiation

Examination or test	Class*
Examination	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m]^2)	—†
Clinical breast examination	C
Bimanual examination and cervical inspection	C
Laboratory test	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

Abbreviations: BMI = body mass index; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Bimanual examination and cervical inspection: Pelvic examination is not necessary before initiation of DMPA because it does not facilitate detection of conditions for which DMPA would be unsafe. Although women with current breast cancer should not use DMPA (U.S. MEC 4), and women with severe hypertension, heart disease, vascular disease, migraine headaches with aura, or certain liver diseases generally should not use DMPA (U.S. MEC 3) (*5*), none of these conditions are likely to be detected by pelvic examination (*120*). A systematic review identified two case-control studies that compared delayed versus immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (*15*). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed (Level of evidence: II-2, fair, direct).

Blood pressure: Women with hypertension generally can use DMPA (U.S. MEC 2), with the exception of women with severe hypertension or vascular disease, who generally should not use DMPA (U.S. MEC 3) (*5*). Screening for hypertension before initiation of DMPA is not necessary because of the low prevalence of undiagnosed severe hypertension and the high likelihood that women with these conditions already would have had them diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a blood pressure measurement before initiation of progestin-only contraceptives (*21*). The prevalence of undiagnosed hypertension among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, the percentage with diagnosed hypertension was 7.8%, and the percentage with undiagnosed hypertension was 1.9% (*144*).

Glucose: Although women with complicated diabetes generally should not use DMPA (U.S. MEC 3) (*5*), screening for diabetes before initiation of DMPA is not necessary because of the low prevalence of undiagnosed diabetes and the high likelihood that women with complicated diabetes would already have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with glucose measurement before initiation of hormonal contraceptives (*14*). The prevalence of diabetes among women of reproductive age is low. During 1999–2008 among women aged 20–44 years

in the United States, the percentage with diagnosed diabetes was 3% and the percentage with undiagnosed diabetes was 0.5% (*144*). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (*145–151*).

Liver enzymes: Although women with certain liver diseases generally should not use DMPA (U.S. MEC 3) (*5*), screening for liver disease before initiation of DMPA is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (*14*). The prevalence of liver disorders among women of reproductive age is low. In 2008 among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (*90*). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (*91*). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (*92*). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (*93*,*94*), although evidence is limited and no evidence exists for DMPA.

Clinical breast examination: Although women with current breast cancer should not use DMPA (U.S. MEC 4) (*5*), screening asymptomatic women with a clinical breast examination before initiating DMPA is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a clinical breast examination before initiation of hormonal contraceptives (*15*). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (*95*).

Other screening: Women with hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, HIV infection, or other STDs can use (U.S. MEC 1) or generally can use (U.S. MEC 2) DMPA (*5*); therefore, screening for these conditions is not necessary for the safe initiation of DMPA.

Routine Follow-Up After Injectable Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time for reinjection. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing injectable users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of the injectable for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

Comments and Evidence Summary. Although no evidence exists regarding whether a routine follow-up visit after initiating DMPA improves correct or continued use, monitoring weight or BMI change over time is important for DMPA users.

A systematic review identified a limited body of evidence that examined whether weight gain in the few months after DMPA initiation predicted future weight gain (*17*). Two studies found significant differences in weight gain or BMI at follow-up periods ranging from 12 to 36 months between early weight gainers (i.e., those who gained >5% of their baseline body weight within 6 months after initiation) and those who were not early weight gainers (*152*,*153*). The differences between groups were more pronounced at 18, 24, and 36 months than at 12 months. One study found that most adolescent DMPA users who had gained >5% of their baseline weight by 3 months gained even more weight by 12 months (*154*) (Level of evidence: II-2, fair, to II-3, fair, direct).

Timing of Repeat Injections

Reinjection Interval

- Provide repeat DMPA injections every 3 months (13 weeks).

Special Considerations

Early Injection

- The repeat DMPA injection can be given early when necessary.

Late Injection

- The repeat DMPA injection can be given up to 2 weeks late (15 weeks from the last injection) without requiring additional contraceptive protection.
- If the woman is >2 weeks late (>15 weeks from the last injection) for a repeat DMPA injection, she can have the injection if it is reasonably certain that she is not pregnant (Box 1). She needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. She might consider the use of emergency contraception if appropriate.

Comments and Evidence Summary. There are no time limits on early injections; injections can be given when necessary (e.g., when a woman cannot return at the routine interval). WHO has extended the time that a woman can have a late reinjection (i.e., grace period) for DMPA use from 2 weeks to 4 weeks on the basis of data from one study showing low pregnancy rates through 4 weeks; however, the CDC expert group did not consider the data to be generalizable to the United States because a large proportion of women in the study were breastfeeding. Therefore, U.S. SPR recommends a grace period of 2 weeks.

A systematic review identified 12 studies evaluating time to pregnancy or ovulation after the last injection of DMPA (*155*). Although pregnancy rates were low during the 2-week interval following the reinjection date and for 4 weeks following the reinjection date, data were sparse and one study included a large proportion of breastfeeding women (*156–158*). Studies also indicated a wide variation in time to ovulation after the last DMPA injection, with the majority ranging from 15 to 49 weeks from the last injection (*159–167*) (Level of evidence: II-2, fair, direct).

Bleeding Irregularities (Including Amenorrhea) During Injectable Use

- Before DMPA initiation, provide counseling about potential changes in bleeding patterns during DMPA use. Amenorrhea and unscheduled spotting or light bleeding is common with DMPA use, and heavy or prolonged bleeding can occur with DMPA use. These bleeding irregularities are generally not harmful and might decrease with continued DMPA use.

Unscheduled Spotting or Light Bleeding

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment option during days of bleeding can be considered:
  - NSAIDs for short-term treatment (5–7 days)
- If unscheduled spotting or light bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Heavy or Prolonged Bleeding

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (such as fibroids or polyps). If an underlying gynecologic problem is identified, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment options during days of bleeding can be considered:
  - NSAIDS for short-term treatment (5–7 days)
  - Hormonal treatment (if medically eligible) with low-dose COCs or estrogen for short-term treatment (10–20 days)
- If heavy or prolonged bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Comments and Evidence Summary. During contraceptive counseling and before initiation of DMPA, information about common side effects such as irregular bleeding should be discussed. Unscheduled bleeding or spotting is common with DMPA use (*168*). Additionally, amenorrhea is common after ≥1 years of continuous use (*168,169*). These bleeding irregularities are generally not harmful. Enhanced counseling among DMPA users detailing expected bleeding patterns and

reassurance that these irregularities generally are not harmful has been shown to reduce DMPA discontinuation in clinical trials (*101*,*102*).

A systematic review, as well as two additional studies, examined the treatment of bleeding irregularities during DMPA use (*122*,*170*,*171*). Two small studies found significant cessation of bleeding within 7 days of starting treatment among women taking valdecoxib for 5 days or mefenamic acid for 5 days compared with placebo (*172*,*173*). Treatment with ethinyl estradiol was found to stop bleeding better than placebo during the treatment period, although rates of discontinuation were high, and safety outcomes were not examined (*174*). In one small study among DMPA users who had been experiencing amenorrhea for 2 months, treatment with COCs was found to alleviate amenorrhea better than placebo (*175*). No studies examined the effects of aspirin on bleeding irregularities among DMPA users.

Combined Hormonal Contraceptives

Combined hormonal contraceptives contain both estrogen and a progestin and include 1) COCs (various formulations), 2) a transdermal contraceptive patch (which releases 150 μg of norelgestromin and 20 μg ethinyl estradiol daily), and 3) a vaginal contraceptive ring (which releases 120 μg etonogestrel and 15 μg ethinyl estradiol daily). Approximately 9 out of 100 women become pregnant in the first year of use with combined hormonal contraceptives with typical use (*59*). These methods are reversible and can be used by women of all ages. Combined hormonal contraceptives are generally used for 21–24 consecutive days, followed by 4–7 hormone-free days (either no use or placebo pills). These methods are sometimes used for an extended period with infrequent or no hormone-free days. Combined hormonal contraceptives do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Initiation of Combined Hormonal Contraceptives

Timing

- Combined hormonal contraceptives can be initiated at any time if it is reasonably certain that the woman is not pregnant (Box 1).

Need for Back-Up Contraception

- If combined hormonal contraceptives are started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If combined hormonal contraceptives are started >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** Combined hormonal contraceptives can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Breastfeeding)

- **Timing:** Combined hormonal contraceptives can be started when the woman is medically eligible to use the method (*176*) and if it is reasonably certain that she is not pregnant. (Box 1).
  - Postpartum women who are breastfeeding should not use combined hormonal contraceptives during the first 3 weeks after delivery (U.S. MEC 4) because of concerns about increased risk for venous thromboembolism and generally should not use combined hormonal contraceptives during the fourth week postpartum (U.S. MEC 3) because of concerns about potential effects on breastfeeding performance. Postpartum, breastfeeding women with other risk factors for venous thromboembolism generally should not use combined hormonal contraceptives 4–6 weeks after delivery (U.S. MEC 3).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (*60*), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (Not Breastfeeding)

- **Timing:** Combined hormonal contraceptives can be started when the woman is medically eligible (*176*) and if it is reasonably certain that she is not pregnant (Box 1).
  - Postpartum women should not use combined hormonal contraceptives during the first 3 weeks after delivery (U.S. MEC 4) because of concerns about increased risk

for venous thromboembolism. Postpartum women with other risk factors for venous thromboembolism generally should not use combined hormonal contraceptives 3–6 weeks after delivery (U.S. MEC 3).

- **Need for back-up contraception:** A woman who is ≥21 days postpartum and whose menstrual cycles have not returned needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postabortion (Spontaneous or Induced)

- **Timing:** Combined hormonal contraceptives can be started within the first 7 days after first or second trimester abortion, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** She needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless combined hormonal contraceptives are started at the time of a surgical abortion.

Switching from Another Contraceptive Method

- **Timing:** Combined hormonal contraceptives can be started immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 7 days after combined hormonal contraceptives are initiated and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

Comments and Evidence Summary. In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting combined hormonal contraceptives likely exceed any risk; therefore, starting combined hormonal contraceptives should be considered at any time, with a follow-up pregnancy test in 2–4 weeks. If a woman needs to use additional contraceptive protection when switching to combined hormonal contraceptives from another contraceptive method, consider continuing her previous method for 7 days after starting combined hormonal contraceptives.

A systematic review of 18 studies examined the effects of starting combined hormonal contraceptives on different days of the menstrual cycle (*22*). Overall, the evidence suggested that pregnancy rates did not differ by the timing of combined hormonal contraceptive initiation (*143*,*177–179*) (Level of evidence: I to II-3, fair, indirect). The more follicular activity that occurred before starting COCs, the more likely ovulation was to occur; however, no ovulations occurred when COCs were started at a follicle diameter of 10 mm (mean cycle day 7.6) or when the ring was started at 13 mm (median cycle day 11) (*180–189*) (Level of evidence: I to II-3, fair, indirect). Bleeding patterns and other side effects did not vary with the timing of combined hormonal contraceptive initiation (*177*,*178*,*190–194*) (Level of evidence: I to II-2, good to poor, direct). Although continuation rates of combined hormonal contraceptives were initially improved by the "quick start" approach (i.e., starting on the day of the visit), the advantage disappeared over time (*178*,*179*,*190–195*) (Level of evidence: I to II-2, good to poor, direct).

Examinations and Tests Needed Before Initiation of Combined Hormonal Contraceptives

Among healthy women, few examinations or tests are needed before initiation of combined hormonal contraceptives (Table 5). Blood pressure should be measured before initiation of combined hormonal contraceptives. Baseline weight and BMI measurements might be useful for monitoring combined hormonal contraceptive users over time. Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*).

Comments and Evidence Summary. Blood pressure: Women who have more severe hypertension (systolic pressure of ≥160 mm Hg or diastolic pressure of ≥100 mm Hg) or vascular disease should not use combined hormonal contraceptives (U.S. MEC 4), and women who have less severe hypertension (systolic pressure of 140–159 mm Hg or diastolic pressure of 90–99 mm Hg) or adequately controlled hypertension generally should not use combined hormonal contraceptives (U.S. MEC 3) (*5*). Therefore, blood pressure should be measured before initiating combined hormonal contraceptives. If access to health care is limited, blood pressure measurements may be obtained in nonclinical settings, such as

TABLE 5. Classification of examinations and tests needed before combined hormonal contraceptive initiation

Examination or laboratory test	Class*
Examination	
Blood pressure	A†
Weight (BMI) (weight [kg]/height [m]^2)	—§
Clinical breast examination	C
Bimanual examination and cervical inspection	C
Laboratory test	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

§ Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

pharmacies or fire stations, and reported by the woman to her provider. Evidence suggests that cardiovascular outcomes are worse among women who did not have their blood pressure measured before initiating COCs.

A systematic review identified six articles from three studies that reported cardiovascular outcomes among women who had blood pressure measurements and women who did not have blood pressure measurements before initiating COCs (*21*). Three case-control studies showed that women who did not have blood pressure measurements before initiating COCs had a higher risk for acute myocardial infarction than women who did have blood pressure measurements (*196–198*). Two case-control studies showed that women who did not have blood pressure measurements before initiating COCs had a higher risk for ischemic stroke than women who did have blood pressure measurements (*199*,*200*). One case-control study showed no difference in the risk for hemorrhagic stroke among women who initiated COCs regardless of whether their blood pressure was measured (*201*). Studies that examined hormonal contraceptive methods other than COCs were not identified (Level of evidence: II-2, fair, direct).

Weight (BMI): Obese women generally can use combined hormonal contraceptives (U.S. MEC 2) (*5*); therefore, screening for obesity is not necessary for the safe initiation of combined hormonal contraceptives. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Bimanual examination and cervical inspection: Pelvic examination is not necessary before initiation of combined hormonal contraceptives because it does not facilitate detection of conditions for which hormonal contraceptives would be unsafe. Women with certain conditions such as current breast cancer, severe hypertension or vascular disease, heart disease, migraine headaches with aura, and certain liver diseases, as well as women aged ≥35 years who smoke ≥15 cigarettes per day, should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives (*5*); however, none of these conditions are likely to be detected by pelvic examination (*120*). A systematic review identified two case-control studies that compared delayed and immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (*15*). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were found (Level of evidence: II-2 fair, direct).

Glucose: Although women with complicated diabetes should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives, depending on the severity of the condition (*5*), screening for diabetes before initiation of hormonal contraceptives is not necessary because of the low prevalence of undiagnosed diabetes and the high likelihood that women with complicated diabetes already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with glucose measurement before initiation of hormonal contraceptives (*14*). The prevalence of diabetes among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, the percentage with diagnosed diabetes was 3% and the percentage with undiagnosed diabetes was 0.5% (*144*). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (*145–151*).

Lipids: Although some women with hyperlipidemias generally should not use combined hormonal contraceptives (U.S. MEC 2/3, depending on the type and severity of the hyperlipidemia and presence of other cardiovascular risk factors) (*5*), screening for hyperlipidemia before initiation of

hormonal contraceptives is not necessary because of the low prevalence of undiagnosed disease in women of reproductive age and the low likelihood of clinically significant changes with use of hormonal contraceptives. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with lipid measurement before initiation of hormonal contraceptives (*14*). The prevalence of hyperlipidemia among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, approximately 10% had hypercholesterolemia, defined as total cholesterol ≥ 240 mg/dL or currently taking lipid-lowering medications, and the prevalence of undiagnosed hypercholesterolemia was approximately 2% (*144*). Studies have shown mixed results about the effects of hormonal methods on lipid levels, and the clinical significance of these changes is unclear (*202–204*). In addition, women with abnormal lipid levels at baseline were not found to have increased risk for adverse changes to their lipid profile when using hormonal methods (*202*).

Liver enzymes: Although women with certain liver diseases should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives (*5*), screening for liver disease before initiation of combined hormonal contraceptives is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (*14*). The prevalence of liver disorders among women of reproductive age is low. In 2008 among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (*90*). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (*91*). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (*92*). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (*93*,*94*), although evidence is limited; no evidence exists for other types of combined hormonal contraceptives.

Thrombogenic mutations: Women with thrombogenic mutations should not use combined hormonal contraceptives (U.S. MEC 4) (*5*) because of the increased risk for venous thromboembolism (*205*). However, studies have shown that universal screening for thrombogenic mutations before initiating COCs is not cost-effective because of the rarity of the conditions and the high cost of screening (*206–208*).

Clinical breast examination: Although women with current breast cancer should not use combined hormonal contraceptives (U.S. MEC 4) (*5*), screening asymptomatic women with a clinical breast examination before initiating combined hormonal contraceptives is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (*15*). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (*95*).

Other screening: Women with anemia, cervical intraepithelial neoplasia, cervical cancer, HIV infection, or other STDs can use (U.S. MEC 1) or generally can use (U.S. MEC 2) combined hormonal contraceptives (*5*); therefore, screening for these conditions is not necessary for the safe initiation of combined hormonal contraceptives.

Number of Pill Packs that Should Be Provided at Initial and Return Visits

- At the initial and return visits, provide or prescribe up to a 1-year supply of COCs (e.g., 13 28-day pill packs), depending on the woman's preferences and anticipated use.
- A woman should be able to obtain COCs easily in the amount and at the time she needs them.

Comments and Evidence Summary. The more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy.

A systematic review of the evidence suggested that providing a greater number of pill packs was associated with increased continuation (*23*). Studies that compared provision of one versus 12 packs, one versus 12 or 13 packs, or three versus seven packs found increased continuation of pill use among women provided with more pill packs (*209–211*). However, one study found that there was no difference in continuation when patients were provided one and then three packs versus four packs all at once (*212*). In addition to continuation, a greater number of pills packs provided was associated with fewer pregnancy tests, fewer pregnancies, and lower cost per client. However, a greater number of pill packs (i.e., 13 packs versus three packs) also was associated with increased pill wastage in one study (*210*) (Level of evidence: I to II-2, fair, direct).

Routine Follow-Up After Combined Hormonal Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems or if she wants to change the method being used. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing combined hormonal contraceptive users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of combined hormonal contraceptives for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Assess blood pressure.
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

Comments and Evidence Summary. No evidence exists regarding whether a routine follow-up visit after initiating combined hormonal contraceptives improves correct or continued use. Monitoring blood pressure is important for combined hormonal contraceptive users. Health-care providers might consider recommending women obtain blood pressure measurements in nonclinical settings (e.g., pharmacy or fire station).

A systematic review identified five studies that examined the incidence of hypertension among women who began using a COC versus those who started a nonhormonal method of contraception or a placebo (*17*). Few women developed hypertension after initiating COCs, and studies examining increases in blood pressure after COC initiation found mixed results. No studies were identified that examined changes in blood pressure among patch or vaginal ring users (Level of evidence: I, fair, to II-2, fair, indirect).

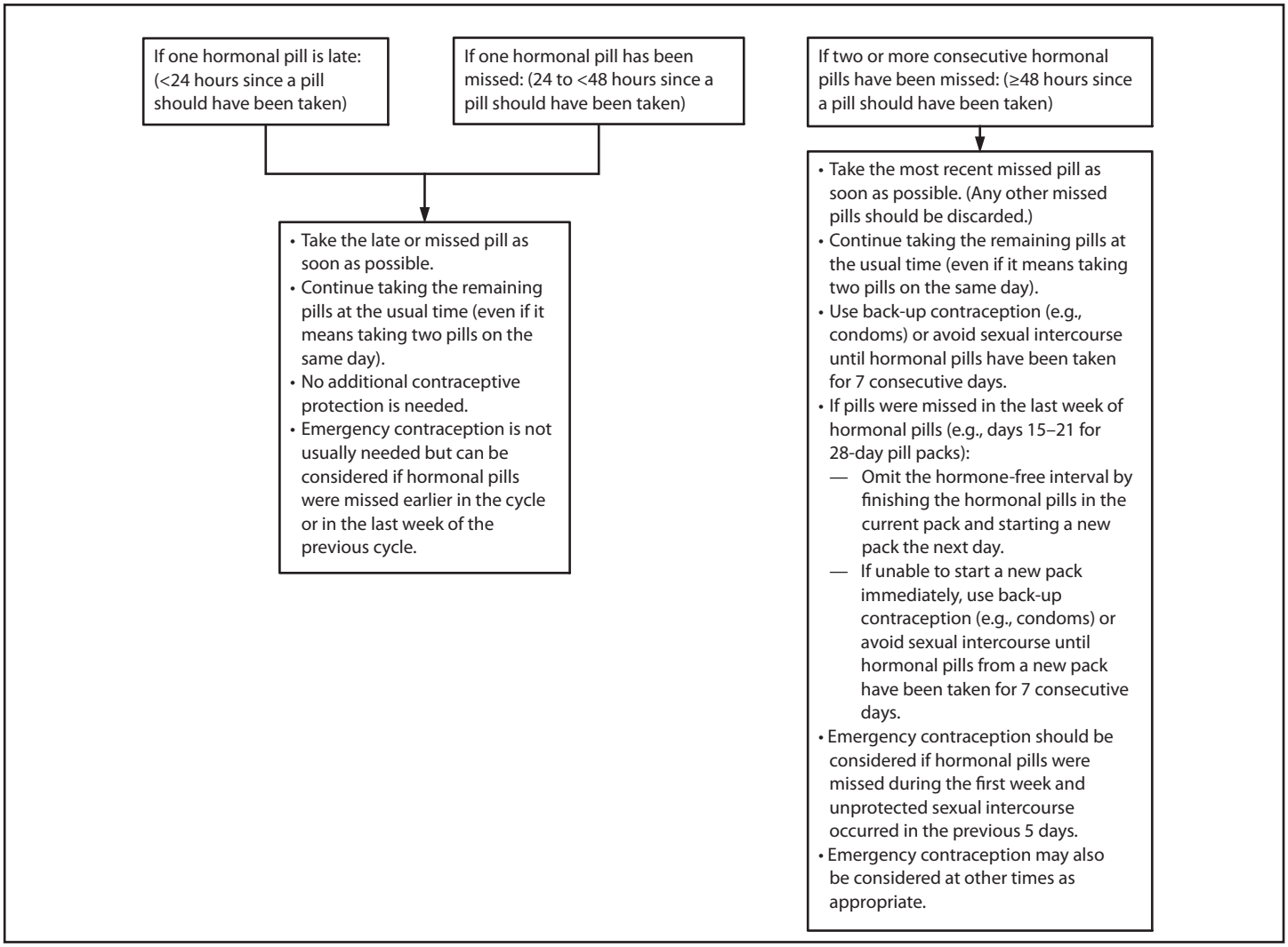
Late or Missed Doses and Side Effects from Combined Hormonal Contraceptive Use

For the following recommendations, a dose is considered late when <24 hours have elapsed since the dose should have been taken. A dose is considered missed if ≥24 hours have elapsed since the dose should have been taken. For example, if a COC pill was supposed to have been taken on Monday at 9:00 a.m. and is taken at 11:00 a.m., the pill is late; however, by Tuesday morning at 11:00 a.m., Monday's 9:00 a.m. pill has been missed and Tuesday's 9:00 a.m. pill is late. For COCs, the recommendations only apply to late or missed hormonally active pills and not to placebo pills. Recommendations are provided for late or missed pills (Figure 2), the patch (Figure 3), and the ring (Figure 4).

Comments and Evidence Summary. Inconsistent or incorrect use of combined hormonal contraceptives is a major cause of combined hormonal contraceptive failure. Extending the hormone-free interval is considered to be a particularly risky time to miss combined hormonal contraceptives. Seven days of continuous combined hormonal contraceptive use is deemed necessary to reliably prevent ovulation. The recommendations reflect a balance between simplicity and precision of science. Women who frequently miss COCs or experience other usage errors with combined hormonal patch or combined vaginal ring should consider an alternative contraceptive method that is less dependent on the user to be effective (e.g., IUD, implant, or injectable).

A systematic review identified 36 studies that examined measures of contraceptive effectiveness of combined hormonal contraceptives during cycles with extended hormone-free intervals, shortened hormone-free intervals, or deliberate nonadherence on days not adjacent to the hormone-free interval (*24*). Most of the studies examined COCs (*188*,*213–240*), two examined the combined hormonal patch (*234*,*241*), and six examined the combined vaginal ring (*185*,*242–246*). No direct evidence on the effect of missed pills on the risk for pregnancy was found. Studies of women deliberately extending the hormone-free interval up to 14 days found wide variability in the amount of follicular development and occurrence of ovulation (*216*,*219*,*221*,*222*,*224*,*225*,*227–230*); in general, the risk for ovulation was low, and among women who did ovulate, cycles were usually abnormal. In studies of women who deliberately missed pills on various days during the cycle not adjacent to the hormone-free interval, ovulation occurred infrequently (*214*,*220–222*,*230*,*231*,*233*,*234*). Studies comparing 7-day hormone-free intervals with shorter hormone-free intervals found lower rates of pregnancy (*213*,*217*,*226*,*232*) and significantly greater suppression of ovulation (*215*,*225*,*236–238*,*240*) among women with shorter intervals in all but one study (*235*), which found no difference. Two studies that compared 30-μg ethinyl estradiol pills with 20-μg ethinyl estradiol pills showed more follicular activity when 20-μg ethinyl estradiol pills were missed (*216*,*219*). In

FIGURE 2. Recommended actions after late or missed combined oral contraceptives



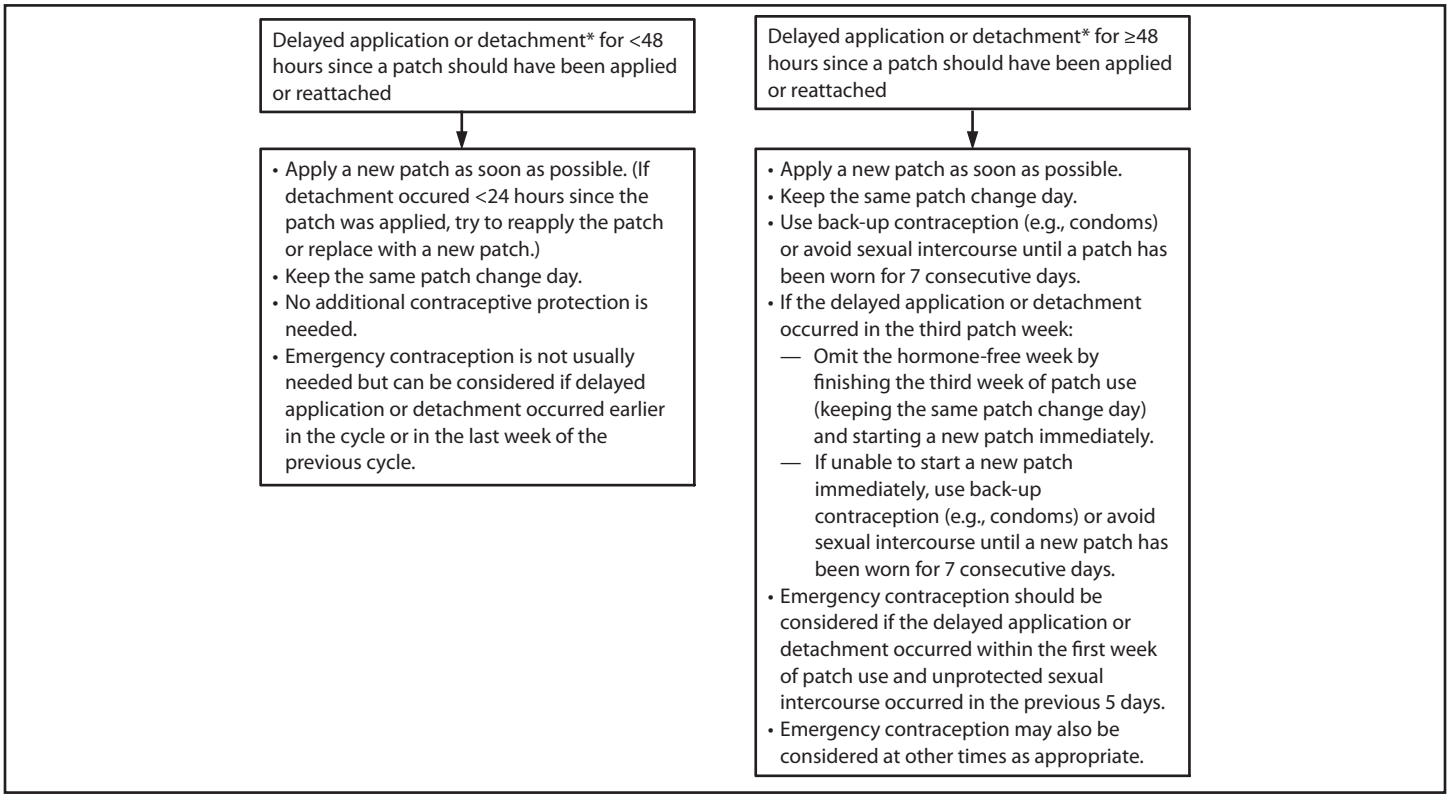
studies examining the combined vaginal ring, three studies found that nondeliberate extension of the hormone-free interval for 24 to <48 hours from the scheduled period did not increase the risk for pregnancy (*242*,*243*,*245*); one study found that ring insertion after a deliberately extended hormone-free interval that allowed a 13-mm follicle to develop interrupted ovarian function and further follicular growth (*185*); and one study found that inhibition of ovulation was maintained after deliberately forgetting to remove the ring for up to 2 weeks after normal ring use (*246*). In studies examining the combined hormonal patch, one study found that missing 1–3 consecutive days before patch replacement (either wearing one patch 3 days longer before replacement or going 3 days without a patch before replacing the next patch) on days not adjacent to the patch-free interval resulted in little follicular activity and low risk for ovulation (*234*), and one pharmacokinetic study found that serum levels of ethinyl estradiol and progestin norelgestromin remained within reference ranges after extending patch wear for 3 days (*241*). No studies were found on extending the patch-free interval. In studies that provide indirect evidence on the effects of missed combined hormonal contraception on surrogate measures of pregnancy, how differences in surrogate measures correspond to pregnancy risk is unclear (Level of evidence: I, good, indirect to II-3, poor, direct).

Vomiting or Severe Diarrhea While Using COCs

Certain steps should be taken by women who experience vomiting or severe diarrhea while using COCs (Figure 5).

Comments and Evidence Summary. Theoretically, the contraceptive effectiveness of COCs might be decreased because of vomiting or severe diarrhea. Because of the lack of evidence that addresses vomiting or severe diarrhea while using COCs, these recommendations are based on the recommendations

FIGURE 3. Recommended actions after delayed application or detachment with combined hormonal patch



* If detachment takes place but the woman is unsure when the detachment occurred, consider the patch to have been detached for ≥48 hours since a patch should have been applied or reattached.

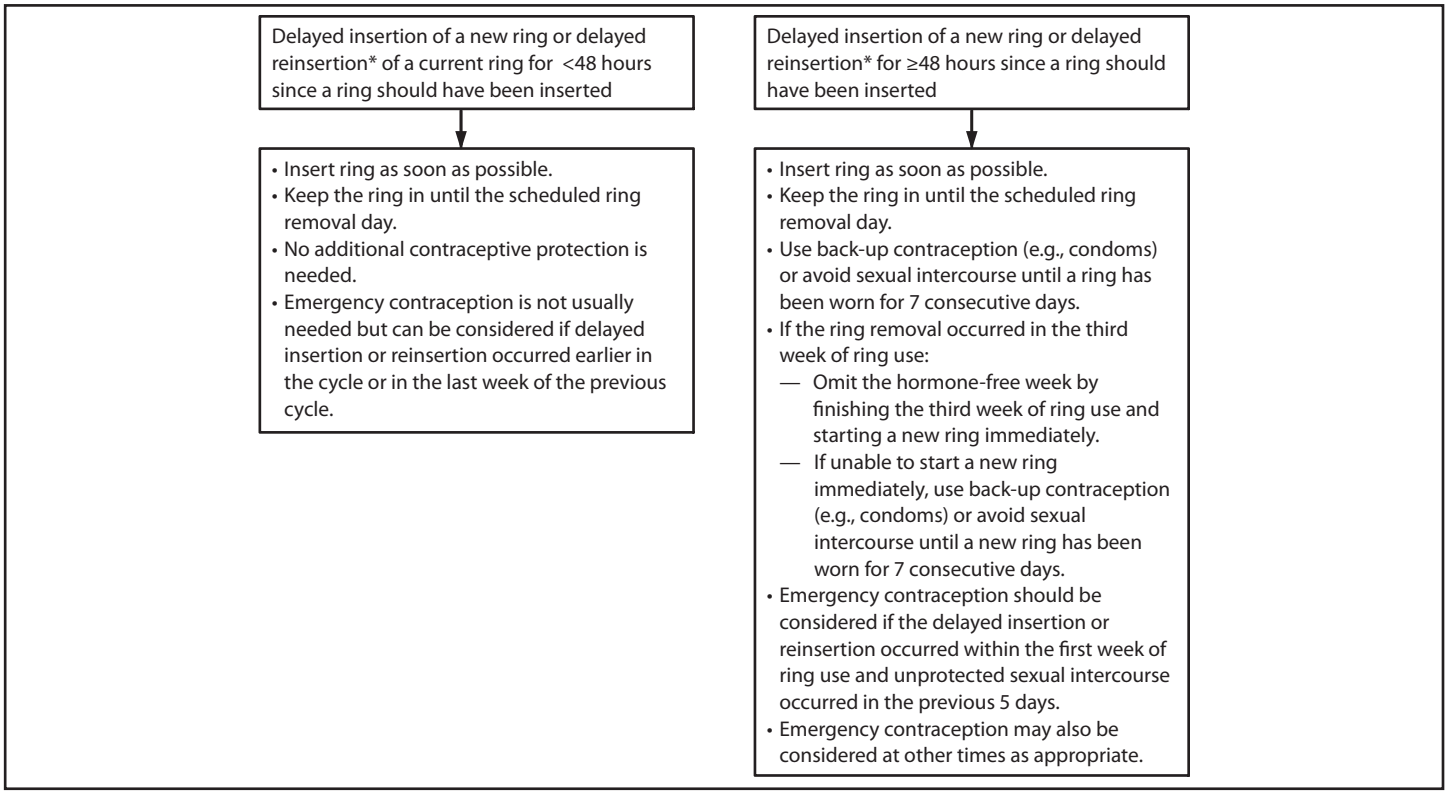
for missed COCs. No evidence was found on the effects of vomiting or diarrhea on measures of contraceptive effectiveness including pregnancy, follicular development, hormone levels, or cervical mucus quality.

Unscheduled Bleeding with Extended or Continuous Use of Combined Hormonal Contraceptives

- Before initiation of combined hormonal contraceptives, provide counseling about potential changes in bleeding patterns during extended or continuous combined hormonal contraceptive use. (Extended contraceptive use is defined as a planned hormone-free interval after at least two contiguous cycles. Continuous contraceptive use is defined as uninterrupted use of hormonal contraception without a hormone-free interval [*247*].)
- Unscheduled spotting or bleeding is common during the first 3–6 months of extended or continuous combined hormonal contraceptive use. It is generally not harmful and decreases with continued combined hormonal contraceptive use.
- If clinically indicated, consider an underlying gynecological problem, such as inconsistent use, interactions with other medications, cigarette smoking, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecological problem is not found and the woman wants treatment, the following treatment option can be considered:
  - Advise the woman to discontinue combined hormonal contraceptive use (i.e., a hormone-free interval) for 3–4 consecutive days; a hormone-free interval is not recommended during the first 21 days of using the continuous or extended combined hormonal contraceptive method. A hormone-free interval also is not recommended more than once per month because contraceptive effectiveness might be reduced.
- If unscheduled spotting or bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Comments and Evidence Summary. During contraceptive counseling and before initiating extended or continuous

FIGURE 4. Recommended actions after delayed insertion or reinsertion with combined vaginal ring



* If removal takes place but the woman is unsure of how long the ring has been removed, consider the ring to have been removed for ≥48 hours since a ring should have been inserted or reinserted.

