



Adult Lead Poisoning Cluster from Ayurvedic Product Usage in Iowa, 2011

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LEAD EXPOSURE INDEX CASE and CLUSTER IDENTIFICATION

In April 2011, an adult white non-Hispanic male seen at a neurology clinic for a two-year follow up of a previous intracranial hemorrhage demonstrated worsening neurological deficits. A heavy metal panel reported a blood lead level of 93.6 µg/dL. The patient reported ingesting two ayurvedic products obtained in India since June 2010. Test results for one product labeled "bhasma" revealed 19,400 mg/Kg lead and 1,430 mg/Kg arsenic. More than 100 adults living in the same rural, predominantly Caucasian, community who also used ayurvedic products were tested over the following six months and over 200 ayurvedic product samples were submitted for heavy metal testing. The company in India supplying the products reported 1,600 customers in the USA and Europe.

Source of Heavy Metal Exposure

Samples of products submitted by the family were tested by the State Hygienic Laboratory at the University of Iowa, April 2011.

Product #1 labeled as "Bhasma" - tan powder in plastic bag
Test results: 19,400 mg/Kg lead
1,430 mg/Kg arsenic

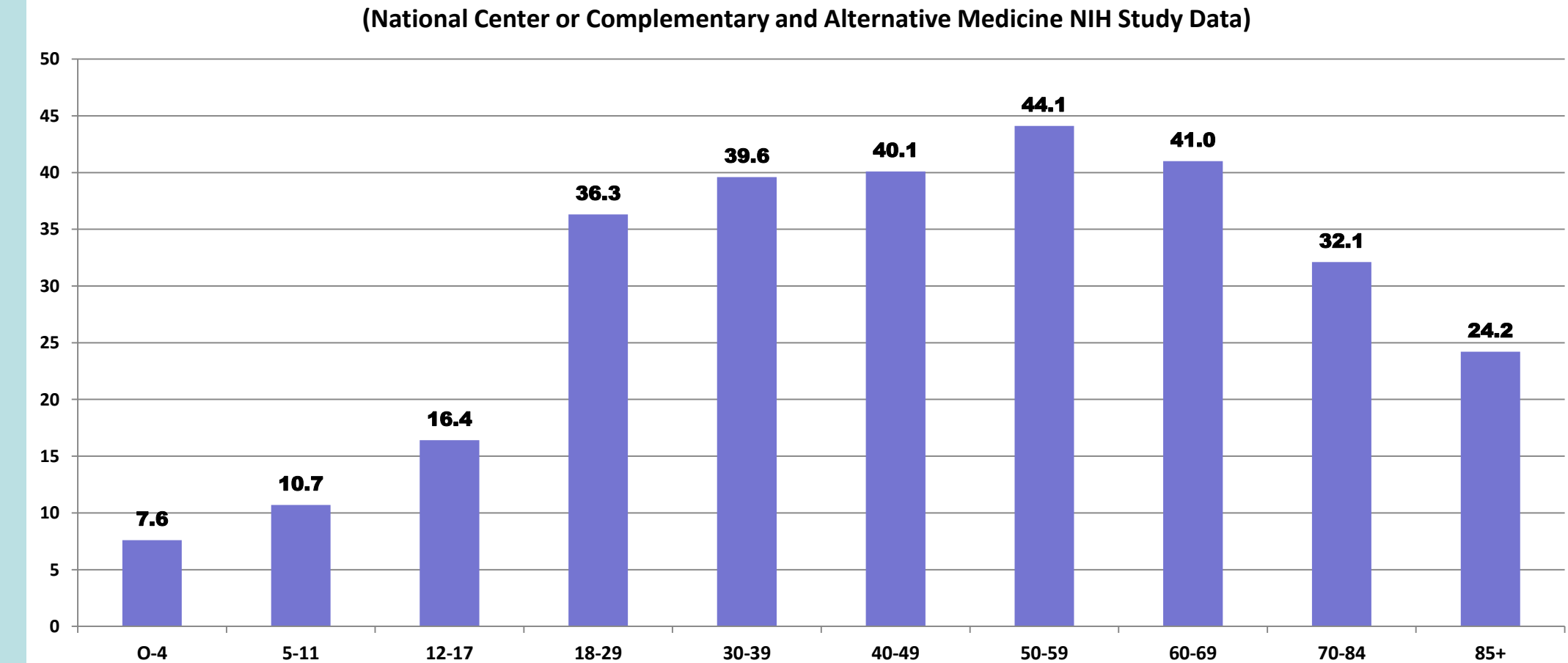


Product #2 labeled as "Smrti" - black/brown paste in clarified butter in plastic bag
Test results: 0.46 mg/kg lead

