Vaccine Adverse Event Reporting System

Vaccines prevent serious illnesses and even death in persons who receive them. Before a vaccine is licensed, the FDA requires a vaccine to go through extensive safety testing to ensure the vaccine is safe. After a vaccine is licensed, the Vaccine Adverse Event Reporting System (VAERS) is one of several mechanisms used to monitor for unforeseen problems, or “adverse events,” after vaccination. Anybody who experiences a problem after vaccination is encouraged to complete a VAERS report including parents, patients and health care providers. VAERS forms are available by calling 1-800-822-7967, or from the VAERS website at http://vaers.hhs.gov.

A limitation of the data provided through VAERS reports is that it can be misinterpreted by some to be proof that a vaccine caused an adverse event, yet we know that correlation does not imply causation. It is not logical to say that because a person never got influenza after being around a person infected with influenza, influenza cannot be spread from person to person. Likewise, it is not logical to say that because an adverse event happened after a person received a vaccine it was automatically caused by that vaccine. VAERS data is simply a tool used to monitor for trends that may indicate an adverse event is more likely to occur after receiving a particular vaccine.

For information regarding VAERS at the Iowa Immunization Program, contact Kelli Smith at 1-800-831-6293, ext. 2.

VFC FluMist Quadrivalent Replacement Program

MedImmune has contracted with McKesson to provide a Replacement Program for unused, expiring VFC FluMist Quadrivalent doses, at no cost to VFC providers. FluMist Quadrivalent doses expiring between November 18, 2013 and January 31, 2014 are eligible for the replacement program.

The link below includes program guidelines and instructions to replace expiring FluMist doses:

Replacement requests can be made starting on November 18, 2013 through January 31, 2014. Please contact the VFC FluMist Quadrivalent Replacement Program at 1-877-633-7375 with replacement requests or for more information.
Interfacing with Electronic Health Records

Does your organization use an electronic health record system? If so, have you considered an interface between your system and IRIS? Please review the IRIS Data Exchange Specifications, found under the Forms tab of IRIS at [https://iris.iowa.gov](https://iris.iowa.gov). To initiate an interface, the first step is to complete the IRIS Data Exchange Onboarding Form.

**IMPORTANT VFC/IRIS REMINDER**

Reminder: The process to enter VFC vaccine orders in IRIS has changed. VFC providers **MUST** now accept VFC vaccine orders electronically into the organization’s IRIS inventory. Failure to receive vaccine orders using this process may result in inaccurate vaccine inventory, unaccounted for vaccines and errors in VFC vaccine doses administered reporting. The following resources are available for users:

1. **Recorded webinar training**
2. **Order receiving instructions**

Please direct questions to the IRIS Help Desk at 800-374-3958 or to the Vaccines for Children Program, 800-831-6293, ext. 4.

**Changing Organization Contact Information**

Organization contact information in IRIS should be updated as staff changes occur at VFC enrolled provider sites. To make changes for all organization contacts, IRIS Admin Users can follow the steps provided in the [How to Change Organization Contact Information Handout](#). If you have questions regarding contact updates in IRIS call the IRIS Help Desk at 1-800-374-3958.
Severe Winter Weather Events - Time to Review your Vaccine Emergency Response Plan

A winter blizzard or ice storm can suddenly put your vaccine supply at risk when power and transportation resources are interrupted. Every Iowa VFC provider should have a written Vaccine Emergency Response Plan that identifies a refrigerator and freezer in another location (ideally, a storage unit with a back-up generator) in which to store vaccine in the event of a power outage or natural disaster. Consider arranging in advance for a local hospital or similar facility to be your back-up vaccine storage location. Be sure back-up location staff understand vaccine storage and will allow you to supervise the management of vaccine and verify storage temperatures so vaccine is not damaged. A template to develop a Vaccine Storage and Handling Plan is available on the Immunization Program web page or by following the link here.

Discontinue Use of Dormitory Refrigerators

The requirement from the Centers for Disease Control and Prevention (CDC) eliminates the use of dormitory or bar-style refrigerator/freezer units for storage of federally purchased vaccines under any circumstances, including temporary storage. All VFC providers who use dorm-style units to store federally purchased VFC vaccines are required to replace it with a recommended storage unit by December 31, 2013. Additional information regarding the requirement is available here. If you have questions regarding the VFC Program vaccine storage and handling requirements and recommendations, please contact Tina Patterson at Tina.Patterson@idph.iowa.gov or 1-800-831-6293, ext. 4.