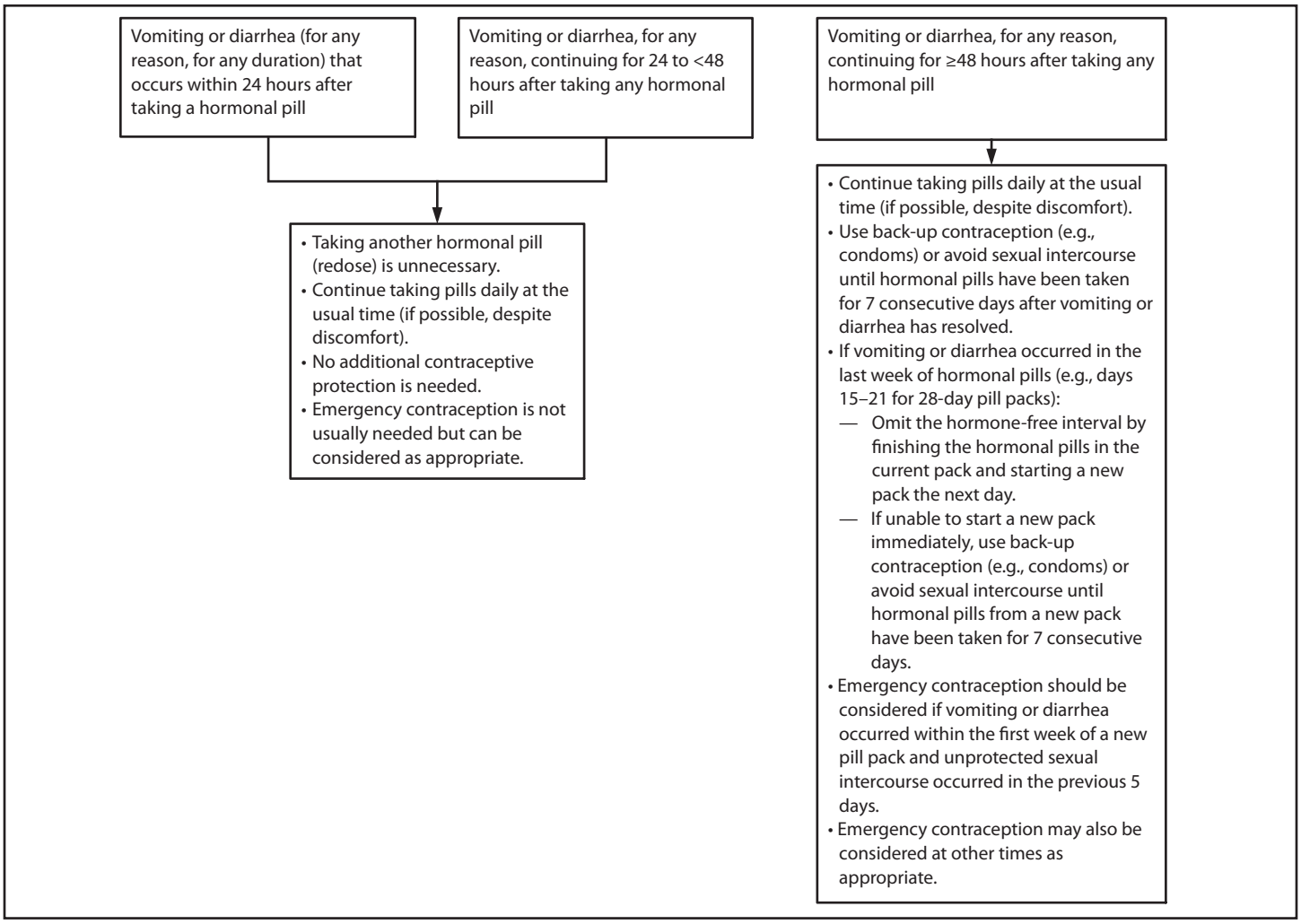
combined hormonal contraceptives, information about common side effects such as unscheduled spotting or bleeding, especially during the first 3–6 months of use, should be discussed (*248*). These bleeding irregularities are generally not harmful and usually improve with persistent use of the hormonal method. To avoid unscheduled spotting or bleeding, counseling should emphasize the importance of correct use and timing; for users of contraceptive pills, emphasize consistent pill use. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce method discontinuation in clinical trials with DMPA (*101*,*102*).

A systematic review identified three studies with small study populations that addressed treatments for unscheduled bleeding among women using extended or continuous combined hormonal contraceptives (*25*). In two separate randomized clinical trials in which women were taking either contraceptive pills or using the contraceptive ring continuously for 168 days, women assigned to a hormone-free interval of 3 or 4 days reported improved bleeding. Although they noted an initial increase in flow, this was followed by an abrupt decrease 7–8 days later with eventual cessation of flow 11–12 days later. These findings were compared with women who continued to use their method without a hormone-free interval, in which a greater proportion reported either treatment failure or fewer days of amenorrhea (*249*,*250*). In another randomized trial of 66 women with unscheduled bleeding among women using 84 days of hormonally active contraceptive pills, oral doxycycline (100 mg twice daily) initiated the first day of bleeding and taken for 5 days did not result in any improvement in bleeding compared with placebo (*251*) (Level of evidence: I, fair, direct).

Progestin-Only Pills

POPs contain only a progestin and no estrogen and are available in the United States. Approximately 9 out of 100 women become pregnant in the first year of use with POPs with typical use (*59*). POPs are reversible and can be used by women of all ages. POPs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

FIGURE 5. Recommended steps after vomiting or diarrhea while using combined oral contraceptives



Initiation of POPs

Timing

- POPs can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).

Need for Back-Up Contraception

- If POPs are started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If POPs are started >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

Special Considerations

Amenorrhea (Not Postpartum)

- **Timing:** POPs can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

Postpartum (Breastfeeding)

- **Timing:** POPs can be started at any time, including immediately postpartum (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (*60*), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycles needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days. If her menstrual cycles have

returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

Postpartum (Not Breastfeeding)

- **Timing:** POPs can be started at any time, including immediately postpartum (U.S. MEC 1), if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** Women who are ≥21 days postpartum and whose menstrual cycles have not returned need to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

Postabortion (Spontaneous or Induced)

- **Timing:** POPs can be started within the first 7 days, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days unless POPs are started at the time of a surgical abortion.

Switching from Another Contraceptive Method

- **Timing:** POPs can be started immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 2 days after POPs are initiated and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 2 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

Comments and Evidence Summary. In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting POPs likely exceed any risk; therefore, starting POPs should be considered at any time, with a follow-up pregnancy test in 2–4 weeks.

Unlike COCs, POPs inhibit ovulation in about half of cycles, although the rates vary widely by individual (*252*). Peak serum steroid levels are reached about 2 hours after administration, followed by rapid distribution and elimination, such that by 24 hours after administration, serum steroid levels are near baseline (*252*). Therefore, taking POPs at approximately the same time each day is important. An estimated 48 hours of POP use has been deemed necessary to achieve the contraceptive effects on cervical mucus (*252*). If a woman needs to use additional contraceptive protection when switching to POPs from another contraceptive method, consider continuing her previous method for 2 days after starting POPs. No direct evidence was found regarding the effects of starting POPs at different times of the cycle.

Examinations and Tests Needed Before Initiation of POPs

Among healthy women, no examinations or tests are needed before initiation of POPs, although a baseline weight and BMI measurement might be useful for monitoring POP users over time (Table 6). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates

TABLE 6. Classification of examinations and tests needed before POP initiation

Examination or laboratory test	Class*
Examination	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m]^2)	—†
Clinical breast examination	C
Bimanual examination and cervical inspection	C
Laboratory test	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.*

* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

for a particular method of contraception. U.S. MEC might be useful in such circumstances (*5*).

Comments and Evidence Summary. Weight (BMI): Obese women can use POPs (U.S. MEC 1) (*5*); therefore, screening for obesity is not necessary for the safe initiation of POPs. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

Bimanual examination and cervical inspection: Pelvic examination is not necessary before initiation of POPs because it does not facilitate detection of conditions for which POPs would be unsafe. Women with current breast cancer should not use POPs (U.S. MEC 4), and women with certain liver diseases generally should not use POPs (U.S. MEC 3) (*5*); however, neither of these conditions are likely to be detected by pelvic examination (*120*). A systematic review identified two case-control studies that compared delayed versus immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (*15*). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed (Level of evidence: II-2 fair, direct).

Liver enzymes: Although women with certain liver diseases generally should not use POPs (U.S. MEC 3) (*5*), screening for liver disease before initiation of POPs is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (*14*). The prevalence of liver disorders among women of reproductive age is low. In 2008 among U.S. adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (*90*). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (*91*). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (*92*). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (*93*,*94*).

Clinical breast examination: Although women with current breast cancer should not use POPs (U.S. MEC 4) (*5*), screening asymptomatic women with a clinical breast examination before initiating POPs is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a clinical breast examination before initiation of hormonal contraceptives (*15*). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women ages 20–49 was approximately 72 per 100,000 women (*95*).

Other screening: Women with hypertension, diabetes, hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, STDs, or HIV infection can use (U.S. MEC 1) or generally can use (U.S. MEC 2) POPs (*5*); therefore, screening for these conditions is not necessary for the safe initiation of POPs.

Number of Pill Packs that Should Be Provided at Initial and Return Visits

- At the initial and return visits, provide or prescribe up to a 1-year supply of POPs (e.g., 13 28-day pill packs), depending on the woman's preferences and anticipated use.
- A woman should be able to obtain POPs easily in the amount and at the time she needs them.

Comments and Evidence Summary. The more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy.

A systematic review of the evidence suggested that providing a greater number of pill packs was associated with increased continuation (*23*). Studies that compared provision of one versus 12 packs, one versus 12 or 13 packs, or three versus seven packs found increased continuation of pill use among women provided with more pill packs (*209–211*). However, one study found that there was no difference in continuation when patients were provided one and then three packs versus four packs all at once (*212*). In addition to continuation, a greater number of pill packs provided was associated with fewer pregnancy tests, fewer pregnancies, and lower cost per client. However, a greater number of pill packs (13 packs versus three packs) also was associated with increased pill wastage in one study (*210*) (Level of evidence: I to II-2, fair, direct).

Routine Follow-Up After POP Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and

different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems or if she wants to change the method being used. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing POP users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of POPs for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

Comments and Evidence Summary. No evidence was found regarding whether a routine follow-up visit after initiating POPs improves correct or continued use.

Missed POPs

For the following recommendations, a dose is considered missed if it has been >3 hours since it should have been taken.

- Take one pill as soon as possible.
- Continue taking pills daily, one each day, at the same time each day, even if it means taking two pills on the same day.
- Use back-up contraception (e.g., condoms) or avoid sexual intercourse until pills have been taken correctly, on time, for 2 consecutive days.
- Emergency contraception should be considered if the woman has had unprotected sexual intercourse.

Comments and Evidence Summary. Inconsistent or incorrect use of oral contraceptive pills is a major reason for oral contraceptive failure. Unlike COCs, POPs inhibit ovulation in about half of cycles, although this rate varies widely by individual (*252*). Peak serum steroid levels are reached about 2 hours after administration, followed by rapid distribution and elimination, such that by 24 hours after administration, serum steroid levels are near baseline (*252*). Therefore, taking POPs at approximately the same time each day is important. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus (*252*). Women who frequently miss POPs should consider an alternative contraceptive method that is less dependent on the user to be effective (e.g., IUD, implant, or injectable). No evidence was found regarding the effects of missed POPs available in the United States on measures of contraceptive effectiveness including pregnancy, follicular development, hormone levels, or cervical mucus quality.

Vomiting or Severe Diarrhea (for any Reason or Duration) that Occurs Within 3 Hours After Taking a Pill

- Take another pill as soon as possible (if possible, despite discomfort).
- Continue taking pills daily, one each day, at the same time each day.
- Use back-up contraception (e.g., condoms) or avoid sexual intercourse until 2 days after vomiting or diarrhea has resolved.
- Emergency contraception should be considered if the woman has had unprotected sexual intercourse.

Comments and Evidence Summary. Theoretically, the contraceptive effectiveness of POPs might be decreased because of vomiting or severe diarrhea. Because of the lack of evidence to address this question, these recommendations are based on the recommendations for missed POPs. No evidence was found regarding the effects of vomiting or diarrhea on measures of contraceptive effectiveness, including pregnancy, follicular development, hormone levels, or cervical mucus quality.

Standard Days Method

SDM is a method based on fertility awareness; users must avoid unprotected sexual intercourse on days 8–19 of the menstrual cycle (*253*). Approximately 5 out of 100 women become pregnant in the first year of use with perfect (i.e., correct and consistent) use of SDM (*253*); effectiveness based on typical use is not available for this method but is expected to be lower than that for perfect use. SDM is reversible and can be used by women of all ages. SDM does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Use of SDM Among Women with Various Menstrual Cycle Durations

Menstrual Cycles of 26–32 Days

- These women may use the method.
- Provide a barrier method of contraception for protection on days 8–19 if she wants one.
- If she has unprotected sexual intercourse during days 8–19, consider the use of emergency contraception if appropriate.

Two or More Menstrual Cycles of <26 or >32 Days Within Any 1 Year of SDM Use

- Advise the woman that the method might not be appropriate for her because of a higher risk for pregnancy. Help her consider another method.

Comments and Evidence Summary. The probability of pregnancy is increased when the menstrual cycle is outside the range of 26–32 days, even if unprotected sexual intercourse is avoided on days 8–19. A study of 7,600 menstrual cycles, including information on cycle length and signs of ovulation, concluded that the theoretical effectiveness of SDM is greatest for women with cycles of 26–32 days, that the method is still effective for women who occasionally have a cycle outside this range, and that it is less effective for women who consistently have cycles outside this range. Information from daily hormonal measurements shows that the timing of the 6-day fertile window varies greatly, even among women with regular cycles (*39*,*254*,*255*).

Emergency Contraception

Emergency contraception consists of methods that can be used by women after sexual intercourse to prevent pregnancy. Emergency contraception methods have varying ranges of effectiveness depending on the method and timing of administration. Four options are available in the United States: the Cu-IUD and three types of ECPs.

Types of Emergency Contraception

Intrauterine Device

- Cu-IUD

ECPs

- Ulipristal acetate (UPA) in a single dose (30 mg)
- Levonorgestrel in a single dose (1.5 mg) or as a split dose (1 dose of 0.75 mg of levonorgestrel followed by a second dose of 0.75 mg of levonorgestrel 12 hours later)
- Combined estrogen and progestin in 2 doses (Yuzpe regimen: 1 dose of 100 μg of ethinyl estradiol plus 0.50 mg of levonorgestrel followed by a second dose of 100 μg of ethinyl estradiol plus 0.50 mg of levonorgestrel 12 hours later)

Initiation of Emergency Contraception

Timing

Cu-IUD

- The Cu-IUD can be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive.
- In addition, when the day of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after sexual intercourse, as long as insertion does not occur >5 days after ovulation.

ECPs

- ECPs should be taken as soon as possible within 5 days of unprotected sexual intercourse.

Comments and Evidence Summary. Cu-IUDs are highly effective as emergency contraception (*256*) and can be continued as regular contraception. UPA and levonorgestrel ECPs have similar effectiveness when taken within 3 days after unprotected sexual intercourse; however, UPA has been shown to be more effective than the levonorgestrel formulation 3–5 days after unprotected sexual intercourse (*257*). The combined estrogen and progestin regimen is less effective than UPA or levonorgestrel and also is associated with more frequent occurrence of side effects (nausea and vomiting) (*258*). The levonorgestrel formulation might be less effective than UPA among obese women (*257*).

Two studies of UPA use found consistent decreases in pregnancy rates when administered within 120 hours of unprotected sexual intercourse (*257*,*259*). Five studies found that the levonorgestrel and combined regimens decreased risk for pregnancy through the fifth day after unprotected sexual intercourse; however, rates of pregnancy were slightly higher when ECPs were taken after 3 days (*260*–*264*). A meta-analysis of levonorgestrel ECPs found that pregnancy rates were low when administered within 4 days after unprotected sexual intercourse but increased at 4–5 days (*265*) (Level of evidence: I to II-2, good to poor, direct).

Advance Provision of ECPs

- An advance supply of ECPs may be provided so that ECPs will be available when needed and can be taken as soon as possible after unprotected sexual intercourse.

Comments and Evidence Summary. A systematic review identified 17 studies that reported on safety or effectiveness of advance ECPs in adult or adolescent women (*26*). Any use of ECPs was two to seven times greater among women who received an advance supply of ECPs. However, a summary estimate (relative risk = 0.97; 95% confidence interval = 0.77–1.22) of five randomized controlled trials did not indicate a significant reduction in unintended pregnancies at 12 months with advance provision of ECPs. In the majority of studies among adults or adolescents, patterns of regular contraceptive use, pregnancy rates, and incidence of STDs did not vary between those who received advance ECPs and those who did not. Although available evidence supports the safety of advance

provision of ECPs, effectiveness of advance provision of ECPs in reducing pregnancy rates at the population level has not been demonstrated (Level of evidence: I to II-3, good to poor, direct).

Initiation of Regular Contraception After ECPs

UPA

- Any regular contraceptive method can be started immediately after the use of UPA.
- The woman needs to abstain from sexual intercourse or use barrier contraception for 14 days or until her next menses, whichever comes first.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

Levonorgestrel and Combined Estrogen and Progestin ECPs

- Any regular contraceptive method can be started immediately after the use of levonorgestrel or combined estrogen and progestin ECPs.
- The woman needs to abstain from sexual intercourse or use barrier contraception for 7 days.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

Comments and Evidence Summary. Data on when a woman can start regular contraception after ECPs are limited to expert opinion and product labeling (*27*). Theoretically, the effectiveness of systemic hormonal contraception might be decreased when administered concurrently or in close succession because of the antiprogestin properties of UPA (*266*,*267*); these theoretical concerns do not exist for combined estrogen and progestin or levonorgestrel formulations of ECPs. The resumption or initiation of regular hormonal contraception after ECP use involves consideration of the risk for pregnancy if ECPs fail and the risks for unintended pregnancy if contraception initiation is delayed until the subsequent menstrual cycle. If a woman is planning to initiate contraception after the next menstrual period after ECP use, the cycle in which ECPs are used might be shortened, prolonged, or involve unscheduled bleeding.

Prevention and Management of Nausea and Vomiting with ECP Use

Nausea and Vomiting

- Levonorgestrel and UPA ECPs cause less nausea and vomiting than combined estrogen and progestin ECPs.
- Routine use of antiemetics before taking ECPs is not recommended. Pretreatment with antiemetics may be considered depending on availability and clinical judgment.

Vomiting Within 3 Hours of Taking ECPs

- Another dose of ECP should be taken as soon as possible. Use of an antiemetic should be considered.

Comments and Evidence Summary. Many women do not experience nausea or vomiting when taking ECPs, and predicting which women will experience nausea or vomiting is difficult. Although routine use of antiemetics before taking ECPs is not recommended, antiemetics are effective in some women and can be offered when appropriate. Health-care providers who are deciding whether to offer antiemetics to women taking ECPs should consider the following: 1) women taking combined estrogen and progestin ECPs are more likely to experience nausea and vomiting than those who take levonorgestrel or UPA ECPs; 2) evidence indicates that antiemetics reduce the occurrence of nausea and vomiting in women taking combined estrogen and progestin ECPs; and 3) women who take antiemetics might experience other side effects from the antiemetics.

A systematic review examined incidence of nausea and vomiting with different ECP regimens and effectiveness of antinausea drugs in reducing nausea and vomiting with ECP use (*28*). The levonorgestrel regimen was associated with significantly less nausea than a nonstandard dose of UPA (50 mg) and the standard combined estrogen and progestin regimen (*268–270*). Use of the split-dose levonorgestrel showed no differences in nausea and vomiting compared with the single-dose levonorgestrel (*260*,*261*,*263*,*271*) (Level of evidence: I, good-fair, indirect). Two trials of antinausea drugs, meclizine and metoclopramide, taken before combined estrogen and progestin ECPs, reduced the severity of nausea (*272*,*273*). Significantly less vomiting occurred with meclizine but not metoclopramide (Level of evidence: I, good-fair, direct). No direct evidence was found regarding the effects of vomiting after taking ECPs.

Female Sterilization

Laparoscopic, abdominal, and hysteroscopic methods of female sterilization are available in the United States, and some of these procedures can be performed in an outpatient procedure or office setting. Fewer than 1 out of 100 women become pregnant in the first year after female sterilization (*59*). Because these methods are intended to be irreversible, all women should be appropriately counseled about the permanency of sterilization and the availability of highly

effective, long-acting, reversible methods of contraception. Female sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

When Hysteroscopic Sterilization Is Reliable for Contraception

- Before a woman can rely on hysteroscopic sterilization for contraception, a hysterosalpingogram (HSG) must be performed 3 months after the sterilization procedure to confirm bilateral tubal occlusion.
- The woman should be advised that she needs to abstain from sexual intercourse or use additional contraceptive protection until she has confirmed bilateral tubal occlusion.

When Laparoscopic and Abdominal Approches Are Reliable for Contraception

- A woman can rely on sterilization for contraception immediately after laparoscopic and abdominal approaches. No additional contraceptive protection is needed.

Comments and Evidence Summary. HSG confirmation is necessary to confirm bilateral tubal occlusion after hysteroscopic sterilization. The inserts for the hysteroscopic sterilization system available in the United States are placed bilaterally into the fallopian tubes and require 3 months for adequate fibrosis and scarring leading to bilateral tubal occlusion. After hysteroscopic sterilization, advise the woman to correctly and consistently use an effective method of contraception while awaiting confirmation. If compliance with another method might be a problem, a woman and her health-care provider may consider DMPA injection at the time of sterilization to ensure adequate contraception for 3 months. Unlike laparoscopic and abdominal sterilizations, pregnancy risk beyond 7 years of follow-up has not been studied among women who received hysteroscopic sterilization.

Pregnancy risk with at least 10 years of follow-up has been studied among women who received laparoscopic and abdominal sterilizations (*274*,*275*). Although these methods are highly effective, pregnancies can occur many years after the procedure, and the risk for pregnancy is higher among younger women (*274*,*276*).

A systematic review was conducted to identify studies that reported whether pregnancies occurred after hysteroscopic sterilization (*29*). Twenty-four studies were identified that reported whether pregnancies occurred after hysteroscopic sterilization and found that very few pregnancies occurred among women with confirmed bilateral tubal occlusion; however, few studies include long-term follow-up, and none with follow-up for >7 years. Among women who had successful bilateral placement, most pregnancies that occurred after hysteroscopic sterilization were in women who did not have confirmed bilateral tubal occlusion at 3 months, either because of lack of follow up or misinterpretation of HSG results (*277–279*). Some pregnancies occurred within 3 months of placement, including among women who were already pregnant at the time of the procedure, women who did not use alternative contraception, or women who had failures of alternative contraception (*277*,*278*,*280–283*). Although these studies generally demonstrated high rates of bilateral placement, some pregnancies occurred as a result of lack of bilateral placement identified on later imaging (*277*,*278*,*280*,*281*,*283*,*284*). Most pregnancies occurred after deviations from FDA directions, which include placement in the early follicular phase of the menstrual cycle, imaging at 3 months to document proper placement, and use of effective alternative contraception until documented occlusion (Level of evidence: II-3, fair, direct).

Male Sterilization

Male sterilization, or vasectomy, is one of the few contraceptive methods available to men and can be performed in an outpatient procedure or office setting. Fewer than 1 woman out of 100 becomes pregnant in the first year after her male partner undergoes sterilization (*59*). Because male sterilization is intended to be irreversible, all men should be appropriately counseled about the permanency of sterilization and the availability of highly effective, long-acting, reversible methods of contraception for women. Male sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

When Vasectomy Is Reliable for Contraception

- A semen analysis should be performed 8–16 weeks after a vasectomy to ensure the procedure was successful.
- The man should be advised that he should use additional contraceptive protection or abstain from sexual intercourse until he has confirmation of vasectomy success by postvasectomy semen analysis.

Other Postprocedure Recommendations

- The man should refrain from ejaculation for approximately 1 week after the vasectomy to allow for healing of surgical sites and, after certain methods of vasectomy, occlusion of the vas.

Comments and Evidence Summary. The Vasectomy Guideline Panel of the American Urological Association performed a systematic review of key issues concerning the practice of vasectomy (*285*). All English-language publications on vasectomy published during 1949–2011 were reviewed. For more information, see the American Urological Association *Vasectomy Guidelines* (available at http://www.auanet.org/education/vasectomy.cfm).

Motile sperm disappear within a few weeks after vasectomy (*286–289*). The time to azoospermia varies widely in different studies; however, by 12 weeks after the vasectomy, 80% of men have azoospermia, and almost all others have rare nonmotile sperm (defined as ≤100,000 nonmotile sperm per milliliter) (*285*). The number of ejaculations after vasectomy is not a reliable indicator of when azoospermia or rare nonmotile sperm will be achieved (*285*). Once azoospermia or rare nonmotile sperm has been achieved, patients can rely on the vasectomy for contraception, although not with 100% certainty. The risk for pregnancy after a man has achieved postvasectomy azoospermia is approximately one in 2,000 (*290–294*).

A median of 78% (range 33%–100%) of men return for a single postvasectomy semen analysis (*285*). In the largest cohorts that appear typical of North American vasectomy practice, approximately two thirds of men (55%–71%) return for at least one postvasectomy semen analysis (*291*,*295–299*). Assigning men an appointment after their vasectomy might improve compliance with follow-up (*300*).

When Women Can Stop Using Contraceptives

- Contraceptive protection is still needed for women aged >44 years if the woman wants to avoid pregnancy.

Comments and Evidence Summary. The age at which a woman is no longer at risk for pregnancy is not known. Although uncommon, spontaneous pregnancies occur among women aged >44 years. Both the American College of Obstetricians and Gynecologists and the North American Menopause Society recommend that women continue contraceptive use until menopause or age 50–55 years (*301*,*302*). The median age of menopause is approximately 51 years in North America (*301*) but can vary from ages 40 to 60 years (*303*). The median age of definitive loss of natural fertility is 41 years but can range up to age 51 years (*304*,*305*). No reliable laboratory tests are available to confirm definitive loss of fertility in a woman. The assessment of follicle-stimulating hormone levels to determine when a woman is no longer fertile might not be accurate (*301*).

Health-care providers should consider the risks for becoming pregnant in a woman of advanced reproductive age, as well as any risks of continuing contraception until menopause. Pregnancies among women of advanced reproductive age are at higher risk for maternal complications, such as hemorrhage, venous thromboembolism, and death, and fetal complications, such as spontaneous abortion, stillbirth, and congenital anomalies (*306–308*). Risks associated with continuing contraception, in particular risks for acute cardiovascular events (venous thromboembolism, myocardial infarction, or stroke) or breast cancer, also are important to consider. U.S. MEC states that on the basis of age alone, women aged >45 years can use POPs, implants, the LNG-IUD, or the Cu-IUD (U.S. MEC 1) (*5*). Women aged >45 years generally can use combined hormonal contraceptives and DMPA (U.S. MEC 2) (*5*). However, women in this age group might have chronic conditions or other risk factors that might render use of hormonal contraceptive methods unsafe; U.S. MEC might be helpful in guiding the safe use of contraceptives in these women.

The incidence of venous thromboembolism was higher among oral contraceptive users aged ≥45 years compared with younger oral contraceptive users in two studies (*309–311*); however, an interaction between hormonal contraception and increased age compared with baseline risk was not demonstrated (*309*,*310*) or was not examined (*311*). The relative risk for myocardial infarction was higher among all oral contraceptive users than in nonusers, although a trend of increased relative risk with increasing age was not demonstrated (*312*,*313*). No studies were found regarding the risk for stroke in COC users aged ≥45 years (Level of evidence: II-2, good to poor, direct).

A pooled analysis by the Collaborative Group on Hormonal Factors and Breast Cancer in 1996 (*314*) found small increased relative risks for breast cancer among women aged ≥45 years whose last use of combined hormonal contraceptives was <5 years previously and for those whose last use was 5–9 years previously. Seven more recent studies suggested small but nonsignificant increased relative risks for breast carcinoma in situ or breast cancer among women who had used oral contraceptives or DMPA when they were aged ≥40 years compared with those who had never used either method (*315–321*) (Level of evidence: II-2, fair, direct).

Conclusion

Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including LARC methods such as IUDs and implants, to reduce the risk for unintended pregnancy. However, with these expanded options

comes the need for evidence-based guidance to help health-care providers offer quality family planning care to their patients, including choosing the most appropriate contraceptive method for individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness. Removing unnecessary barriers can help patients access and successfully use contraceptive methods. Several medical barriers to initiating and continuing contraceptive methods might exist, such as unnecessary screening examinations and tests before starting the method (e.g., a pelvic examination before initiation of COCs), inability to receive the contraceptive on the same day as the visit (e.g., waiting for test results that might not be needed or waiting until the woman's next menstrual period to start use), and difficulty obtaining continued contraceptive supplies (e.g., restrictions on number of pill packs dispensed at one time). Removing unnecessary steps, such as providing prophylactic antibiotics at the time of IUD insertion or requiring unnecessary follow-up procedures, also can help patients access and successfully use contraception.

Most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method. Routine follow-up for most women includes assessment of her satisfaction with the contraceptive method, concerns about method use, and changes in health status or medications that could affect medical eligibility for continued use of the method. Because changes in bleeding patterns are one of the major reasons for discontinuation of contraception, recommendations are provided for the management of bleeding irregularities with various contraceptive methods. In addition, because women and health-care providers can be confused about the procedures for missed pills and dosing errors with the contraceptive patch and ring, the instructions are streamlined for easier use. ECPs and emergency use of the Cu-IUD are important options for women, and recommendations on using these methods, as well as starting regular contraception after use of emergency contraception, are provided. Male and female sterilization are highly effective methods of contraception for men, women, and couples who have completed childbearing; for men undergoing vasectomy and women undergoing a hysteroscopic sterilization procedure, additional contraceptive protection is needed until the success of the procedure can be confirmed.

CDC is committed to working with partners at the federal, national, and local levels to disseminate, implement, and evaluate the recommendations in U.S. SPR so that the information reaches health-care providers. Strategies for dissemination and implementation include collaborating with other federal agencies and professional and service organizations to widely distribute the recommendations through presentations, electronic distribution, newsletters, and other publications; development of provider tools and job aids to assist providers in implementing the new recommendations; and training activities for students, as well as for continuing education. CDC will conduct a survey of family planning health-care providers before and after release of this report to assess attitudes and practices related to contraceptive use. Results from this survey will assist CDC in evaluating the impact of these recommendations on the provision of contraceptives in the United States. Finally, CDC will continually monitor new scientific evidence and will update these recommendations as warranted by new evidence. Updates to the recommendations, as well as provider tools and other resources, are available on the CDC U.S. SPR website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm).

Acknowledgment

This report is based, in part, on the work of the Promoting Family Planning Team, Department of Reproductive Health and Research, World Health Organization, and its development of the *Selected Practice Recommendations for Contraceptive Use*.

References

1. Finer LB, Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006. Contraception 2011;84:478–85.
2. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. Stud Fam Plann 2008;39:18–38.
3. Trussell J. The cost of unintended pregnancy in the United States. Contraception 2007;75:168–70.
4. Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect Sex Reprod Health 2006;38:90–6.
5. CDC. U.S. medical eligibility criteria for contraceptive use. MMWR 2010;59(No. RR-4).
6. World Health Organization. Selected practice recommendations for contraceptive use. Second ed. Geneva: World Health Organization; 2004.
7. World Health Organization. Selected practice recommendations for contraceptive use. 2008 update. Geneva, Switzerland: World Health Organization; 2008. Available at http://whqlibdoc.who.int/hq/2008/WHO_RHR_08.17_eng.pdf.
8. Faculty of Sexual and Reproductive Health Care. UK Selected Practice Recommendations for Contraceptive Use. London, England: Faculty of Sexual and Reproductive Health Care; 2002. Available at http://www.fsrh.org/pdfs/SelectedPracticeRecommendations2002.pdf.
9. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg 2010;8:336–41.
10. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000;283:2008–12.
11. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med 2001;20(Suppl):21–35.
12. Tepper NK, Marchbanks PA, Curtis KM. Use of a checklist to rule out pregnancy: a systematic review. Contraception 2013;87:661–5.