BACKGROUND:

According to a 2008 National Institutes of Health National Center for Complementary and Alternative Medicine (NCCAM) study, complementary and alternative medicine (CAM) is used by 38% of the U.S. adult population. People of all backgrounds use CAM, but use is greater among women and those with higher levels of education and income. Nonvitamin, nonmineral natural products are the most commonly used therapy among adults – 17.7%

U.S. Population using Complementary and Alternative Medicine by Age - 2007



Ayurvedic Medicine – an Introduction Excerpts from NCCAM online materials

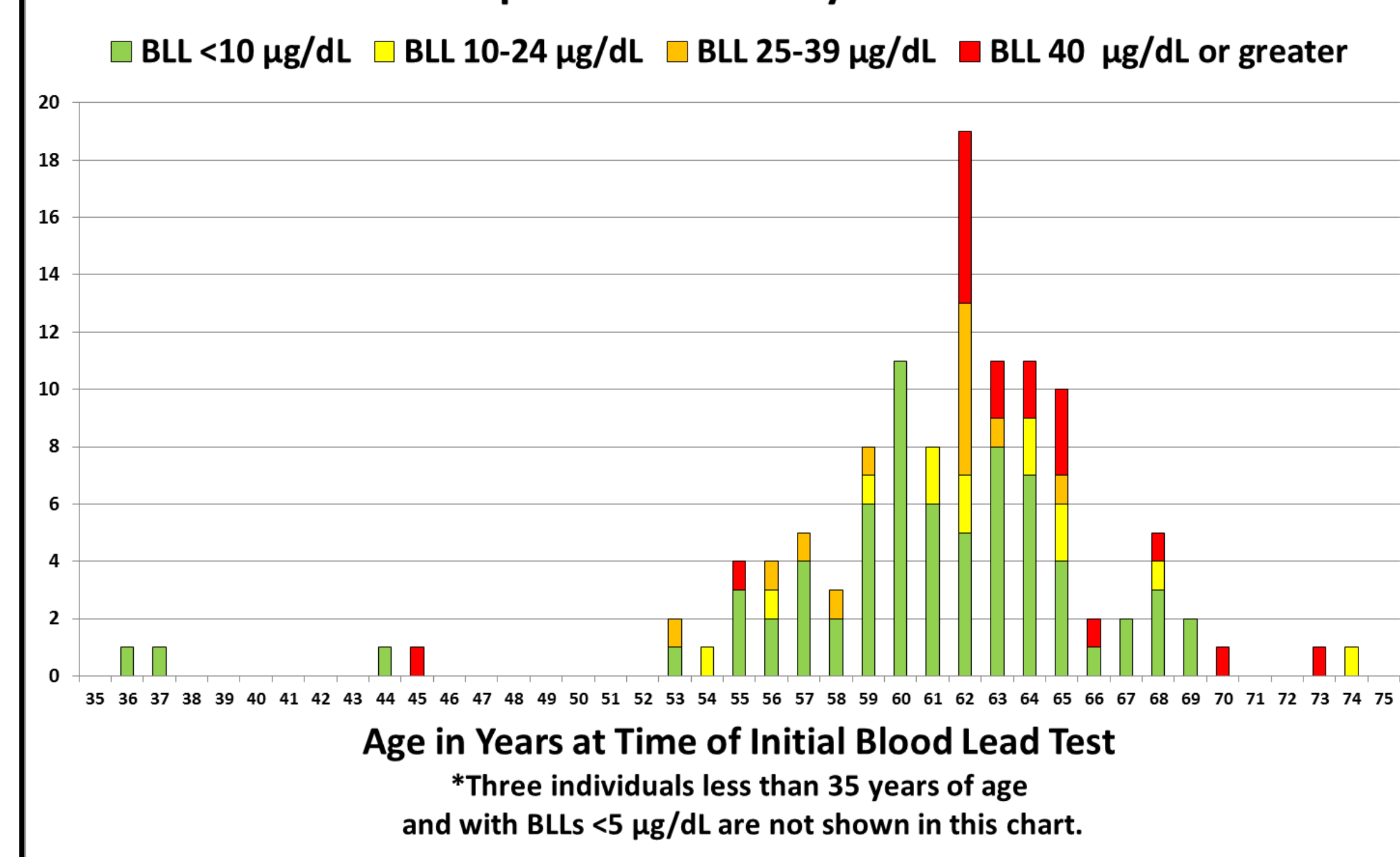
Ayurvedic medicine (also called Ayurveda) is one of the world's oldest medical systems. It originated in India and has evolved there over thousands of years. Ayurvedic medicine continues to be practiced in India, where nearly 80 percent of the population uses it exclusively or combined with conventional (Western) medicine. Ayurvedic practice involves the use of medications that typically contain herbs, metals, minerals, or other materials.