VFC Vaccine Distribution

During the holiday season McKesson will NOT ship vaccine from December 20, 2013 – January 2, 2014. VFC Program providers should monitor existing vaccine inventory and place an order in advance of shipping black out to ensure adequate vaccine supply. If you have any questions regarding vaccine orders please contact Tina Patterson or Janean Iddings at 1-800-831-6293 ext. 4 and ext. 5 respectively.
Q. Sometimes patients age 65 years and older who have received the standard-dose influenza vaccine inquire about receiving the high-dose product (Fluzone High-Dose, sanofi), also. Is this okay to administer?
A: No. ACIP does not recommend anyone receive more than one dose of influenza vaccine in a season except for certain children age 6 months through 8 years for whom two doses are recommended.

Q: Would giving an older patient 2 doses of standard-dose influenza vaccine be the same as administering the high-dose product?
A: No, and this is not recommended.

Q: How soon after bone marrow transplant do we start to vaccinate our patients against influenza?
A: Inactivated influenza vaccine should be administered beginning at least 6 months after bone marrow transplant and annually thereafter for the life of the patient. A dose of inactivated influenza vaccine can be given as early as 4 months after transplant, but a second dose should be considered in this situation. A second dose is recommended routinely for all children receiving influenza vaccine for the first time. For more information about vaccination of people who receive hematopoietic stem cell transplantation, visit this CDC web page: www.cdc.gov/vaccines/pubs/hemato-cell-transplts.htm.

Q: We inadvertently administered intradermal influenza vaccine (Fluzone ID, sanofi) to a patient who is not in the recommended age range of 18 through 64 years. What should we do now?
A: Because people younger than age 9 years or older than 65 years are more likely to have skin that is too thin for proper intradermal administration, a dose given to a person in these age ranges should be considered invalid, and the patient should be revaccinated. For people age 9 through 17 years, the dose is considered valid and does not have to be repeated if the clinician is certain that the dose was administered intradermally rather than subcutaneously. If there is any doubt about whether the dose was injected intradermally, it should be repeated.

Q: I heard pertussis immunity wanes significantly by 5 years after the kindergarten dose of DTaP. Should we hold off on vaccinating kindergarteners until closer to age 6 years so their immunity will last until they turn 11 and can get the Tdap booster?
A: A study in the New England Journal of Medicine published September 13, 2012 entitled, “Waning Protection after Fifth Dose of Acellular Pertussis Vaccine in Children” found that the time since the fifth dose of DTaP was significantly longer for children who were PCR-positive for pertussis (1699 days; 95% confidence interval [CI], 1627 to 1772) than for PCR-negative controls (1028 days; 95% CI, 1003 to 1053) (P<0.001). Case children received their fifth dose of DTaP significantly earlier than controls (approximately 22 months earlier). While some providers may have begun recommending the kindergarten dose of DTaP closer to age 6 in an effort to maintain immunity until the adolescent booster dose of Tdap at age 11 years, it has not become an official Advisory Committee on Immunization Practices (ACIP) recommendation. The current recommendation is that DTaP be administered at ages 2, 4, 6, 15-18 months, and 4-6 years. It is still an acceptable practice to administer a 5th dose of DTaP any time between ages 4 and 6 years.
Iowa Department of Public Health, Immunization Bureau Email Lists
The Iowa Immunization Program has several email list serves available to help health care providers receive important and timely immunization related information. Providers can send a blank email to the addresses below to receive updates directly in their inbox.

- VFC List: join-VFC@lists.ia.gov
- Immunization Program List: join-IMMUNIZATION@lists.ia.gov
- IRIS List: join-IRISUSERS@lists.ia.gov

Universal Immunization Symbol
Good news! The universal immunization symbol is ready and available for use by all immunization advocates. It is designed for all immunization organizations and advocates to display as a way to show solidarity in their awareness of and support for immunization.

The concept is that, just as a pink ribbon is associated with breast cancer, and a puzzle piece with autism, so this image is the recognized symbol of immunization. Organizations are encouraged to work together and use this symbol as a statement of broad support of immunization.

It is a reflection of all of our voices and is a solid addition to each organization’s individual image library. The symbol does not replace organizational or campaign logos, but is rather a symbol to be used when we wish to collectively present a united front in support of immunization.