13. Whiteman MK, Tyler CP, Folger SG, Gaffield ME, Curtis KM. When can a woman have an intrauterine device inserted? A systematic review. Contraception 2013;87:666–73.
14. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM. Laboratory screening prior to initiating contraception: a systematic review. Contraception 2013;87:645–9.
15. Tepper NK, Curtis KM, Steenland MW, Marchbanks PA. Physical examination prior to initiating hormonal contraception: a systematic review. Contraception 2013;87:650–4.
16. Steenland MW, Zapata LB, Brahmi D, Marchbanks PA, Curtis KM. The effect of follow-up visits or contacts after contraceptive initiation on method continuation and correct use. Contraception 2013;87:625–30.
17. Steenland MW, Zapata LB, Brahmi D, Marchbanks PA, Curtis KM. Appropriate follow up to detect potential adverse events after initiation of select contraceptive methods: a systematic review. Contraception 2013;87:611–24.
18. Godfrey EM, Folger SG, Jeng G, Jamieson DJ, Curtis KM. Treatment of bleeding irregularities in women with copper-containing IUDs: a systematic review. Contraception 2013;87:549–66.
19. Tepper NK, Steenland MW, Gaffield ME, Marchbanks PA, Curtis KM. Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review. Contraception 2013;87:655–60.
20. Kapp N, Gaffield ME. Initiation of progestogen-only injectables on different days of the menstrual cycle and its effect on contraceptive effectiveness and compliance: a systematic review. Contraception 2013;87:576–82.
21. Tepper NK, Curtis KM, Steenland MW, Marchbanks PA. Blood pressure measurement prior to initiating hormonal contraception: a systematic review. Contraception 2013;87:631–8.
22. Brahmi D, Curtis KM. When can a woman start combined hormonal contraceptives (CHCs)? A systematic review. Contraception 2013; 87:524–38.
23. Steenland MW, Rodriguez MI, Marchbanks PA, Curtis KM. How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? A systematic review. Contraception 2013;87:605–10.
24. Zapata LB, Steenland MW, Brahmi D, Marchbanks PA, Curtis KM. Effect of missed combined hormonal contraceptives on contraceptive effectiveness: a systematic review. Contraception 2013;87:685–700.
25. Godfrey EM, Whiteman MK, Curtis KM. Treatment of unscheduled bleeding in women using extended- or continuous-use combined hormonal contraception: a systematic review. Contraception 2013;87:567–75.
26. Rodriguez MI, Curtis KM, Gaffield ML, Jackson E, Kapp N. Advance supply of emergency contraception: a systematic review. Contraception 2013;87:590–601.
27. Salcedo J, Rodriguez MI, Curtis KM, Kapp N. When can a woman resume or initiate contraception after taking emergency contraceptive pills? A systematic review. Contraception 2013;87:602–4.
28. Rodriguez MI, Godfrey EM, Warden M, Curtis KM. Prevention and management of nausea and vomiting with emergency contraception: a systematic review. Contraception 2013;87:583–9.
29. Cleary TP, Tepper NK, Cwiak C, et al. Pregnancies after hysteroscopic sterilization: a systematic review. Contraception 2013;87:539–48.
30. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM. Hemoglobin measurement prior to initiating copper intrauterine devices: a systematic review. Contraception 2013;87:639–44.
31. Folger SG, Jamieson DJ, Godfrey EM, Zapata LB, Curtis KM. Evidence-based guidance on selected practice recommendations for contraceptive use: identification of research gaps. Contraception 2013;87:517–23.
32. CDC. Sexually transmitted diseases treatment guidelines. MMWR 2010;59(No. RR-12).
33. Mohllajee AP, Curtis KM, Flanagan RG, Rinehart W, Gaffield ML, Peterson HB. Keeping up with evidence a new system for WHO's evidence-based family planning guidance. Am J Prev Med 2005;28:483–90.
34. Stanback J, Nakintu N, Qureshi Z, Nasution M. Does assessment of signs and symptoms add to the predictive value of an algorithm to rule out pregnancy? J Fam Plann Reprod Health Care 2006;32:27–9.
35. Stanback J, Nanda K, Ramirez Y, Rountree W, Cameron SB. Validation of a job aid to rule out pregnancy among family planning clients in Nicaragua. Rev Panam Salud Publica 2008;23:116–8.
36. Stanback J, Qureshi Z, Sekadde-Kigondu C, Gonzalez B, Nutley T. Checklist for ruling out pregnancy among family-planning clients in primary care. Lancet 1999;354:566.
37. Torpey K, Mwenda L, Kabaso M, et al. Excluding pregnancy among women initiating antiretroviral therapy: efficacy of a family planning job aid. BMC Public Health 2010;10:249.
38. Cole LA, Ladner DG, Byrn FW. The normal variabilities of the menstrual cycle. Fertil Steril 2009;91:522–7.
39. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ 2000;321:1259–62.
40. Donnet ML, Howie PW, Marnie M, Cooper W, Lewis M. Return of ovarian function following spontaneous abortion. Clin Endocrinol (Oxf) 1990;33:13–20.
41. Lahteenmaki P. Postabortal contraception. Ann Med 1993;25:185–9.
42. Stoddard A, Eisenberg DL. Controversies in family planning: timing of ovulation after abortion and the conundrum of postabortion intrauterine device insertion. Contraception 2011;84:119–21.
43. Jackson E, Glasier A. Return of ovulation and menses in postpartum, non-lactating women: a systematic review. Obstet Gynecol 2011;117:657–62.
44. Kennedy KI, Rivera R, McNeilly AS. Consensus statement on the use of breastfeeding as a family planning method. Contraception 1989;39:477–96.
45. Food and Drug Administration. 510(k) premarket notification. Silver Spring, MD: Food and Drug Administration; 2013. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
46. Cervinski MA, Gronowski AM. Reproductive-endocrine point-of-care testing: current status and limitations. Clin Chem Lab Med 2010;48:935–42.
47. Cole LA. Human chorionic gonadotropin tests. Expert Rev Mol Diagn 2009;9:721–47.
48. Eichner SF, Timpe EM. Urinary-based ovulation and pregnancy: point-of-care testing. Ann Pharmacother 2004;38:325–31.
49. Wilcox AJ, Baird DD, Dunson D, McChesney R, Weinberg CR. Natural limits of pregnancy testing in relation to the expected menstrual period. JAMA 2001;286:1759–61.
50. Korhonen J, Alfthan H, Ylostalo P, Veldhuis J, Stenman UH. Disappearance of human chorionic gonadotropin and its alpha- and beta-subunits after term pregnancy. Clin Chem 1997;43:2155–63.
51. Reyes FI, Winter JS, Faiman C. Postpartum disappearance of chorionic gonadotropin from the maternal and neonatal circulations. Am J Obstet Gynecol 1985;153:486–9.
52. Steier JA, Bergsjo P, Myking OL. Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion, and removed ectopic pregnancy. Obstet Gynecol 1984;64:391–4.
53. Bracken MB. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. Obstet Gynecol 1990;76:552–7.
54. Gray RH, Pardthaisong T. In utero exposure to steroid contraceptives and survival during infancy. Am J Epidemiol 1991;134:804–11.
55. Pardthaisong T, Gray RH. In utero exposure to steroid contraceptives and outcome of pregnancy. Am J Epidemiol 1991;134:795–803.
56. Jaffe B, Harlap S, Baras M, et al. Long-term effects of MPA on human progeny: intellectual development. Contraception 1988;37:607–19.
57. Pardthaisong T, Yenchit C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. Contraception 1992;45:313–24.
58. Brahmi D, Steenland MW, Renner RM, Gaffield ME, Curtis KM. Pregnancy outcomes with an IUD in situ: a systematic review. Contraception 2012;85:131–9.

59. Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.
60. Labbok M, Perez A, Valdes V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. Adv Contracept 1994;10:93–109.
61. Teva Women's Health. ParaGard physicians prescribing information. Sellersville, PA: Teva Women's Health; 2013. Available at http://www.paragard.com/images/ParaGard_info.pdf.
62. Bayer HealthCare Pharmaceuticals. Mirena physicians prescribing information. Wayne, NJ: Bayer HealthCare Pharmaceuticals; 2013. Available at http://www.berlex.com/html/products/pi/Mirena_PI.pdf.
63. Farley TM, Rosenberg MJ, Rowe PJ, Chen JH, Meirik O. Intrauterine devices and pelvic inflammatory disease: an international perspective. Lancet 1992;339:785–8.
64. Mohllajee AP, Curtis KM, Peterson HB. Does insertion and use of an intrauterine device increase the risk of pelvic inflammatory disease among women with sexually transmitted infection? A systematic review. Contraception 2006;73:145–53.
65. Rivera R, Almonte H, Arreola M, et al. The effects of three different regimens of oral contraceptives and three different intrauterine devices on the levels of hemoglobin, serum iron and iron binding capacity in anemic women. Contraception 1983;27:311–27.
66. Effects of contraceptives on hemoglobin and ferritin. Task Force for Epidemiological Research on Reproductive Health, United Nations Development Programme/United Nations Population Fund/World Health Organization/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland. Contraception 1998;58:262–73.
67. Calzolari E, Guglielmo R, Viola F, Migliore L. Hematological parameters and iron therapy in women with IUDs: experimental study. Minerva Ginecol 1981;33:355–62.
68. Hassan EO, El-Husseini M, El-Nahal N. The effect of 1-year use of the CuT 380A and oral contraceptive pills on hemoglobin and ferritin levels. Contraception 1999;60:101–5.
69. Andersson K, Odlind V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. Contraception 1994;49:56–72.
70. Andrade AT, Pizarro E, Shaw STJ, Souza JP, Belsey EM, Rowe PJ. Consequences of uterine blood loss caused by various intrauterine contraceptive devices in South American women. World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction. Contraception 1988;38:1–18.
71. Blum M, Ariel J, Zacharowitch D. Ferritin, a faithful reflection of iron deficiency in IUD wearers with mild vaginal spotting. Adv Contracept 1991;7:39–42.
72. El-sheikha Z, Hamza A, Mahmoud M. Menstrual blood loss of TCu-380 A and TCu-200 B IUDs. Popul Sci 1990;9:55–62.
73. Gallegost AJ, Aznar R, Merino G, Guizer E. Intrauterine devices and menstrual blood loss: a comparative study of eight devices during the first six months of use. Contraception 1978;17:153–61.
74. Gao J, Zeng S, Sun BL, et al. Menstrual blood loss, haemoglobin and ferritin concentration of Beijing women wearing steel ring, VCu 200, and TCu 220c IUDs. Contraception 1986;34:559–71.
75. Goh TH, Hariharan M. Effect of laparoscopic sterilization and insertion of Multiload Cu 250 and Progestasert IUDs on serum ferritin levels. Contraception 1983;28:329–36.
76. Goh TH, Hariharan M, Tan CH. A longitudinal study of serum iron indices and haemoglobin concentration following copper-IUD insertion. Contraception 1980;22:389–95.
77. Guillebaud J, Bonnar J, Morehead J, Matthews A. Menstrual blood-loss with intrauterine devices. Lancet 1976;1:387–90.
78. Haugan T, Skjeldestad FE, Halvorsen LE, Kahn H. A randomized trial on the clinical performance of Nova T380 and Gyne T380 Slimline copper IUDs. Contraception 2007;75:171–6.
79. Kivijarvi A, Timonen H, Rajamaki A, Gronroos M. Iron deficiency in women using modern copper intrauterine devices. Obstet Gynecol 1986;67:95–8.
80. Larsson B, Hamberger L, Rybo G. Influence of copper intrauterine contraceptive devices (Cu-7-IUD) on the menstrual blood-loss. Acta Obstet Gynecol Scand 1975;54:315–8.
81. Larsson G, Milsom I, Jonasson K, Lindstedt G, Rybo G. The long-term effects of copper surface area on menstrual blood loss and iron status in women fitted with an IUD. Contraception 1993;48:471–80.
82. Malmqvist R, Petersohn L, Bengtsson LP. Menstrual bleeding with copper-covered intrauterine contraceptive devices. Contraception 1974;9:627–33.
83. Milsom I, Andersson K, Jonasson K, Lindstedt G, Rybo G. The influence of the Gyne-T 380S IUD on menstrual blood loss and iron status. Contraception 1995;52:175–9.
84. Milsom I, Rybo G, Lindstedt G. The influence of copper surface area on menstrual blood loss and iron status in women fitted with an IUD. Contraception 1990;41:271–81.
85. Piedras J, Cordova MS, Perez-Toral MC, Lince E, Garza-Flores J. Predictive value of serum ferritin in anemia development after insertion of T Cu 220 intrauterine device. Contraception 1983;27:289–97.
86. Sivin I, Alvarez F, Diaz J, et al. Intrauterine contraception with copper and with levonorgestrel: a randomized study of the TCu 380Ag and levonorgestrel 20 mcg/day devices. Contraception 1984;30:443–56.
87. Sivin I. Two years of intrauterine contraception with levonorgestrel and with copper: a randomized comparison of the TCu 380Ag and levonorgestrel 20 mcg/day devices. Contraception 1987;35:245–55.
88. Tchai BS, Kim SW, Han JH, Im MW. Menstrual blood loss, iron nutriture, and the effects of Alza-T IPCS 52, T-Cu 220C and Lippes Loop D in Korean women. Seoul J Med 1987;28:51–9.
89. Wright EA, Kapu MM, Isichei UP. Zinc depletion and menorrhagia in Nigerians using copper T-200 intrauterine device. Trace Elem Med 1989;6:147–9.
90. Pleis JR, Lucas JW, Ward BW. Summary health statistics for U.S. adults: National Health Interview Survey, 2008. Vital Health Stat 10 2009;10:1–157.
91. CDC. Viral hepatitis surveillance, United States, 2009. Atlanta, GA: CDC; 2011. Available at http://www.cdc.gov/hepatitis/Statistics/2009Surveillance/PDFs/2009HepSurveillanceRpt.pdf.
92. Kohler BA, Ward E, McCarthy BJ, et al. Annual report to the nation on the status of cancer, 1975–2007, featuring tumors of the brain and other nervous system. J Natl Cancer Inst 2011;103:714–36.
93. Kapp N, Curtis KM. Hormonal contraceptive use among women with liver tumors: a systematic review. Contraception 2009;80:387–90.
94. Kapp N, Tilley IB, Curtis KM. The effects of hormonal contraceptive use among women with viral hepatitis or cirrhosis of the liver: a systematic review. Contraception 2009;80:381–6.
95. National Cancer Institute. National Cancer Institute at the National Institutes for Health [homepage]. Bethesda, MD: National Cancer Institute. Available at http://www.cancer.gov.
96. Watson M, Saraiya M, Benard V, et al. Burden of cervical cancer in the United States, 1998–2003. Cancer 2008;113(Suppl):2855–64.
97. CDC. Cervical cancer screening among women aged 18-30 years—United States, 2000–2010. MMWR 2013;61:1038–42.
98. Curtis KM, Nanda K, Kapp N. Safety of hormonal and intrauterine methods of contraception for women with HIV/AIDS: a systematic review. AIDS 2009;23(Suppl 1):S55–67.
99. Grimes DA, Schulz KF. Prophylactic antibiotics for intrauterine device insertion: a metaanalysis of the randomized controlled trials. Contraception 1999;60:57–63.

100. Wilson W, Taubert KA, Gewitz M, et al. Prevention of infective endocarditis: guidelines from the American Heart Association: a guideline from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation 2007;116:1736–54.
101. Canto De Cetina TE, Canto P, Ordonez Luna M. Effect of counseling to improve compliance in Mexican women receiving depot-medroxyprogesterone acetate. Contraception 2001;63:143–6.
102. Lei ZW, Wu SC, Garceau RJ, et al. Effect of pretreatment counseling on discontinuation rates in Chinese women given depo-medroxyprogesterone acetate for contraception. Contraception 1996;53:357–61.
103. Toppozada M, Anwar M, Abdel Rahman H, Gaweesh S. Control of IUD-induced bleeding by three non-steroidal anti-inflammatory drugs. Contracept Deliv Syst 1982;3:117–25.
104. Toppozada M, El-Attar A, El-Ayyat MA, Khamis Y. Management of uterine bleeding by PGs or their synthesis inhibitors. Adv Prostaglandin Thromboxane Res 1980;8:1459–63.
105. Wu S, Wang C, Cheng W, et al. Randomized multi-center study of baofuxin for treatment of bleeding side-effect induced by IUD. Reprod Contracept 2000;11:152–7.
106. Mercorio F, De Simone R, Di Carlo C, et al. Effectiveness and mechanism of action of desmopressin in the treatment of copper intrauterine device-related menorrhagia: a pilot study. Hum Reprod 2003;18:2319–22.
107. Pedron N, Lozano M, Aznar R. Treatment of hypermenorrhea with mefenamic acid in women using IUDs. Contracept Deliv Syst 1982;3:135–9.
108. Pizarro E, Mehech G, Hidalgo M, Munoz G, Romero C. Effect of meclofenamic acid on menstruation in hypermenorrheic women using intrauterine devices. Rev Chil Obstet Ginecol 1988;53:43–56.
109. Chinese National IUD Research Working Group. Prevention and treatment of IUD-induced menorrhagia with antifibrinolytic and antiprostaglandin drugs. Zhonghua Fu Chan Ke Za Zhi 1987;22:291–4, 312.
110. Di Lieto A, Catalano D, Miranda L, Paladini A. Action of a prostaglandin synthetase inhibitor on IUD associated uterine bleeding. Clin Exp Obstet Gynecol 1987;14:41–4.
111. Ylikorkala O, Viinikka L. Comparison between antifibrinolytic and antiprostaglandin treatment in the reduction of increased menstrual blood loss in women with intrauterine contraceptive devices. Br J Obstet Gynaecol 1983;90:78–83.
112. Food and Drug Administration. FDA prescribing information. Cyklokapron: tranexamic acid injection. New York, New York; 2011. Available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019281s030lbl.pdf.
113. Food and Drug Administration. FDA prescribing information. Lysteda: tranexamic acid tablets. Parsippany, New Jersey; 2011. Available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022430s002lbl.pdf.
114. Pedron N, Lozano M, Gallegos AJ. The effect of acetylsalicylic acid on menstrual blood loss in women with IUDs. Contraception 1987;36:295–303.
115. Hidalgo M, Bahamondes L, Perrotti M, Diaz J, Dantas-Monteiro C, Petta C. Bleeding patterns and clinical performance of the levonorgestrel-releasing intrauterine system (Mirena) up to two years. Contraception 2002; 65:129–32.
116. Larsson B, Wennergren M. Investigation of a copper-intrauterine device (Cu-IUD) for possible effect on frequency and healing of pelvic inflammatory disease. Contraception 1977;15:143–9.
117. Soderberg G, Lindgren S. Influence of an intrauterine device on the course of an acute salpingitis. Contraception 1981;24:137–43.
118. Teisala K. Removal of an intrauterine device and the treatment of acute pelvic inflammatory disease. Ann Med 1989;21:63–5.
119. Altunyurt S, Demir N, Posaci C. A randomized controlled trial of coil removal prior to treatment of pelvic inflammatory disease. Eur J Obstet Gynecol Reprod Biol 2003;107:81–4.
120. Stewart FH, Harper CC, Ellertson CE, Grimes DA, Sawaya GF, Trussell J. Clinical breast and pelvic examination requirements for hormonal contraception: current practice vs evidence. JAMA 2001;285:2232–9.
121. Mansour D, Korver T, Marintcheva-Petrova M, Fraser IS. The effects of Implanon on menstrual bleeding patterns. Eur J Contracept Reprod Health Care 2008;13(Suppl 1):13–28.
122. Abdel-Aleem H, D'Arcangues C, Vogelsong K, Gulmezoglu AM. Treatment of vaginal bleeding irregularities induced by progestin only contraceptives. Cochrane Database Syst Rev 2007;CD003449.
123. Archer DF, Philput CB, Levine AS, et al. Effects of ethinyl estradiol and ibuprofen compared to placebo on endometrial bleeding, cervical mucus and the postcoital test in levonorgestrel subcutaneous implant users. Contraception 2008;78:106–12.
124. Buasang K, Taneepanichskul S. Efficacy of celecoxib on controlling irregular uterine bleeding secondary to Jadelle use. J Med Assoc Thai 2009;92:301–7.
125. Phaliwong P, Taneepanichskul S. The effect of mefenamic acid on controlling irregular uterine bleeding second to Implanon use. J Med Assoc Thai 2004;87(Suppl 3):S64–8.
126. Weisberg E, Hickey M, Palmer D, et al. A randomized controlled trial of treatment options for troublesome uterine bleeding in Implanon users. Hum Reprod 2009;24:1852–61.
127. Weisberg E, Hickey M, Palmer D, et al. A pilot study to assess the effect of three short-term treatments on frequent and/or prolonged bleeding compared to placebo in women using Implanon. Hum Reprod 2006;21:295–302.
128. Cheng L, Zhu H, Wang A, Ren F, Chen J, Glasier A. Once a month administration of mifepristone improves bleeding patterns in women using subdermal contraceptive implants releasing levonorgestrel. Hum Reprod 2000;15:1969–72.
129. Alvarez-Sanchez F, Brache V, Thevenin F, Cochon L, Faundes A. Hormonal treatment for bleeding irregularities in Norplant implant users. Am J Obstet Gynecol 1996;174:919–22.
130. Diaz S, Croxatto HB, Pavez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of Norplant implants. Contraception 1990;42:97–109.
131. Witjaksono J, Lau TM, Affandi B, Rogers PA. Oestrogen treatment for increased bleeding in Norplant users: preliminary results. Hum Reprod 1996;11(Suppl 2):109–14.
132. Abdel-Aleem H, Shaaban OM, Amin AF, Abdel-Aleem AM. Tamoxifen treatment of bleeding irregularities associated with Norplant use. Contraception 2005;72:432–7.
133. Phupong V, Sophonsritsuk A, Taneepanichskul S. The effect of tranexamic acid for treatment of irregular uterine bleeding secondary to Norplant use. Contraception 2006;73:253–6.
134. D'Arcangues C, Piaggio G, Brache V, et al. Effectiveness and acceptability of vitamin E and low-dose aspirin, alone or in combination, on Norplant-induced prolonged bleeding. Contraception 2004;70:451–62.
135. Subakir SB, Setiadi E, Affandi B, Pringgoutomo S, Freisleben HJ. Benefits of vitamin E supplementation to Norplant users–in vitro and in vivo studies. Toxicology 2000;148:173–8.
136. Petta C, Faundes A, Dunson T, Ramos M, DeLucio M, Faundes D. Timing of onset of contraceptive effectiveness in Depo-Provera users. II. Effects on ovarian function. Fertil Steril 1998;70:817–20.

137. Petta C, Faundes A, Dunson T, Ramos M, DeLucio M, Faundes D. Timing of onset of contraceptive effectiveness in Depo-Provera users: Part I. Changes in cervical mucus. Fertil Steril 1998;69:252–7.
138. Siriwongse T, Snidvongs W, Tantayaporn P, Leepipatpaiboon S. Effect of depo-medroxyprogesterone acetate on serum progesterone levels when administered on various cycle days. Contraception 1982;26:487–93.
139. Balkus J, Miller L. Same-day administration of depot-medroxyprogesterone acetate injection: a retrospective chart review. Contraception 2005; 71:395–8.
140. Morroni C, Grams M, Tiezzi L, Westhoff C. Immediate monthly combination contraception to facilitate initiation of the depot medroxyprogesterone acetate contraceptive injection. Contraception 2004;70:19–23.
141. Nelson A, Katz T. Initiation and continuation rates seen in 2-year experience with Same Day injections of DMPA. Contraception 2007;75:84–7.
142. Rickert V, Tiezzi L, Lipshutz J, Leon J, Vaughan R, Westhoff C. Depo Now: preventing unintended pregnancies among adolescents and young adults. J Adolesc Health 2007;40:22–8.
143. Sneed R, Westhoff C, Morroni C, Tiezzi L. A prospective study of immediate initiation of depo medroxyprogesterone acetate contraceptive injection. Contraception 2005;71:99–103.
144. Cox S, Dietz P, Bowman B, Posner S. Prevalence of chronic conditions among women of reproductive age. Third National Summit on Preconception Health and Health Care; Tampa, FL.
145. Diab KM, Zaki MM. Contraception in diabetic women: comparative metabolic study of Norplant, depot medroxyprogesterone acetate, low dose oral contraceptive pill and CuT380A. J Obstet Gynaecol Res 2000;26:17–26.
146. Garg SK, Chase HP, Marshall G, Hoops SL, Holmes DL, Jackson WE. Oral contraceptives and renal and retinal complications in young women with insulin-dependent diabetes mellitus. JAMA 1994;271:1099–102.
147. Grigoryan OR, Grodnitskaya EE, Andreeva EN, Chebotnikova TV, Melnichenko GA. Use of the NuvaRing hormone-releasing system in late reproductive-age women with type 1 diabetes mellitus. Gynecol Endocrinol 2008;24:99–104.
148. Kahn HS, Curtis KM, Marchbanks PA. Effects of injectable or implantable progestin-only contraceptives on insulin-glucose metabolism and diabetes risk. Diabetes Care 2003;26:216–25.
149. Lopez LM, Grimes DA, Schulz KF. Steroidal contraceptives: effect on carbohydrate metabolism in women without diabetes mellitus. Cochrane Database Syst Rev 2009;CD006133.
150. Rogovskaya S, Rivera R, Grimes DA, et al. Effect of a levonorgestrel intrauterine system on women with type 1 diabetes: a randomized trial. Obstet Gynecol 2005;105:811–5.
151. Troisi RJ, Cowie CC, Harris MI. Oral contraceptive use and glucose metabolism in a national sample of women in the united states. Am J Obstet Gynecol 2000;183:389–95.
152. Bonny A, Secic M, Cromer B. Early weight gain related to later weight gain in adolescents on depot medroxyprogesterone acetate. Obstet Gynecol 2011;117:793–7.
153. Le Y, Rahman M, Berenson A. Early weight gain predicting later weight gain among depot medroxyprogesterone acetate users. Obstet Gynecol 2009;114:279–84.
154. Risser WL. Weight change in adolescents who used hormonal contraception. J Adolesc Health 1999;24:433–6.
155. Paulen ME, Curtis KM. When can a woman have repeat progestogen-only injectables—depot medroxyprogesterone acetate or norethisterone enantate? Contraception 2009;80:391–408.
156. Pardthaisong T. Return of fertility after use of the injectable contraceptive Depo Provera: up-dated data analysis. J Biosoc Sci 1984;16:23–34.
157. Schwallie PC, Assenzo JR. The effect of depo-medroxyprogesterone acetate on pituitary and ovarian function, and the return of fertility following its discontinuation: a review. Contraception 1974;10:181–202.
158. Steiner MJ, Kwok C, Stanback J, et al. Injectable contraception: what should the longest interval be for reinjections? Contraception 2008;77:410–4.
159. Bassol S, Garza-Flores J, Cravioto MC, et al. Ovarian function following a single administration of depo-medroxyprogesterone acetate (DMPA) at different doses. Fertil Steril 1984;42:216–22.
160. Fotherby K, Koetsawang S, Mathrubutham M. Pharmacokinetic study of different doses of Depo Provera. Contraception 1980;22:527–36.
161. Fotherby K, Saxena BN, Shrimanker K, et al. A preliminary pharmacokinetic and pharmacodynamic evaluation of depot-medroxyprogesterone acetate and norethisterone oenanthate. Fertil Steril 1980;34:131–9.
162. Garza-Flores J, Cardenas S, Rodriguez V, Cravioto MC, Diaz-Sanchez V, Perez-Palacios G. Return to ovulation following the use of long-acting injectable contraceptives: a comparative study. Contraception 1985;31:361–6.
163. Jain J, Dutton C, Nicosia A, Wajszczuk C, Bode FR, Mishell DR Jr. Pharmacokinetics, ovulation suppression and return to ovulation following a lower dose subcutaneous formulation of Depo-Provera. Contraception 2004;70:11–8.
164. Lan PT, Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Return of ovulation following a single injection of depo-medroxyprogesterone acetate: a pharmacokinetic and pharmacodynamic study. Contraception 1984;29:1–18.
165. Ortiz A, Hirol M, Stanczyk FZ, Goebelsmann U, Mishell DR. Serum medroxyprogesterone acetate (MPA) concentrations and ovarian function following intramuscular injection of depo-MPA. J Clin Endocrinol Metab 1977;44:32–8.
166. Saxena BN, Dusitsin N, Tankeyoon M, Chaudhury RR. Return of ovulation after the cessation of depot-medroxy progesterone acetate treatment in Thai women. J Med Assoc Thai 1980;63:66–9.
167. Toh YC, Jain J, Rahnny MH, Bode FR, Ross D. Suppression of ovulation by a new subcutaneous depot medroxyprogesterone acetate (104 mg/0.65 mL) contraceptive formulation in Asian women. Clin Ther 2004;26:1845–54.
168. Hubacher D, Lopez L, Steiner MJ, Dorflinger L. Menstrual pattern changes from levonorgestrel subdermal implants and DMPA: systematic review and evidence-based comparisons. Contraception 2009;80:113–8.
169. Arias RD, Jain JK, Brucker C, Ross D, Ray A. Changes in bleeding patterns with depot medroxyprogesterone acetate subcutaneous injection 104 mg. Contraception 2006;74:234–8.
170. Dempsey A, Roca C, Westhoff C. Vaginal estrogen supplementation during Depo-Provera initiation: a randomized controlled trial. Contraception 2010;82:250–5.
171. Harel Z, Biro F, Kollar L, Riggs S, Flanagan P, Vaz R. Supplementation with vitamin C and/or vitamin B(6) in the prevention of Depo-Provera side effects in adolescents. J Pediatr Adolesc Gynecol 2002;15:153–8.
172. Nathirojanakun P, Taneepanichskul S, Sappakitkumjorn N. Efficacy of a selective COX-2 inhibitor for controlling irregular uterine bleeding in DMPA users. Contraception 2006;73:584–7.
173. Tantiwattanakul P, Taneepanichskul S. Effect of mefenamic acid on controlling irregular uterine bleeding in DMPA users. Contraception 2004;70:277–9.

174. Said S, Sadek W, Rocca M, et al. Clinical evaluation of the therapeutic effectiveness of ethinyl oestradiol and oestrone sulphate on prolonged bleeding in women using depot medroxyprogesterone acetate for contraception. World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Long-acting Systemic Agents for Fertility Regulation. Hum Reprod 1996;11(Suppl 2):1–13.
175. Sadeghi-Bazargani H, Ehdaeivand F, Arshi S, Eftekhar H, Sezavar H, Amanati L. Low-dose oral contraceptive to re-induce menstrual bleeding in amenorrheic women on DMPA treatment: a randomized clinical trial. Med Sci Monit 2006;12:CR420–5.
176. CDC. Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised recommendations for the use of contraceptive methods during the postpartum period. MMWR 2011;60:878–83.
177. Westhoff C, Morroni C, Kerns J, Murphy PA. Bleeding patterns after immediate vs. conventional oral contraceptive initiation: a randomized, controlled trial. Fertil Steril 2003;79:322–9.
178. Westhoff C, Heartwell S, Edwards S, et al. Initiation of oral contraceptives using a quick start compared with a conventional start—A randomized controlled trial. Obstet Gynecol 2007;109:1270–6.
179. Edwards SM, Zieman M, Jones K, Diaz A, Robilotto C, Westhoff C. Initiation of oral contraceptives—start now! J Adolesc Health 2008;43:432–6.
180. Baerwald AR, Olatunbosun OA, Pierson RA. Ovarian follicular development is initiated during the hormone-free interval of oral contraceptive use. Contraception 2004;70:371–7.
181. Baerwald AR, Pierson RA. Ovarian follicular development during the use of oral contraception: a review. J Obstet Gynaecol Can 2004;26:19–24.
182. Duijkers IJM, Klipping C, Verhoeven CHJ, Dieben TOM. Ovarian function with the contraceptive vaginal ring or an oral contraceptive: a randomized study. Human Reproduction 2004;19):2668–73.
183. Killick S, Eyong E, Elstein M. Ovarian follicular development in oral contraceptive cycles. Fertil Steril 1987;48:409–13.
184. Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? Br Med J (Clin Res Ed) 1985;290:1474–5.
185. Mulders TM, Dieben TO, Bennink HJ. Ovarian function with a novel combined contraceptive vaginal ring. Hum Reprod 2002;17:2594–9.
186. Schwartz JL, Creinin MD, Pymar HC, Reid L. Predicting risk of ovulation in new start oral contraceptive users. Obstet Gynecol 2002;99:177–82.
187. Sitavarin S, Jaisamrarn U, Taneepanichskul S. A randomized trial on the impact of starting day on ovarian follicular activity in very low dose oral contraceptive pills users. J Med Assoc Thai 2003;86:442–8.
188. Smith SK, Kirkman RJ, Arce BB, McNeilly AS, Loudon NB, Baird DT. The effect of deliberate omission of Trinordiol or Microgynon on the hypothalamo-pituitary-ovarian axis. Contraception 1986;34:513–22.
189. Taylor DR, Anthony FW, Dennis KJ. Suppression of ovarian function by Microgynon 30 in day 1 and day 5 "starters." Contraception 1986; 33:463–71.
190. Lara-Torre E, Schroeder B. Adolescent compliance and side effects with Quick Start initiation of oral contraceptive pills. Contraception 2002;66:81–5.
191. Murthy AS, Creinin MD, Harwood B, Schreiber CA. Same-day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation methods. Contraception 2005;72:333–6.
192. Westhoff C, Osborne L, Schafer J, Morroni C. Bleeding patterns after immediate initiation of an oral compared with a vaginal hormonal contraceptive. Obstet Gynecol 2005;106:89–96.
193. Yeshaya A, Orvieto R, Kaplan B, et al. Flexible starting schedule for oral contraception: effect on the incidence of breakthrough bleeding and compliance. Eur J Contracept Reprod Health Care 1998;3:121–3.
194. Yeshaya A, Orvieto R, Kauschansky A, et al. A delayed starting schedule of oral contraception: the effect on the incidence of breakthrough bleeding and compliance in women. Eur J Contracept Reprod Health Care 1996;1:263–5.
195. Westhoff C, Kerns J, Morroni C, Cushman LF, Tiezzi L, Murphy PA. Quick start: novel oral contraceptive initiation method. Contraception 2002;66:141–5.
196. Acute myocardial infarction and combined oral contraceptives: results of an international multicentre case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet 1997;349:1202–9.
197. Dunn N, Thorogood M, Faragher B, et al. Oral contraceptives and myocardial infarction: results of the MICA case-control study. BMJ 1999;318:1579–83.
198. Lewis MA, Heinemann LA, Spitzer WO, MacRae KD, Bruppacher R. The use of oral contraceptives and the occurrence of acute myocardial infarction in young women. Results from the Transnational Study on Oral Contraceptives and the Health of Young Women. Contraception 1997;56:129–40.
199. Ischaemic stroke and combined oral contraceptives: results of an international, multicentre, case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet 1996;348:498–505.
200. Heinemann LA, Lewis MA, Spitzer WO, Thorogood M, Guggenmoos-Holzmann I, Bruppacher R. Thromboembolic stroke in young women. A European case-control study on oral contraceptives. Transnational Research Group on Oral Contraceptives and the Health of Young Women. Contraception 1998;57:29–37.
201. Haemorrhagic stroke, overall stroke risk, and combined oral contraceptives: results of an international, multicentre, case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet 1996;348:505–10.
202. Berenson AB, Rahman M, Wilkinson G. Effect of injectable and oral contraceptives on serum lipids. Obstet Gynecol 2009;114:786–94.
203. Dilbaz B, Ozdegirmenci O, Caliskan E, Dilbaz S, Haberal A. Effect of etonogestrel implant on serum lipids, liver function tests and hemoglobin levels. Contraception 2010;81:510–4.
204. Nelson A. Combined oral contraceptives. In: Hatcher RA, Trussel J, Nelson A, Cates W Jr, Stewart FH, Kowal D, eds. Contraceptive technology. 19th ed. New York, NY: Ardent Media, Inc; 2007:193–270.
205. Mohllajee AP, Curtis KM, Martins SL, Peterson HB. Does use of hormonal contraceptives among women with thrombogenic mutations increase their risk of venous thromboembolism? A systematic review. Contraception 2006;73:166–78.
206. Wu O, Robertson L, Twaddle S, et al. Screening for thrombophilia in high-risk situations: systematic review and cost-effectiveness analysis. The Thrombosis: Risk and Economic Assessment of Thrombophilia Screening (TREATS) study. Health technology assessment (Winchester, England) 2006;10:1–110.
207. Blickstein D, Blickstein I. Oral contraception and thrombophilia. Curr Opin Obstet Gynecol 2007;19:370–6.
208. Wu O, Greer IA. Is screening for thrombophilia cost-effective? Curr Opin Hematol 2007;14:500–3.
209. Foster D, Hulett D, Bradsberry M, Darney P, Policar M. Number of oral contraceptive pill packages dispensed and subsequent unintended pregnancies. Obstet Gynecol 2011;117:566–72.
210. Foster D, Parvataneni R, de Bocanegra H, Lewis C, Bradsberry M, Darney P. Number of oral contraceptive pill packages dispensed, method continuation, and costs. Obstet Gynecol 2006;108:1107–14.