In the United States more than 200,000 U.S. adults had used Ayurvedic medicine in the previous year according to the 2007 National Health Interview Survey.

FINDINGS

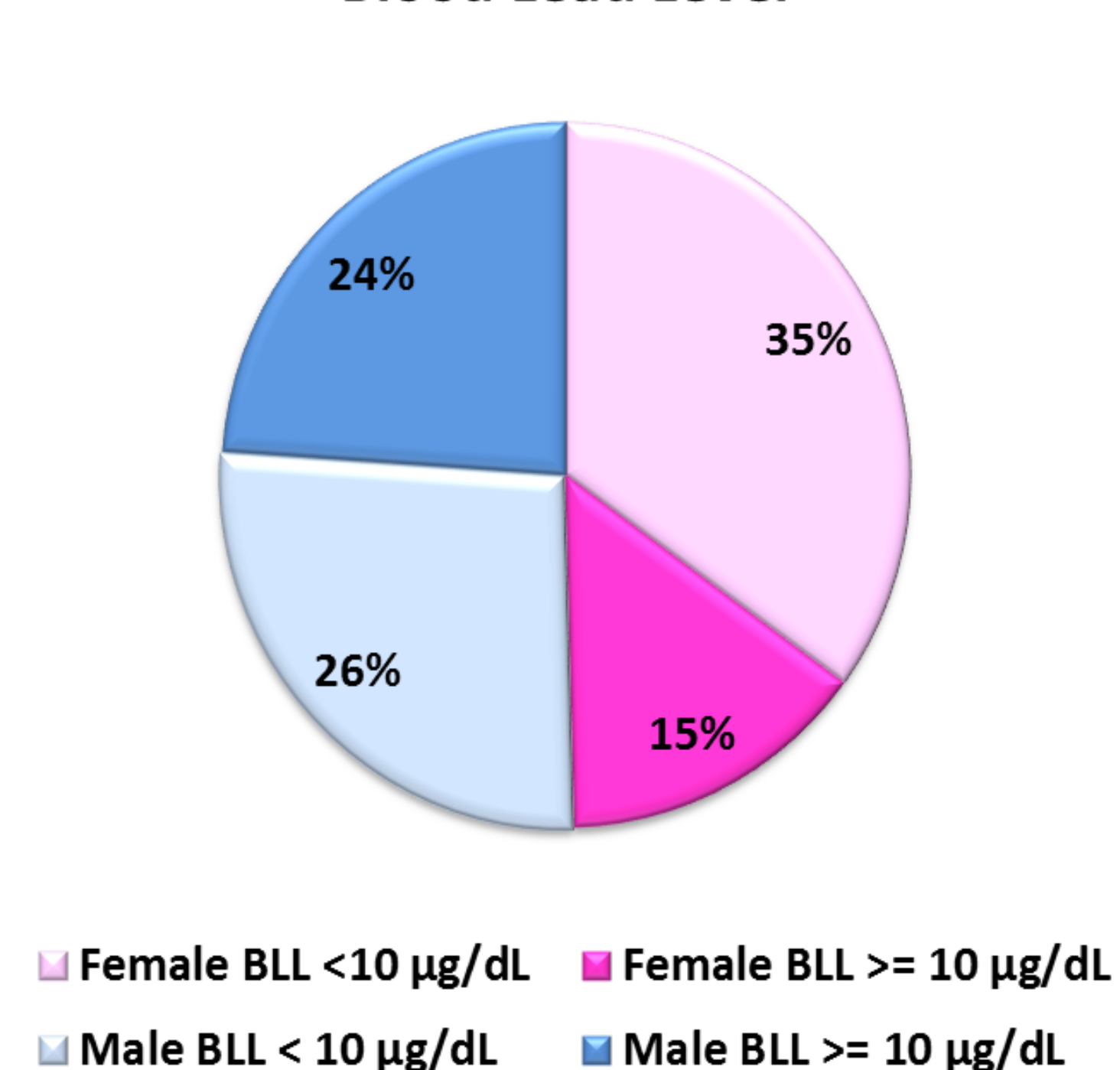
45 out of 117 Iowans 16 years of age or older tested between April 2011-January 2012 who declared using ayurvedic products were identified as cases with an elevated blood lead level (EBL) of 10 µg/dL or greater. Four adults had elevated blood mercury levels (10 ng/ml or greater). The mean age of the Iowa cases was 62 years (range 45 - 74). The mean initial EBL was 37 µg/dL (range 11-94) with 32 of 45 (71%) having initial EBL results of 25 µg/dL or greater.