The symbol’s use is limited only by our imaginations. It’s envisioned that the image will be used on anything from Web sites, brochures and other print materials, to T-shirts, pins, and social media sites. In the spring of 2013, immunization coalitions around the country voiced a desire for a universal symbol. Putting thought into action, a small group representing the coalitions worked together to identify several potential designs. These designs were put forward, and through a public vote, this symbol was chosen.

The umbrella, representing protection of the community, tells the story of the power of immunizations. The symbol, in several formats, is housed on Google Docs, and is available to all immunization advocates as a free download. In addition to the logo in full color, black, or white, there is also a Style Guide and Read Me guide on how to download and use the symbol:
https://drive.google.com/folderview?id=0B07MTd0yDhmyY05hTFFFRElITTg&usp=sharing

HPV Resources
HPV vaccine remains underutilized in the United States. CDC has new resources available to support physician recommendations for HPV. This HPV tip sheet provides physicians with helpful responses for questions about the vaccine.
Tips and Time-savers for Talking with Parents about HPV Vaccine

Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. For example, you can say “Your child needs these shots today,” and name all of the vaccines recommended for the child’s age.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents’ questions helps you save time and give an effective response. CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver.

**CDC RESEARCH SHOWS:**

The “HPV vaccine is cancer prevention” message resonates strongly with parents. In addition, studies show that a strong recommendation from you is the single best predictor of vaccination.

**TRY SAYING:** HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That’s why I’m recommending that your daughter/son receive the first dose of HPV vaccine today.

**CDC RESEARCH SHOWS:**

Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against.

**TRY SAYING:** HPV can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men. There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine. There are also many more precancerous conditions requiring treatment that can have lasting effects.

**CDC RESEARCH SHOWS:**

Parents want a concrete reason to understand the recommendation that 11–12 year olds receive HPV vaccine.

**TRY SAYING:** We’re vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity. We vaccinate people well before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children well before they get exposed to HPV.

**CDC RESEARCH SHOWS:**

Parents may be concerned that vaccinating may be perceived by the child as permission to have sex.

**TRY SAYING:** Research has shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.

**CDC RESEARCH SHOWS:**

Parents might believe their child won’t be exposed to HPV because they aren’t sexually active or may not be for a long time.

**TRY SAYING:** HPV is so common that almost everyone will be infected at some point. It is estimated that 79 million Americans are currently infected with 14 million new HPV infections each year. Most people infected will never know. So even if your son/daughter waits until marriage to have sex, or only has one partner in the future, he/she could still be exposed if their partner has been exposed.

**CDC RESEARCH SHOWS:**

Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision.

**TRY SAYING:** I strongly believe in the importance of this cancer-preventing vaccine, and I have given HPV vaccine to my son/daughter/grandchild/niece/nephew/friend’s children. Experts (like the American Academy of Pediatrics, cancer doctors, and the CDC) also agree that this vaccine is very important for your child.

**CDC RESEARCH SHOWS:**

Understanding that the side effects are minor and emphasizing the extensive research that vaccines must undergo can help parents feel reassured.

**TRY SAYING:** HPV vaccine has been carefully studied by medical and scientific experts. HPV vaccine has been shown to be very effective and very safe. Like other shots, most side effects are mild, primarily pain or redness in the arm. This should go away quickly, and HPV vaccine has not been associated with any long-term side effects. Since 2006, about 57 million doses of HPV vaccine have been distributed in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.

**CDC RESEARCH SHOWS:**

Parents want to know that HPV vaccine is effective.

**TRY SAYING:** In clinical trials of boys and girls, the vaccine was shown to be extremely effective. In addition, studies in the U.S. and other countries that have introduced HPV vaccine have shown a significant reduction in infections caused by the HPV types targeted by the vaccine.

**CDC RESEARCH SHOWS:**

Many parents do not know that the full vaccine series requires 3 shots. Your reminder will help them to complete the series.

**TRY SAYING:** I want to make sure that your son/daughter receives all 3 shots of HPV vaccine to give them the best possible protection from cancer caused by HPV. Please make sure to make appointments on the way out, and put those appointments on your calendar before you leave the office today!

[www.cdc.gov/vaccines/teens](http://www.cdc.gov/vaccines/teens) | PreteenVaccines@cdc.gov

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

HPV YOU ARE THE KEY TO CANCER PREVENTION