211. White KO, Westhoff C. The effect of pack supply on oral contraceptive pill continuation: a randomized controlled trial. Obstet Gynecol 2011; 118:615–22.
212. Chin Quee D, Cuthbertson C, Janowitz B. Over-the-counter pill provision: evidence from Jamaica. Stud Fam Plann 2006;37:99–110.
213. Anttila L, Kunz M, Marr J. Bleeding pattern with drospirenone 3 mg+ethinyl estradiol 20 mcg 24/4 combined oral contraceptive compared with desogestrel 150 mcg+ethinyl estradiol 20 mcg 21/7 combined oral contraceptive. Contraception 2009;80:445–51.
214. Chowdhury V, Joshi UM, Gopalkrishna K, Betrabet S, Mehta S, Saxena BN. 'Escape' ovulation in women due to the missing of low dose combination oral contraceptive pills. Contraception 1980;22:241–7.
215. Christin-Maitre S, Serfaty D, Chabbert-Buffet N, Ochsenbein E, Chassard D, Thomas JL. Comparison of a 24-day and a 21-day pill regimen for the novel combined oral contraceptive, nomegestrol acetate and 17beta-estradiol (NOMAC/E2): a double-blind, randomized study. Hum Reprod 2011;26:1338–47.
216. Creinin MD, Lippman JS, Eder SE, Godwin AJ, Olson W. The effect of extending the pill-free interval on follicular activity: triphasic norgestimate/35 micro g ethinyl estradiol versus monophasic levonorgestrel/20 micro g ethinyl estradiol. Contraception 2002;66:147–52.
217. Dinger J, Minh TD, Buttmann N, Bardenheuer K. Effectiveness of oral contraceptive pills in a large U.S. cohort comparing progestogen and regimen. Obstet Gynecol 2011;117:33–40.
218. Elomaa K, Lahteenmaki P. Ovulatory potential of preovulatory sized follicles during oral contraceptive treatment. Contraception 1999;60:275–9.
219. Elomaa K, Rolland R, Brosens I, et al. Omitting the first oral contraceptive pills of the cycle does not automatically lead to ovulation. Am J Obstet Gynecol 1998;179:41–6.
220. Endrikat J, Wessel J, Rosenbaum P, Dusterberg B. Plasma concentrations of endogenous hormones during one regular treatment cycle with a low-dose oral contraceptive and during two cycles with deliberate omission of two tablets. Gynecol Endocrinol 2004;18:318–26.
221. Hamilton CJ, Hoogland HJ. Longitudinal ultrasonographic study of the ovarian suppressive activity of a low-dose triphasic oral contraceptive during correct and incorrect pill intake. Am J Obstet Gynecol 1989;161:1159–62.
222. Hedon B, Cristol P, Plauchut A, et al. Ovarian consequences of the transient interruption of combined oral contraceptives. Int J Fertil 1992;37:270–6.
223. Killick SR. Ovarian follicles during oral contraceptive cycles: their potential for ovulation. Fertil Steril 1989;52:580–2.
224. Killick SR, Bancroft K, Oelbaum S, Morris J, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. Adv Contracept 1990;6:33–40.
225. Klipping C, Duijkers I, Trummer D, Marr J. Suppression of ovarian activity with a drospirenone-containing oral contraceptive in a 24/4 regimen. Contraception 2008;78:16–25.
226. Klipping C, Marr J. Effects of two combined oral contraceptives containing ethinyl estradiol 20 microg combined with either drospirenone or desogestrel on lipids, hemostatic parameters and carbohydrate metabolism. Contraception 2005;71:409–16.
227. Landgren BM, Csemiczky G. The effect of follicular growth and luteal function of "missing the pill." A comparison between a monophasic and a triphasic combined oral contraceptive. Contraception 1991;43:149–59.
228. Landgren BM, Diczfalusy E. Hormonal consequences of missing the pill during the first two days of three consecutive artificial cycles. Contraception 1984;29:437–46.
229. Letterie GS. A regimen of oral contraceptives restricted to the periovulatory period may permit folliculogenesis but inhibit ovulation. Contraception 1998;57:39–44.
230. Letterie GS, Chow GE. Effect of "missed" pills on oral contraceptive effectiveness. Obstet Gynecol 1992;79:979–82.
231. Morris SE, Groom GV, Cameron ED, Buckingham MS, Everitt JM, Elstein M. Studies on low dose oral contraceptives: plasma hormone changes in relation to deliberate pill ('Microgynon 30') omission. Contraception 1979;20:61–9.
232. Nakajima ST, Archer DF, Ellman H. Efficacy and safety of a new 24-day oral contraceptive regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 micro g (Loestrin 24 Fe). Contraception 2007;75:16–22.
233. Nuttall ID, Elstein M, McCafferty E, Seth J, Cameron ED. The effect of ethinyl estradiol 20 mcg and levonorgestrel 250 mcg on the pituitary-ovarian function during normal tablet-taking and when tablets are missed. Contraception 1982;26:121–35.
234. Pierson RA, Archer DF, Moreau M, Shangold GA, Fisher AC, Creasy GW. Ortho Evra/Evra versus oral contraceptives: follicular development and ovulation in normal cycles and after an intentional dosing error. Fertil Steril 2003;80:34–42.
235. Rible RD, Taylor D, Wilson ML, Stanczyk FZ, Mishell DR Jr. Follicular development in a 7-day versus 4-day hormone-free interval with an oral contraceptive containing 20 mcg ethinyl estradiol and 1 mg norethindrone acetate. Contraception 2009;79:182–8.
236. Schlaff WD, Lynch AM, Hughes HD, Cedars MI, Smith DL. Manipulation of the pill-free interval in oral contraceptive pill users: the effect on follicular suppression. Am J Obstet Gynecol 2004;190:943–51.
237. Spona J, Elstein M, Feichtinger W, et al. Shorter pill-free interval in combined oral contraceptives decreases follicular development. Contraception 1996;54:71–7.
238. Sullivan H, Furniss H, Spona J, Elstein M. Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60 microg) and ethinyl estradiol (15 microg) on ovarian activity. Fertil Steril 1999;72:115–20.
239. Wang E, Shi S, Cekan SZ, Landgren BM, Diczfalusy E. Hormonal consequences of "missing the pill." Contraception 1982;26:545–66.
240. Willis SA, Kuehl TJ, Spiekerman AM, Sulak PJ. Greater inhibition of the pituitary–ovarian axis in oral contraceptive regimens with a shortened hormone-free interval. Contraception 2006;74:100–3.
241. Abrams LS, Skee DM, Natarajan J, et al. Pharmacokinetics of norelgestromin and ethinyl estradiol delivered by a contraceptive patch (Ortho Evra/Evra) under conditions of heat, humidity, and exercise. J Clin Pharmacol 2001;41:1301–9.
242. Ahrendt HJ, Nisand I, Bastianelli C, et al. Efficacy, acceptability and tolerability of the combined contraceptive ring, NuvaRing, compared with an oral contraceptive containing 30 microg of ethinyl estradiol and 3 mg of drospirenone. Contraception 2006;74:451–7.
243. Bjarnadottir RI, Tuppurainen M, Killick SR. Comparison of cycle control with a combined contraceptive vaginal ring and oral levonorgestrel/ethinyl estradiol. Am J Obstet Gynecol 2002;186:389–95.
244. Brucker C, Karck U, Merkle E. Cycle control, tolerability, efficacy and acceptability of the vaginal contraceptive ring, NuvaRing: results of clinical experience in Germany. Eur J Contracept Reprod Health Care 2008;13:31–8.
245. Dieben TO, Roumen FJ, Apter D. Efficacy, cycle control, and user acceptability of a novel combined contraceptive vaginal ring. Obstet Gynecol 2002;100:585–93.
246. Mulders TM, Dieben TO. Use of the novel combined contraceptive vaginal ring NuvaRing for ovulation inhibition. Fertil Steril 2001;75:865–70.
247. Guilbert E, Boroditsky R, Black A, et al. Canadian Consensus Guideline on Continuous and Extended Hormonal Contraception, 2007. J Obstet Gynaecol Can 2007;29(Suppl 2):S1–32.

248. Wiegratz I, Stahlberg S, Manthey T, et al. Effect of extended-cycle regimen with an oral contraceptive containing 30 mcg ethinylestradiol and 2 mg dienogest on bleeding patterns, safety, acceptance and contraceptive efficacy. Contraception 2011;84:133–43.
249. Sulak PJ, Kuehl TJ, Coffee A, Willis S. Prospective analysis of occurrence and management of breakthrough bleeding during an extended oral contraceptive regimen. Am J Obstet Gynecol 2006;195:935–41.
250. Sulak PJ, Smith V, Coffee A, Witt I, Kuehl AL, Kuehl TJ. Frequency and management of breakthrough bleeding with continuous use of the transvaginal contraceptive ring: a randomized controlled trial. Obstet Gynecol 2008;112:563–71.
251. Kaneshiro B, Edelman A, Carlson N, Morgan K, Nichols M, Jensen J. Treatment of unscheduled bleeding in continuous oral contraceptive users with doxycycline: a randomized controlled trial. Obstet Gynecol 2010; 115:1141–9.
252. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50:S1–195.
253. Arevalo M, Jennings V, Sinai I. Efficacy of a new method of family planning: the Standard Days Method. Contraception 2002;65:333–8.
254. Arevalo M, Sinai I, Jennings V. A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning. Contraception 1999;60:357–60.
255. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211–5.
256. Cleland K, Zhu H, Goldstuck N, Cheng L, Trussell J. The efficacy of intrauterine devices for emergency contraception: a systematic review of 35 years of experience. Hum Reprod 2012;27:1994–2000.
257. Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet 2010;375:555–62.
258. Raymond E, Taylor D, Trussell JMJS. Minimum effectiveness of the levonorgestrel regimen of emergency contraception. Contraception 2004;69:79–81.
259. Fine P, Mathe H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48–120 hours after intercourse for emergency contraception. Obstet Gynecol 2010;115:257–63.
260. Dada OA, Godfrey EM, Piaggio G, von Hertzen H. A randomized, double-blind, noninferiority study to compare two regimens of levonorgestrel for emergency contraception in Nigeria. Contraception 2010;82:373–8.
261. Ngai SW, Fan S, Li S, et al. A randomized trial to compare 24 h versus 12 h double dose regimen of levonorgestrel for emergency contraception. Hum Reprod 2005;20:307–11.
262. Ellertson C, Evans M, Ferden S, et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. Obstet Gynecol 2003;101:1168–71.
263. Von Hertzen H, Piaggio G, Ding J, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet 2002;360:1803–10.
264. Rodrigues I, Grou F, Joly J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. Am J Obstet Gynecol 2001;184:531–7.
265. Piaggio G, Kapp N, von Hertzen H. Effect on pregnancy rates of the delay in the administration of levonorgestrel for emergency contraception: a combined analysis of four WHO trials. Contraception 2011;84:35–9.
266. Watson Pharma Inc. Prescribing Information for Ella. 2010. Morristown, NJ.
267. Emergency contraceptive pills. Medical and service delivery guidelines. 2012. Available at http://www.cecinfo.org/custom-content/uploads/2013/03/Medical-and-Service-Delivery-Guidelines-English-2012.pdf.
268. Creinin MD, Schlaff W, Archer DF, et al. Progesterone receptor modulator for emergency contraception - A randomized controlled trial. Obstet Gynecol 2006;108:1089–97.
269. Farajkhoda T, Khoshbin A, Enjezab B, Bokaei M, Zarchi MK. Assessment of two emergency contraceptive regimens in Iran: levonorgestrel versus the Yuzpe. Niger J Clin Pract 2009;12:450–2.
270. Ho PC, Kwan MSW. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. Hum Reprod 1993;8:389–92.
271. Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception 2002;66:269–73.
272. Raymond EG, Creinin MD, Barnhart KT, Lovvorn AE, Rountree RW, Trussell J. Meclizine for prevention of nausea associated with use of emergency contraceptive pills: a randomized trial. Obstet Gynecol 2000;95:271–7.
273. Ragan RE, Rock RW, Buck HW. Metoclopramide pretreatment attenuates emergency contraceptive-associated nausea. Am J Obstet Gynecol 2003;188:330–3.
274. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol 1996;174:1161–8, 8–70.
275. Peterson HB. Sterilization. Obstet Gynecol 2008;111:189–203.
276. Lawrie TA, Nardin JM, Kulier R, Boulvain M. Techniques for the interruption of tubal patency for female sterilisation. Cochrane Database Syst Rev 2011; (2):CD003034.
277. Veersema S, Vleugels MP, Moolenaar LM, Janssen CA, Brolmann HA. Unintended pregnancies after Essure sterilization in the Netherlands. Fertil Steril 2010;93:35–8.
278. Levy B, Levie MD, Childers ME. A summary of reported pregnancies after hysteroscopic sterilization. J Minim Invasive Gynecol 2007;14:271–4.
279. Legendre G, Levaillant JM, Faivre E, Deffieux X, Gervaise A, Fernandez H. 3D ultrasound to assess the position of tubal sterilization microinserts. Hum Reprod 2011;26:2683–9.
280. Duffy S, Marsh F, Rogerson L, et al. Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. BJOG 2005;112:1522–8.
281. Levie MD, Chudnoff SG. Prospective analysis of office-based hysteroscopic sterilization. J Minim Invasive Gynecol 2006;13:98–101.
282. Arjona JE, Mino M, Cordon J, Povedano B, Pelegrin B, Castelo-Branco C. Satisfaction and tolerance with office hysteroscopic tubal sterilization. Fertil Steril 2008;90:1182–6.
283. Grosdemouge I, Engrand JB, Dhainault C, et al. La pratique francaise de la pose des implants de sterilisation tubaire Essure. Gynecol Obstet Fertil 2009;37:389–95.
284. Shavell VI, Abdallah ME, Diamond MP, Berman JM. Placement of a permanent birth control device at a university medical center. J Reprod Med 2009;54:218–22.
285. American Urological Association. Vasectomy guideline 2012. Available at http://www.auanet.org/education/vasectomy.cfm.
286. Bedford J, Zelikovsky G. Viability of spermatozoa in the human ejaculate after vasectomy. Fertil Steril 1979;32:460–3.
287. Edwards I. Earlier testing after vasectomy, based on the absence of motile sperm. Fertil Steril 1993;59:431–6.
288. Jouannet P, David G. Evolution of the properties of semen immediately following vasectomy. Fertil Steril 1978;29:435–41.
289. Labrecque M, Hays M, Chen-Mok M, Barone M, Sokal D. Frequency and patterns of early recanalization after vasectomy. BMC Urol 2006;6:25.
290. Philp T, Guillebaud J, Budd D. Complications of vasectomy: review of 16,000 patients. Br J Urol 1984;56:745–8.

291. Alderman PM. The lurking sperm. A review of failures in 8879 vasectomies performed by one physician. JAMA 1988;259:3142–4.
292. Black T, Francome C. The evolution of the Marie Stopes electrocautery no-scalpel vasectomy procedure. J Fam Plann Reprod Health Care 2002;28:137–8.
293. Davies AH, Sharp RJ, Cranston D, Mitchell RG. The long-term outcome following "special clearance" after vasectomy. Br J Urol 1990;66:211–2.
294. Philp T, Guillebaud J, Budd D. Late failure of vasectomy after two documented analyses showing azoospermic semen. Br Med J (Clin Res Ed) 1984;289:77–9.
295. Belker A, Sexter M, Sweitzer S, Raff M. The high rate of noncompliance for post-vasectomy semen examination: medical and legal considerations. J Urol 1990;144:284–6.
296. Chawla A, Bowles B, Zini A. Vasectomy follow-up: clinical significance of rare nonmotile sperm in postoperative semen analysis. Urology 2004;64:1212–5.
297. Labrecque M, Bedard L, Laperriere L. Efficacy and complications associated with vasectomies in two clinics in the Quebec region. Can Fam Physician 1998;44:1860–6.
298. Labrecque M, Nazerali H, Mondor M, Fortin V, Nasution M. Effectiveness and complications associated with 2 vasectomy occlusion techniques. J Urol 2002;168:2495–8.
299. Maatman TJ, Aldrin L, Carothers GG. Patient noncompliance after vasectomy. Fertil Steril 1997;68:552–5.
300. Dhar NB, Jones JS, Bhatt A, Babineau D. A prospective evaluation of the impact of scheduled follow-up appointments with compliance rates after vasectomy. BJU Int 2007;99:1094–7.
301. Hillard PJ, Berek JS, Barss VA, et al. Guidelines for women's health care: a resource manual. 3rd ed. Washington, DC: American College of Obstetricians and Gynecologists; 2007.
302. The North American Menopause Society. Prescription hormonal therapies. Menopause practice: a clinician's guide. 4th ed. 2010.
303. Te Velde ER, Pearson PL. The variability of female reproductive ageing. Hum Reprod Update 2002;8:141–54.
304. Broekmans FJ, Soules MR, Fauser BC. Ovarian aging: mechanisms and clinical consequences. Endocr Rev 2009;30:465–93.
305. Wood JW. Fecundity and natural fertility in humans. Oxf Rev Reprod Biol 1989;11:61–109.
306. Bateman BT, Simpson LL. Higher rate of stillbirth at the extremes of reproductive age: a large nationwide sample of deliveries in the United States. Am J Obstet Gynecol 2006;194:840–5.
307. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010; 116:1302–9.
308. Balasch J, Gratacós E. Delayed childbearing: effects on fertility and the outcome of pregnancy. Curr Opin Obstet Gynecol 2012;24:187–93.
309. Lidegaard O, Lokkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. BMJ 2009;339:b2890.
310. Lidegaard O, Nielsen LH, Skovlund CW, Skjeldestad FE, Lokkegaard E. Risk of venous thromboembolism from use of oral contraceptives containing different progestogens and oestrogen doses: Danish cohort study, 2001–9. BMJ 2011;343:d6423.
311. Nightingale AL, Lawrenson RA, Simpson EL, Williams TJ, MacRae KD, Farmer RD. The effects of age, body mass index, smoking and general health on the risk of venous thromboembolism in users of combined oral contraceptives. Eur J Contracept Reprod Health Care 2000;5:265–74.
312. Slone D, Shapiro S, Kaufman DW, Rosenberg L, Miettinen OS, Stolley PD. Risk of myocardial infarction in relation to current and discontinued use of oral contraceptives. N Engl J Med 1981;305:420–4.
313. Tanis BC, van den Bosch MA, Kemmeren JM, et al. Oral contraceptives and the risk of myocardial infarction. N Engl J Med 2001;345:1787–93.
314. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53 297 women with breast cancer and 100 239 women without breast cancer from 54 epidemiological studies. Lancet 1996;347:1713–27.
315. Gill JK, Press MF, Patel AV, Bernstein L. Oral contraceptive use and risk of breast carcinoma in situ (United States). Cancer Causes Control 2006;17:1155–62.
316. Kumle M, Weiderpass E, Braaten T, Persson I, Adami HO, Lund E. Use of oral contraceptives and breast cancer risk: the Norwegian-Swedish Women's Lifestyle and Health Cohort Study. Cancer Epidemiol Biomarkers Prev 2002;11:1375–81.
317. Marchbanks PA, McDonald JA, Wilson HG, et al. Oral contraceptives and the risk of breast cancer. N Engl J Med 2002;346:2025–32.
318. Newcomb PA, Longnecker MP, Storer BE, et al. Recent oral contraceptive use and risk of breast cancer (United States). Cancer Causes Control 1996;7:525–32.
319. Rosenberg L, Palmer JR, Rao RS, et al. Case-control study of oral contraceptive use and risk of breast cancer. Am J Epidemiol 1996;143:25–37.
320. Rosenberg L, Zhang Y, Coogan PF, Strom BL, Palmer JR. A case-control study of oral contraceptive use and incident breast cancer. Am J Epidemiol 2009;169:473–9.
321. Shapiro S, Rosenberg L, Hoffman M, et al. Risk of breast cancer in relation to the use of injectable progestogen contraceptives and combined estrogen/progestogen contraceptives. Am J Epidemiol 2000;151:396–403.

Appendix A

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Key:
1. No restriction (method can be used)
2. Advantages generally outweigh theoretical or proven risks
3. Theoretical or proven risks usually outweigh the advantages
4. Unacceptable health risk (method not to be used)

Updated June 2012. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

Most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the male latex condom reduces the risk of STIs and HIV.

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Menarche to <18=1		Menarche to <20=2		Menarche to <20=2	
		≥40=2		18-45=1		18-45=1		18-45=1		≥20=1		≥20=1	
				>45=1		>45=2		>45=1					
Anatomic abnormalities	a) Distorted uterine cavity									4		4	
	b) Other abnormalities									2		2	
Anemias	a) Thalassemia	1		1		1		1		1		2	
	b) Sickle cell disease†	2		1		1		1		1		2	
	c) Iron-deficiency anemia	1		1		1		1		1		2	
Benign ovarian tumors	(including cysts)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	2*		2*		2*		2*		2		1	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer†												
	i) current	4		4		4		4		4		1	
	ii) past and no evidence of current disease for 5 years	3		3		3		3		3		1	
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		2*		2*					
	b) 1 month or more postpartum	2*		1*		1*		1*					
Cervical cancer	Awaiting treatment	2		1		2		2		4	2	4	2
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		2		1		2		2		2		1	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Cirrhosis	a) Mild (compensated)	1		1		1		1		1		1	
	b) Severe† (decompensated)	4		3		3		3		3		1	
DVT/PE	a) History of DVT/PE, not on anticoagulant therapy												
	i) higher risk for recurrent DVT/PE	4		2		2		2		2		1	
	ii) lower risk for recurrent DVT/PE	3		2		2		2		2		1	
	b) Acute DVT/PE	4		2		2		2		2		2	
	c) DVT/PE and established on anticoagulant therapy for at least 3 months												
	i) higher risk for recurrent DVT/PE	4*		2		2		2		2		2	
	ii) lower risk for recurrent DVT/PE	3*		2		2		2		2		2	
	d) Family history (first-degree relatives)	2		1		1		1		1		1	
	e) Major surgery												
	(i) with prolonged immobilization	4		2		2		2		2		1	
	(ii) without prolonged immobilization	2		1		1		1		1		1	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes mellitus	a) History of gestational diabetes mellitus only	1		1		1		1		1		1	
	b) Non-vascular disease												
	(i) non-insulin dependent	2		2		2		2		2		1	
	(ii) insulin dependent†	2		2		2		2		2		1	
	c) Nephropathy/ retinopathy/ neuropathy†	3/4*		2		3		2		2		1	
	d) Other vascular disease or diabetes of >20 years' duration†	3/4*		2		3		2		2		1	
Endometrial cancer†		1		1		1		1		4	2	4	2
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		1		1		1		1		1		2	
Epilepsy†	(see also Drug Interactions)	1*		1*		1*		1*		1		1	
Gallbladder disease	a) Symptomatic												
	(i) treated by cholecystectomy	2		2		2		2		2		1	
	(ii) medically treated	3		2		2		2		2		1	
	(iii) current	3		2		2		2		2		1	
	b) Asymptomatic	2		2		2		2		2		1	
Gestational trophoblastic disease	a) Decreasing or undetectable ß-hCG levels	1		1		1		1		3		3	
	b) Persistently elevated ß-hCG levels or malignant disease†	1		1		1		1		4		4	
Headaches	a) Non-migrainous	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Migraine												
	i) without aura, age <35	2*	3*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	ii) without aura, age ≥35	3*	4*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	iii) with aura, any age	4*	4*	2*	3*	2*	3*	2*	3*	2*	3*	1*	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
History of bariatric surgery†	a) Restrictive procedures	1		1		1		1		1		1	
	b) Malabsorptive procedures	COCs: 3 P/R: 1		3		1		1		1		1	
History of cholestasis	a) Pregnancy-related	2		1		1		1		1		1	
	b) Past COC-related	3		2		2		2		2		1	
History of high blood pressure during pregnancy		2		1		1		1		1		1	
History of pelvic surgery		1		1		1		1		1		1	
HIV	High risk	1		1		1*		1		2	2	2	2
	HIV infected (see also Drug Interactions)†	1*		1*		1*		1*		2	2	2	2
	AIDS (see also Drug Interactions) †	1*		1*		1*		1*		3	2*	3	2*
	Clinically well on therapy	If on treatment, see Drug Interactions								2	2	2	2
Hyperlipidemias		2/3*		2*		2*		2*		2*		1*	
Hypertension	a) Adequately controlled hypertension	3*		1*		2*		1*		1		1	
	b) Elevated blood pressure levels (properly taken measurements)												
	(i) systolic 140-159 or diastolic 90-99	3		1		2		1		1		1	
	(ii) systolic ≥160 or diastolic ≥100†	4		2		3		2		2		1	
	c) Vascular disease	4		2		3		2		2		1	
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		2		1		1		1	
Ischemic heart disease†	Current and history of	4		2	3	3		2	3	2	3	1	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	2		2		2		2		2		1	
	ii) Hepatocellular adenoma†	4		3		3		3		3		1	
	b) Malignant†	4		3		3		3		3		1	
Malaria		1		1		1		1		1		1	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		3*		2*		2		1	
Obesity	a) ≥30 kg/m^2 BMI	2		1		1		1		1		1	
	b) Menarche to <18 years and ≥30 kg/m^2 BMI	2		1		2		1		1		1	
Ovarian cancer†		1		1		1		1		1		1	
Parity	a) Nulliparous	1		1		1		1		2		2	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		2		1		1		1		1	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)												
	(i) with subsequent pregnancy	1		1		1		1		1	1	1	1
	(ii) without subsequent pregnancy	1		1		1		1		2	2	2	2
	b) Current	1		1		1		1		4	2*	4	2*
Peripartum cardiomyopathy†	a) Normal or mildly impaired cardiac function												
	(i) <6 months	4		1		1		1		2		2	
	(ii) ≥6 months	3		1		1		1		2		2	
	b) Moderately or severely impaired cardiac function	4		2		2		2		2		2	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	1*		1*		1*		1*		2		2	
	c) Immediately post-septic abortion	1*		1*		1*		1*		4		4	
Postpartum (see also Breastfeeding)	a) <21 days	4		1		1		1					
	b) 21 days to 42 days												
	(i) with other risk factors for VTE	3*		1		1		1					
	(ii) without other risk factors for VTE	2		1		1		1					
	c) >42 days	1		1		1		1					

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) <10 minutes after delivery of the placenta									2		1	
	b) 10 minutes after delivery of the placenta to < 4 weeks									2		2	
	c) ≥4 weeks									1		1	
	d) Puerperal sepsis									4		4	
Pregnancy		NA*		NA*		NA*		NA*		4*		4*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2/3*		1		2	1	2	1
	b) Not on immunosuppressive therapy	2		1		2		1		1		1	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver†	1		1		1		1		1		1	
Severe dysmenorrhea		1		1		1		1		1		2	
STIs	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		1		1		4	2*	4	2*
	b) Other STIs (excluding HIV and hepatitis)	1		1		1		1		2	2	2	2
	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		1		1		2	2	2	2
	d) Increased risk of STIs	1		1		1		1		2/3*	2	2/3*	2
Smoking	a) Age <35	2		1		1		1		1		1	
	b) Age ≥35, <15 cigarettes/day	3		1		1		1		1		1	
	c) Age ≥35, ≥15 cigarettes/day	4		1		1		1		1		1	
Solid organ transplantation†	a) Complicated	4		2		2		2		3	2	3	2
	b) Uncomplicated	2*		2		2		2		2		2	
Stroke†	History of cerebrovascular accident	4		2	3	3		2	3	2		1	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Superficial venous thrombosis	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial thrombophlebitis	2		1		1		1		1		1	
Systemic lupus erythematosus†	a) Positive (or unknown) antiphospholipid antibodies	4		3		3	3	3		3		1	1
	b) Severe thrombocytopenia	2		2		3	2	2		2*		3*	2*
	c) Immunosuppressive treatment	2		2		2	2	2		2		2	1
	d) None of the above	2		2		2	2	2		2		1	1
Thrombogenic mutations†		4*		2*		2*		2*		2*		1*	
Thyroid disorders	Simple goiter/ hyperthyroid/ hypothyroid	1		1		1		1		1		1	
Tuberculosis† (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		1*		1		1	
	b) Pelvic	1*		1*		1*		1*		4	3	4	3
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*		2*		3*		3*		4*	2*	4*	2*
Uterine fibroids		1		1		1		1		2		2	
Valvular heart disease	a) Uncomplicated	2		1		1		1		1		1	
	b) Complicated†	4		1		1		1		1		1	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		2		2		1	1	1	
	b) Heavy or prolonged bleeding	1*		2*		2*		2*		1*	2*	2*	
Viral hepatitis	a) Acute or flare	3/4*	2	1		1		1		1		1	
	b) Carrier/Chronic	1	1	1		1		1		1		1	

See table footnotes on page 54.

Appendix A (*Continued*)

Summary Chart of *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Drug Interactions													
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		1		1		2/3*	2*	2/3*	2*
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		1		2*		2/3*	2*	2/3*	2*
	c) Ritonavir-boosted protease inhibitors	3*		3*		1		2*		2/3*	2*	2/3*	2*
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1		2*		1		1	
	b) Lamotrigine	3*		1		1		1		1		1	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampicin or rifabutin therapy	3*		3*		1		2*		1		1	

Abbreviations: AIDS = acquired immunodeficiency syndrome; BMI = body mass index; C = continuation of contraceptive method; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; I = initiation of contraceptive method; LNG-IUD = levonorgestrel-releasing intrauterine device; NA = not applicable; PE = pulmonary embolism; STI = sexually transmitted infection; VTE = venous thromboembolism.

Source: Modified from CDC. Summary chart of U.S. medical eligibility criteria for contraceptive use. Atlanta, GA: CDC; 2012. (Available at http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm.)

* Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

† Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Appendix B

When To Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back-up) needed	Examinations or tests needed before initiation*
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection†
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection†
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI (weight [kg]/height [m]^2) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

† Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (Box 2). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Appendix C

Examinations and Tests Needed Before Initiation of Contraceptive Methods

The examinations or tests noted apply to women who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (U.S. MEC), might be useful in such circumstances (*5*). The following classification was considered useful in differentiating the applicability of the various examinations or tests:

Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B: contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

Class C: does not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relationship of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions.

No examinations or tests are needed before initiating condoms or spermicides. A bimanual examination is necessary for diaphragm fitting. A bimanual examination and cervical inspection are needed for cervical cap fitting.

TABLE. Examinations and tests needed before initiation of contraceptive methods

	Contraceptive method and class							
Examination or test	Cu-IUD and LNG-IUD	Implant	Injectable	CHC	POP	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/ height [m]^2)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Appendix D

Routine Follow-Up After Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

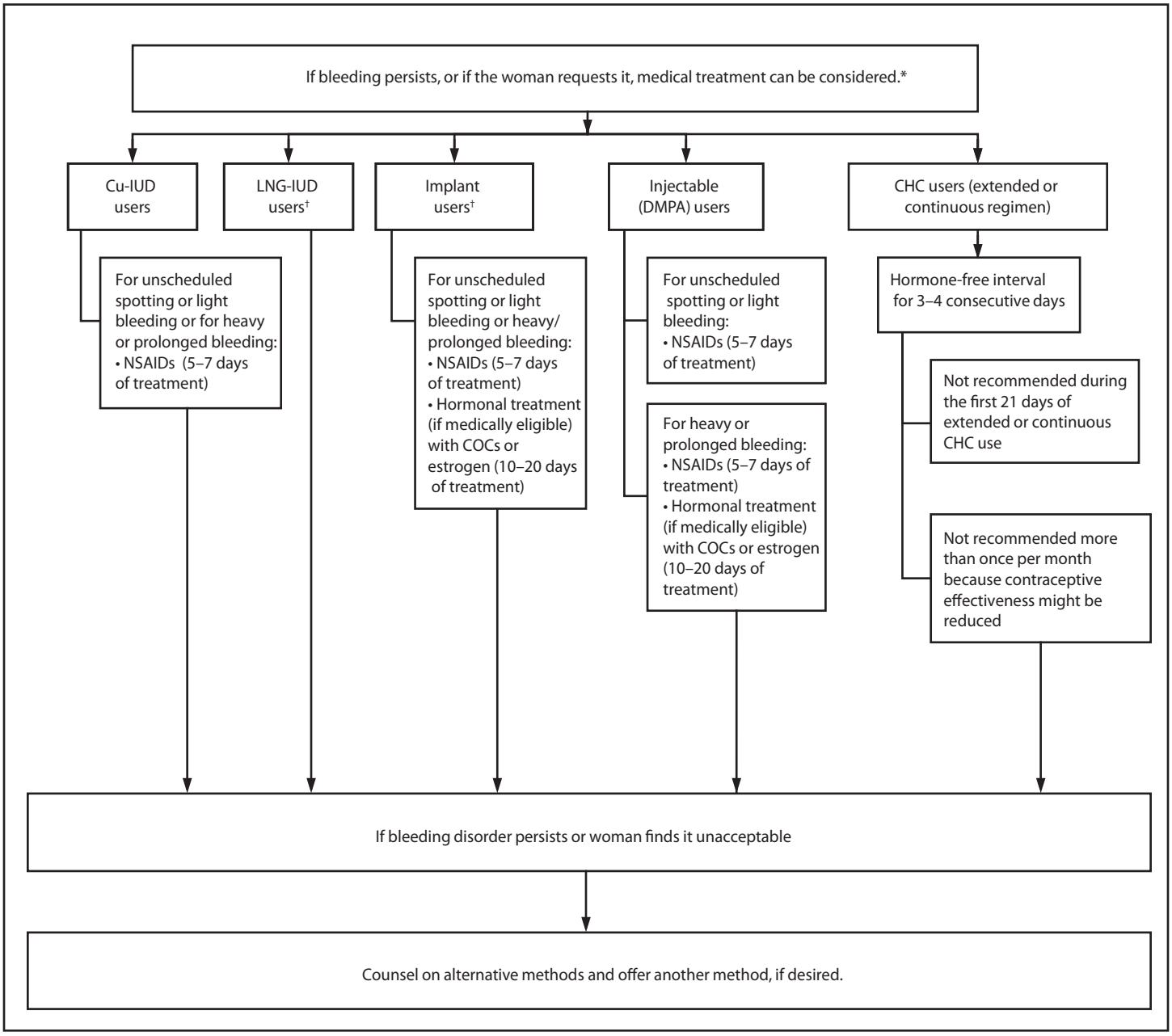
TABLE. Routine follow-up after contraceptive initiation

	Contraceptive method				
Action	**Cu-IUD or LNG-IUD**	**Implant**	**Injectable**	**CHC**	**POP**
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 2).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

Appendix E

Management of Women with Bleeding Irregularities While Using Contraception



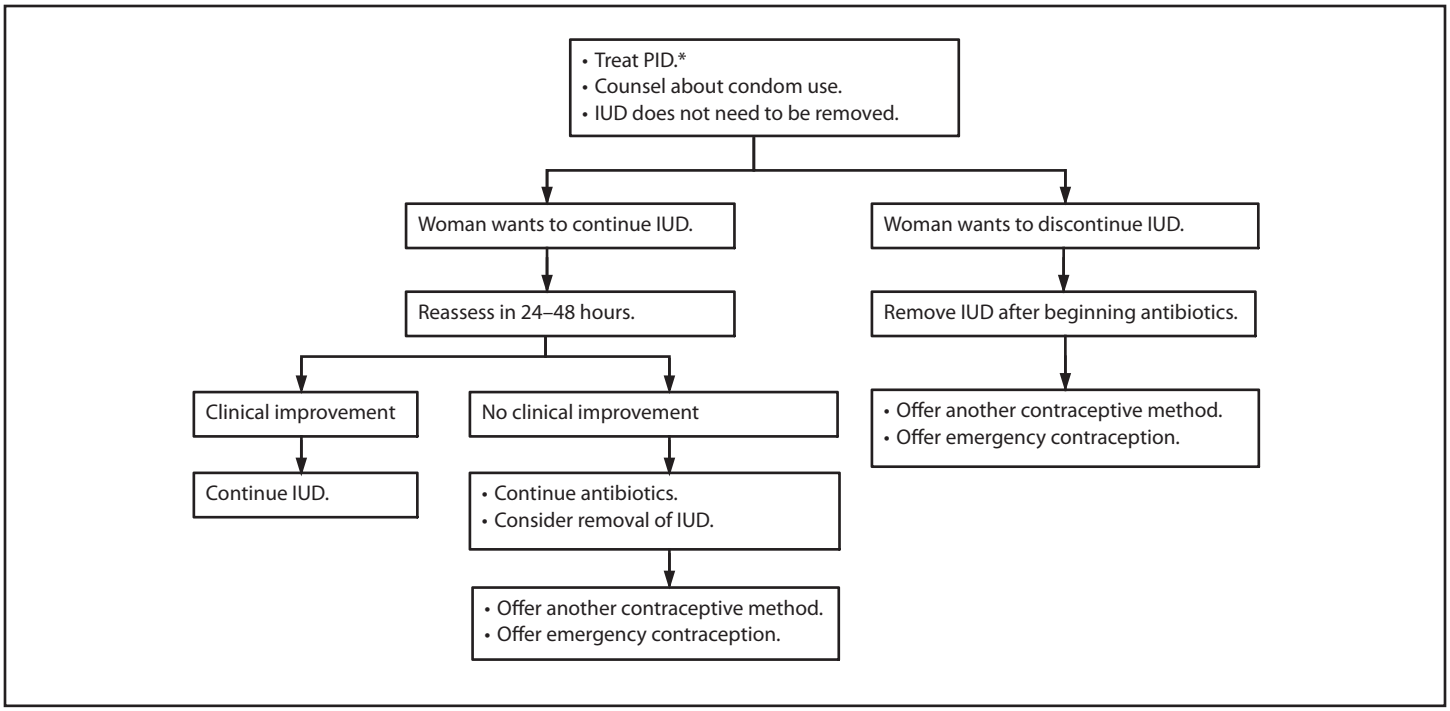
Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.

† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

Appendix F

Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have Pelvic Inflammatory Disease



Abbreviations: Cu-IUD = copper-containing IUD; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing IUD; PID = pelvic inflammatory disease.
* Treat according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment).

U.S. Selected Practice Recommendations for Contraceptive Use Participants

CDC Steering Committee

Kathryn M. Curtis, PhD (Chair), Denise J. Jamieson, MD, Polly A. Marchbanks, PhD, Naomi K. Tepper, MD, CDC, Atlanta, Georgia.

Invited Meeting Participants, October 21–22, 2010, Atlanta, Georgia

Herbert B. Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Abbey Berenson, MD, University of Texas Medical Branch, Nassau Bay, Texas; Philip Darney, MD, University of California, San Francisco, California; David Eisenberg, MD, Washington University, St. Louis, Missouri; Paula Hillard, MD, Stanford University, Palo Alto, California; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Trent MacKay, MD, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Mary Mitchell, American College of Obstetricians and Gynecologists, Washington, DC; Michael Policar, MD, University of California, San Francisco, California; Sarah Prager, University of Washington, Seattle, Washington.

Systematic Review Presenters and Authors Meeting, October 4–7, 2011, Atlanta, Georgia

Kathryn M. Curtis, PhD, Suzanne G. Folger, PhD, Emily M. Godfrey, MD, Denise J. Jamieson, MD, Gary Jeng, PhD, Polly A. Marchbanks, PhD, Sarah Murtaza, MPH, Maria W. Steenland, MPH, Naomi K. Tepper, MD, Crystal P. Tyler, PhD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia; Dalia Brahmi, MD, Ipas, Carrboro, NC; Nathalie Kapp, MD, Mary Lyn E. Gaffield, PhD, Maria I. Rodriguez, MD, World Health Organization, Geneva, Switzerland; Tara P. Cleary, MD, Carrie Cwiak, MD, Emory University, Atlanta, Georgia; Jennifer Salcedo, MD, University of California, Los Angeles, California; Ira Sharlip, MD, American Urological Association and University of California, San Francisco, California.

Invited Meeting Participants, October 4–7, 2011, Atlanta, Georgia

Willard Cates, Jr., MD, FHI360, Research Triangle Park, North Carolina (Chair); Herbert B. Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Rebecca Allen, MD, American Society for Reproductive Medicine and Brown University, Providence, Rhode Island; Abbey Berenson, MD, University of Texas Medical Branch, Nassau Bay, Texas; Paul Blumenthal, MD, Stanford University, Palo Alto, California; Mitchell Creinin, MD, University of California, Davis, California; Vanessa Cullins, MD, Planned Parenthood Federation of America, New York, New York; Jennifer Dietrich, MD, Baylor College of Medicine, Houston, Texas; Linda Dominguez, Southwest Women's Health, Albuquerque, New Mexico; Alison Edelman, MD, Oregon Health Sciences University, Portland, Oregon; David Eisenberg, MD, Washington University, St. Louis, Missouri; Melissa Gilliam, MD, The University of Chicago, Chicago, Illinois; Marji Gold, MD, Albert Einstein College of Medicine, Bronx, New York; Alisa Goldberg, MD, Brigham and Women's Hospital and Planned Parenthood of Massachusetts, Boston, Massachusetts; Robert Hatcher, MD, Emory University, Atlanta, Georgia; Mark Hathaway, MD, Association for Reproductive Health Professionals and Washington Hospital Center, Washington, DC; Stephen Heartwell, DrPH, Susan Thompson Buffett Foundation, Omaha, Nebraska; Paula Hillard, MD, Stanford University, Palo Alto, California; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Hal Lawrence, MD, American College of Obstetricians and Gynecologists, Washington, DC; Laura MacIsaac, MD, Albert Einstein School of Medicine, New York, New York; Trent MacKay, MD, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Mary Mitchell, American College of Obstetricians and Gynecologists, Washington, DC; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Patricia Murphy, DrPH, University of Utah, Salt Lake City, Utah; Kavita Nanda, MD, FHI360, Research Triangle Park, North Carolina; Deborah Nucatola, MD, Planned Parenthood Federation of America, New York, New York; Jeffrey Peipert, MD, Washington University, St. Louis, Missouri; Michael Policar, MD, University of California, San Francisco, California; Sarah Prager, University of Washington, Seattle, Washington; Ira Sharlip, MD, American Urological Association and University of California, San Francisco, California; David Soper, MD, University of South Carolina, Charleston, South Carolina; Lisa Soule, MD, Food and Drug Administration, Silver Spring, Maryland; Maria Trent, MD, Johns Hopkins University, Baltimore, Maryland; James Trussell, PhD, Princeton University, Princeton, New Jersey; Carolyn Westhoff, MD, Columbia University, New York, New York; Mimi Zieman, MD, Emory University, Atlanta, Georgia.

External Reviewers

Courtney Benedict, MSN, Planned Parenthood Federation of America, Sonoma, California; Gale Burstein, MD, Erie County Department of Health, Buffalo, New York; Lucy Chie, MD, Harvard Medical School, Boston, Massachusetts; Kelly Culwell, MD, University of California, Davis, California; Sharon Schnare, MSN, University of Washington, Seattle, Washington.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit MMWR's free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30333 or to *mmwrq@cdc.gov.*

All material in the *MMWR* Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

U.S. Government Printing Office: 2013-623-210/81600 Region IV ISSN: 1057-5987

Iowa Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program

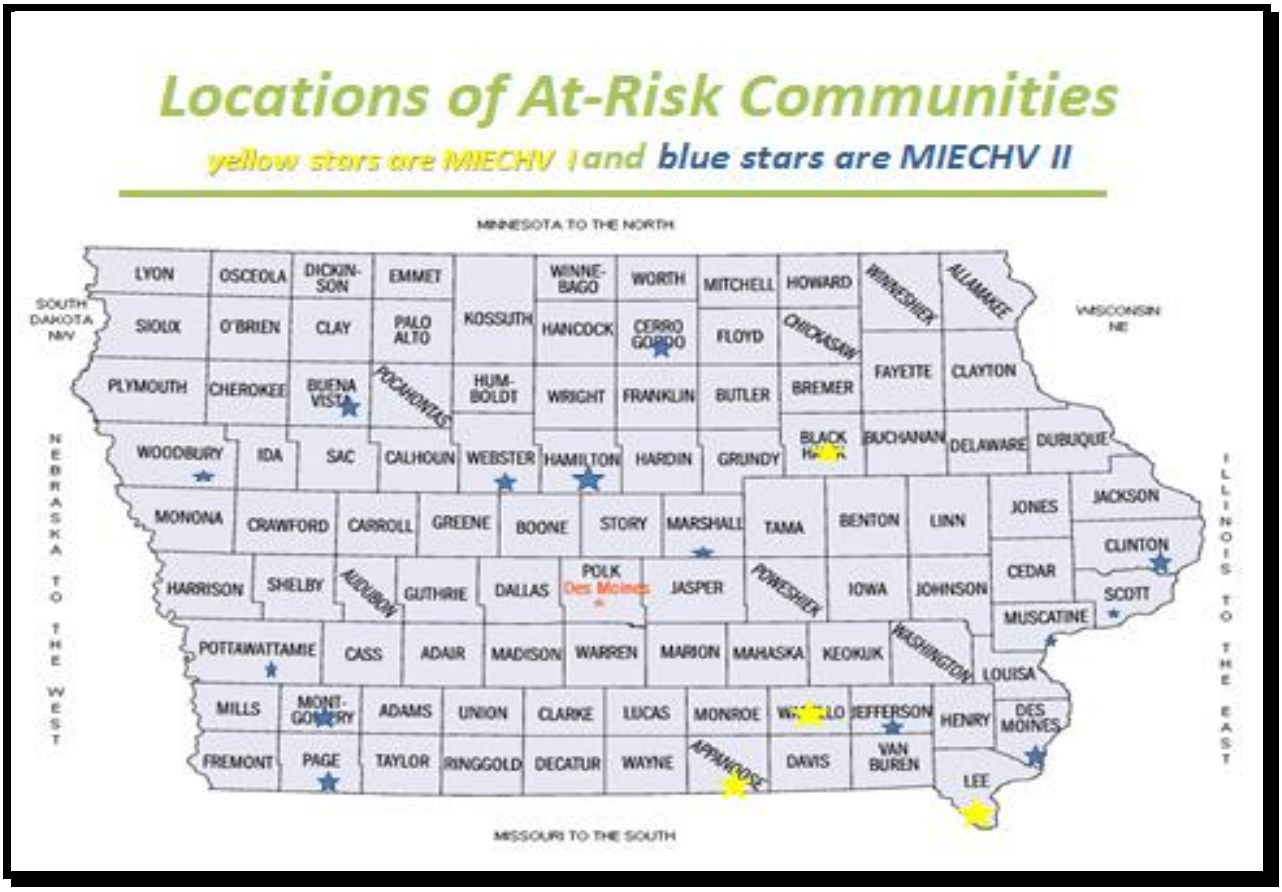
Brief Overview

Health Resources Services Administration provides $7,740,642 annually to Iowa for maternal, infant and early childhood home visitation programs. Contractors are required to use evidence-based home visiting models and establish quantifiable, measurable benchmarks that demonstrate:

- improvements in maternal and child health,
- childhood injury prevention,
- school readiness and achievement,
- crime or domestic violence,
- family economic self-sufficiency, and coordination with community resources and supports.

Iowa Priorities:

- Increase the number of families served by evidence-based home visiting programs in at-risk communities
- Develop a statewide maternal, infant and early childhood home visiting data systems capabilities
- Reduce barriers to access to health care, mental health care, substance abuse treatment and counseling, and dental care for low income families
- Develop home visiting infrastructure with focus on quality and systems coordination
- Support healthy home environments and stable family relationships to protect families from domestic violence and child abuse and neglect



Iowa Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program

Statewide Infrastructure Building Activities

- *Access to Web-Based Data Collection and Reporting System*
- *Statewide Coordinated Intake System for Family Support Services and Early Intervention*
- *Exploration of creative uses of tele-health technology to enhance family support services*
- *Creation of the virtual home visitor system*
- *Development of a Learning Management System for family support field staff*
- *Creation of endorsements/specializations for family support field staff*
- *Development of a "Q" score for family support workers*
- *Family Support workforce study and plan to diversify the field*
- *Home Visiting Evaluation*
- *Family Support Competency requirements for workers and supervisors*
- *Family Support Research summit*

MIECHV Home Visiting Contractors

Community Service Area	Contractor	Sub-Contractors	Model	Planned Capacity	Annual Funding
Appanoose/Wapello	Southern Iowa Economic Association	Children and Families of Iowa	Healthy Families America	40	$275,000
Black Hawk	Operation Threshold	Tri-County Family and Child Council Lutheran Services in Iowa	Healthy Families America	55	$475,000
			Home-based Early Head Start	35	
Buena Vista	Upper Des Moines Opportunity	N/A	Home-based Early Head Start	6	$60,000
Cerro Gordo	Lutheran Services in Iowa	N/A	Healthy Families America	36	$180,000
Clinton, Muscatine, Scott	Lutheran Services in Iowa	Genesis Health Systems Clinton Visiting Nurse Association	Healthy Families America	299	$1,607,252
			Nurse Family Partnership	62	
Des Moines, Lee	Lee County Public Health	Des Moines County Public Health	Healthy Families America	50	$320,000
Hamilton, Webster	TBD	TBD	TBD	TBD	$90,000
Jefferson	Lutheran Services in Iowa	N/A	Healthy Families America	12	$60,000
Marshall	Mid Iowa Community Action	N/A	Home-based Early Head Start	9	$90,000
Montgomery, Page, Pottawattamie	Promise Partners	Southwest Iowa Families West Central Development Corporation Visiting Nurse Association of Omaha	Healthy Families America	30	$495,000
			Home-based Early Head Start	24	
			Nurse Family Partnership	50	
Woodbury	Siouxland Human Investment Partnership	Siouxland Health Department Crittenton Center Lutheran Services in Iowa Community Action Agency of Siouxland	Healthy Families America	84	$555,000
			Home-based Early Head Start	27	

Iowa Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program

MIECHV State Team

Janet Horras	Director	Janet.Horras@idph.iowa.gov
PJ West	Program Manager	PJ.West@idph.iowa.gov

January 2013 – Iowa Department of Public Health – Bureau of Family Health
This publication was made possible by Grant Number D89MC23537 from the Health Resources and Services Administration.
Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Health Resources and Services Administration.

Preventive Male Sexual and Reproductive Health Care:

Recommendations for Clinical Practice

Prepared by Arik V. Marcell, MD, MPH and the
Male Training Center for Family Planning and Reproductive Health

2014

MALE TRAINING CENTER
FOR FAMILY PLANNING & REPRODUCTIVE HEALTH

Suggested Citation: Marcell, A.V. and the Male Training Center for Family Planning and Reproductive Health. Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice. Philadelphia, PA: Male Training Center for Family Planning and Reproductive Health and Rockville, MD: Office of Population Affairs; 2014.

Support: This project was supported through the Male Training Center for Family Planning and Reproductive Health's cooperative agreement with the Office of Family Planning, Office of Population Affairs, Department of Health and Human Services (cooperative agreement FPTPA006011).

Acknowledgements: Numerous people were involved in the preparation of this report. Particular thanks go to individuals who participated in the development of the recommendations on the Technical Panel of Men's Clinical Services and feedback from the Male Training Center's (MTC) staff, faculty and advisory committee (see Appendix 2 for full list of contributors).

Thanks also go to Lorrie Gavin, PhD and staff from the CDC's Division of Reproductive Health and other CDC Divisions. Thanks also go to Celia Neustadt, Baltimore, Maryland for her assistance in preparing the background materials for the technical panel.

Thanks also go to the Office of Population Affairs U.S. Department of Health and Human Services for their assistance and support of this report.

Disclaimer: The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Office of Population Affairs or the Department of Health and Human Services.

© Male Training Center for Family Planning and Reproductive Health
2014

Permission is required to reproduce any part of this publication. Permission will be freely granted to educational or non-profit organizations. Others will be requested to pay a small fee. Please contact:

Male Training Center
c/o AccessMatters
1700 Market Street, 18th Floor
Philadelphia, PA 19103
Tel: +1 (215) 985-2600 x2659
Email: info@maletrainingcenter.org

This report and additional online content are available at www.maletrainingcenter.org
For corrigenda subsequent to printing, please see www.maletrainingcenter.org
For latest data, please visit www.maletrainingcenter.org

Table of Contents

Introduction 1

Methods 3

Summary of Recommended Services 4

Discussion 6

References 25

About the Male Training Center 33

Tables

Table 1 Checklist of Recommended Services 5

Table 2A Detailed Summary of Recommended Service Content 8

Table 2B Frequency for Delivering Recommended Services 22

Table 3 Checklist and Rationale for Services Not Recommended 23

Appendices

Appendix 1 Professional Organizations Included in the Final Review 30

Appendix 2 Male Training Center's Staff, Technical Panel, Advisory Committee & Other Contributors for Feedback on Men's Clinical Services 31

Introduction

The purpose of the Male Training Center (MTC) for Family Planning and Reproductive Health is to assist with improving the delivery of family planning and sexual and reproductive health [subsequently also called sexual and reproductive health] services for reproductive-aged males in Title X supported health and social service settings or other clinical settings that serve this population. The Male Training Center recognizes that reproductive-aged males in the U.S. have substantial sexual and reproductive health needs [1], but adequate integration of sexual and reproductive health care for this population is lacking. The Male Training Center also recognizes that the nation is lacking in recognized standards of care for delivering sexual and reproductive clinical and preventive services to males [2]. Although a number of professional organizations promote the delivery of clinical preventive services inclusive of sexual health [3-5], there is minimal guidance by national professional organizations as to what preventive sexual and reproductive health services to deliver to reproductive-aged males, unlike recommendations outlined for women [6].

The goal of this *Recommendations for Clinical Practice* document is to describe best practice recommendations for the organization and delivery of preventive clinical sexual and reproductive health services for reproductive-aged males. This document is intended for all levels of staff in clinical settings that offer services for male clients from adolescence through adulthood. Specifically, this document can serve as a guide in determining what clinical preventive sexual and reproductive health services for males should be provided or improved and examples of how to do so. Further, these recommendations for standards of care may be useful to a variety of other stakeholders, including insurers, by setting coverage standards for male clinical services as well as policy makers and advocates.

The content of this document is being addressed at an important time in the history of health care services. Historically, many women in the U.S. have gained access to reproductive health care through Medicaid waivers, State Plan Amendments, and publicly-supported health plans for low-income women and/or women with children. In addition to these programs which expand health care coverage, many adolescents and female adults have increased access to preventive sexual and reproductive health services now that the U.S. Department of Health and Human Services has adopted recommendations by the Institute of Medicine's report, *Clinical Preventive Services for Women: Closing the Gaps,* that outlines gaps in women's preventive health care services under the Patient Protection and Affordable Care Act (ACA) [7]. The U.S. Supreme Court's ruling on the ACA also affords coverage for preventive sexual and reproductive health care services for the first time in our nation's history. As health care providers and programs implement ACA, they will need guidance to help them provide the most effective and efficient services for individuals experiencing increased access to care, including males.

It is thus the long-term goal of this document to improve the practice of medicine with a particular emphasis on how clinical practice can incorporate preventive sexual and reproductive health care for reproductive-aged males by meeting males' current and emerging sexual and reproductive health needs.

Methods

This document outlines recommendations for delivering core clinical preventive sexual and reproductive health care services to reproductive-aged males. This document is based on two efforts: 1) MTC's support of a Federal effort to develop recommendations for providing family planning services to men and women, which culminated in the publication of the *Providing Quality Family Planning Services (QFP): Recommendations of CDC and the U.S. Office of Population Affairs* [8, 9]; and 2) deliberations by the MTC about other sexual and reproductive health services males might need outside of the family planning setting during the Men's Health Technical Panel that was convened by the MTC in July 2011.

The process of developing the *QFP:*

- Identified Federal and national professional medical organizations to include in the synthesis [refer to Appendix 1]. The Institute of Medicine criteria for 'trustworthy' clinical practice guidelines was used to decide which professional medical organizations to include in the review [10].
- Compiled and summarized current recommendations for preventive sexual and reproductive health care services for reproductive-aged males. For the purpose of this review, "services" refers to the clinical preventive care components of a client's health history; physical exam; and laboratory test; and counseling for behavior change.
- Conducted systematic reviews on areas where guidance was lacking.

The Men's Health Technical Panel [Appendix 2] Members:

- In advance of the meeting, reviewed and provided feedback on
  - the framework for sexual and reproductive health care goals for reproductive-aged males and services that included preventing sexually transmitted diseases (STDs), human immunodeficiency virus (HIV), unintended pregnancy, and reproductive health-related cancers; promoting sexual health and development; promoting healthy relationships; planning for the timing and spacing of children; and addressing issues related to sexual function and fertility [11]. This relied on definitions of sexual and reproductive health by the 1994 Cairo United Nations International Conference on Population and Development and the World Health Organization for developing a framework for sexual and reproductive health care for reproductive-aged males [11, 12], secondary to the lack of any organizing care framework.
  - the Federal and national professional medical organizations to include.
- During and after the meeting, reviewed and provided feedback on
  - screening components of clinical care to be or not be provided based on the compiled synthesized evidence as well as systematic reviews on areas where guidance was lacking. This included considering inconsistent recommendations across Federal and professional organizations as well as services not recommended for care delivery because they have been shown to be ineffective or even harmful.

Since the field of males' preventive sexual and reproductive health care lacks clinical studies with males that examine service effectiveness on the full array of sexual and reproductive health care, expert review was also taken into consideration to inform best practice for health professionals working with this population until a sufficient evidence-base is developed and appropriately reviewed. Further, since the purpose of the MTC's effort was on the broader content of men's sexual and reproductive health, and not just on family planning, deliberations by the MTC resulted in the inclusion of five additional services to this document (assessment for intimate partner and sexual violence and issues with sexual function and counseling on sexuality/relationships, issues with sexual function, and condoms with opportunities for demonstration and practice).

Recommended core preventive sexual and reproductive health care services for reproductive-aged males are summarized in this document as follows:

- A summary of recommended services is provided on pg. 4.
- Table 1 (pg. 5) provides a checklist of these services.
- Table 2A (pg. 8) provides a detailed summary of service content and examples of how to provide these services.
- Table 2B (pg. 22) provides the frequency for delivering these services.
- Table 3 (pg. 23) provides a checklist and rationale for services that are not recommended.

Summary of Recommended Services

Preventive sexual and reproductive health care services recommended for reproductive-aged males are designed to assist providers in organizing and promoting the delivery of these services to reproductive-aged male patients. These core recommended services include components of screening questions about a client's history; performing a physical exam; performing screening laboratory tests; and counseling on key sexual and reproductive health topics. When an above service result indicates the potential presence of a health condition, further steps should be taken to provide or refer for treatment consistent with current professional standards of care. For example, this includes following the established CDC's STD Treatment Guidelines for persons presenting with STD symptoms or who screen positive for an STD [13]. Refer to Table 1 for a checklist of recommended services.

History Components

Preventive sexual and reproductive health history assessment for males includes taking…

- A reproductive life plan to determine family planning or preconception health needs or difficulty achieving pregnancy
- A standard medical history including pregnancy and fatherhood status
- Additional visit-specific history components related to preconception health and basic infertility
- Comprehensive sexual health assessment (e.g., asking about sexual practices, partners, pregnancy prevention, protection from STDs, past STD history)
- Problems with sexual function **[additional service recommended by MTC]**
- Intimate partner and sexual violence **[additional service recommended by MTC]**

Taking a history also includes services that, while traditionally may be considered more distally related to males' sexual and reproductive health, have overlap and involve screening for…

- Alcohol and other drug use (e.g., alcohol and other drug use before and during sex may lead to lack of condom use, risk for acquiring STDs/HIV and/or unintended pregnancy or problems with sexual function)
- Tobacco use (e.g., nicotine can impair male reproductive function)
- Depression (e.g., certain male populations may be at increased risk for depression including those struggling with issues of sexual identity, experiencing stress during the coming-out process, experiencing a relationship break-up, or struggling with self-esteem, and certain classes of anti-depressants may lead to problems with sexual function)

History assessment also includes…

- Vaccination history as pertaining to the past receipt of sexual and reproductive health-related immunizations (e.g., human papillomavirus (HPV) vaccine)

Physical Exam Components

Preventive sexual and reproductive health physical exam services for males include…

- Height/weight for calculation of body mass index (BMI)
- Blood pressure
- Examination of external genital/perianal region for male adolescents

Laboratory Test Components

Preventive sexual and reproductive health laboratory services for males based on specific at-risk categories (including age for some) include screening for…

- Chlamydia
- Gonorrhea
- Syphilis
- HIV/AIDS
- Hepatitis C
- Diabetes

Counseling Components

Sexual and reproductive health services for males include counseling on…

- Condoms with demonstration/practice **[additional service recommended by MTC]**
- STDs/HIV
- Pregnancy prevention including male and female methods and emergency contraception
- Preconception health
- Sexuality/relationships **[additional service recommended by MTC]**
- Sexual dysfunction **[additional service recommended by MTC]**
- Infertility

Table 1 Checklist of Recommended Services

Services / Components	Core SRH*
History	
Reproductive life plan [1]	√
Standard medical history [2]	√
Additional visit specific history [3]	√
Sexual health assessment [4]	√
Problems with sexual function	√
Intimate partner & sexual violence	√
Alcohol & other drug use	√
Tobacco use	√
Immunizations	√
Depression	√
Physical Exam	
Height, weight & BMI	√
Blood pressure	√
External genital/perianal exam	√ [5]
Laboratory Tests	
Chlamydia	√ [6]
Gonorrhea	√ [7]
Syphilis	√ [8]
HIV/AIDS	√ [9]
Hepatitis C	√ [10]
Diabetes	√ [11]
Key SRH Counseling	
Condoms with demonstration/practice	√
STD/HIV	√
Pregnancy prevention including male & female methods & EC	√
Preconception health	√
Sexuality/relationships	√ [12] / √ [13]
Sexual dysfunction	√
Infertility	√

*Refer to Table 2A for guidance regarding "how to" elements

BMI: body mass index; EC: emergency contraception; HIV/AIDS: human immunodeficiency virus/acquired immune deficiency syndrome; HCV: hepatitis C virus; MSM: men who have sex with men; SRH: sexual and reproductive health; STD: sexually transmitted disease

KEY FOR TABLE

1. Assess for number of children fathered/want (more) children &, if so, when?
2. Assess for medical & surgical history, medications & allergies.
3. Assess for visit specific additional history items (e.g., as part of STD visit, infertility visit, preconception care visit, etc.).
4. Assess for sexual health practices, partners (sexuality & relationships), pregnancy prevention methods, protection from STDs and STD history.
5. Among male adolescents also document sexual maturity rating.
6. Screen at risk males: MSM; males in teen, correctional facilities, high school & STD clinics; attending National Job Training Program; in military <30 years; entering jails <30 years; entering juvenile facilities; & high prevalence communities.
7. Screen at risk males: MSM; persons reporting multiple or anonymous sex partners; engaging in sex & illicit drug use (e.g., methamphetamine).
8. Screen at risk males: MSM; persons engaging in high-risk sexual behavior; commercial sex workers; persons who exchange sex for drugs; adult correctional facilities; & high prevalence communities.
9. Screen all clients aged 13-64 years & subsequently test high risk individuals at least annually. High risk includes: MSM; injection drug users & their sex partners; persons who exchange sex for money or drugs; sex partners of HIV-infected persons; & persons who themselves or whose sex partners have had >1 sex partner since most recent HIV test.
10. Conduct one-time testing without prior ascertainment of HCV risk for persons born during 1945–1965, a population with a disproportionately high prevalence of HCV infection and related disease.
11. Screen asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.
12. Among males dealing with issues of sexuality inclusive of individual support, support for families, &/or referral to local resources as appropriate.
13. Among male adolescents, support having healthy relationships.

Discussion

This document describes best practice recommendations for the organization and delivery of preventive clinical sexual and reproductive health services for reproductive-aged males in the U.S. by using an evidence-informed approach that takes into account both evidence and expert review. Although expert review may be on the lower end of the evidence ladder [14], it has merit and can be useful in the context when high-quality evidence in the published literature is lacking [15-17] and when its limitations are mitigated through the use of explicit and transparent procedures. This guidance can serve as the basis for the standard of core clinical preventive sexual and reproductive health care delivery to reproductive-aged males in settings that serve this population (e.g., primary care, school-based health, justice, family planning and STD settings), although implementation may need to vary depending on the clinical setting and/or reason for visit.

These services, specifically for the context of clinical care, address a broad array of males' sexual and reproductive health. The scope of sexual and reproductive health care goals recommended in this document is consistent with broader definitions of sexual and reproductive health promoted by the World Health Organization [12] and includes preventing sexually transmitted diseases (STDs), human immunodeficiency virus (HIV), unintended pregnancy, and reproductive health-related cancers; promoting sexual health and development; promoting healthy relationships; planning for the timing and spacing of children; and addressing issues related to sexual function and fertility.

The content of preventive sexual and reproductive health care services described in this document is specific for reproductive-aged males. While some recommendations are similar to those for women, others are uniquely for males based on current evidence. Further, sexual and reproductive health behaviors and outcomes may be best approached by directly or indirectly engaging couples. Although recommendations described in this document focus on services for individuals, the MTC encourages practitioners to consider their relevance to patients' partners and the importance of partner outreach, regardless of a partners' gender.

The guidance described in this document highlights best practices for delivering sexual and reproductive health care to reproductive-aged males. Whereas the QFP had a more focused approach to providing guidance on family planning and preconception health, the MTC's approach emphasized addressing broader content on men's sexual and reproductive health. Further, content in this document highlights services important for men who have sex with men (MSMs) since this population has substantial sexual and reproductive health needs [18] beyond HIV concerns which may also include planning families.

This document can serve as the foundation for establishing national standards of preventive clinical sexual and reproductive health care for reproductive-aged males within a larger agenda for male health as recommended by the Institute of Medicine's report, Clinical Preventive Services for Women: Closing the Gaps: "a parallel approach could be equally useful for determining covered preventive services for men, …, and male adolescents" (Recommendation 6.3) [7]. Future work can also extend standards of care described here for males across the lifespan including older-aged males as well as younger boys and their families. These standards should ensure, as recommended for women, that all men with reproductive capacity have the full range of contraceptive methods available to them including sterilization procedures (e.g., vasectomy), and related patient education and counseling.

During its review of Federal and professional clinical guidelines, the MTC identified substantial gaps in recommendations on preventive clinical sexual and reproductive health care services for reproductive-aged males. One major contributing factor to this gap is a lack of research conducted among males in clinical settings in the area of males' sexual and reproductive health. Another contributing factor is a lack of coordinated and integrated discourse across the fields of reproductive health care, family planning and sexual health. The MTC hopes that this document can help stimulate both discourse and research in these areas which can in turn inform the evidence base and, ultimately, clinical care for this population. This document also highlights services that should no longer be delivered to reproductive-aged males based on current evidence. Finally, regular updates to these recommendations will be necessary for content areas in which further data is still being accumulated and thus current guidance is lacking.

Investment in training and capacity-building will be necessary to successfully implement this guidance. Programs and staff, including clinicians, health counselors and educators, managers and administrative staff, and other clinic staff,

Discussion

will need to ensure they have the requisite knowledge, skills, and resources to effectively implement these recommendations. Programs may want to consider alternate staffing approaches to ensure efficient implementation. The MTC has tools available on its website (www.maletrainingcenter.org), including tools for billing and coding for male services, patient educational materials, and training materials for conducting a male patient examination. The MTC has released a report on a national summary of clinicians' scope of practice pertaining to clinical services provided to males within the context of family planning settings [19]. The MTC is available to help provide training and technical assistance with implementation of these recommendations, including support for issues associated with clinicians' scope of practice.

Table 2A Detailed Summary of Recommended Service Content

History	
Reproductive life plan	Assess among all individuals capable of having a child whether they have a reproductive life plan [20] by asking: • Have you ever made someone pregnant/are you currently a father? • Do you want to have (more) children? • How many (more) children would you like to have and when?
Standard medical history	Assess for medical and surgical history, current medications and supplements, allergies, family medical history and pregnancy and father history [20, 21].
Additional visit – specific history	**Preconception health** [20] • Past medical and surgical history that may impair his reproductive health (e.g., genetic defects, history of reproductive failures, &/or conditions that can reduce sperm quality, such as obesity, diabetes mellitus, varicocele and STDs). • Occupational or environmental exposures. **Basic infertility** [21] • Additional medical history including: – Childhood illnesses and developmental history; – Systemic medical illnesses (e.g., diabetes mellitus) and prior surgeries; – Medications (prescription and non-prescription) and allergies; – Lifestyle exposures and a review of systems; – Family reproductive history; and – Review of past infections such as sexually transmitted diseases. • Reproductive history including: – Coital frequency and timing; – Duration of infertility and prior fertility; – Sexual history including STDs; and – Gonadal toxin exposure including heat.

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Sexual health assessment	Use the 5 P's approach to conduct a sexual health assessment [13, 22, 23]: 1. ***Practices:*** Assess for the types of sexual behavior that your patient engages in, such as vaginal, anal, and/or oral sex. 2. ***Partners:*** Ask questions to determine the number, sex, and concurrency of your patient's sex partners. You may need to define the term "partner" to the patient or use other, relevant terminology. 3. ***Pregnancy prevention:*** Discuss current and future contraceptive options with partner. 4. ***Protection* from STDs:** Ask about condom use, with whom they do or do not use condoms, and situations that make it harder or easier to use condoms. 5. ***Past* STD history**: Ask about history of STDs, including whether their partners have ever had an STD (The likelihood of an STD is higher with a past history of an STD).
Problems with sexual function	Ask do you have any difficulty with intercourse/problems when having sex? • Asking males about problems with sexual function is particularly important to identify underlying cardiovascular disease among men who present with symptoms of sexual dysfunction routinely starting at age 25. Specific questions include if the male is experiencing sexual dysfunction such as inability to obtain and maintain an adequate erection for satisfactory sexual activity (impotence, erectile dysfunction [ED]), premature or delayed ejaculation, loss of libido, painful intercourse, and also priapism, a prolonged painful erection not associated with sexual desire [24-26].
Intimate partner & sexual violence	Assess for history of abuse including intimate partner and sexual violence [4, 27]. Given that abuse may be bidirectional within the context of relationships [28], assessing for both experience and perpetration may be warranted along with a history of childhood/family violence exposure. Note: providers must comply with state mandatory reporting guidelines regarding abuse, rape and incest [29]. • **An example evidence-based approach for assessment includes:** HITS... (Hurt, Insult, Threaten, Scream) [30] How often does your partner: **H** Physically HURT you? **I** INSULT or talk down to you? **T** THREATEN you with harm? **S** SCREAM or curse at you? Score each item using 1 to 5 on a Likert scale as follows: never (1); rarely (2); sometimes (3); fairly often (4); frequently (5). Scores for this inventory range from 4 to 20. A score of greater than 10 is considered positive for partner violence. Provide counseling and referral as appropriate.