Iowans Tested who Declared Using Ayurvedic Products by Age and Initial Blood Lead Test Result April 2011-January 2012*



Descriptors for the cluster population do not follow traditional demographic profiles, with much of the information obtained indirectly, limiting the ability to quantify the findings. Some of the people involved in this cluster reside in Iowa part-time or on an extended temporary basis as they pursue their interest in alternative lifestyle philosophies and medicine. Many had travelled to India for an initial treatment at the ayurvedic medicine clinic from which they were purchasing their ayurvedic products. Those most likely to have used products that intentionally contained heavy metals mixed with herbs (the rasa shastra class of ayurvedic medicines) were reportedly seeking alternative treatment options for serious medical conditions such as cardiovascular disease, stroke, and cancer. Over 95% were white and non-Hispanic. Products from the same clinic were involved in the lead poisoning of a pregnant Iowa woman from the same town as this cluster in 2007 who was diagnosed with a blood lead level of 102 µg/dL.

Iowa Adult Ayurvedic Cluster by Gender and Blood Lead Level



Only one blood lead test result was reported for an Iowa child using ayurvedic products from the same supplier (parent also tested) with a resulting BLL of <5 µg/dL. Known adult blood lead tests linked to product usage from the same supplier for non-Iowa residents included four tests with BLLs <10 µg/dL, and four test results ranging from 23-55 µg/dL. These reports included people from California, New Mexico, Bermuda, and Wisconsin.

PRODUCT TESTING

Product testing revealed high levels of lead, mercury, arsenic, and other heavy metals in numerous products. Analysis was performed by the State Hygienic Laboratory at the University of Iowa, Ankeny using ICP/MS, and the EPA 6020 B method. Many dilutions were required due to the high levels encountered. Subsequent limited mercury speciation testing by Thermo Fisher Scientific found no organic and low inorganic mercury in the five products tested. The mercury present in the 97 products was most likely elemental, explaining the lack of acute mercury poisoning experienced by this cluster of adults.

Results in µg/g (ppm)	Silver (Ag)	Aluminum (Al)	Arsenic (As)	Barium (Ba)	Cadmium (Cd)	Mercury (Hg)	Nickel (Ni)	Lead (Pb)	Antimony (Sb)	Titanium (Ti)	Thallium (Tl)
Mean	165	565	913	36	5	16,368	9	1,889	11	32	3
N	7	48	82	38	1	97	12	164	25	39	1
Min	13	10	1	6	5	1	6	1	1	5	3
Max	330	2,191	44,800	118	5	279,000	16	43,200	72	114	3



Not all samples were homogeneous. Products were received as pills, pastes, liquids, and powders. Analysis was done by weight as received.



Product photos provided by State Hygienic Laboratory at the University of Iowa.

CONCLUSIONS – PUBLIC HEALTH CONCERNS

The clinic outside of the U.S. supplying the products acknowledged a problem with contamination by a sub-contractor, in part due to the findings of heavy metals in products that were meant to be entirely herbal. Their products from the rasa shastra class of ayurvedic medications were designed to contain heavy metals mixed with herbs, which they claim would have had no toxicity if the sub-contractor had manufactured them correctly using ancient methods. Whether or not products containing heavy metals can be rendered safe for human consumption remains controversial. There was no recall of the products. This was the second known lead poisoning caused by this clinic's products in Iowa since 2007.

The use of alternative medicine practices and products continues to expand into the mainstream population in the USA. Users may have an increased risk of exposure to toxic substances, especially when the products are manufactured outside of the USA. Consumers and medical practitioners need to be aware of the potential risks and proactively discuss the use of all supplements to determine the need for testing or intervention.



LIMITATIONS

The ability to correlate specific product exposure to persons with abnormal test results was limited. Many of the people using the ayurvedic products declined to participate in the epidemiologic investigation. Most products submitted for testing had handwritten labels and were not identified by a lot or batch number from the supplier. Some products with similar or identical names had dissimilar test results. For this reason, a list of the products tested by name and their test results is of limited value as a predictor of risk.

In the United States, Ayurvedic medications are regulated as dietary supplements. As such, they are not required to meet the safety and efficacy standards for conventional medicines. For this Iowa cluster, the FDA had limited ability to intervene because the products were reported by the users to be obtained directly from a supplier outside of the USA. Ayurvedic products purchased in the county of residence in Iowa did not demonstrate heavy metal contamination.

REFERENCES

- FDA: Use Caution with Ayurvedic Products. October, 2008 www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm050819.pdf
- Barnes PM, Bloom B, Nahin R. *CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007.* December 2008.
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