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Alcohol & other drug use	Assess for alcohol misuse in adults and adolescents and for other drug use [4, 31-36]. • **Example evidence-based approaches for assessment include:** A. Among Adolescents through age 21 – CRAFFT [37]: During the past 12 months, did you: 1. Drink any alcohol (more than a few sips)? (Do not count sips of alcohol taken during family or religious events.) 2. Smoke any marijuana or hashish? 3. Use anything else to get high? ("Anything else" includes illegal drugs, over the counter and prescription drugs, and things that you sniff or "huff.") If patient answered "no" to all of the above 3 questions, ask only CAR question below. If patient answered "yes" to any of the above 3 questions, ask all questions below. **C** Have you ever ridden in a CAR driven by someone (including yourself) who was "high" or had been using alcohol or drugs? **R** Do you ever use alcohol or drugs to RELAX, feel better about yourself, or fit in? **A** Do you ever use alcohol/drugs while you are by yourself, ALONE? **F** Do you ever FORGET things you did while using alcohol or drugs? **F** Do your family or FRIENDS ever tell you that you should cut down on your drinking or drug use? **T** Have you gotten into TROUBLE while you were using alcohol or drugs? Probability of abuse/dependence increases with increasing yes answers to above questions. B. Alcohol screening and brief intervention for youth. A practitioner's guide [38]: STEP 1: ASK THE TWO SCREENING QUESTIONS For Middle School (ages 11–14): **Friends: Any drinking?** "Do you have any friends who drank beer, wine, or any drink containing alcohol in the *past year?*" ANY drinking by friends heightens concern. **Patient: How many days?** "How about you—in the past year, on how many days have you had more than a few sips of beer, wine, or any drink containing alcohol?" Classify ANY drinking: Moderate or Highest Risk. For High School (ages 14–18) **Patient: How many days?** "In the past year, on how many days have you had more than a few sips of beer, wine, or any drink containing alcohol?" Classify Lower, Moderate, or Highest Risk. **Friends:** How much? "If your friends drink, how many drinks do they usually drink on an occasion?" Binge drinking by friends heightens concern. *(3 to 5+ drinks)* Counseling guidance is provided based on assessment per above (refer to original source for specifics).

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Alcohol & other drug use ***– continued***	STEP 2: GUIDE PATIENT *For patients who DO NOT drink…* STEP 2: ASSESS RISK *For patients who DO drink…* STEP 3: ADVISE AND ASSIST *For patients who DO drink…* STEP 4: AT FOLLOWUP, CONTINUE SUPPORT *For patients who DID drink…* C. Among Adults - **CAGE**: **C** Have you ever felt you needed to CUT down on your drinking? **A** Have people ANNOYED you by criticizing your drinking? **G** Have you ever felt GUILTY about drinking? **E** Have you ever felt you needed a drink first thing in the morning (EYE-OPENER) to steady your nerves or to get rid of a hangover? Two "yes" responses indicate that the possibility of alcoholism should be investigated further. Offer behavioral counseling interventions to reduce alcohol misuse in adults and adolescents and for other drug use.

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Tobacco use	Assess all adults and adolescents about smoking and use of other tobacco products [4, 35, 39-44]. • **Example assessment approaches include:** A. The Hooked on Nicotine Checklist (HONC) [45] 1. Have you ever tried to quit, but couldn't? 2. Do you smoke now because it is really hard to quit? 3. Have you ever felt like you were addicted to tobacco? 4. Do you ever have strong cravings to smoke? 5. Have you ever felt like you really needed a cigarette? 6. Is it hard to keep from smoking in places where you are not supposed to, like school? *When you tried to stop smoking…(or, when you haven't used tobacco for a while…)* 7. Did you find it hard to concentrate because you couldn't smoke? 8. Did you feel more irritable because you couldn't smoke? 9. Did you feel a strong need or urge to smoke? 10. Did you feel nervous, restless, or anxious because you couldn't smoke? A positive response to any question signals a loss of autonomy and the onset of dependence. B. The "5 A's" approach Developed by the National Cancer Institute (NCI), this approach can be used by health care providers when caring for persons with nicotine dependence [46]. This counseling technique requires less than 3 minutes and includes a mnemonic of the following "5 A's": 1. **ASK:** "Do you smoke cigarettes or use tobacco?" 2. **ADVISE:** "Quitting smoking/tobacco use is the most important thing you can do to protect your health now & in the future. The clinic staff & I will help you." 3. **ASSESS:** "Are you willing to make a quit attempt in the next 30 days?" 4. **ASSIST:** 1 - Help develop a quit plan including setting a quit date in the next 2 weeks, telling friends and family of intent to quit & request support, anticipate challenges to quit, & remove nicotine products from environment; 2 - Give key advice including total abstinence, reviewing past quit experiences in any & factors that hindered past quit attempts, & limit or abstain from alcohol; & 3 - Consider use of nicotine replacement therapy or refer to someone who can. 5. **ARRANGE:** Refer to intensive services (help lines, websites, treatment programs and follow-up to review progress. Data from randomized control studies conducted in 1989 among adult patients utilizing this technique demonstrated 5 to 15 percent abstinence from smoking at one year. An even shorter version of this, a "2A and an R" model — Ask, Advise and Refer — has been promoted as the minimal acceptable intervention. Provide or refer those who use tobacco products to evidence-based tobacco cessation interventions including referral to quitlines: • You Can Quit Smoking Now — www.smokefree.gov • www.teenquit.com/QuitLines/index.asp • HHS National Quitline Number (1-800-QUITNOW)

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Immunizations	Assess and offer all clients (as needed) [4, 13, 47, 48]: • **Human papillomavirus (HPV) vaccination** for males aged 11-26 (minimum age 9) [recommendations include starting at age 11-12 year olds and catch up vaccine among males ages 13-21 who have not been vaccinated previously or have not completed the 3-dose series through age 21; males aged 22-26 years may be vaccinated (permissive recommendation for this age group). Routine vaccination is recommended among at risk males, including MSM and immune-compromised males, through age 26 years [49, 50]. • **Hepatitis B vaccination (HBV)** among persons aged <19 years and for all adults who are at risk (as defined by at risk for infection by sexual exposure including MSM; injection-drug users; household contacts of persons with chronic HBV infection; developmentally disabled persons in long-term care facilities; persons at risk for occupational exposure to HBV; hemodialysis patients; persons with chronic liver disease; travelers to HBV-endemic regions; and HIV-positive persons) or who request vaccination. o Anti-HBV testing may be considered among adult men at high risk (e.g., intravenous drug user & MSM) in context of vaccination, but not among adolescents who are asymptomatic for HBV [51]. However, young MSM might require more thorough evaluation. • **Hepatitis A (HAV)** among persons at risk as defined by MSM; users of injection and non-injection drugs; persons who have occupational risk for infection; persons with clotting-factor disorders; vaccination of persons with chronic liver disease; Hepatitis A vaccination during outbreaks; and persons traveling to or working in countries that have high or intermediate endemicity of infection.

Table 2A Detailed Summary of Recommended Service Content, cont.

History	
Depression	Assess adolescents and adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment and follow up [4, 52-55]. • Staff assisted care supports are defined as clinical staff that assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management or mental health treatment. For example, the minimal effective staff supports consisted of a screening nurse who advised primary care clinicians of a positive screen and provided a protocol facilitating referral to behavioral therapy. Assess for risk of suicide among persons reporting symptoms of depression and other risk factors (mania or hypomania, or mixed states especially when complicated by comorbid substance abuse, irritability, agitation, or psychosis; previous suicide attempts; family history of suicide; friends who have committed suicide; access to a gun; history of mood/conduct or psychotic disorders; impulsive behaviors or attention deficit/hyperactivity disorder; concerns about sexual identity; history of physical/sexual abuse) [4, 55-58]. • **Example screening approaches include:** A. Screening for depression in primary care with two verbally asked questions [59] 1. During the past month have you often been bothered by feeling down, depressed, or hopeless? and, 2. During the past month have you often been bothered by little interest or pleasure in doing things? B. Things to watch for when assessing potential risk (P.L.A.I.D. P.A.L.S.) [60]: **P**lan – Do they have one? **L**ethality – Is it lethal? Can they die? **A**vailability – Do they have the means to carry it out? **I**llness – Do they have a mental or physical illness? **D**epression – Chronic or specific incident(s)? **P**revious attempts – How many? How recent? **A**lone – Are they alone? Do they have a support system? Partner? Are they alone right now? **L**oss – Have they suffered a loss? Death, job, relationship, self esteem? **S**ubstance abuse (or use) – Drugs, alcohol, medicine? Current, chronic?

Table 2A Detailed Summary of Recommended Service Content, cont.

Physical Exam	
Height, weight and BMI	Assess all adolescent and adult clients for obesity including measurement of weight, height, and calculation of body mass index (BMI) [4, 61-66]. Obese persons should be offered or referred to intensive counseling and multicomponent behavioral interventions [4, 61, 62, 66].
Blood pressure	Measure blood pressure among adults every 2 years if normal (blood pressure <120/80) and every year if the client has pre-hypertension (blood pressure 120-139/80-89) and in adolescents measure blood pressure annually [4, 20, 67-69].
External genital/ perianal exam	Perform external genital/perianal exam to document normal growth and development and other common genital findings, including hydrocele, varicocele, and signs of STDs [4, 70, 71]. Components of this exam include inspecting skin and hair, palpating inguinal nodes, scrotal contents and penis, and inspecting perinanal region (as indicated, e.g., history of receptive anal sex). Perform a genital exam as part of the evaluation for male infertility [21] including • Examination of the penis; including the location of the urethral meatus; • Palpation of the testes and measurement of their size; • Presence and consistency of both the vas deferens and epididymis; • Presence of a varicocele; • Secondary sex characteristics including body habitus, hair distribution and breast development; and • Digital rectal exam in all men 18 and older if there are signs and symptoms of prostatitis (dysuria, pelvic pain, hematospermia) or ejaculate volume is lower than 1.5 mL. The diagnosis of congenital bilateral absence of the vasa deferentia (CBAVD) is established by physical examination (scrotal exploration is not needed to make this diagnosis).
Laboratory Tests	
Chlamydia	Screen at risk male adolescents and adults under age 25 years for Chlamydia (urine-based nucleic-acid amplification tests (NAATs) is the preferred approach). At risk includes MSM, and specific settings in which to screen males, e.g., adolescent clinics, correctional facilities, STD clinics and high prevalence communities [4, 13, 72-74]. • Additional guidance recommends screening men who are attending National Job Training Program, in military <30 years of age with any lifetime sexual experience, entering jails <30 years of age, entering juvenile facilities, in communities with high Chlamydia prevalence (programs here should consider screening men <25 years of age in emergency departments, attending high school clinics, and attending adolescent clinics) [73]. • Males with Chlamydia infection should be re-screened for reinfection at 3 months. • Screening includes for urethral infection with *C. trachomatis* in men who have had insertive anal intercourse during the preceding year and rectal infection with *C. trachomatis* in men who have had receptive anal intercourse during the preceding year (NAAT of a rectal swab is the preferred approach). • Screening for *C. trachomatis* pharyngeal infection is not recommended.

Table 2A Detailed Summary of Recommended Service Content, cont.

Laboratory Tests	
Gonorrhea	Screen at risk male adolescents and adults for gonorrhea (urine-based nucleic-acid amplification tests (NAATs) is the preferred approach) [4, 13, 74, 75]. At risk populations include MSM. • Males with gonorrhea infection should be re-screened for reinfection at 3 months. • More frequent STD screening (i.e., at 3–6-month intervals) is indicated for MSM who have multiple or anonymous partners. • MSM who have sex in conjunction with illicit drug use (particularly methamphetamine use) or whose sex partners participate in these activities should be screened more frequently. • The following screening tests need to be performed at least annually for sexually active MSM: screen for urethral infection with *N. gonorrhoeae* in men who have had insertive intercourse and screen for rectal infection with *N. gonorrhoeae* in men who have had receptive anal intercourse (NAAT of a rectal swab is the preferred approach); and screen for pharyngeal infection with *N. gonorrhoeae* in men who have had receptive oral intercourse (NAAT is the preferred approach) during the preceding year, respectively.
Syphilis	Screen persons at increased risk for syphilis infection. Populations at increased risk include MSM and men who engage in high-risk sexual behavior such as commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities, and those in high prevalence communities [4, 13, 76]. • Young MSM might require more frequent STD screening based on risky behaviors (i.e., at 3–6-month intervals) as is indicated for MSM who have multiple or anonymous partners. • MSM who have sex in conjunction with illicit drug use (particularly methamphetamine use) or whose sex partners participate in these activities may need to be screened more frequently.
HIV/AIDS	Screen for HIV infection all clients aged 13-64 years and all persons at high risk for HIV should be re-screened at least annually [4, 13, 77-81]. Persons likely to be at high risk include MSM; injection drug users and their sex partners; persons who exchange sex for money or drugs; sex partners of HIV-infected persons; and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. • CDC recommends that screening be provided after the patient is notified that testing will be performed as part of general medical consent unless the patient declines (opt-out screening).

Table 2A Detailed Summary of Recommended Service Content, cont.

Laboratory Tests	
Hepatitis C	Screen for hepatitis C virus (HCV) infection and HCV-related chronic disease by conducting one-time testing without prior ascertainment of HCV risk for persons born during 1945–1965, a population with a disproportionately high prevalence of HCV infection and related disease [82, 83]. Anti-HCV testing is recommended for routine screening of persons at risk for infection or based on a recognized exposure (e.g., MSM, injecting drug user, high risk sexual behavior). Among MSM and intravenous drug users, screening among past or current drug users should include HCV testing [13]. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions.
Diabetes	Screen for diabetes among asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg [20, 84].
Key Sexual and Reproductive Health Counseling	
Condoms with demonstration/practice	Offer male patients to view and practice condom demonstration [4, 13, 85]. • For example, condom demonstration and practice should include steps for putting on (and removing) a condom including 1) pinching the tip of the condom, 2) rolling the condom down to base while leaving the tip pinched, 3) after ejaculation occurs, holding the condom at its base before withdrawing, 4) holding the condom at its tip and base and removing it from the penis, and 5) throwing it away. [86] • Other teachable points include 1) checking the expiration date, 2) checking the package for air bubbles, 3) not opening the package with teeth or a sharp object, 4) using only water-based lubricants with latex condoms, and 5) not using spermicides (e.g., nonoxynol-9) since they can break down latex and increase susceptibility to STDs including HIV. • Other points for discussion for optimal use include partners 1) discussing contraception methods in advance including who will purchase condoms; 2) latex allergies; 3) the type of condom used (ie, latex, polyurethane, lambskin) and condom characteristics (e.g., size, ribbed, lubricated, contain spermicides, etc.) and 4) try different condoms to find the one that fits and feels the best; condoms are available in different sizes and varying thickness.
STD/HIV	Provide high intensity behavioral counseling about STD prevention for all sexually active male adolescents and adult men at increased risk on an annual basis [23]. • For example, this consists of two separate 20-minute clinical sessions 1 week apart. During the first session, a patient is assessed for personal risk, barriers to risk reduction, and a small risk-reduction step within 1 week is identified. During the second session, the prior week's behavioral change successes and barriers are reviewed, support for changes made is provided, barriers and facilitators to change is identified, and a long-term plan for risk-reduction is developed. Provide access to HIV pre-exposure prophylaxis (PREP) and post-exposure prophylaxis (PEP) as appropriate [87, 88].

Table 2A Detailed Summary of Recommended Service Content, cont.

Key Sexual and Reproductive Health Counseling	
Pregnancy prevention including male & female methods & EC	Counsel male patients about male methods (e.g., vasectomy, condoms, withdrawal) & female hormonal contraception methods (e.g., long-acting reversible methods, combination methods and emergency contraception (EC)) and provide EC in advance as allowed by state law [4, 13, 89, 90]. • Work with the client to establish a patient-centered plan for using the contraceptive method(s) of choice including addressing the "4 Cs" (choice, correct use, consistent use, continued use and switching) and effectiveness; understanding side effects; involvement of partner in plan and plan for follow-up. • Promote dual protection for a client who is at risk for contracting an STD (i.e., effective method to prevent pregnancy plus a condom to prevent infection).
Preconception health	Provide support to address males' sexual and reproductive health in their own right that may also otherwise impact future reproductive capacity, to improve health outcomes for males' partners including direct benefits (e.g., decreased infection transmission between partners) and indirect benefits (e.g., shared health practices promoted by the male partner), as critical partners in family planning and to ensure all pregnancies are planned and wanted, and to improve males' capacity for parenting and fathering as well as improved outcomes for their children [20].
Sexuality & relationships	**Sexuality:** Provide support to males who may be dealing with issues of sexuality that can affect their psychosocial and physical health via individual support, support for families, and/or referral to local resources as appropriate [4, 13]. • **An example sexuality assessment tool:** A. Adapted from Helping families with lesbian, gay, bisexual and transgender children [91]: • Have you ever been hit, slapped or physically hurt because of your LGBT identity? • Have you ever experienced verbal harassment or name-calling because of your LGBT identity? • Have you ever been excluded from family events and family activities because of your LGBT identity? • Have you ever been blocked access to LGBT friends, events, and resources? • Have you ever been blamed when you have been discriminated against because of your LGBT identity? • Have you ever been pressured to be more (or less) masculine or feminine? • Have you ever been told that God will punish you because you are gay? • Have you ever been told your family is ashamed of you or that how you look or act will shame the family? • Have you ever been told to keep you LGBT identity a secret in the family and not letting you talk about your identity with others? **Relationships:** Provide support to adolescents in how to have healthy relationships [4]. • **Example assessment approaches include:** A. From Building Healthy Teen Relationships [92]: Friend, girlfriend, or boyfriend – all deserve healthy relationships.

Table 2A Detailed Summary of Recommended Service Content, cont.

Key Sexual and Reproductive Health Counseling	
Sexuality & relationships – *continued*	**Respect.** Are you accepted for who you are? No one should pressure you into doing things you are not comfortable with such as drinking, drugs, or unwanted physical contact. **Safety.** Do you feel emotionally and physically safe? You should feel comfortable being you without fear of being put down. Being hurt or feeling pressured is definitely not safe! **Support.** Do your friends care for you and want what is best for you? Your friends should understand if you can't hang out because you have to study or if you have plans with other friends. **Individuality.** Do you pretend to like something you don't or be someone you aren't? Be yourself; after all, being an individual is what makes you, you! **Equality.** Do you have an equal say in relationships and but equal effort into the relationship? From the activities you do together to the friends you hang out with, you should have equal say in the choices made in relationships. **Acceptance.** Do your friends or girlfriend or boyfriend accept you for who you really are? You shouldn't have to change who you are, or compromise your beliefs to make someone like you. **Honesty and Trust.** Are you always honest? Honesty builds trust. You can't have a healthy relationship without trust! If you have ever caught your friend or boyfriend or girlfriend in a huge lie, you know that it takes time to rebuild trust. **Communication.** Do you talk face to face (nt jst txt!) about your feelings? Listen to one another and hear each other out. Text or Facebook messages should be respectful, not mean or inappropriate. **Signs of Unhealthy Relationships** • Texts you all the time to find out where you are, who you're with, or what you're doing. • Has to be with you all the time. • Doesn't listen to your opinion. • Makes all the decisions in the relationship. • Makes fun of you or puts you down when you are alone or with friends. • Does things to upset you or make you cry. • Wants you to change who you are. • Asks you to give up activities you enjoy. • Won't let you hang with your friends. • Pressures you to do things you are not comfortable with. • Makes you feel guilty, "gets back at you" or punishes you for things you do for yourself. • Threatens to hurt you or him/herself as a way to control you. B. From Stanford University Family Abuse Prevention Council [93]: A healthy relationship is based on caring and respect. Both partners: • Communicate openly. • Trust each other. • Share decisions. • Compromise when there is disagreement. • Take responsibility for their own actions.

Table 2A Detailed Summary of Recommended Service Content, cont.

Key Sexual and Reproductive Health Counseling	
Sexuality & relationships – *continued*	Warning signs of an unhealthy relationship include: • Jealousy, accusing you of things you didn't do. • Making all of the decisions about what to do and where to go. • Not letting you hang out with your friends. • Putting you down in front of other people. • Telling you what to wear or how to act. • Texting and checking up on you all of the time. • Blaming you for problems, guilt trip. • Hitting or hurting. • Threatening you if you try to leave. • Forcing sex, refusing to practice safe sex.
Sexual dysfunction	Provide support based on etiology of sexual problem. Note that sexual dysfunction in men represents a group of common medical conditions that need to be managed from a multidisciplinary perspective. For specific evaluation, treatment guidelines, and algorithms developed for every sexual dysfunction in men, including erectile dysfunction; disorders of libido, orgasm, and ejaculation; Peyronie's disease; and priapism, refer to the following resources [94, 95]: • Montorsi F, Adaikan G, Becher E, et al. Summary of the recommendations on sexual dysfunctions in men. J Sex Med 2010 Nov;7(11):3572-3588. • Montorsi F, Basson R, Adaikan G, et al., eds. Sexual medicine: Sexual dysfunctions in men and women. Paris, France: Editions 21; Co-Sponsored by International Consultation on Urological Diseases (ICUD) and International Society for Sexual Medicine (ISSM); http://www.icud.info, 2010. Note also that erectile dysfunction (ED) can be seen as an early sign of systemic cardiovascular disease and that this can offer an opportunity for prevention, particularly in high-risk and underserved minority populations [24, 25]. • According to the Minority Health Institute (MHI) algorithm, all men 25 years old and older regardless of sexual dysfunction complaints should be asked about ED & the presence of ED should prompt an aggressive assessment for cardiovascular risk and occult systemic vascular disease [24]. • According to the consensus study from the Second Princeton Consensus Conference, its algorithm for evaluation emphasizes the importance of risk factor evaluation and management for all patients with ED based on risk stratification for cardiovascular disease (low, intermediate (including those requiring further evaluation), and high risk) and that increasing evidence supports the role of lifestyle intervention in ED, specifically weight loss & increased physical activity, particularly in patients with ED & concomitant cardiovascular disease [25].

Table 2A Detailed Summary of Recommended Service Content, cont.

Key Sexual and Reproductive Health Counseling	
Infertility	Provide basic infertility services, which include the initial infertility history and physical exam (as described above), and appropriate education and referrals as needed, in accordance with professional recommendations, in male partners of an infertile couple if pregnancy has not occurred within one year of regular unprotected intercourse [21]. • An early evaluation may be warranted if a known male or female infertility risk factor exists or if a man questions his fertility potential as outlined here: – A couple attempting to conceive should have an evaluation for infertility if pregnancy fails to occur within one year of regular unprotected intercourse. – An evaluation should be done before one year if 1. Male infertility risk factors such as a history of bilateral cryptorchidism are known to be present; 2. Female infertility risk factors, including advanced female age (over 35 years), are suspected; or 3. The couple questions the male partner's fertility potential. – Men who question their fertility status despite the absence of a current partner should have an evaluation of their fertility potential. • Counseling and referral provided during the clinical visit should be driven by information elicited from the client during the initial infertility history and physical exam (as described above). • Referral may be needed for further evaluation, including semen analysis (2 specimens), endocrine evaluation for testosterone and Follicle Stimulation Hormone (FSH) levels, or post-ejaculate urinalysis (when the ejaculate volume is less than 1mL). • For patients who fall under the definition above, but are concerned about infertility, if there is no apparent cause, providers should provide education about how to maximize fertility.

Table 2B Frequency for Delivering Recommended Services

Service	To Be Done	Accomplishes This Recommended Practice
History	Every encounter*	• Reproductive life plan • Reason for visit • Standard medical history • Sexual health assessment • Sexual dysfunction • Partner violence • Tobacco, alcohol, drug use
History	At least annually	• Immunizations • Depression
Physical exam	At least annually	• Height, weight, BMI calculation • Blood pressure • Genital exam (among male adolescents)
Laboratory tests	At least annually	• If at risk, STD testing should be considered: – Chlamydia – Gonorrhea – Syphilis – HIV/AIDS – Hepatitis C • If at risk, diabetes testing should be considered
Counseling	Periodicity based on need	• Demonstrate condom/practice • STD/HIV counseling • Pregnancy prevention including male & female methods & EC • Preconception health • Sexuality/relationships • Sexual dysfunction • Infertility

**May be an opportunity to offer these services using clinical judgment*
BMI: body mass index; EC: Emergency Contraception; HIV/AIDS: human immunodeficiency virus/acquired immune deficiency syndrome; SRH: sexual and reproductive health; STD: sexually transmitted disease

Table 3 Checklist and Rationale for Services Not Recommended

Summary of services where evidence supports recommendations AGAINST delivery for males	
History	
Teaching testicular self-exam (TSE)	Not recommended to routinely counsel about testicular self exam for cancer for male adolescents and adults and may cause harm. There is also no evidence that teaching young men how to examine themselves for testicular cancer would improve health outcomes, even among men at high risk, including men with a history of undescended testes or testicular atrophy [96, 97].
Physical exam	
Testicular cancer screen	Not recommended to routinely examine testicles for testicular cancer for asymptomatic male adolescents and adults and may cause harm. However, clinicians should be aware that patients who present with symptoms of testicular cancer are frequently misdiagnosed as having other genital complaints, such as epididymitis, testicular trauma, hydrocele or other benign disorders [96, 97]. Refer to physical examination for recommendations about male genital exam.
Laboratory tests	
Gonorrhea	Not recommended to routinely screen for gonorrhea infection in men and who are at low risk for infection [75].
Hepatitis B	Not recommended to routinely screen the general asymptomatic population for chronic hepatitis B virus infection [51].
Hepatitis C	Not recommended to routinely screen for hepatitis C virus (HCV) in asymptomatic adults who are not born during 1945–1965 and not at increased risk [83].
Herpes Simplex	Not recommended for routine serological screening for herpes simplex virus in asymptomatic adolescents and adults [98]. Young MSM might require more thorough evaluation. Type-specific herpes simplex virus serologic assays might be useful in the following scenarios: 1) recurrent genital symptoms or atypical symptoms with negative herpes simplex virus cultures; 2) a clinical diagnosis of genital herpes without laboratory confirmation; or 3) a partner with genital herpes. herpes simplex virus serologic testing should be considered for persons presenting for an STD evaluation (especially for those persons with multiple sex partners), persons with HIV [13].
Syphilis	Not recommended to routinely screen asymptomatic persons who are not at increased risk for syphilis infection [76].
PSA for Prostate Cancer	Not recommended to use prostate-specific antigen (PSA)-based screening for prostate cancer by the U.S. Preventive Services Task Force [99]. Other organizations make different recommendations [100-104]: • American Urological Association: Recommends using both a prostate-specific antigen (PSA) test and a digital rectal exam routine detection to men aged 40 and older who have a life expectancy of at least 10 years. • American Cancer Society: Recommends starting at age 50 for men at average risk, at age 45 among men at high risk (e.g., African Americans and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer at an early age (younger than age 65)) and age 40 among men at higher risk (e.g., those with several first-degree relatives who had prostate cancer at an early age). ➤

Table 3 Checklist and Rationale for Services Not Recommended, cont.

Laboratory tests	
PSA for Prostate Cancer – *continued*	• American College of Preventive Medicine: Recommends against routine population screening with digital rectal exams and prostate-specific antigen. Men age 50 or older with a life expectancy of greater than 10 years should be given information about the potential benefits and harms of screening and allowed to make their own choice about screening, in consultation with their physician.
Services that are no longer recommended by organizations for males	
Physical exam	
Hernia	No evidence to support routine screening for hernia unless clinically indicated. Evidence does not exist that reviews the harms and benefits to routinely screen for hernia.
Laboratory tests	
Urinalysis	Not recommended for routine screening urinalysis of male clients. Despite an appearance of "lack of guidance" in recommendations for screening for urinalysis in men, all organizations agree that males do not require routine screening for urinalysis which represents an update from older recommendations that did recommend routine screening for a variety of reasons: leukocyte esterase test, kidney function [e.g., protein, red blood cells]) [105].
Hemoglobin/hematocrit	Not recommended for routine screening blood count (hemoglobin/hematocrit) of male clients. Despite an appearance of "lack of guidance" in recommendations for hemoglobin/hematocrit screening for men, all organizations agree that males do not require routine screening for hemoglobin/hematocrit which represents an update from older recommendations that did recommend routine screening.
Services for which evidence is still being accumulated for males	
Laboratory tests	
Trichomonas	Evidence is still being accumulated to determine routine screening for trichomonas for males. Organizations do not review and thus make any recommendations for routine trichomonas screening among males.
Human papillomavirus	Evidence is still being accumulated to determine routine screening for human papillomavirus for males. Organizations do not review and thus make any recommendations for routine human papillomavirus screening among males.
Anal cytology	Evidence is still being accumulated to determine routinely perform anal cytology (Pap smear) for males. Although there may be a role of anal cytology among men who have had receptive anal intercourse; the evidence described as limited. HIV-infected MSM also have increased incidence of anal cancer. Screening for anal cytologic abnormalities among this population can be considered; however, evidence is limited concerning the natural history of anal intraepithelial neoplasias, the reliability of screening methods, the safety and response to treatments, and the programmatic support needed for such a screening activity [13] [106].

References

1. Marcell AV, Waks A, Lindberg LD, et al. Males' sexual and reproductive health needs across the lifespan; under review.
2. Sonfield A. Looking at men's sexual and reproductive health needs. The Guttmacher Report on Public Policy 2002;5(2):7-10.
3. Elster A, Kuzsets N. American Medical Association Guidelines for Adolescent Preventive Services (GAPS). Baltimore, MD: Williams & Wilkins, 1993.
4. Hagan JF, Jr., Shaw JS, Duncan P, et al. Bright Futures: Guidelines for health supervision of infants, children, and adolescents-Third edition. Elk Grove Village, IL: American Academy of Pediatrics, 2008.
5. American Academy of Family Physicians. Adolescent health care, sexuality and contraception 2006. *http://www.aafp.org/about/policies/a-z.html* American Academy of Family Physicians Policies. [accessed June 1, 2013].
6. ACOG Committee on Adolescent Health Care. Tool Kit for Teen Care. Washington, DC: American College of Obstetricians and Gynecology; 2009 Second Edition.
7. IOM (Institute of Medicine). Clinical preventive services for women: Closing the gaps. Report Brief. Washington, DC: The National Academies Press; 2011.
8. Centers for Disease Control and Prevention. Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. Prepared by Gavin L, Moskosky S, Carter M, Curtis K, Glass E, Godfrey E, Marcell AV, Mautone-Smith N, Pazol K, Tepper N, Zapata L. MMWR 2014;63 No. 4;1-54.
9. Marcell AV, Gavin L, Moskoskys, et al. Developing Federal recommendations for providing quality family planning services: Clinical services for men. American Journal of Preventive Medicine; under review.
10. IOM (Institute of Medicine). Clinical practice guidelines we can trust. Washington, DC: The National Academies Press; 2011.
11. ICPD Programme of Action Summary. International Conference on Population and Development Cairo, Egypt: United Nations Department of Public Information; DPI/1618/POP–March 1995, 1994: *http://www.unfpa.org/public/home/sitemap/icpd/International-Conference-on-Population-and-Development/ICPD-Summary.*
12. World Health Organization. Defining sexual health: report of a technical consultation on sexual health, 28-31 January 2002, Geneva. Geneva, Switzerland: WHO Press: *http://www.who.int/reproductivehealth/publications/sexual_health/en/; 2006.*
13. Workowski KA, Berman S. Sexually transmitted diseases treatment guidelines, 2010. MMWR Recomm Rep 2010 Dec 17;59(RR-12):1-110.
14. Atkins D, Eccles M, Flottorp S, et al. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches The GRADE Working Group. BMC Health Serv Res 2004;4(1):38.
15. Grol R. Successes and failures in the implementation of evidence-based guidelines for clinical practice. Med Care 2001 Aug;39(8 Suppl 2):II46-54.
16. Cheung AH, Zuckerbrot RA, Jensen PS, et al. Expert survey for the management of adolescent depression in primary care. Pediatrics 2008 Jan;121(1):e101-107.
17. Bridevaux IP, Silaghi AM, Vader JP, et al. Appropriateness of colorectal cancer screening: appraisal of evidence by experts. Int J Qual Health Care 2006 Jun;18(3):177-182.
18. IOM (Institute of Medicine). The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding. Washington, DC: The National Academies Press; 2011.
19. The Male Training Center for Family Planning and Reproductive Health. Scope of clinical practice state-by-state guidance in provision of services. Philadelphia, PA and Baltimore, MD: AccessMatters and The Johns Hopkins University; 2013. Available at: www.maletrainingcenter.org.
20. Frey KA, Navarro SM, Kotelchuck M, et al. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008 Dec;199(6 Suppl 2): S389-395.
21. American Urological Association Education and Research Inc. The Optimal Evaluation of the Infertile Male: AUA Best Practice Statement. Linthicum, MD: American Urological Association; 2010.
22. Promoting healthy sexual development and sexuality (Bright Future Theme 8). In: Hagan JF, Jr., Shaw JS, Duncan P, eds. Bright Futures: Guidelines for health supervision of infants, children, and adolescents-Third edition. Elk Grove Village, IL: American Academy of Pediatrics, 2008.
23. U.S. Preventive Services Task Force. Behavioral counseling to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Oct 7;149(7): 491-496.

References

24. Billups KL, Bank AJ, Padma-Nathan H, et al. Erectile dysfunction is a marker for cardiovascular disease: results of the minority health institute expert advisory panel. J Sex Med 2005 Jan;2(1):40-52.
25. Kostis JB, Jackson G, Rosen R, et al. Sexual dysfunction and cardiac risk (the Second Princeton Consensus Conference). Am J Cardiol 2005 Jul 15;96(2): 313-321.
26. American Urological Association Board of Directors. Diagnostic evaluation of erectile dysfunction. 2012 [accessed June 1, 2013]; Available from: *http://www.auanet.org/about/policy-statements/evaluation-of-erectile-dysfunction.cfm*
27. Jenny C, Crawford-Jakubiak JE, Committee on Child Abuse and Neglect. American Academy of Pediatrics Clinical Report – The evaluation of children in the primary care setting when sexual abuse is suspected. Pediatrics. 2013 Aug 1 132(2):e558-e567.
28. Hamel J. Toward a gender-inclusive conception of intimate partner violence research and theory: Part 2 – New directions. International Journal of Men's Health 2009;8(1):41-59.
29. Child Welfare Information Gateway. Mandatory reporters of child abuse and neglect: Summary of state laws. Washington, DC: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, U.S. Department of Health and Human Services; *http://www.childwelfare.gov/systemwide/laws_policies/statutes/manda.cfm; 2010.*
30. Rabin RF, Jennings JM, Campbell JC, et al. Intimate partner violence screening tools: a systematic review. Am J Prev Med 2009 May;36(5):439-445 e434.
31. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2013 May 4 [Epub ahead of print].
32. Screening for illicit drug use: U.S. Preventive Services Task Force recommendation statement. AHRQ Publication Number 08-05108-EF-3. Rockville, MD: Agency for Healthcare Research and Quality; *http://www.uspreventiveservicestaskforce.org/uspstf/uspsdrug.htm;* 2008.
33. Kokotailo PK. Alcohol use by youth and adolescents: A pediatric concern. Pediatrics May;125(5):1078-1087.
34. Heyman RB, Anglin TM, Copperman SM, et al. Marijuana: A continuing concern for pediatricians. American Academy of Pediatrics. Committee on Adolescence and Committee on Substance Abuse. Pediatrics 1999;104(4):982-985.
35. Kulig JW. American Academy of Pediatrics. Committee on Substance Abuse. Tobacco, alcohol, and other drugs: The role of the pediatrician in prevention, identification, and management of substance abuse. Pediatrics 2005;115(3):816-821.
36. Williams JF, Storck M, American Academy of Pediatrics. Committee on Adolescence and Committee on Native American Child Health. Inhalant abuse. Pediatrics 2007 May;119(5):1009-1017.
37. Knight JR, Shrier LA, Bravender TD, et al. A new brief screen for adolescent substance abuse. Arch Pediatr Adolesc Med 1999;153(6):591-596.
38. National Institute on Alcohol Abuse and Alcoholism in collaboration with the American Academy of Pediatrics. Alcohol screening and brief intervention for youth. A practitioner's guide. Rockville, MD: National Institute on Alcohol Abuse and Alcoholism; *http://www.niaaa.nih.gov/YouthGuide;* 2011.
39. Moyer VA, U.S. Preventive Services Task Force. Primary care interventions to prevent tobacco use in children and adolescents: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013 Aug 26 [Epub ahead of print].
40. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med 2009 Apr 21;150(8):551-555.
41. Committee on Environmental Health; Committee on Substance Abuse; Committee on Adolescence; Committee on Native American Child. From the American Academy of Pediatrics: Policy statement – Tobacco use: A pediatric disease. Pediatrics 2009 Nov;124(5):1474-1487.
42. American Academy of Nurse Practitioners Practice Committee. Tobacco Use Position Paper. Austin, TX: American Academy of Nurse Practitioners; 2000.
43. Fiore M, Jaen C, Baker T, et al. Treating tobacco use and dependence: 2008 Update. Rockville, MD: US Department of Health and Human Services, 2008:Available online at: *http://www.surgeongeneral.gov/tobacco/index.htm* (accessed June 27, 2011).
44. Novak J, Yousey Y, Jones DC, et al. NAPNAP Position Statement on Prevention of Tobacco Use and Effects in the Pediatric Population. Cherry Hill, NJ: National Association of Pediatric Nurse Practitioners; 2009.

References

45. DiFranza JR, Savageau JA, Fletcher K, et al. Measuring the loss of autonomy over nicotine use in adolescents: the DANDY (Development and Assessment of Nicotine Dependence in Youths) study. Arch Pediatr Adolesc Med 2002 Apr;156(4):397-403.
46. Epps RP, Manley MW. A physician's guide to preventing tobacco use during childhood and adolescence. Rockville, MD: National Cancer Institute; 1990.
47. Koslap-Petraco MB, Tempfer T, Linguiti Pron A. NAPNAP Position Statement on Immunizations. J Pediatr Health Care 2006;20:41A-42A.
48. Advisory Committee for Immunization Practices (ACIP). Vaccine recommendations of the ACIP. Available from: *http://www.cdc.gov/vaccines/acip/index.html* [accessed June 1, 2013].
49. Friedman L, Bell DL, Kahn JA, et al. Human papillomavirus vaccine: An updated position statement of the Society for Adolescent Health and Medicine. J Adolesc Health 2011 Feb;48(2):215-216.
50. Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males - Advisory Committee on Immunization Practices (ACIP), 2011. MMWR Morb Mortal Wkly Rep 2011 Dec 23;60:1705-1708.
51. Screening for Hepatitis B virus infection: U.S. Preventive Services Task Force recommendation statement. Rockville, MD: Agency for Healthcare Research and Quality; *http://www.uspreventiveservicestaskforce.org/uspstf/uspshepb.htm;* 2004.
52. Screening and treatment for major depressive disorder in children and adolescents: U.S. Preventive Services Task Force Recommendation Statement. Pediatrics 2009 Apr;123(4):1223-1228.
53. Screening for depression in adults: U.S. preventive services task force recommendation statement. Ann Intern Med 2009 Dec 1;151(11):784-792.
54. Melnyk B, Baker D, Hawkins Walsh E, et al. NAPNAP Position Statement on Intergration of Mental Health Care in Pediatric Primary Care Settings. J Pediatr Health Care 2007;21:29A-30A.
55. Birmaher B, Brent D, Bernet W, et al. Practice parameter for the assessment and treatment of children and adolescents with depressive disorders. J Am Acad Child Adolesc Psychiatry 2007 Nov;46(11): 1503-1526.
56. Practice parameter for the assessment and treatment of children and adolescents with suicidal behavior. American Academy of Child and Adolescent Psychiatry. J Am Acad Child Adolesc Psychiatry 2001 Jul;40(7 Suppl):24S-51S.
57. Screening for suicide risk: U.S. Preventive Service Task Force recommendation and rationale statement. Ann Intern Med 2004 May 18;140(10):820-821.
58. Shain BN, American Academy of Pediatrics Committee on Adolescence. Suicide and suicide attempts in adolescents. Pediatrics 2007 Sep;120(3):669-676.
59. Arroll B, Khin N, Kerse N. Screening for depression in primary care with two verbally asked questions: cross sectional study. BMJ 2003 Nov 15;327(7424): 1144-1146.
60. San Francisco Suicide Prevention. P.L.A.I.D.P.A.L.S. 2006 [cited June 2012]; Available from: *http://www.sfsuicide.org/prevention-strategies/warning-signs/p-l-a-i-d-p-a-l-s/*
61. Moyer VA, U.S. Preventive Services Task Force. Screening for and management of obesity in adults: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med 2012 Jun 26;157(5): 373-378.
62. Barton M, U.S. Preventive Services Task Force. Screening for obesity in children and adolescents: U.S. Preventive Services Task Force recommendation statement. Pediatrics 2010 Feb;125(2):361-367.
63. Krebs NF, Jacobson MS, Committee on Nutrition. American Academy of Pediatrics. Prevention of pediatric overweight and obesity. Pediatrics 2003 Aug;112(2):424-430.
64. Kohn M, Rees JM, Brill S, et al. Preventing and treating adolescent obesity: A position paper of the Society for Adolescent Medicine. J Adolesc Health 2006 Jun;38(6):784-787.
65. Duderstadt KG, Anderson D, Barber C, et al. NAPNAP position statement on the identification and prevention of overweight and obesity in the pediatric population. J Pediatr Health Care 2009;23:15A-16A.
66. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. Washington, DC: National Heart, Lung and Blood Institute. National Institutes of Health; *http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf;* 1998
67. The fourth report on the diagnosis and evaluation and treatment of high blood pressure in children and adolescents. Pediatrics 2004;114(2):555-576.
68. U.S. Preventive Services Task Force. Screening for high blood pressure: U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med 2007 Dec 4;147(11):783-786.

References

69. National Heart Lung and Blood Institute. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure 2004. *http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf* [Accessed July 7, 2011].
70. Marcell AV, Bell DL, Joffe A. The male genital examination: A position paper of the Society for Adolescent Health and Medicine. J Adolesc Health 2012 Apr;50(4):424-425.
71. Marcell AV, Wibbelsman C, Siegel W, et al. Male adolescent sexual and reproductive health care: Clinical report for the Committee on Adolescence. American Academy of Pediatrics. Pediatrics 2011;128(5):e1-19.
72. U.S. Preventive Services Task Force. Screening for Chlamydial infection: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2007;147(2):128-134.
73. Division of STD Prevention. Male Chlamydia Screening Consultation. Atlanta, Georgia: National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. U.S. Centers for Disease Control and Prevention, 2006: *http://www.cdc.gov/std/chlamydia/*.
74. Burstein GR, Eliscu A, Ford K, et al. Expedited partner therapy for adolescents diagnosed with chlamydia or gonorrhea: a position paper of the Society for Adolescent Medicine. J Adolesc Health 2009 Sep;45(3):303-309.
75. U.S. Preventive Services Task Force. Screening for gonorrhea: U.S. Preventive Service Task Force recommendation statement. Ann Fam Med 2005 May-Jun;3(3):263-267.
76. Calonge N. Screening for syphilis infection: U.S. Preventive Service Task Force recommendation statement. Ann Fam Med 2004;2(4):362-365.
77. Moyer VA, U.S. Preventive Services Task Force. Screening for HIV: U.S. Preventive Service Task Force recommendation statement. Ann Intern Med 2013 Apr 30 [Epub ahead of print].
78. Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR 2006;55(No. RR-14):1-17.
79. Adolescents and human immunodeficiency virus infection: the role of the pediatrician in prevention and intervention. Committee on Pediatric AIDS and Committee on Adolescence. American Academy of Pedistrics. Pediatrics 2001 Jan;107(1):188-190.
80. D'Angelo LJ, Samples C, Rogers AS, et al. HIV infection and AIDS in adolescents: an update of the position of the Society for Adolescent Medicine. J Adolesc Health 2006 Jan;38(1):88-91.
81. Qaseem A, Snow V, Shekelle P, et al. Screening for HIV in health care settings: A guidance statement from the American College of Physicians and HIV Medicine Association. Ann Intern Med 2009 Jan 20;150(2): 125-131.
82. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. MMWR Recomm Rep 2012 Aug 17;61(RR-4):1-32.
83. Moyer VA, U.S. Preventive Services Task Force. Screening for Hepatitis C virus infection in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013 June 25 [Epub ahead of print].
84. U.S. Preventive Services Task Force. Screening for type 2 diabetes mellitus in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Jun 3;148(11):846-854.
85. Marcell AV, Esterline K, Rompalo A, et al. Effectiveness of condom demonstrations to increase condom use and decrease negative sexual and reproductive health outcomes among males in clinical settings; under review.
86. Oberne A, McDermott RJ. How many steps does it take to put on a condom? A commentary. J Sch Health. 2010;80(5):211-3.
87. Interim Guidance for Clinicians Considering the Use of Preexposure Prophylaxis for the Prevention of HIV Infection in Heterosexually Active Adults. MMWR Morb Mortal Wkly Rep 2012 Aug 10;61:586-589.
88. Smith DK, Grohskopf LA, Black RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR Recomm Rep 2005 Jan 21;54(RR-2):1-20.
89. American Urological Association. Vasectomy: AUA Guideline. Linthicum, MD: American Urological Association; 2012.
90. Marcell AV, Waks A, Rompalo A, et al. What do we know about males and emergency contraception? A synthesis of the literature. Perspectives on Sexual and Reproductive Health 2012;44(3):184-193.

References

91. Ryan C. Supportive families, healthy children: Helping families with lesbian, gay, bisexual and transgender children. San Francisco, CA: Marian Wright Education Institute, San Francisco State University. familyproject.sfsu.edu, 2009.
92. Building healthy teen relationships Boise, ID: Idaho Coalition Against Sexual and Domestic Violence; *http://idvsa.org/;* and *http://lovewhatsreal.com/* Accessed 9/10/12.
93. Healthy teen relationships. Palo Alto, CA: Stanford University Family Abuse Prevention Council; *http://domesticabuse.stanford.edu/documents/Teen%20healthy%20relationships.pdf* Accessed 9/10/12.
94. Montorosi F, Basson R, Adaikan G, et al., eds. Sexual medicine: Sexual dysfunctions in men and women. Paris, France: Editions 21; Co-Sponsored by International Consultation on Urological Diseases (ICUD) and International Society for Sexual Medicine (ISSM); *http://www.icud.info/sexualmedicine2010.html,* 2010.
95. Montorsi F, Adaikan G, Becher E, et al. Summary of the recommendations on sexual dysfunctions in men. J Sex Med 2010 Nov;7(11):3572-3588.
96. U.S. Preventive Services Task Force. Screening for testicular cancer: U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med 2011 Apr 5;154(7):483-486.
97. American Cancer Society. Detailed guide: Testicular cancer: Can testicular cancer be found early?: American Cancer Society; *http://www.cancer.org/Cancer/TesticularCancer/DetailedGuide/;* 2011.
98. Screening for Genital Herpes: U.S. Preventive Services Task Force recommendation statement. Rockville, MD: Agency for Healthcare Research and Quality; *http://www.uspreventiveservicestaskforce.org/uspstf/uspsherp.htm;* 2005.
99. Moyer VA. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2012 Jul 17;157(2): 120-134.
100. Chou R, Croswell JM, Dana T, et al. Screening for prostate cancer: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2011 Dec 6;155(11):762-771.
101. American College of Preventive Medicine. Clinical Preventive Services. [cited June 4, 2011]; Available from: *http://www.acpm.org/?page=Policy_Statements*
102. Ferrini R, Woolf SH. American College of Preventive Medicine practice policy. Screening for prostate cancer in American men. Am J Prev Med 1998 Jul;15(1): 81-84.
103. American Cancer Society. Recommendations for prostate cancer early detection. 2010 Revised: 12/01/2010 [cited 2011 March 22]; Available from: *http://www.cancer.org/Cancer/ProstateCancer/MoreInformation/ProstateCancerEarlyDetection/*
104. American Urological Association Board of Directors. Early detection of prostate cancer: *http://www.auanet.org/about/policy-statements/early-detection-of-prostate-cancer.cfm;* 2013.
105. Lin K, Fajardo K. Screening for asymptomatic bacteriuria in adults: evidence for the U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med 2008 Jul 1;149(1): W20-24.
106. American Cancer Society. Anal Cancer. 2010 Revised: 12/22/2010 [cited 2011 March 22]; Available from: *http://www.cancer.org/Cancer/AnalCancer/DetailedGuide/index.htm*

Appendix 1 Professional Organizations Included in the Final Review

American Academy of Child and Adolescent Psychiatry (AACAP)	www.aacap.org
American Academy of Family Physicians (AAFP)	www.aafp.org
American Academy of Nurse Practitioners (AANP)	www.aanp.org
American Academy of Pediatrics (AAP)	www.aap.org; brightfutures.aap.org
American Cancer Society (ACS)	www.cancer.org
American College of Physicians/ American Society of Internal Medicine (ACP)	www.acponline.org
American College of Preventive Medicine (ACPM)	www.acpm.org
American Diabetes Association (ADA)	www.diabetes.org; professional.diabetes.org
American Heart Association (AHA)	www.heart.org
American Medical Association (AMA)	www.ama-assn.org
American Society for Reproductive Medicine (ASRM)	www.asrm.org
American Urological Association (AUA)	www.auanet.org
Centers for Disease Control and Prevention (CDC)	
• HIV/AIDS	www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
• Immunization	www.cdc.gov/vaccines/acip/index.html
• STD treatment	www.cdc.gov/std/dstdp; www.cdc.gov/std/treatment/2010/STD-Treatment-2010-RR5912.pdf
• Select Panel on Preconception Care	www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm
Family Violence Prevention Fund – Futures Without Violence (FVPF)	www.futureswithoutviolence.org/section/aboutus
National Association of Pediatric Nurse Practitioners (NAPNAP)	www.napnap.org
National Heart, Lung, and Blood Institute (NHLBI)	www.nhlbi.nih.gov
Society for Adolescent Health and Medicine (SAHM)	www.adolescenthealth.org
U.S. Public Health Service (USPHS)	www.usphs.gov
U.S. Preventive Services Task Force (USPSTF)	www.uspreventiveservicestaskforce.org

Appendix 2 Male Training Center's Staff, Technical Panel, Advisory Committee & Other Contributors for Feedback on Men's Clinical Services

Male Training Center

AccessMatters (formerly Family Planning Council)

Robert McKenna, MS, MCHES, PhD, Director/MTC Co-Principle Investigator

Daryn Eikner, MS, Director of Service Improvement

Shelley Miller, MA, Deputy Director of Training & Performance Improvement

The Johns Hopkins University

Anne Rompalo, MD, ScM, Medical Director/Co-Principle Investigator

Arik V. Marcell, MD, MPH, Associate Medical Director/Co-Principle Investigator

M. Terry Hogan, MPH, Program Administrator

Men's Health Technical Panel

David Bell, MD, MPH, Assistant Professor, Columbia University

Willard Cates, MD, MPH, President of Research, Family Health International and Professor University of North Carolina, Chapel Hill

Linda Creegan, MS, FNP, Clinical Training Coordinator, California STD/HIV Prevention Training Center

Dennis Fortenberry, MD, MS, Associate Professor, Indiana University School of Medicine

Robert Garofalo, MD, MPH, Associate Professor, Children's Memorial Hospital, Northwestern University

Wendy Grube, PhD, CRNP, Practice Assistant Professor, University of Pennsylvania School of Nursing

Robert L. Johnson, MD, FAAP, Professor and Dean, New Jersey Medical School

Arik V. Marcell, MD, MPH, FAAP, Associate Professor, Johns Hopkins School of Medicine*

Demetrius Porche, DNS, APRN, PhD, FAANP, Dean, Louisiana State University Health Sciences Center School of Nursing

Anne Rompalo, MD, ScM, Associate Professor, Johns Hopkins School of Medicine

Jacki Witt, JD, MSN, RNC, WHNP, CNM, Project Director, Clinical Training Center for Family Planning, University of Missouri, Kansas City

Thomas Walsh, MD, Assistant Professor of Urology, University of Washington Medical Center

Sandra Wolf, MD, Associate Professor, Drexel University School of Medicine

**Chair*

Male Training Center Advisory Committee

Alfonso Carlon, Project Director, Cardea Services

Clare Coleman, President & CEO, National Family Planning and Reproductive Health Association

Dana Cropper Williams, MPA, MHR, Training Director, National Coalition of STD Directors

Nancy Keohane, RNC MSN OGNP, Virginia Department of Health, Family Planning Program Manager, State Family Planning Administrators

Patricia Paluzzi, CNM, DrPH, President, CEO, Healthy Teen Network

Demetrius Porche, DNS, APRN, PhD, FAANP, Dean, Louisiana State University Health Sciences Center School of Nursing

Sandy Rice, MEd, Vice President/Project Director, Cardea Services

Adam Sonfield, MPP, Senior Public Policy Associate, Guttmacher Institute

Erik Vecere, Vice President of National Programming, National Fatherhood Initiative

Gayla Winston, MPH, President, Family Planning Councils of America, Inc.

Sandy Worthington, MSN, WHNP-BC, CNM, Director of Medical Continuing Education and Special Projects, Planned Parenthood Federation of America

Appendix 2 Male Training Center's Staff, Technical Panel, Advisory Committee & Other Contributors for Feedback on Men's Clinical Services, cont.

Office of Population Affairs

Marilyn Keefe, MPH, Deputy Assistant Secretary for Population Affairs
Susan Moskosky, MS, RNC, Deputy Director
David Johnson, MPH, Public Health Advisor

Centers for Disease Control

Lorrie Gavin, PhD, Division of Reproductive Health, CDC
Naomi Tepper, MD, MPH, Division of Reproductive Health, CDC
Dmitry Kissin, MD, MPH, Division of Reproductive Health, CDC
Elissa Meites, MD, MPH, Division of STD Prevention, CDC
Emily Godfrey, MD, MPH, Associate Professor, University of Illinois at Chicago and Fellow, CDC

Any disclosures from participants are available upon request

About the Male Training Center

The purpose of the Male Training Center is to help improve delivery of family planning and reproductive health services for males in Title X, and other sexual and reproductive health, and social service settings. The Male Training Center has five major aims designed to make information, resources, and learning opportunities accessible for staff working in Title X services: 1) national partnership building; 2) development, compilation, coordination, and dissemination of training information; 3) design and facilitation of training events; 4) translating research into practice; and 5) capacity building of Title X training, research, and service grantees.

Established in 2009, the Male Training Center is a project of AccessMatters, formerly Family Planning Council, and a collaboration with the Johns Hopkins University School of Medicine, Center for Sexually Transmitted Disease and Reproductive Health Research, Prevention, and Training.

The Male Training Center seeks guidance and input into project activities from its advisory committee members, consisting of individuals representing international, national, and regional organizations with shared interest in quality family planning and reproductive health services for males.

The Male Training Center was originally funded through a cooperative agreement (FPTPA006011) with the Office of Population Affairs, Department of Health and Human Services from September 2009 through December 2012. Although this funding has ended, the Male Training Center is committed to continuing its work to improve the delivery of services to males in all settings.

For more information contact:

Male Training Center
c/o AccessMatters
1700 Market Street, 18th Floor
Philadelphia, PA 19103
Tel: +1 (215) 985-2600 x2659
Email: info@maletrainingcenter.org
http://www.maletrainingcenter.org/

About Arik V. Marcell, MD, MPH

Dr. Marcell is an Associate Professor with a primary appointment in the Johns Hopkins University School of Medicine's Department of Pediatrics and a joint appointment in the Bloomberg School of Public Health's Department of Population, Family and Reproductive Health. He is a board certified pediatrician and adolescent medicine specialist. Dr. Marcell is a nationally recognized expert in male adolescent and young adult health. He has extensive experience training health professionals on the delivery of male sexual and reproductive health care and conducting theory-driven research designed to better understand and improve adolescent and young adult males' involvement in sexual and reproductive health care.

Notes

MALE TRAINING CENTER

FOR FAMILY PLANNING & REPRODUCTIVE HEALTH

Checklist for Required Annual Trainings and Certifications for Title X

****All staff must complete the Title X Orientation FP 101 and FP 201 within 6 months of hire****

****See IDPH FP Policy Manual for required content****

Topic	Completed/date
Title X FP Manual location and use	
Prohibition against abortion **(IDPH policy 238)**	
Voluntary Participation **(IDPH policy 205) Voluntary participation signature form** 1. Sub-recipient staff has been formally notified annually that services must be provided on a voluntary basis, the acceptance of family planning services cannot be a prerequisite for other services and staff has been informed on an annual basis that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure.	
Conflict of Interest **(IDPH policy 207) Conflict of Interest signature form**	
Non-discrimination **(IDPH policy 203, 204)**	
Human Trafficking **(IDPH policy 234)**	
Child and Sexual Abuse reporting (as required by Iowa law, reminded annually) **(IDPH policy 230)**	
Eligibility **(IDPH policy 203)** 1. Any client requesting family planning services is eligible. No person shall be denied services due to inability to pay. 2. Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(a)(5)).	
Confidentiality **(IDPH policy 206)**	
Interpreter policy **(IDPH policy 232, 203, 204)**	
Required adolescent counseling **(IDPH policy 303)** 1. Regarding their decision to be sexually active; 2. All clients under the age of 18 will be encouraged to talk with their parents/guardian or a trusted adult about their decision to seek family planning services. Resources should be provided to parents and guardians to assist them in these discussions. (Family Involvement) 3. Regarding resisting coercive sexual activity, sexual violence and human trafficking. 4. Abstinence as an acceptable birth control method, including alternative methods of sexual expression. 5. Comprehensive information about how to prevent pregnancy and STDs 6. Confidentiality and any limitations but that parents or guardians cannot be notified before or after a minor has requested or received Title X services without written consent. Parental consent for treatment will not be required for adolescent services.	

Referrals for Home Visitation: **(IDPH policy 303)** 1. All Iowa Department of Public Health Family Planning Contract agencies will have policies and provide appropriate referrals to youth, including but not limited to, referrals of pregnant and parenting youth to home visitation programs in their area.	
Pregnancy testing **(IDPH policy 304)** 1. Clients requesting information on options for the management of unintended pregnancy must be given non-directive counseling on prenatal care, delivery, infant care, foster care, adoption, and pregnancy termination. The agency must provide this information and counseling with the exception of any options about which the pregnant woman indicates she does not wish to receive information. 2. Clients, who, after counseling, desire termination, must be provided information for referral to a resource where termination may be obtained. If the client requests an abortion referral, the counselor may not take further affirmative action (such as negotiating a fee reduction, making an appointment, or providing transportation).	
Cultural competency **(IDPH policy 232, 204, 203, 225)** Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).	
Emergency management **(IDPH policy 233)** A written plan of action for the management of emergencies (29CFR 1910. Subpart E) and clinic facilities must meet applicable standards established by Federal, State and local governments (fide, building and licensing codes)	

Implementation, Evaluation and Monitoring Template

This document discusses the implementation and evaluation plan for the IDPH Title X Family Planning Project.

Program Requirements Section	Implementation and evaluation strategy
Section 7: Use of Grant Funds All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. The Notice of Award (NOA) provides other stipulations regarding the use of funds. Funds must be used in accordance with the Title X family planning services projects regulations, the terms and conditions of the award, and the HHS grants administration regulations set out at 45 CFR parts 74 and 92.	Implementation: IDPH will have policies directing the use of funds, specific stipulations in the NOA and the budgeting process. IDPH sub-recipients will have policies on the use of grant funds, and restriction on abortion and lobbying activities Evidence: 1) Policies are audited at site visits or at the time of submission to IDPH (See Appendix 4,6,8) 2) Evidence that the policies are followed are present in fiscal audits, or are observed at the time of site visits. **IDPH Policy: 103, 402**
Section 8.1 Voluntary Participation Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)). A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).	Implementation: IDPH and sub-recipients will have policies (i.e., staff training, clinical protocols, and consent forms) that ensure clients receive services on a voluntary basis. Client's receipt of services cannot be a prerequisite to eligibility for, receipt of any other services, assistance or participation in any other program offered by sub-recipient or IDPH. IDPH has written policies and procedures that require their service sites and sub-recipients to inform staff that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure. Evidence: 1) IDPH has written policies and procedures that specify services are provided on a voluntary basis. IDPH will

DRAFT

	monitor sub-recipient policies and procedures to assure that all sub-recipients provide services solely on a voluntary basis. 2) Documentation (e.g., staff circulars, training curriculum and records) shows sub-recipient and IDPH staff has been formally informed on an annual basis that services must be provided on a voluntary basis, the acceptance of family planning services cannot be a prerequisite for other services and staff has been informed on an annual basis that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure. Signed acknowledgement is present in personal files. 3) Clinical protocols include a written statement that clients may not be coerced to use contraception, or to use any particular method of contraception. 4) General consent forms state that services are provided on a voluntary basis and the receipt of FP services is not a prerequisite to receiving other services. . 5) Medical chart review demonstrates that each client has signed a general consent form stating services are voluntary. 6) Observation of counseling process demonstrates that it is client- centered (see Appendix D of QFP), participation in the program is voluntary and clients are not coerced to use any particular method of contraception. **IDPH Policy: 205**

DRAFT

8.2 Prohibition Against Abortion Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Grantees and sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning. Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled Provision of Abortion-Related Services in Family Planning Services Projects, which is available at 65 Fed. Reg. 41281 and the final rule entitled Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, which is available at 65 Fed. Reg. 41270. Grantees are also responsible for monitoring sub-recipients' compliance with this section.	Implementation: IDPH and sub-recipients have polices that contain language on Section 1008 prohibiting abortion as a method of contraception. IDPH and sub-recipient contracts have polices that contain language on Section 1008 prohibiting abortion as a method of contraception. Evidence: 1) IDPH has certified compliance with this requirement as part of the grant application. 2) IDPH has written policies and procedures that prohibit sub-recipients and/or service sites from providing abortion. 3) IDPH includes language in sub-recipient contracts addressing this requirement. 4) Financial evidence demonstrates that Title X funds are not being used for abortion services and adequate separation exists between Title X and non-Title X activities. **IDPH Policy: 238**
8.3.1 Structure and Management The grantee must have a written agreement with each sub-recipient and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Title X Program Requirements, as well as other applicable requirements (45 CFR parts 74 and 92).	Implementation: IDPH will establish a written contract with all sub-recipient agencies as the result of the competitive bid process. IDPH FP Manual will establish written guidelines and standards for all delegated project activities that are consistent with the QFP and Program Requirements for Title X Funded Family Planning Projects. Evidence: 1) Written contracts are executed 2) IDPH FP Manual is current **IDPH Policy: 220; Sub-recipient contract; Title X RFP**

DRAFT

8.3.2 Structure and Management If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by the grantee must be maintained by the sub-recipient (45 CFR parts 74 and 92).	Implementation: IDPH policies and contract requires any sub recipient that wished to further subcontract to have a written contract with its subcontractor and that subcontractors are aware of Title X requirements and are carrying out the scope of the sub-contract in accordance with Title X requirements. IDPH contract states that IDPH must approve all subcontracts prior to execution. Evidence: 1) Evidence of appropriate language in contracts 2) Evidence of approval of all subcontracts by IDPH staff. 3) Documentation demonstrates that the grantee assures that a plan for monitoring the entity for compliance with Title X requirements is in place. **IDPH Policy: 220**
8.3.3 Structure and Management The grantee must ensure that all services purchased for project participants will be authorized by the project director or his designee on the project staff (42 CFR 59.5(b)(7)).	Implementation/Evidence: There are written polices for approval processes for participants showing that the authorizing official is the project director or a designee. Sub-recipient agencies have written policies for approval processes for purchases for the project participants. **IDPH Policy: 103**

DRAFT

8.3.4 Structure and Management The grantee must ensure that services provided through a contract or other similar arrangements are paid for under agreements that include a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary (42 CFR 59.5(b)(9)).	Implementation: IDPH has polices that address the sub-recipient responsibilities in establishing a schedule of discounts (fee schedule). IDPH contract requires annual cost analysis to assure the rates are reasonable and necessary. Evidence: 1) Cost analyses are reviewed and feedback is given on annual cost analysis. 2) Evidence that each sub-recipient has submitted the schedule of discounts and FP Client Income Schedule as required by their contract. **IDPH Policy: 210, 211**
8.3.5 Structure and Management Sub-recipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5 (a)(10)).	Implementation: IDPH provides opportunity for sub-recipient agencies to participate in IDPH policies and guidelines through the Medical Advisory Committee, the FP Directors group, and the Training Advisory Committee (TAC). The TAC meets regularly, the FP Directors meet 3 times per year and the MAC meets at least annually. Not all meetings are in person, some are done by conference call or virtual meeting. Evidence: 1) Meeting summaries and/or minutes are available from all committee meetings. Actions are clearly described when they occur. **IDPH Policy: 214,217,220,227**

DRAFT

8.3.6 Financial Management System The grantee and each sub-recipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures must be maintained as required (45 CFR parts 74.20 and 92.20).	Implementation: IDPH procedures and policies will reflect federal regulations as applicable. IDPH sub-recipients procedures and policies will be supported by federal regulations. Evidence Includes: 1) IDPH and sub-recipients will have written financial management policies and procedures for the Title X project. 2) Sub-recipients will submit monthly expenditure reports and monthly income reports into Iowagrants.gov. 3) Sub-recipients will submit the results of an independent audit conducted annually. 4) Records are retained per IDPH protocol. 5) Audits evidence procedures and policies are followed. **IDPH Policy: 201, NOA, RFP, Sub-recipient contracts**
8.4.1 Charges, billing and collections Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)). If the sub-recipient has lawful access to other valid means of income verification because of the client's participation in another program the sub-recipient may use those data rather than re-verify income or rely solely on client's self-report.	Implementation: IDPH and sub-recipient agencies will have written policies and procedures for establishing charges, processing billing and collecting accounts. Evidence Includes: 1) IDPH and sub-recipient policies and procedures assure that clients whose documented income is at or below 100% FPL are not charged for services. 2) IDPH assures that project sites have current information on the Federal Poverty Guidelines. 3) Income determination is completed for each client, regardless of potential payer source. 4) Financial documentation indicates clients whose document income is at or below 100% FPL are not charged for services 5) Financial documentation indicates that projects

DRAFT

	determine if a third party is authorized or legally obligated to pay for services, and third parties are billed as appropriate. **IDPH Policy: 210, Audit tool**
8.4.2 Charges, billing and collections Schedule of Discounts A schedule of discounts, based on ability to pay, is required for individuals with family incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).	Implementation: IDPH policies and procedures require sub-recipients to have policies and procedures to outline a schedule of discounts to be developed annually and updated periodically to reflect discounts, and include the rationale used to justify that the client's ability to pay is considered. Evidence: 1) The schedule of discounts and fee schedules are submitted to IDPH annually and when updated for approval. 2) The schedule of discounts must have at least 4 proportional incremental categories. 3) Sub-recipient service site documentation indicates client income is assessed and discounts are appropriately applied to the cost of services **IDPH Policy: 210, Sub-recipient contract, RFP/RFA**
8.4.3 Charges, billing and collections Waiving of fees for good cause: Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).	Implementation: IDPH policies and procedures require sub-recipients to have policies and procedures to outline how fees can be waived for good cause, including who has the authority to waive those fees. Evidence: 1) Sub-recipients have a written policy on waived fees 2) Documentation onsite demonstrates determination of waived fees is made by the appropriate personnel, documented and the client is informed of the decision.

DRAFT

	IDPH Policy: 210

8.4.4 Charges, billing and collections For persons whose income exceeds 250% of the FPL, charges are made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).	Implementation: IDPH policy requires sub-recipients to have written policies complying with the IDPH policy. Evidence: 1) Sub-recipients have written policies in place describing billing processes for persons with family incomes above 250% FPL. 2) Documentation onsite demonstrates determination appropriate placement on the schedule of discounts and correct application of fees. 3) Cost analysis is used to determine the fee schedule to clients above 250% FLP. **IDPH Policy: 210, 211**
8.4.5 Income of minors Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2).	Implementation: IDPH policy will require sub-recipients to implement policy that eligibility discounts for unemancipated minors who receive confidential services must be based on the income of the minor Evidence: 1) Sub-recipient policies are in place 2) Documentation demonstrates onsite that the policy is correctly implemented. **IDPH Policy: 211**
8.4.6 Third Party Liability Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all	Implementation: IDPH and sub-recipient policy assures all reasonable efforts are made to obtain payment from third party payers prior to any discounts. An exception is required for confidential clients.

DRAFT

reasonable efforts must be made to obtain third party payment without the application of any discounts (42 CFR 59.5(a)(9)). Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. 1)	Evidence: 2) IDPH sub-recipients obtain contracts and credential providers with third party payers 3) IDPH Sub-recipients obtain contracts and credential providers with Medicaid. 4) IDPH sub-recipients appropriate file claims without applying any discounts to third party payers except where required (i.e. Medicaid 340B drugs) 5) Documentation on site demonstrates that confidential clients do not have claims submitted to third party payers 6) Policy and practice demonstrates that insured clients whose family income is at or below 250% FPL do not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. **IDPH Policy: 210**
8.4.7 Medicaid participation Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or sub-recipient agency is required (42 CFR 59.5(a)(9)]	Implementation: IDPH policy requires all sub-recipients to have policy and practices to participate with Iowa Medicaid. IDPH sub-recipients should also contract with other state Medicaid agencies when appropriate. Evidence: 1) Sub-recipients have signed agreements with Medicaid 2) Documentation and audits demonstrate that sub-recipients follow all Iowa Medicaid Enterprise billing practices. **IDPH Policy: 210**
8.4.8 Collections	Implementation: IDPH policy requires sub-recipients to have policy and practice about collection procedures that

DRAFT

Reasonable efforts to collect charges without jeopardizing client confidentiality must be made	protect confidential clients and are applied uniformly. Sub-recipient agencies may use collection agencies. Written policy must be submitted to IDPH for approval prior to implementation. Evidence: 1) Evidence on site demonstrates that sub-recipients have written, approved policies for collection of fees and the policy is being followed. **IDPH Policy: 210**
8.4.9 Donations Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies	Implementation: IDPH policy requires sub-recipients requesting donations to have written policy. Donations must be voluntary, clients must not be pressured to make donation and donations may not be a prerequisite to receiving services. Evidence: 1) IDPH sub-recipients have written policy on donation that adheres to IDPH policy. 2) Evidence exists that the policy is followed. Onsite documentation and observation may include signage, financial counseling scripts, or other evidence that demonstrates clients are not pressured to make donations and that donations are not a prerequisite to the provision of services or supplies. **IDPH Policy: 210**
8.5.1 Project Personnel Grantees and sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the	Implementation: IDPH and sub-recipient policies and procedures provide evidence that there is no discrimination in personnel administration. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination,

DRAFT

Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language.	compensation, benefits, and grievance procedures. Evidence: 1) IDPH and sub-recipient policies are in place that adhere to applicable state and federal requirements. 2) Evidence exists that personnel policies are readily available to all Title X staff. **IDPH Policy: 213**
8.5.2 Project staff Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).	Implementation: IDPH and sub-recipient policies document how the project operationalizes cultural competency. Evidence: 1) Records document cultural competence training, in-services, client satisfaction surveys. 2) IDPH procedures demonstrate how the IDPH will assure cultural competency training has occurred at sub-recipient agency sites. 3) Grantee IDPH will monitor how service-sites access language translation services when appropriate as part of the annual site visit. **IDPH Policy: 213**
8.5.3 Project director Projects must be administered by a qualified project director. Change in Status, including Absence of Principle Investigator/Project Director and Other Key Personnel requires pre-approval by the Office of Grants Management. For more information, see HHS Grants Policy Statement, 2007 Section II-54.	Implementation/Evidence Includes: 1) The approved grant application includes required information for the project director. 2) Any changes in project director are submitted to and approved by the Office of Grants Management within 10 days of changes. 3) Review of project director resume lists qualifications. 4) IDPH requires sub-recipients to notify IDPH in writing of changes within 10 days of changes to key personnel.

DRAFT

	IDPH Policy: 213, Contract
8.5.4 Medical Director Projects must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6))	Implementation: IDPH and sub-recipient policies document the presence of a physician with training or experience in family planning to direct clinical practice. Evidence: 1) Organizational charts demonstrate that the project operates under the direction of a physician 2) Curriculum vitae of Medical Director indicates special training or experience in family planning 3) Minutes indicate involvement of the Medical Director in program operations 4) IDPH has a MOA with the IDPH FP Medical Director 5) Sub-recipient agencies demonstrate an MOA/MOU, contract or agreement with their FP Medical Director. **IDPH Policy: 213, 222**
8.5.5 Salary limits Appropriate salary limits will apply as required by law.	Evidence: 1) Documentation such as budgets and payroll records that indicate that the grantee is complying with required salary limits. **IDPH Policy: 103**
8.6.1 Staff Training Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).	Implementation: IDPH policy will provide clear guidance on orientation of all staff to Title X. IDPH, in collaboration with FPCI will provide opportunity for all staff to be trained on emerging issues and best practices through the training advisory committee. Evidence Includes: 1) IDPH records demonstrate the assessment(s) of staff training needs and a training plan that addresses key components of the Title X program priority areas. If a

DRAFT

	sub-recipient sub-contracts for services, the IDPH ensures that sub-recipients maintain a training plan that complies with this section. 2) IDPH maintains documentation of in-service and assured that sub-recipient maintains training attendance records 3) IDPH documentation demonstrates that oversight of sub-recipient training plans and activities during site visits. **IDPH Policy: 104, 105, 106, 107**
8.6.2 Staff training The project's training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking	Implementation: IDPH policies will require all sub-recipients to train on the Federal/State requirements for reporting or notification of child abuse, sexual abuse, rape or incest and human trafficking Evidence: 1) Sub-recipient personnel files contain record of the required trainings. IDPH monitors personnel records during site visits. **IDPH Policy: 215, 230, 234**
8.6.3 Family Involvement The project's training plan should provide for routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.	Implementation: IDPH policies will require all sub-recipients to train on the involving family members in the decision of minors to seek services and on counseling minors on how to resist sexual coercion and/or birth control sabotage. Evidence: 1) Sub-recipients will document in personnel files that all staff are reminded annually about this requirement. **IDPH Policy: 215, 303**

DRAFT

8.7 Planning and Evaluation Grantees must ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)).	Implementation: IDPH's project records include the results of at least one needs assessment used to develop the funding application. Written goals and objectives will reflect the results of the needs assessment. IDPH project includes a plan for monitoring the delivery of all services as described in the QFP, and compare actual activities to those proposed in the project application. Evidence: 1) IDPH will collect and submit data for the Family Planning Annual Report (FPAR) in a timely, complete and accurate manner 2) IDPH will document the use of ongoing (i.e., at least annually) quality improvement processes of all service sites and documents steps taken in response to any findings. 3) IDPH assures sub-recipients compile and report FPAR data in a timely, complete and accurate manner 4) IDPH requires client satisfaction surveys and cost analysis to be submitted annually and evaluates the impacts of the program through performance measures. 5) IDPH has monitoring tools to show actual outcomes and compliance with Title X requirements. 6) Sub-recipient agencies use Health Information Technology **IDPH Policy: 401, 403**
9.1 Priority for project services is to persons from low- income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).	Implementation: IDPH funding application identifies priority populations including low income families. Evidence: 1) FPAR data demonstrates the IDPH priority population. 2) Sub-recipients submit outreach reports that indicate

DRAFT

	outreach occurred in low income and hard to reach population settings. 3) Sub-recipient sites are located in areas that are easily accessible by the priority populations. **IDPH Policy: 201, 202, 203, 217**
9.2 Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).	Implementation: IDPH has written policies and procedures that require their sites and sub-recipients to receive training in culturally competent care and confidentiality for all populations including: LGBTQ, adolescents, individuals with limited English-speaking skills, and the disabled. Evidence: 1) Documentation (e.g., training records) that demonstrates staff have received training in providing culturally competent care to populations identified in the needs assessment (as defined above). 2) IDPH observation of the clinic environment demonstrates that it is welcoming (i.e., Privacy, cleanliness of exam rooms, ease of access to service, fair and equitable charges for services including waiver of fees for “good cause”, language assistance) 3) Client surveys document that clients perceive providers and other clinic staff to be respectful 4) See fiscal section for billing and collection guidance. **IDPH Policy: 203, 204, 232, 220**
9.3 Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).	Implementation: IDPH and sub-recipient have written policies and procedures that require their sites and any sub-recipient sites to provide service without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies or marital status.

DRAFT

	Evidence: 1) Policy reviewed at site visits by IDPH 2) Documentation exists that staff is informed of this requirement on an annual basis. 3) Observation at clinic sites demonstrates that education materials are evaluated and tailored specifically to age, literacy, and language preferences of most commonly seen clients. **IDPH Policy: 203, 204**
9.4 Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).	Implementation: IDPH and sub-recipient have policies related to referrals to and from other community providers. Evidence: 1) Sub-recipient response to a competitive application for funding identifies the social service, health care and mental health needs in the communities and collaborating partner agencies. 2) Current (i.e., signed within the past 12 months) Memoranda of Understand with relevant referral agencies exist, including: child care agencies, transport providers, WIC programs, child protective services, etc. when possible. 3) Medical chart review documents appropriate referrals and related care coordination efforts. **IDPH Policy: 224**
9.5 Projects must provide for coordination and use of referral arrangements with other providers of health	Implementation: IDPH and sub-recipient have policies related to care coordination and referrals. Evidence: 1) Clinic protocols state that clients are asked about other sources of primary care; and care should be coordinated

DRAFT

	with those other sources, if relevant. 2) Current (i.e., updated within the past 12 months) clinic protocols have a written description of referral policies and procedures. 3) Current (i.e., signed within the past 12 months) Memoranda of Understand with relevant referral agencies exist, including: emergency care, HIV/AIDS care and treatment agencies, infertility specialists, and chronic care management providers when possible. **IDPH Policy: 224**
9.6 All grantees should assure services provided within their project operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.	Implementation: IDPH and all sub-recipient agencies have clinical protocols that are in accordance with nationally recognized standard of care, submitted for approval by IDPH and signed by the local medical directors. Evidence: 1) Sub-recipient policies are updated, signed by the medical director, reflect the QFP and are submitted annually to IDPH in electronic form. 2) IDPH manual is current and updated, and signed by the Title X medical director 3) IDPH manual is available to all Title X staff at sub-recipient agencies. 4) IDPH Medical Advisory Committee participates in the development and maintenance of the IDPH manual. **IDPH Policy: 220, 221, Clinical Policy Section 300**
9.7 All projects must provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation,	Implementation: IDPH has written policies and procedures requiring sub-recipients and service sites to provide clinical services that are in accordance with QFP, to provide referrals to other medical facilities when medically indicated (including emergencies), and to assist clients in finding

DRAFT

examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.	potential alternative sources of reimbursement for the referral care Evidence: 1) Clinic protocols state that the following services will be offered to female, male and adolescent clients: contraceptive, pregnancy testing and counseling, services to assist with achieving pregnancy, basic infertility services, STD services, and preconception health services. 2) Breast and cervical cancer screening will be offered to female clients. 3) Have a written description of referral policies and procedures for the services listed above. 4) Memoranda of Understand (when possible) with relevant referral agencies exist. 5) Medical records demonstrate that clients who come for contraceptive, pregnancy testing, counseling to achieve pregnancy and/or basic infertility services are also offered STD, preconception, and related preventive health services **IDPH Policy: 220, 221, 223, 236, Clinical policy section 300**
9.8 All projects must offer a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents).	Implementation: IDPH grant application specifically identifies a broad range of contraceptive methods available, either on site or by referral, and that all services listed in the QFP will be offered to female and male clients, including adolescents. Evidence: 1) A review of the current stock of contraceptive methods demonstrates that a broad range of methods are

DRAFT

	available onsite or by referral. 2) Clinic protocols state that the following services will be provided to female and male clients: contraceptive, pregnancy testing and counseling, achieving pregnancy, basic infertility services, STD services, preconception health services. 3) A review of the service site's FPAR data demonstrates that a reasonable proportion of clients seen are adolescents (e.g., close to the national average across all funded clinics). 4) A review of the service site's FPAR data demonstrates that a reasonable proportion of clients seen are male. **IDPH Policy: 221, Clinical policy section 300, sub-recipient contracts, RFP, RFA, FPAR**
9.9 Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).	Implementation: IDPH policy states that sub-recipient and service sites must provide services without the imposition of any durational residence requirement or that the client be referred by a physician Evidence: 1) Written clinic policies explicitly address this requirement **IDPH Policy: 203**
9.10 Projects must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5)).	Implementation: IDPH and sub-recipient policy provide for pregnancy diagnosis and counseling to all clients requesting this service. Evidence: 1) Clinic inventory and medical records review demonstrates that pregnancy testing is available and offered to all clients in need of this service 2) FPAR data demonstrates service are being provided

DRAFT

	IDPH Policy: 221, 304
9.11 Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: • prenatal care and delivery; • infant care, foster care, or adoption; and • pregnancy termination. If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).	Implementation: IDPH and sub-recipients have written policy and procedures requiring the provision of options counseling to pregnant women Evidence: 1) Clinic protocols ensure that clients are provided with neutral, factual information, and non-directive counseling about all 3 options, except for those options that she does not wish to receive information about, and that referrals that are requested by the client are provided to her 2) Medical records of clients receiving pregnancy testing and counseling document that they were provided information about all 3 options, except those for which she did not want to receive information and that referrals were made as requested **IDPH Policy: 304**
9.12 Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act.	Implementation: IDPH and sub-recipients will have written policies that address all legislative mandates. Evidence: 1) Sub-recipients have policies that their staff is informed annually that (a) clinic staff must encourage family participation in the decision of minors to seek FP services, (b) minors must be counseled on how to resist attempts to coerce them into engaging in sexual activities, and (c) State law must be followed requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest. 2) Documentation (e.g., staff circulars, training curriculum)

DRAFT

	that staff has been formally informed on an annual basis about items a-c above. 3) Clinic protocols and policies have written statements related to items a-c above. 4) Administrative records document any incidents of mandatory reporting. **IDPH Policy: 230, 303**
10.0 Confidentiality Every project must have safeguards to ensure client confidentiality. Information obtained by the project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the	Implementation: IDPH and sub-recipient have policies that safeguards must be in place to protect confidentiality. Evidence: 1) Documentation (e.g., staff circulars, training curriculum) that staff has been formally informed on an annual basis about policies related to preserving client confidentiality and privacy. 2) All sub-recipients have policies relating to the confidentiality of minors. 3) Health records (including electronic record systems) have systems in place to ensure confidentiality, privacy and access to personal health information. 4) Documentation exists that clients are notified of their right to confidentiality. 5) HIPPA notices are provided to clients 6) Facility layout promotes confidentiality and privacy **IDPH Policy: 206, 210, 221, 222,**
11.1 Title X grantees and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the	Implementation: IDPH and sub-recipients have a written policy and procedures for ensuring that a plan for community participation is developed and implemented. Evidence: 1) The plan provides an opportunity for community

DRAFT

population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).	participation in the project and that those participants include individuals who are broadly representative of the population to be serviced, and who are knowledgeable about the community's needs for family planning services. 2) Documentation demonstrates that the community engagement plan has been implemented (e.g. reports, meeting minutes, etc.) 3) Client satisfaction surveys are used to gather community input. **IDPH Policy: 217, 227, Client Satisfaction Surveys**
11.2 -11.3 Projects must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)).	Implementation: IDPH and sub-recipients will have written policies about the community education programs. Evidence: 1) IDPH assures that the sub-recipient has developed a community education and service promotion plan that enhances community understanding of the objectives of the project, makes the community aware of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial 2) Documentation that the plan has been implemented (media spots, flyers, photos, logs) is submitted to the IDPH annually and is discussed at site visits. 3) Data is used to as an evaluation strategy. **IDPH Policy: 217**
12.1 Title X grantees and sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials	Implementation: IDPH has policies that assure that sub-recipient agency has policies and procedures that ensure materials are reviewed prior to being made available to the project.

DRAFT

developed or made available under the project prior to their distribution (Section 1006 (d)(2), PHS Act; 42 CFR 59.6(a)).	Evidence: 1) Committee meeting minutes are reviewed at site visits 2) Review tools are used at each sub-recipient site to assure continuity of reviews. **IDPH Policy: 216**
12.2 The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2).	Evidence: 1) The committee roster is comprised of members who are broadly representative of the population served. 2) Documentation (meeting minutes, lists of board members, etc.) demonstrates this requirement has been met **IDPH Policy: 216**
12.3-12.6 Each Title X grantee must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6 (b)(1)). The Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).	Evidence: 1) IDPH and sub-recipient has policies and procedures addressing this element 2) IDPH maintains and updates Lists/Rosters of Advisory Committee members for project and reviews same at sub-recipient levels 3) Advisory Committee meeting minutes are maintained and indicate that the committee is active **IDPH Policy: 216**
13.1 Facilities and Accessibility of Services Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons	Implementation: IDPH and sub-recipient agencies have policy to address accessibility Evidence: 1) Sub-recipients have policies and procedures that assure access to timely language translation services 2) Educational materials are tailored to literacy, age, and

DRAFT

(August 4, 2003) (HHS Grants Policy Statement 2007, II-23).	language preferences of client populations 3) Service site documentation indicates that staff are aware of the policies and processes exist to access language translation services when needed **IDPH Policy: 204**
13.1.1Projects may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR 84).	Implementation: IDPH and sub-recipient policies and procedures ensure access to services for individuals with disabilities at their sites and at all sub-recipients Evidence: 1) Grantee maintains documentation of any accommodations made for disabled individuals 2) The project sites are free from obvious structural or other barriers that would prevent disabled individuals from accessing services **IDPH Policy: 204**
13.2 Emergency management A written plan of action for the management of emergencies (29CFR 1910. Subpart E) and clinic facilities must meet applicable standards established by Federal, State and local governments (fide, building and licensing codes)	Implementation: IDPH and sub-recipients will have written emergency plans including disaster plans (fir, bomb, terrorism, earthquake, flood); Evidence: 1) Staff can identify evacuation plans and routes 2) Staff has completed training and understands their role in a emergency 3) Exists are recognizable and free from barriers. **IDPH Policy: 207**
13.3 Standards of Conduct	Implementation: IDPH will have policies to prevent employees, consultants or committee members from using their positions for purposes that are, or give the appearance of, motivated by a desire for private financial gain for themselves or others.

DRAFT

	Evidence: 1) Written conflict of interest documents are signed and updated annually at IDPH and all sub-recipient agencies. **IDPH Policy: 207**
13.4 Human Subjects research	Implementation: IDPH policy will state that any Human Subject Research done in the Title X project will have IDP approval. Sub-recipient agencies must notify IDPH of any such research. Evidence: 1) Human Subject research activities are known by IDPH 2) IRB approval is on file with IDPH 3) IDPH notifies Regional Program Consultant in writing when research projects involving human subjects occur. **IDPH Policy: 209**
13.5 Financial and Reporting Requirements Audits of grantees and sub-recipients must be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133). Grantees must comply with the financial and other reporting requirements set out in the HHS grants administration regulations (45 CFR parts 74 and 92), as applicable. In addition, grantees must have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS. Grantees	Implementation: IDPH procedures and policies will reflect federal regulations as applicable. IDPH sub-recipients procedures and policies will be supported by federal regulations. Evidence Includes: 1) IDPH and sub-recipients will have written financial management policies and procedures for the Title X project. 2) Sub-recipients will submit monthly expenditure reports and monthly income reports into Iowagrants.gov. 3) Sub-recipients will submit the results of an independent audit conducted annually. 4) Records are retained per IDPH protocol.

DRAFT

must demonstrate continued institutional, managerial, and financial capacity (including funds sufficient to pay the non-Federal share of the project cost) to ensure proper planning, management, and completion of the project as described in the award (42 CFR 59.7(a)). Grantees must reconcile reports, ensuring that disbursements equal obligations and drawdowns. HHS is not liable should the recipient expenditures exceed the actual amount available for the grant.	5) Audits evidence procedures and policies are followed. **IDPH Policy: 103, 402**

DRAFT

Title X Program Policy Notice

Integrating with Primary Care Providers

Release Date: November 22, 2016 **OPA Program Policy Notice: 2016 – 11**

I. Purpose

The purpose of this Program Policy Notice (PPN) is to clarify how Title X grantees may remain in compliance with *Program Requirements for Title X Funded Family Planning Projects* when integrating services with Health Resources & Services Administration (HRSA) Health Center Program grantees and look-alikes (i.e., health centers that receive funding under Section 330 of the Public Health Service Act, which authorizes the Health Center Program, as well as those that have been determined to meet Section 330 requirements but do not receive grant funding under that program). This PPN applies only to integrated settings, and not to settings in which only Health Center Program services are provided. We address three issues commonly faced by integrated Title X and HRSA-funded health center providers:

1) How to bill clients receiving Title X family planning services in compliance with Title X and Health Center Program Sliding Fee Discount Schedules and billing guidelines;

2) How to report data to the Family Planning Annual Report (FPAR) and to the Uniform Data System (UDS) appropriately; and,

3) How to preserve Title X client confidentiality when billing for services provided.

II. Background

In 2014, the Office of Population Affairs (OPA) released new Title X program guidelines consisting of two parts:

1) *Program Requirements for Title X Funded Family Planning Projects* (Title X Program Requirements); and,

2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* (QFP).

Title X Program Requirements align closely with the Title X statute and family planning services project implementing regulations (42 CFR part 59, subpart A), as well as other applicable federal statutes, regulations, and policies. This PPN is intended to help Title X grantees address integrated care settings with regard to Title X Program Requirements.

III. Clarification

This section provides clarification for some of the most common issues facing Title X Family Planning (FP) providers when integrating with primary care organizations, and suggests sample strategies to overcome these issues. Endnotes are provided for reference to the applicable section(s) of the Title X and HRSA Health Center Program Requirements aligned with each strategy.

Issue 1: Nominal Charge and Sliding Fee Discount Schedules (SFDS)

Strategy

The HRSA Health Center Program and the OPA Title X Program have unique Sliding Fee Discount Schedule (SFDS) program requirements, which include having differing upper limits. HRSA's policies, currently contained in Policy Information Notice (PIN) 2014-02, allow health centers to accommodate the further discounting of services as required by Title X regulations. Title X agencies (or providers) that are integrated with or receive funding from the HRSA Health Center Program may have dual fee discount schedules: one schedule that ranges from 101% to 200% of the Federal Poverty Level (FPL) for all health center services, and one schedule that ranges from 101% to 250% FPL for clients receiving **only** Title X family planning services directly related to preventing or achieving pregnancy, and as defined in their approved Title X project.

Title X agencies and providers may consult with the health center if they have additional questions regarding implementing discounting schedules that comply with Title X and Health Center Program requirements, which may result in the health center needing to consult their HRSA Health Center Program Project Officer.

To decide which SFDS to use, the health center should determine whether a client is receiving **only Title X family planning services** (Title X family planning services are defined by the service contract between the Title X grantee and health center) or **health center services in addition to Title X family planning services within the same visit.**

The following guidance applies specifically to clients who receive **only Title X family planning services** that are directly related to preventing or achieving pregnancy:

- Clients receiving only Title X family planning services with family incomes at or below 100% of the FPL must not be charged for services received. In order to comply with Title X regulations, any nominal fee typically collected by a HRSA health center program grantee or look-alike would **not be charged to the client receiving only Title X family planning services.**[i]

- Clients receiving only Title X family planning services with family incomes that are between 101% FPL and 250% FPL must be charged in accordance with a specific Title X SFDS based on the client's ability to pay. Any differences between charges based on applying the Title X SFDS and the health center's discounting schedule could be allocated to Title X grant funds. This allocation is aligned with the guidance provided in HRSA's PIN 2014-02, as discussed above. This PIN states that program grantees, "*may receive or have access to other funding sources (e.g.,*

Federal, State, local, or private funds) that contain terms and conditions for reducing patient costs for specific services. These terms and conditions may apply to patients over 200 percent of the FPG [Federal Poverty Guidelines]. *In such cases, it is permissible for a health center to allocate a portion (or all) of this patient's charge to this grant or subsidy funding source."*[ii]

- Note that unemancipated minors who receive confidential Title X family planning services must be billed according to the income of the minor.[iii]

The following guidance applies specifically to clients who receive **health center services in addition to Title X family planning services within the same visit:**

- For clients receiving health center services in addition to Title X family planning services, as defined above, within the same visit, the health center or look-alike may utilize its health center discounting schedule (which ranges from 101% to 200% FPL) including collecting one nominal fee for health center services provided to clients with family incomes at or below 100% FPL.

Issue 2: Fulfilling Data Reporting Requirements

Strategy

To comply with mandatory program reporting requirements for both the Title X and HRSA Health Center Program, health centers that are integrated with Title X funded agencies must provide data on services provided that are relevant to either or both through FPAR and UDS, as appropriate. In cases where a data element is applicable to both FPAR and UDS, reporting such data to each report does not result in "double" credit for services provided; rather, it ensures that both Title X and HRSA receive accurate information on services provided to clients during the given reporting period.

Further instructions on how a family planning "user" is defined can be found in the FPAR Forms & Instructions guidance document.

Issue 3: Sliding Fee Discount Schedule eligibility for individuals seeking confidential services

Strategy

For individuals requesting that Title X family planning services provided to them are confidential (i.e., they do not want their information disclosed in any way, including for third-party billing), the provider should ensure that appropriate measures are in place to protect the client's information, beyond HIPAA privacy assurances.[iv] Providers **may not bill third-party payers** for services in such cases where confidentiality cannot be assured (e.g., a payer does not suppress Explanation of Benefits documents and does not remove such information from claims history and other documents accessible to the policy holder). Providers may request payment from clients at the time of the visit for any confidential services provided that cannot be disclosed to third-party payers, as long as the provider uses the appropriate SFDS. Inability to pay, however, cannot be a barrier to services.[v] Providers may bill third-party payers for services that the client identifies as non-confidential.

Endnotes

[i] Section 8.4 of the Title X Program Requirements contains information related to charges, billing, and collections. The program requirements in section 8.4 most relevant to charging clients at or below 100% of the FPL, between 101% and 250% of the FPL, and above 250% of the FPL, are as follows:

Title X Program Requirement 8.4.1. *Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).*

Within the parameters set out by the Title X statute and program requirements, Title X grantees have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population. Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.

Title X Program Requirement 8.4.2. *A schedule of discounts, based on ability to pay, is required for individuals with family incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).*

Title X Program Requirement 8.4.3. *Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).*

Title X Program Requirement 8.4.4. *For persons from families whose income exceeds 250% of the FPL, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).*

[ii] HRSA Policy Information Notice PIN 2014-02, "Sliding Fee Discount and Related Billing and Collections Program Requirements." *Individuals and families with annual incomes above 200 percent of the FPG are not eligible for sliding fee discounts. However, health centers may receive or have access to other funding sources (e.g., Federal, State, local, or private funds) that contain terms or conditions for reducing patient costs for specific services. These terms and conditions may apply to patients over 200 percent of the FPG. In such cases, it is permissible for a health center to allocate a portion (or all) of this patient's charge to this grant or subsidy funding source.*

[iii] Title X Program Requirement 8.4.5. *Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2).*

[iv] Title X Program Requirement 8.4.8. *Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.*

HRSA PIN 2014-02. *Patient privacy and confidentiality must be protected throughout the (SFDS eligibility determination) process. The act of billing and collecting from patients should be conducted in an efficient, respectful and culturally appropriate manner, assuring that procedures do not present a barrier to care and patient privacy and confidentiality are protected throughout the process.*

[v] Title X Program Requirement 8.4.3, repeated. *Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).*

Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

INFORMATIONAL LETTER NO.1730-MC-FFS-D

DATE: November 4, 2016

TO: All Iowa Medicaid Providers

APPLIES TO: Managed Care, Fee-for-Service, Dental

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Affordable Care Act Section 1557 Communications Requirements

EFFECTIVE: Immediately

New guidance has been issued by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) on Affordable Care Act (ACA) Section 1557.

ACA Section 1557 prohibits discrimination based on race, color, national origin, sex, age or disability in health programs and activities that receive Federal funds. Section 1557 assists populations that have been most vulnerable to discrimination in health care and health coverage, including: women, members of the lesbian, gay, bisexual and transgender (LGBT) community, individuals with disabilities and individuals with limited English proficiency (LEP).

Section 1557 builds on long-standing Federal civil rights laws

- Title VI of the Civil Rights Act of 1964
- Title IX of the Education Amendments of 1972
- Section 504 of the Rehabilitation Act of 1973
- Age Discrimination Act of 1975

OCR's final regulation implementing Section 1557 was published in the Federal Register on May 18, 2016 (Nondiscrimination in Health Programs and Activities, Final Rule (81 FR 31376)). The final regulations can be found at 45 CFR Part 92.

Section 1557 requirements directly impact communications and operations. This informational letter provides guidance on the communications requirements of Section 1557. An additional informational letter addresses the operational requirements of Section 1557.

To ensure compliance, the IME is providing Section 1557 communications guidance below.

Providers and covered entities must inform members of their rights to be treated with dignitiy and respect and to access information and services in a manner which is accessible. To accomplish this, communications must include a nondiscrimination notice or statement and taglines in top lanugages for those with LEP.

There are TWO TIERS of communications requirements. You must first determine if the communications piece is 'Significant Communications' or 'Small-Size Significant Communications,' then add the appropriate required content.

- **Significant Communications:** Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual.
  REQUIRED CONTENT:
  - Nondiscrimination Notice (sample text available here[1])
  - Top 15 LEP Taglines (sample text available here[2])

- **Small-Size Significant Communications:** Significant publications or significant communications that are small in size such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms.
  REQUIRED CONTENT:
  - Nondiscrimination Statement (sample text available here[3])
  - Top 2 LEP Taglines (sample text available here[4])

Determining whether a communications piece is a 'Significant Communications' or 'Small-Size Significant Communications' is up to the discretion of the provider or covered entity.

The top 15 languages in Iowa used by those with LEP:

Rank	State	Language	Estimated Population
1	IA	Spanish	49,357
2	IA	Chinese	6,025
3	IA	Vietnamese	4,552
4	IA	Serbo-Croatian	3,795
5	IA	German	2,624
6	IA	Arabic	2,213
7	IA	Laotian	1,997
8	IA	Korean	1,950
9	IA	Hindi	1,078
10	IA	French	937
11	IA	Pennsylvanian Dutch	875
12	IA	Thai	872
13	IA	Tagalog	789
14	IA	Karen	780
15	IA	Russian	614

[1] http://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf
[2] http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html
[3] http://www.hhs.gov/sites/default/files/sample-ce-statement-english.pdf
[4] http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html

In addition to the types of commumications identified above, the notice and taglines must be posted online and in physical locations:

- **Online**

  REQUIRED CONTENT:
  - Nondiscrimination Notice (sample text available here[5]) must be accessible from the covered entities' homepage.
  - Top 15 LEP Taglines (sample text available here[6]) must be posted on the covered entities' webpage.

- **Physical Location**

  REQUIRED CONTENT:
  - Nondiscrimination Notice (sample text available here[7]) must be posted in conspicuous physical locations where the provider or covered entity interacts with the public.
  - Top 15 LEP Taglines (sample text available here[8]) must be posted in conspicuous physical locations where the provider or covered entity interacts with the public.

The covered entity may combine the content of the required nondiscrimination notice with other notices, so long as it is consistent with the intent of Section 1557.

Who must comply with section 1557?

All health programs and activities that receive Federal financial assistance from HHS, which includes Iowa Medicaid providers, must comply with ACA Section 1557.

Health program or activity is broadly defined in the regulation and includes:

- The provision or administration of health related services, including behavioral health services
- State agencies, including Medicaid, Children's Health Insurance Program (CHIP), Basic Health Programs
- Medicare programs
- Hospitals
- Nursing facilities, intermediate care facilities for persons with intellectual/developmental disabilities, community residential facilities
- Health-related insurance
- Wellness programs
- Health research and education programs
- Includes all of the operations of an entity principally engaged in health services or health coverage.

When do these requirements go into effect?

The communications requirements—the posting of LEP taglines and nondiscrimination notice or statement in significant communications is effective October 17, 2016.

---

[5] http://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf
[6] http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html
[7] http://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf
[8] http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html

OCR has indicated they intend to provide covered entities flexibility to implement requirements as long as the actions do not compromise intent to clearly inform individuals of their Section 1557 rights.

OCR has noted that covered entities which distribute significant publications or significant communications will need to update these publications to include the required notice and taglines. Covered entities may exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

This guidance is being issued by the IME to assist providers and covered entities with coming into compliance. This letter is not exhaustive and the IME strongly encourages providers and covered entities to review the ACA Section 1557 requirements in full, which can be found here[9], along with other useful resources and training materials.

If you have any questions, please contact the IME Provider Services Unit at 1-800-338-7909 or email imeproviderservices@dhs.state.ia.us.

[9] http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html

FAMILY PLANNING - FISCAL REVIEW
Iowa Department of Public Health

Date:_____ **Agency:**_____ **State Staff:**_____

Local Staff:_____

Things to be on the lookout for (an overview):

i. Review fiscal policies for references to Federal regulations.
ii. Review budget control policies and practices to insure they meet standard practice.
iii. Review internal controls at the Sub recipients to be sure they meet federal and state requirements.
iv. Insure the program can track and report the total amount of program generated income including the source of income and how the funds are spent.
v. Insure that program income earned during the project period is used for the purposes of the Federal award (to further the objectives of the program).
vi. Review cost principles used at the Grantee and sub recipient agencies in determining the allowable costs of work performed. These principles must be consistent with 2 CFR - Subpart E—Cost Principles, and the terms and conditions of the Federal award.
vii. Review that the sub recipient has submitted the required financial reports for the project period on time and in accordance with the guidelines established for that reporting.
viii. Review how the sub recipient agencies insure compliance with Title X fiscal requirements.
ix. Review the audits of the sub recipients to determine if there are any audit findings and that the agency can continue as a “going concern”.
x. Review that the sub recipients have appropriate procurement standards consistent with Federal and state guidelines.

Section 8.2. Prohibition of Abortion

	Yes	No	N/A
1. Financial documentation at service sites demonstrates that Title X funds are not being used for abortion services and adequate separation exists between Title X and non-Title X activities.			

Section 8.3: Structure and Management

	Yes	No	N/A
1. Where required services are provided by referral, the grantee is expected to have written agreements for the provision of services and reimbursement of costs as appropriate.			

Section 8.3.4: Schedule of Rates and Payment Procedures

	Yes	No	N/A
1. SR documents clearly indicate the schedule of rates and payment procedures for services.			
2. The SR can substantiate that the rates are reasonable and necessary. This includes demonstrating the process and/or rationale used to determine payments, examples of financial records, applicable internal controls.SR has policies and procedures assuring that clients whose documented income is at or below 100% FPL are not charged for services and that third party payers are billed.			

Section 8.4: Charges, Billings, and Collections

	Yes	No	N/A
1. SR documentation on site establishes that clients are project services or be subjected to any variation in quality of services because of inability to pay.			
2. SR should not have a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services.			

8.4.1 FPL Guidance, Third Party Billing, and Income Verification

	Yes	No	N/A
1. SR has policies and procedures assuring that clients whose documented income is at or below 100% FPL are not charged for services and that third party payers are billed.			
2. Financial documentation at the service site(s) indicates clients whose documented income is at or below 100% FPL are not charged for services.			
3. Financial documentation at the service site(s) indicates that if a third party is authorized or legally obligated to pay for services, the project has billed accordingly.			
4. Service sites follow a written policy and procedure for verifying client income that is aligned with Title X requirements.			
5. Service site policy and procedures for verifying client income does not present a barrier to receipt of services.			

Section 8.4.2: Discount Schedules

1. SR has policies and procedures requiring that a schedule of discounts be developed for services provided in the project and updated periodically to be in line with the FPL.			
2. Service site documentation indicates client income is assessed and discounts are appropriately applied to the cost of services.			

Section 8.4.3: Fee Waiver

1. SR has policies and procedures that require clients (or financial records) be referred to the service site director for review and consideration of waiver of charges.			
2. SR has documentation at the service site demonstrating a determination is made by the service site director, is documented and the client is informed of the determination.			

Section 8.4.4: Reasonable Costs/Fee Schedules

1. SR has documented policies and procedures for determining the cost of services.			
2. Financial records indicate client income is assessed and that charges are applied appropriately to recover the cost of services			

Section 8.4.5: Discount Eligibility for Minors

1. SR policies require service sites to have a process for determining whether a minor is seeking confidential services and stipulates that charges to adolescents seeking confidential services will be based solely on the adolescent's income.			
2. Client records at service sites indicate appropriate implementation of policy.			

Section 8.4.6: Voluntary Donations

1. Grantee policies and procedures indicate if the project service sites may request and/or accept donations.			
2. Onsite documentation and observation demonstrates that clients are not pressured to make donations and that donations are not a prerequisite to the provision of services or supplies. Observation may include signage, financial counseling scripts, or other evidence.			
3. Grantee policies and procedures indicate if the project service sites may request and/or accept donations.			

Section 8.5: Project Personnel	**Yes**	**No**	**N/A**
1. Documentation such as budgets and payroll records indicate the SR is complying with required salary limits as documented in most current FP services Funding Opportunity Announcements (FOA).			
2. Time studies justify payroll records.			

Section 10: Confidentiality	**Yes**	**No**	**N/A**
Third party billing is processed in a manner that does not breach client confidentiality, particularly in sensitive cases (e.g., adolescents or young adults seeking confidential services, or individuals for whom billing the policyholder could result in interpersonal violence).			

Quick Overview

Patient Fee and Collections (review income, fee schedules & policies)	**Yes**	**No**	**N/A**
Review client income verification forms and procedures			
Is income verified?			
Is income verification a barrier to services?			
Can fees be waived for good cause?			
Is confidential minor income assessment based on the minor's income only?			
Are donations voluntary?			
Are there failed appointment or supply pickup fees?			
Are postage & handling fees are based on income?			
Are discounts applied to balances after insurance pays?			
Review payment & collection policies			
Billing procedures safeguard confidentiality for no-contact clients			
Contraceptive supplies are not rationed for non payment			
Are all third parties billed for total charges without discounts?			
Is there a method for aging outstanding accounts? Describe			
Review of agency policy regarding availability of services regardless of ability to pay Describe_____			
Review policies for referring clients to collection agencies: Comments			

Comments: