

Lead Poisoning in Pregnant Women Who Used Ayurvedic Medications from India — New York City, 2011–2012

Lead poisoning still occurs in the United States despite extensive prevention efforts and strict regulations. Exposure to lead can damage the brain, kidneys, and nervous and reproductive systems. Fetal exposure to lead can adversely affect neurodevelopment, decrease fetal growth, and increase the risk for premature birth and miscarriage (1). During 2011–2012, the New York City Department of Health and Mental Hygiene (DOHMH) investigated six cases of lead poisoning associated with the use of 10 oral Ayurvedic medications made in India. All six cases were in foreign-born pregnant women assessed for lead exposure risk by health-care providers during prenatal visits, as required by New York state law. Their blood lead levels (BLLs) ranged from 16 to 64 $\mu\text{g}/\text{dL}$. Lead concentrations of the medications were as high as 2.4%; several medications also contained mercury or arsenic, which also can have adverse health effects. DOHMH distributed information about the medications to health-care providers, product manufacturers, and government agencies in the United States and abroad, via postal and electronic mail. DOHMH also ordered a local business selling contaminated products to cease sales. Health-care providers should ask patients, especially foreign-born or pregnant patients, about any use of foreign health products, supplements, and remedies such as Ayurvedic medications. Public health professionals should consider these types of products when investigating heavy metal exposures and raise awareness among health-care providers and the public regarding the health risks posed by such products.

The six patients in this report all were asymptomatic pregnant women whose health-care providers assessed them to be at risk for lead exposure. New York state law requires assessment of patients for risk of lead exposure during the first prenatal visit and testing of those determined to be at risk; CDC also recommends routine testing of pregnant women from at-risk populations (e.g., recent immigrants and women who use traditional remedies) (1). The New York State Department of Health forwards all blood lead test results from New York City residents to DOHMH,

which conducts follow-up interviews and case investigations for adults identified with BLLs $\geq 10 \mu\text{g}/\text{dL}$. Identification and removal of the lead source is the main priority. Women in the second half of pregnancy with BLLs 45–69 $\mu\text{g}/\text{dL}$ are considered for chelation therapy. Pregnant women with BLLs $\geq 70 \mu\text{g}/\text{dL}$ are considered for chelation regardless of trimester. Pregnant women with lead encephalopathy should receive chelation regardless of trimester (1).

During 2004–2012, through case investigations and agency sweeps of local stores triggered by investigations or published reports, DOHMH identified 22 oral medications, supplements, or remedies containing high levels of heavy metals (Table). Twenty of the 22 products were brought into the United States (one product lacked country of origin information). DOHMH identified 10 of these 22 products during investigations of the six pregnant women with lead poisoning described in this report.

Case Reports

Patient 1. In January 2011, a woman born in India, aged 30 years, had a BLL of 64 $\mu\text{g}/\text{dL}$ during week 27 of pregnancy. The woman took 1–2 capsules daily for 4 months of Pregnota, an Ayurvedic medication manufactured and purchased in India. She had obtained Pregnota from a practitioner in India

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who prescribed it for pregnancy-related nausea and vomiting. Testing found Pregna contained 1.2% lead. Based on her reported use, the woman had consumed approximately 9–18 mg of lead daily, or 1.1–2.2 g of lead over the 4 months. The woman was hospitalized and received chelation therapy with calcium disodium ethylenediaminetetraacetic acid. Her BLL decreased to 36 $\mu\text{g}/\text{dL}$ 5 days after chelation and to 20 $\mu\text{g}/\text{dL}$ 3 months later (2 weeks after delivering). Her newborn's BLL was 23 $\mu\text{g}/\text{dL}$ at 3 days after birth.

Patient 2. In May 2011, a woman born in Colombia, aged 36 years, had a BLL of 16 $\mu\text{g}/\text{dL}$ reported during week 5 of pregnancy. She had used two Ayurvedic medications manufactured in India for skin problems (1 tablet of each daily) approximately 1–2 months before pregnancy and sporadically used the medications during the first month of pregnancy. She reported purchasing the medications, which were made in India, in New York City. Vatvidhwansan Ras (Figure) contained 2% lead, 1.5% mercury and 130 parts per million (ppm) arsenic. Kankayan Bati (Gulma) contained 12 ppm lead, 35 ppm mercury, and 9.5 ppm arsenic. Although difficult to ascertain exposure, if the woman ingested 1 tablet daily of each pill for 3 months, she would have consumed approximately 3 mg of lead daily, or 270 mg of lead during the entire period. In July, after discontinuing use, her BLL decreased to 10 $\mu\text{g}/\text{dL}$. In November, 3 months before delivery, her BLL was 1 $\mu\text{g}/\text{dL}$. The newborn's BLL was not measured.

Patient 3. In June 2011, a woman born in India, aged 24 years, had a BLL of 49 $\mu\text{g}/\text{dL}$ reported during week 15 of

pregnancy. She ingested two tablets of the Ayurvedic prenatal medication Garbhupal Ras daily to “keep her pregnancy and fetus healthy.” She started use at approximately week 9 of pregnancy and continued for about 6 weeks. Her father, an Ayurvedic practitioner in India, prescribed and mailed the medication to her in an unlabeled container. Garbhupal Ras was found to contain 2.2% lead. Based on her reported use, the woman had consumed approximately 7 mg of lead daily or 300 mg of lead over the 6-week period. The product also was found to contain 1.9% mercury and 410 ppm arsenic. Seven weeks later, after discontinuing use, the woman's BLL decreased to 26 $\mu\text{g}/\text{dL}$. Her newborn's BLL was 7 $\mu\text{g}/\text{dL}$ at birth.

Patient 4. In August 2011, a woman born in India, aged 35 years, had a BLL of 42 $\mu\text{g}/\text{dL}$ reported during week 8 of pregnancy. She had a history of miscarriages and used four Ayurvedic medications approximately 2 months before pregnancy to promote fertility. She ceased use upon learning she was pregnant. She had obtained the medications while in India from an Ayurvedic practitioner. One of the medications, Ovarin (Figure), was found to contain as much as 1.2% lead, 1,000 ppm arsenic, and 1.8% mercury, and the woman reported ingesting 1–2 capsules of Ovarin daily. Based on her reported use, the woman had consumed approximately 6–12 mg of lead daily, or 360–720 mg of lead during the 2 months. She miscarried at approximately 11 weeks' gestation.

Patient 5. In January 2012, a woman born in India, aged 33 years, had a BLL of 52 $\mu\text{g}/\text{dL}$ reported during week 10 of pregnancy. She began using five different Ayurvedic

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TABLE. Ayurvedic medications and other health remedies that have been identified with high heavy metal content — New York City Department of Health and Mental Hygiene, 2004–2012

Product	Manufacturer	Country where manufactured	Country where purchased	Usage reported or labeled	Heavy metal content	Rasa shastra*
Calabash Chalk (Nzu)	Unknown	Unknown	United States	Morning sickness	10 ppm As 6.6 ppm Pb	NA
Emperor's Tea Pill (concentrated) [†]	Lanzhou Traditional Herbs	China	United States	Natural balance	5,400 ppm Pb 3,200 ppm Hg	NA
Garbha Chintamani Ras (Vrihat) (Swarna Yukt) [§]	Baidyanath	India	India	Reproductive health	52,000 ppm As 120 ppm Pb	Yes
Garbha Dharak Yog [§]	Vyas Pharmaceuticals	India	India	Reproductive health	100,000 ppm Hg 140 ppm As 110 ppm Pb	Yes
Garbhupal Ras [§]	Unknown	India	India	To keep pregnancy and fetus healthy	22,000 ppm Pb 19,000 ppm Hg 410 ppm As	Yes
Garbhupal Ras [§]	Shri Vishwamitra Ayurved Pharmaceuticals	India	India	To have a male baby	15,000 ppm Pb 4,400 ppm Hg 81 ppm As	Yes
Hepatico Extract (concentrated) [¶]	Lanzhou Traditional Herbs	China	United States	Promote a healthy liver and maintain regularity	5,900 ppm Pb 5,100 ppm Hg	NA
Jambrulin	Unjha Ayurvedic Pharmacy	India	United States	Diabetes	24,300 ppm Pb 35 ppm Hg	Yes
Kankayan Bati (Gulma) [§]	Baidyanath	India	United States	Skin problems	12 ppm Pb 35 ppm Hg 9.5 ppm As	No
Lakshmilash Ras (Nardiya)	Baidyanath	India	United States	Chronic fever, cold, and cough	260 ppm Pb 14,100 ppm Hg 42 ppm As	Yes
Laxmana Louh [§]	Vyas Pharmaceuticals	India	India	Reproductive health	180 ppm Pb 120 ppm Hg 12 ppm As	Yes
Maha Sudarshan	Arya Aushadhi Pharmaceutical Works	India	United States	Flu and body ache	41 ppm Pb 2,190 ppm Hg 11 ppm As	No

See table footnotes on page 644.

medications to improve fertility and one to improve skin complexion about 7 months before her pregnancy. She used each product once or twice daily for approximately 4 months. An Ayurvedic practitioner had provided her with the medications during a previous visit to India. Elevated levels of lead, mercury, or arsenic were found in five of the six medications. Ovarin was found to contain 2.4% lead, 7% mercury, and 100 ppm arsenic. Garbha Dharak Yog was found to contain 10% mercury, 140 ppm arsenic, and 110 ppm lead. Laxmana Louh was found to contain 180 ppm lead, 120 ppm mercury, and 12 ppm arsenic. Garbha Chintamani Ras (Vrihat) (Swarna

Yukt) was found to contain 5.2% arsenic and 120 ppm lead. Pigmento was found to contain 2.9% mercury, 27 ppm arsenic, and 7.3 ppm lead. Based on her reported use, the woman had consumed approximately 12–24 mg of lead daily, or 1.4–2.9 g of lead during the 4 months. She miscarried during week 12 of pregnancy.

Patient 6. In May 2012, a woman born in India, aged 35 years, had a BLL of 24 µg/dL reported during week 22 of pregnancy. In January, she had begun using six medications to increase her chances of “having a male baby.” She obtained the medications from her mother-in-law, who visited an Ayurvedic

TABLE. (Continued) Ayurvedic medications and other health remedies that have been identified with high heavy metal content — New York City Department of Health and Mental Hygiene, 2004–2012

Product	Manufacturer	Country where manufactured	Country where purchased	Usage reported or labeled	Heavy metal content	Rasa shastra*
Mahashakti Rasayan	Vyas Pharmaceuticals	India	India	Weakness	9,400 ppm Pb 70,000 ppm Hg 1,700 ppm As	Yes
Mahayogaraj Guggulu (enriched with silver)	Baidyanath	India	United States	Rheumatic pain	47,000 ppm Pb 4,800 ppm Hg 4,300 ppm As	Yes
Ovarin [§]	Ban Labs Ltd.	India	India	Facilitate ovulation Reproductive health	24,000 ppm Pb 70,000 ppm Hg 1,000 ppm As	Yes
Pigmento [§]	Charak Pharma Pvt. Ltd.	India	India	Improve skin complexion	29,000 ppm Hg 27 ppm As 7.3 ppm Pb	Yes
Pregnita [§]	Ajmera Pharmaceuticals	India	India	Pregnancy-related nausea and vomiting	12,000 ppm Pb	Yes
Sorin	Research Drugs & Pharmaceuticals	India	India	Eczema	46,707 ppm Pb	Yes
Tierra Santa	Unknown	Mexico	United States	Cleanse stomach for pregnancy	13 ppm Pb 11 ppm As	NA
Vasant Kusumakar Ras (with Gold and Pearl)	Dabur	India	India	Diabetes and weakness	29 ppm Pb 31,000 ppm Hg	Yes
Vatvidhwansan Ras [§]	Baidyanath	India	United States	Skin problems	20,000 ppm Pb 15,000 ppm Hg 130 ppm As	Yes
Vita Breath	American Herbal Laboratories	United States	United States	Incontinence and to test the "strength of meridians"	1,100 ppm Pb	NA

Abbreviations: Pb = lead; Hg = mercury; As = arsenic; NA = not applicable (product is not Ayurvedic).

* Rasa shastra is the ancient practice of deliberately combining herbs with "bhasmas" (elaborately prepared metal, mineral, and gem compounds perceived to be safe) to enhance therapeutic benefit. Ayurvedic medications are divided into two major categories: herbal only and rasa shastra. Source: Saper RB, Phillips RS, Sehgal A, et al. Lead, mercury, and arsenic in US- and Indian-manufactured Ayurvedic medicines sold via the Internet. *JAMA* 2008;300:915–23.

† Lot no. 010705, expiration date: July 2010.

§ The 10 products associated with the six cases described in this report.

¶ Lot no. 040804, expiration date: August 2009; lot no. 100105, expiration date: January 2010; lot no. 110604, expiration date: June 2009.

practitioner in India on her behalf. She took the medication 1–3 times a day until she discontinued use in June. One of the medications, Garbhupal Ras, was found to contain 1.5% lead, 0.44% mercury, and 81 ppm arsenic. Based on her reported use, the woman had consumed approximately 2–7 mg of lead daily, or 300–1,000 mg over the 5 months. Her BLL decreased to 11 µg/dL 5 weeks after discontinuing the medications. The woman had not yet delivered as of August 20.

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Editorial Note

Foreign-born pregnant women might be at increased risk for lead poisoning. Reasons include use of certain foreign products and increased bone stores of lead from past exposures. The body's demand for calcium increases during pregnancy to support fetal bone development, which might release these bone

What is already known on this topic?

Foreign-born populations, including pregnant women, might have increased risk for lead poisoning because of their use of foreign medications or dietary supplements containing high levels of lead. Numerous cases of heavy metal poisonings associated with the use of health products made or brought from abroad have been documented.

What is added by this report?

During 2011–2012, six pregnant women with elevated blood lead levels were identified in New York City as a result of required prenatal screening. All six were foreign-born users of oral Ayurvedic medications made in India. The products used contained up to 2.4% lead, and several contained mercury and arsenic, which also can have adverse health effects.

What are the implications for public health practice?

Products containing lead and other heavy metals are available to consumers through travel abroad or other channels in which regulation is limited or unenforceable. When lead poisoning is suspected, public health workers and health-care providers should consider as potential risk factors the use of foreign medications, dietary supplements, or traditional remedies, especially among foreign-born persons and, importantly, among pregnant women. Health-care providers should advise patients to stop using foreign products that might contain heavy metals and consider testing patients for exposure to lead or other heavy metals if use is reported.

stores. In 2011, of the 205 New York City women reported to DOHMH with BLLs $\geq 10 \mu\text{g/dL}$, 118 (58%) were pregnant, and 98 (83%) of the pregnant women were foreign-born (New York City Department of Health and Mental Hygiene, unpublished data, 2011). More than 70% of pregnant women with elevated BLLs interviewed by DOHMH in 2011 reported using foreign traditional or familiar products from their ancestral countries, such as cosmetics, medications, remedies, food, and pottery, suggesting that health-care providers should question pregnant women about their use of such products.

Pregnant women present a unique concern, because lead exposure can adversely affect the health of both mother and child. Fetal lead exposure increases the risks for low birth weight, developmental delay, reduced intelligence, and behavioral problems (1). Pregnant women exposed to lead might be at increased risk for gestational hypertension and spontaneous abortion (1). Exposure to other heavy metals, such as arsenic and mercury, also can have adverse health effects. Two of the six patients miscarried before 20 weeks' gestation. Both patients were taking Ayurvedic medications to promote fertility, and it is unknown whether underlying reproductive problems or heavy metal exposures contributed to the miscarriages.

Numerous cases of heavy metal poisonings associated with the use of foreign medications, supplements, traditional

FIGURE. Two of 10 Ayurvedic medications associated with lead poisoning in six pregnant women — New York City Department of Health and Mental Hygiene, 2011–2012



Photos / New York City Department of Health and Mental Hygiene

remedies, or other health products have been documented (2–5). In one study, 20% of South Asian herbal medications purchased in Boston-area stores contained heavy metals (6). Heavy metals might not be listed as ingredients and might only be identified by testing. Some heavy metal inclusion might result from incidental contamination during production (e.g., the use of contaminated raw ingredients or poor manufacturing equipment), whereas other inclusion might be intentional for perceived therapeutic benefits.

The cases of lead poisoning described in this report were associated with the use of Ayurvedic medications. Ayurveda is a millennia-old medical system closely connected to traditional culture and religion in India (7,8). According to a national survey, an estimated 214,000 adults in the United States visited an Ayurvedic practitioner in 2007, an increase of 39% since 2002 (8). Most Ayurvedic medications are marketed either as dietary supplements or for drug uses not approved by the Food and Drug Administration (FDA). None of the nine medications with labeling information that were used by the patients in this report has been the subject of an FDA import alert.* However, in a 2008 update, FDA urged consumers to use caution with Ayurvedic products.† Although not all Ayurvedic medications include heavy metals intentionally, all six patients in this report used “rasa shastra” medications. Rasa shastra is a type of Ayurvedic medication that is intentionally prepared with metal, mineral, or gem compounds (9). These compounds, called “bhasmas,” sometimes are indicated on product labels.

* Information available at <http://www.fda.gov/forconsumers/consumerupdates/ucm269384.htm>.

† Information available at <http://www.fda.gov/downloads/forconsumers/consumerupdates/ucm050819.pdf>.

DOHMH visits local stores to assess availability of products identified through case investigations and published reports or to collect and test products that are suspect. Stores selling contaminated products, such as the local business that sold medications to patient 2, are prohibited from any further sales of identified products and are ordered to return remaining stock to distributors. DOHMH also alerts local health-care providers through its Health Alert Network and notifies manufacturers. DOHMH reports contaminated products to the FDA dietary supplements adverse event reporting website[§] and appropriate foreign authorities. Reporting to FDA is important to systematically gather data and understand the scope of the problem. Information regarding these products is forwarded to FDA global offices to encourage collaborative efforts to improve product safety in the United States and abroad.

The cases of lead poisoning among the six pregnant women underscore the importance of risk assessment for lead exposure and blood lead testing in at-risk populations. Health-care providers should 1) be aware that users might not readily disclose use of health products; 2) ask patients about their use of prescription and nonprescription medications and supplements, including Ayurvedic medications and other traditional remedies; 3) advise patients to stop using suspect products; and 4) consider testing patients for exposure to lead or other heavy metals if use is reported. Public health workers and health-care providers should consider the use of foreign supplements, medications, traditional remedies, or other health products as potential risk factors when investigating lead and other heavy

metal poisonings, especially in foreign-born populations, and particularly among pregnant women. Risk assessments and testing conducted during prenatal visits are critical to identifying and intervening in heavy metal poisoning cases. Public health measures, such as blood lead testing and surveillance in the United States and elsewhere, are necessary to assess the extent of lead exposure and develop appropriate interventions.

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[§] Available at <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>.

Vaccination Coverage Among Children in Kindergarten — United States, 2011–12 School Year

In 2011, CDC reported 17 outbreaks of measles and 222 measles cases, most of which were imported cases in unvaccinated persons. This was the highest number of measles cases in any year in the United States since 1996 and highlights the importance of monitoring measles vaccination coverage at the local level (1). To identify areas of undervaccination for measles and other vaccine-preventable diseases, state and local health departments monitor compliance with school immunization requirements using annual school vaccination assessment reports, supported as a CDC immunization funding objective for the 64 grantees, including the 50 states, the District of Columbia (DC), five cities, and eight other reporting areas. CDC also monitors progress toward meeting *Healthy People 2020* objectives (2) for the vaccination of children entering kindergarten. This report summarizes vaccination coverage, exemption rates, and reporting methods from the 2011–12 school year kindergarten vaccination assessments submitted by 56 grantees, including 49 states, DC, one city, and five other reporting areas. Median coverage with 2 doses of measles, mumps, and rubella (MMR) vaccine was 94.8% among 47 reporting states and DC. Total exemption rates, including medical, religious, and philosophic exemptions, among 49 reporting states and DC, ranged from <0.1% to 7.0% (median: 1.5%). Although statewide levels of vaccination coverage are at or very near target levels, locally low vaccination coverage for extremely transmissible diseases such as measles remains a threat to health. Monitoring MMR vaccination coverage at the local and state level will continue to be critical as long as the risk for measles importation and outbreaks exist.

Healthy People 2020 objectives include maintaining vaccination coverage among children in kindergarten (objective IID-10) and increasing the number of states (including DC) collecting kindergarten vaccination coverage data in accordance with CDC minimum standards (objective IID-19) (2).^{*} The coverage target is ≥95% vaccination coverage for the following vaccines: MMR; diphtheria, tetanus toxoid, and acellular

pertussis (DTaP)[†]; poliovirus; hepatitis B (HepB); and varicella. The reporting target is 50 states and DC collecting kindergarten vaccination coverage data in accordance with CDC minimum standards.

Vaccination coverage among children entering school is assessed annually by federal immunization grantees. Generally, at the start of the school year, health department or school personnel conduct a vaccination coverage survey or census of enrolled students to determine compliance with school requirements established to protect children from vaccine-preventable diseases. Children receiving an exemption to school requirements are included as enrolled students. Results of the school-level reviews are reported to the grantee health department, which then reports aggregated totals to CDC; not all states reported both vaccination coverage levels and exemption rates. All 54 grantees reporting vaccination coverage by vaccine assessed public schools, and all but North Dakota, Oklahoma, and Palau included private schools in their assessments (Table 1). Surveys were completed by census (36 grantees) or a sample (20 grantees). For grantees surveying <95% of the population of enrolled kindergarten students, data were weighted based on the estimated size of the population of children in kindergarten. Survey methods varied across grantees; however, 20 of the grantees targeted by the *Healthy People 2020* objective collected data in accordance with CDC minimum standards.

Vaccination status of kindergarteners was considered up-to-date if they had received all of the vaccine doses required for school entry in their state or area. All reporting grantees required 2 doses of MMR vaccine and 3 or 4 doses of poliovirus vaccine. School entry requirements for other vaccinations varied by grantee: 52 grantees required 4 or 5 doses of DTaP vaccine, 50 grantees required 3 doses of HepB vaccine, and 13 grantees required 1 dose and 37 grantees required 2 doses of varicella vaccine.[§] The types of exemptions and the process for obtaining exemptions varied by grantee (3). All reporting

^{*} States are asked to use comparable methods to allow comparison and to ensure that the information collected is accurate. The methodology must include these standards: meeting all age-appropriate recommendations of the Advisory Committee on Immunization Practices, including 2 doses of varicella; census or CDC-recommended sampling methodology; validation of data collected by school administrators through subsampling a percentage of schools; data collection by trained personnel; data on vaccination history from a health-care provider; and data collected by December 31 of each year.

[†] DTaP vaccination coverage might include some diphtheria and tetanus toxoids and pertussis vaccine (DTP) or diphtheria and tetanus toxoids (DT) vaccinations if administered in another country or if the vaccination provider continued to use these vaccines after 2000.

[§] One state (South Dakota) assessed vaccination coverage for 3 doses of HepB vaccine, but HepB vaccination is not a requirement for school entry. One state (Nevada) assessed vaccination coverage for 2 doses of varicella vaccine, but the number of doses required varied by school district.

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TABLE 1. Estimated vaccination coverage among children enrolled in kindergarten, by state/area, type of survey conducted, and vaccine — United States, 2011–12 school year

State/Area	Total kindergarten population*	Total surveyed	% surveyed†	Type of survey conducted§	MMR¶ (%)	DTaP/DT** (%)	Polio (%)	Hepatitis B (%)	Varicella	
									1 dose (%)	2 doses (%)
Alabama	73,190	73,190	100.0	Census	93.6	93.6	93.6	—††	93.2	—††
Alaska	10,286	750	7.3	Nonrandom cluster	95.5	96.0	97.4	97.1	—§§	93.6
Arizona	88,293	85,514	96.9	Census	94.7	94.9	94.9	96.3	96.9	—††
Arkansas	38,754	35,720	92.2	Census	94.9	84.1	84.3	98.1	—§§	95.4
California	542,544	529,400	97.6	Census	93.2	93.0	93.2	95.7	96.1	—††
Colorado	70,142	318	0.5	SRS	86.8	85.5	87.4	93.1	—§§	84.0
Connecticut	45,695	45,695	100.0	Census	97.4	97.8	97.7	98.0	—§§	97.1
Delaware	11,327	833	7.4	2-stage cluster	96.9	96.9	96.9	96.9	—§§	96.9
District of Columbia	6,854	6,854	100.0	Census	94.0	91.1¶¶	93.0	96.6	—§§	93.5
Florida	225,532	225,532	100.0	Census	92.6	92.6	92.6	92.6	—§§	92.6
Georgia	143,065	2,685	1.9	2-stage cluster	96.6	96.7	96.7	96.7	—§§	96.6
Hawaii	19,443	1,506	7.7	2-stage cluster	94.4	93.3¶¶	93.7	94.9	95.7	—††
Idaho	22,762	22,762	100.0	Census	89.2	89.0¶¶	89.6	92.3	—§§	85.8
Illinois	163,311	163,311	100.0	Census	97.3	96.4	96.2	—††	98.0	—††
Indiana	83,416	56,342	67.5	Census	93.3	90.2¶¶	90.4	93.2	—§§	91.9
Iowa	40,978	40,978	100.0	Census	91.1	91.1	91.1	91.1	—§§	91.1
Kansas	38,402	20,255	52.7	Mixed design	88.2	88.0¶¶	96.9	95.8	—§§	85.9
Kentucky	58,185	53,441	91.8	Census	92.0	93.7	95.0	93.3	75.7	—††
Louisiana	69,013	69,013	100.0	Census	98.1	98.9	99.6	99.3	—§§	97.2
Maine	13,829	13,415	97.0	Census	93.0	96.6	96.1	—††	94.9	—††
Maryland	72,957	49,024	67.2	Census	98.7	99.6	99.7	99.6	99.7	—††
Massachusetts	79,551	77,535	97.5	Census	94.2	92.5¶¶	93.3	97.8	—§§	92.7
Michigan	124,962	124,962	100.0	Census	95.0	95.6	95.9	96.8	—§§	93.2
Minnesota	71,213	70,649	99.2	Census	95.7	95.5¶¶	95.8	97.5	—§§	94.9
Mississippi	44,912	44,912	100.0	Census	99.2	99.2¶¶	99.2	99.2	—§§	99.2
Missouri	75,240	3,523	4.7	2-stage cluster	96.8	97.1	97.2	96.0	—§§	95.1
Montana	12,128	12,128	100.0	Census	95.0	94.8	95.7	—††	—§§	—††
Nebraska	26,715	25,794	96.6	Census	99.0	99.7***	99.5	99.3	—§§	96.8
Nevada	36,557	1,915	5.2	2-stage cluster	95.3	97.2	98.3	97.8	—§§	90.3
New Hampshire	13,022	13,022	100.0	Census	—†††	—†††	—†††	—†††	—†††	—†††
New Jersey	118,669	114,666	96.6	Census	—†††	—†††	—†††	—†††	—†††	—†††
New Mexico	29,159	587	2.0	2-stage cluster	95.7	96.9	97.6	97.3	—§§	94.2
New York State	236,016	236,016	100.0	Census	96.9	97.9***	98.4	98.2	98.4	—††
North Carolina	128,854	122,892	95.4	Census	97.2	97.0	97.3	98.0	98.1	—††
North Dakota	8,412	487	5.8	Convenience§§§	90.6	91.2	90.6	91.4	—§§	88.9
Ohio	Unknown¶¶¶	138,075	NA	Convenience	96.1	95.9****	96.2****	99.0****	—§§	95.4****
Oklahoma	52,987	48,191	90.9	Census§§§	95.0	94.6¶¶	94.6	97.7	97.8	—††
Oregon	45,855	45,855	100.0	Census	94.0	93.7¶¶	94.0	94.6	95.0	—††
Pennsylvania	148,042	146,502	99.0	Census	86.9	91.1**	95.5	94.4	—§§	85.1
Rhode Island	12,552	1,745	13.9	2-stage cluster	91.7	93.4¶¶	92.6	93.1	—§§	91.3
South Carolina	59,307	6,340	10.7	1-stage cluster	94.5	96.5	96.7	96.6	97.1	—††
South Dakota	12,127	12,127	100.0	Census	97.4	97.5	97.2	95.4	—§§	95.5
Tennessee	83,950	83,878	99.9	Census	97.3	97.3	97.3	97.3	—§§	97.3
Texas	388,178	388,178	100.0	Census	99.3	99.3¶¶	99.3	99.7	—§§	99.2
Houston, TX	Unknown	3,100	NA	2-stage cluster	99.5	97.7¶¶¶¶	99.5****	99.9****	—§§	—††
Utah	53,800	53,800	100.0	Census	98.0	97.7	98.1	99.1	99.5	—††
Vermont	6,548	6,548	100.0	Census	92.9	92.7	92.7	95.6	—§§	90.3
Virginia	101,121	4,394	4.3	2-stage cluster	93.0	98.6	93.0	92.7	—§§	90.6
Washington	85,134	75,870	89.1	Census	91.8	90.9¶¶	91.0	93.0	—§§	90.4
West Virginia	22,449	21,299	94.9	Convenience	92.0	92.6	92.6	93.3	—§§	88.9
Wisconsin	70,672	1,630	2.3	2-stage cluster	93.1	87.7	96.9	96.2	—§§	91.0
Wyoming	NA	NA	NA	Not conducted	—§§	—§§	—§§	—§§	—§§	—§§
Median††††					94.8	95.2	95.9	96.6	97.0	93.2
American Samoa	NA	NA	NA	Not conducted	—§§	—§§	—§§	—§§	—§§	—§§
Guam	2,702	1,243	46.0	2-stage cluster	83.6	94.3	89.3	83.1	—††	—††
Marshall Islands	NA	NA	NA	Not conducted	—§§	—§§	—§§	—§§	—§§	—§§
Micronesia	NA	NA	NA	Not conducted	—§§	—§§	—§§	—§§	—§§	—§§
N. Mariana Islands	962	962	100.0	Census	84.0§§§§	90.0§§§§	84.0§§§§	94.9§§§§	—§§	73.5
Palau	234	230	98.3	Census§§§	96.5	98.7	98.7	99.6	—††	—††
Puerto Rico	41,379	1,062	2.6	2-stage cluster	96.6	94.2¶¶	96.3	99.2	—§§	87.8
U.S. Virgin Islands	1,604	402	25.1	2-stage cluster	81.7	78.1	62.5	84.0	—§§	78.2

See table footnotes on page 649.

TABLE 1. (Continued) Estimated vaccination coverage among children enrolled in kindergarten, by state/area, type of survey conducted, and vaccine — United States, 2011–12 school year

Abbreviation: NA = not available.

* The reported number of enrolled children is an estimate.
 † The proportion of eligible children for whom vaccination data were collected.
 ‡ Sample designs varied by state/area. Census means that all schools and all children within schools were included in the assessment. SRS means a simple random sample design was used. Mixed design means a census was conducted among public schools, and a 2-stage cluster sample was conducted among private schools. 1-stage or 2-stage cluster sample means that schools were randomly selected, and all children in the selected schools were assessed (1-stage) or a random sample of children within the schools were selected (2-stage). Convenient sample means that the selection process is unspecified.
 ¶ Measles, mumps, and rubella.
 ** Diphtheria and tetanus toxoids and acellular pertussis vaccine. DTaP vaccination coverage might include some DTP (diphtheria and tetanus toxoids and pertussis vaccine) or DT (diphtheria and tetanus toxoids) vaccinations if administered in another country or vaccination provider continued to use after 2000. Pertussis vaccine is not required in Pennsylvania; the estimate for Pennsylvania represents DT only.
 †† Vaccine not required for school entry.
 ††† Coverage levels for 1 dose of varicella are not presented when coverage for 2 doses of varicella were reported.
 ¶¶ Reported estimate is for 5 doses of DTaP.
 *** Reported estimate is for 3 doses of DTaP.
 †††† Did not report antigen-specific information.
 §§§ Represents public school children only.
 ¶¶¶ Number of children enrolled in private school is unknown.
 **** Estimates are based on total children surveyed because total children enrolled is unknown.
 ††††† The center of the estimates in the distribution. The median is based on estimates for 49 states and the District of Columbia.
 §§§§ Estimates are based on Advisory Committee on Immunization Practices requirements rather than state/jurisdiction requirements; otherwise, 100% of children met state estimates.

grantees allowed medical exemptions, 47 allowed religious exemptions, and 20 allowed philosophic exemptions; two grantees (Mississippi and West Virginia) did not allow exemptions for religious or philosophic reasons. Exemption data reported to CDC were nonspecific; exemptions for one vaccine, a required vaccine dose, or for all required vaccines were not differentiated by type of exemption. Vaccination and/or exemption status might not have been reported as final for each surveyed child because some children might have been in the process of obtaining required vaccines and final vaccination and/or exemption status might have been updated after the survey was completed.

Overall, among grantees in the 47 states and DC that reported 2011–12 school vaccination coverage, median MMR vaccination coverage was 94.8%, with a range of 86.8% in Colorado to 99.3% in Texas; four jurisdictions of these grantees reported <90% MMR coverage (Table 1). Median coverage with 2 doses of varicella vaccine among 33 grantees reporting was 93.2%, with a range of 84.0% in Colorado to 99.2% in Mississippi and Texas. The median coverage levels for DTaP, poliovirus, and HepB vaccines all were at or above the *Healthy People 2020* target of 95%.

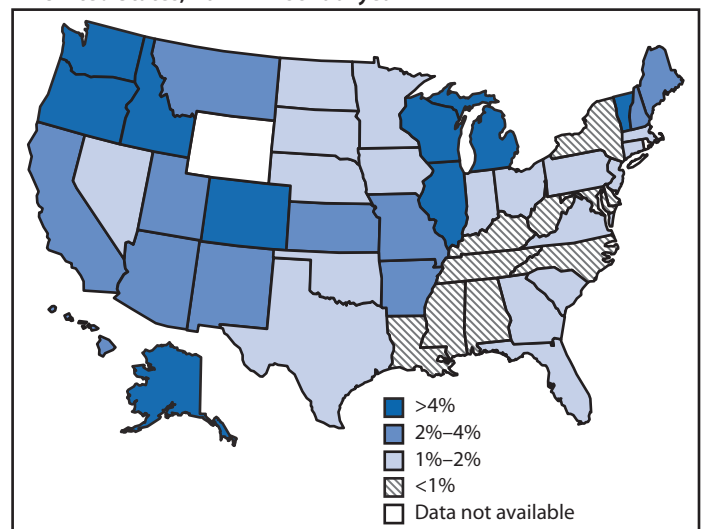
Overall, among the grantees in the 49 states and DC that reported exemptions for the 2011–12 school year, 10 reported <1%, and nine reported >4% total exemption rates (Figure), with a range of <0.1% in Mississippi to 7.0% in Alaska (Table 2). An estimated 89,133 exemptions were reported, for a total estimated population of 4,124,185 kindergarten children. The median total exemption level was 1.5%, a median increase of 0.2 percentage points compared with the 2009–10 school year. The largest increase in exemption levels was reported by Arkansas, with an increase of 3.4 percentage points; the largest decrease was reported by Nebraska, with a

decrease of 2.3 percentage points. Where reported separately, the median medical exemption level was 0.3 %, with a range of 0.0% in New Mexico and North Dakota to 1.3% in DC. Where allowed and reported separately, the median nonmedical exemption level was 1.2 %, with a range of 0.04% in Delaware and Kentucky to 5.8% in Oregon.

Reported by

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FIGURE. Estimated percentage of children enrolled in kindergarten who have been exempted from receiving one or more vaccines* — United States, 2011–12 school year



* Exemptions might not reflect a child's vaccination status. Children with an exemption who did not receive any vaccines are indistinguishable from those who have an exemption but are up-to-date for one or more vaccines.

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TABLE 2. Number and percentage* of children enrolled in kindergarten with a reported exemption to vaccination, by state/area and type of exemption — United States, 2011–12 school year

State/Area	Medical exemptions [†]		Nonmedical exemptions [†]				Total exemptions			
	No.	(%)	Religious (No.)	Philosophic (No.)	Total (No.)	(%)	Total (No.)	2009–10 (%)	2011–12 (%)	Difference (%)
Alabama	109	0.1	356	— [§]	356	0.5	465	0.5	0.6	0.2
Alaska	10	1.3	43	— [§]	43	5.7	53	5.5	7.0	1.5
Arizona	239	0.3	— [¶]	2,948	2,948	3.5	3,187	3.0	3.7	0.8
Arkansas	168	0.5	— [¶]	1,234	1,234	3.4	1,402	0.6	3.9	3.4**
California	871	0.2	— [¶]	12,665	12,665	2.4	13,536	2.2	2.6	0.4
Colorado	— ^{††}	— ^{††}	— ^{§§}	— ^{¶¶}	— ^{§§¶¶}	— ^{§§¶¶}	18	— ^{***}	5.6	— ^{***}
Connecticut	137	0.3	472	— [§]	472	1.0	609	1.1	1.3	0.3
Delaware	1	0.2	6	— [§]	6	0.4	7	0.8	0.6	-0.2
District of Columbia	91	1.3	53	— [§]	53	0.8	144	1.1	2.1	1.0
Florida	724	0.3	2,771	— [§]	2,771	1.2	3,495	1.3	1.5	0.3
Georgia	2	0.1	57	— [§]	57	1.2	59	1.1	1.3	0.2
Hawaii	2	0.1	58	— [§]	58	3.8	60	3.6	3.9	0.3
Idaho	61	0.3	114	1,051	1,165	5.1	1,226	3.8	5.4	1.6**
Illinois	1,745	1.1	7,270	— [§]	7,270	4.5	9,015	4.3	5.5	0.2
Indiana	137	0.2	514	— [§]	514	0.9	651	1.1	1.2	0.1
Iowa	195	0.5	412	— [§]	412	1.0	607	1.4	1.5	0.1
Kansas	123	0.6	332	— [§]	332	1.7	455	1.0	2.3	1.3
Kentucky	104	0.2	214	— [§]	214	0.4	318	0.6	0.6	-0.1
Louisiana	166	0.2	50	334	384	0.6	550	0.8	0.8	0.0
Maine	47	0.4	13	457	470	3.5	517	3.3	3.9	0.6
Maryland	161	0.3	293	— [§]	293	0.6	454	0.8	0.9	0.1
Massachusetts	325	0.4	742	— [§]	742	1.0	1,067	1.1	1.4	0.3
Michigan	767	0.6	952	5,213	6,165	4.9	6,932	4.4	5.5	1.1
Minnesota	59	0.1	— ^{§§}	1,086	1,086	1.5	1,145	— ^{***}	1.6	— ^{***}
Mississippi	16	0.0	— [¶]	— [§]	— ^{¶§}	— ^{¶§}	16	0.0	0.0	0.0
Missouri	19	0.6	71	— [§]	71	1.8	90	1.1	2.4	1.3
Montana	52	0.4	312	— [§]	312	2.6	364	3.1	3.0	-1.2
Nebraska	126	0.5	251	— [§]	251	1.0	377	3.8	1.5	-2.3**
Nevada	4	0.2	38	— [§]	38	1.5	42	2.0	1.8	-0.2
New Hampshire	34	0.3	251	— [§]	251	1.9	285	— ^{***}	2.2	— ^{***}
New Jersey	226	0.2	1,278	— [§]	1,278	1.1	1,504	1.0	1.3	0.4
New Mexico	0	0.0	12	— [§]	12	2.0	12	0.7	2.0	1.3
New York State	331	0.1	1,283	— [§]	1,283	0.5	1,614	0.6	0.7	-0.1
North Carolina	186	0.2	817	— [§]	817	0.7	1,003	0.8	0.8	0.0
North Dakota	0	0.0	0	5	5	1.0	5	0.8	1.0	0.2
Ohio	275	0.2 ^{†††}	— ^{§§}	1,582	1,582	1.3	1,857	1.4	1.5	0.2
Oklahoma	74	0.2	135	339	474	1.0	548	1.1	1.1	0.0
Oregon	80	0.2	2,648	— [§]	2,648	5.8	2,728	5.4	5.9	0.5
Pennsylvania	598	0.4	2,083	0	2,083	1.4	2,681	1.5	1.8	0.4
Rhode Island	5	0.3	12	— [§]	12	0.7	17	0.5	1.0	0.5
South Carolina	5	0.1	59	— [§]	59	1.0	64	0.8	1.1	0.2
South Dakota	30	0.2	120	— [§]	120	1.0	150	1.1	1.2	0.2
Tennessee	153	0.2	417	— [§]	417	0.5	570	0.5	0.7	0.2
Texas	2,058	0.5	— [¶]	3,889	3,889	1.0	5,947	1.4	1.5	1.1
Houston	4	0.1 ^{†††}	— [¶]	0	0 [¶]	0.0 [¶]	4	— ^{***}	0.1	— ^{***}
Utah	79	0.1	24	1,929	1,953	3.6	2,032	3.8	3.8	0.0
Vermont	21	0.3	9	342	351	5.4	372	5.8	5.7	-0.1
Virginia	15	0.3	61	— [§]	61	0.8	76	0.9	1.0	0.1
Washington	376	0.5	170	2,926	3,096	4.2	3,472	6.2	4.7	-1.5
West Virginia	44	0.2	— [¶]	— [§]	— ^{¶§}	— ^{¶§}	44	1.3	0.2	-1.1
Wisconsin	7	0.4	2	67	69	4.1	76	3.7	4.5	0.8
Wyoming	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}
Median^{§§§}		0.3				1.2		1.1	1.5	0.2
American Samoa	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}
Guam	0	0.0	0	— [§]	0	0.0	0	— ^{***}	0.0	— ^{***}
Marshall Islands	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}
Micronesia	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}	— ^{***}
N. Mariana Islands	0	0.0	0	0	0	0.0	0	— ^{***}	0.0	— ^{***}
Palau	3	1.3	— ^{¶¶¶}	— ^{¶¶¶}	— ^{¶¶¶}	— ^{¶¶¶}	3	— ^{***}	1.3	— ^{***}
Puerto Rico	0	0.0	0	— [§]	0	0.0	0	— ^{***}	0.0	— ^{***}
U.S. Virgin Islands	0	0.0	2	— [§]	2	0.5	2	— ^{***}	0.5	— ^{***}

See table footnotes on page 651.

TABLE 2. (Continued) Number and percentage* of children enrolled in kindergarten with a reported exemption to vaccination, by state/area and type of exemption — United States, 2011–12 school year

* All estimates of percentages of children with exemptions are weighted to the number of enrolled children unless otherwise noted. Number of exemptions are unweighted counts.
 † Medical and nonmedical exemptions might not be mutually exclusive. Some children might have both medical and nonmedical exemptions.
 ‡ Exemptions because of philosophic reasons are not allowed.
 § Exemptions because of religious reasons are not allowed.
 ** Rate differences between 2009–10 school year and 2010–11 school year are greater than 1.5 percentage points.
 †† Exemptions because of medical reasons are allowed but are not reported separately from other exemptions.
 ‡‡ Exemptions because of religious reasons are allowed but are not reported separately from other exemptions.
 ¶¶ Exemption because of philosophic reasons are allowed but are not reported separately from other exemptions.
 *** Did not report exemptions to CDC.
 ††† Estimates are based on total children surveyed because total children enrolled is unknown.
 §§§ The median is based on estimates for 49 states and District of Columbia.
 ¶¶¶ Exemptions are allowed but not tracked.

Editorial Note

Sustaining high vaccination coverage among school children is vital to prevent outbreaks and avoid reestablishment of diseases that have been eliminated in the United States. The median MMR and 2-dose varicella vaccination coverage levels for children entering kindergarten for the 2011–12 school year were below the *Healthy People 2020* target of $\geq 95\%$. The high number of measles cases reported in Europe in 2011 contributed to record numbers of imported cases in the United States (1). Among the U.S. measles cases in persons aged 16 months through 19 years reported in 2011, 76% were in persons not vaccinated for a nonmedical reason (1). Achieving high MMR vaccination coverage rates early in life, including $>90\%$ 1-dose coverage at age 12–15 months and $>95\%$ 2-dose coverage among school-aged children, is essential to maintain measles elimination in the United States (4). Although median MMR vaccination coverage among children entering kindergarten was close to the $\geq 95\%$ target, MMR vaccination coverage and exemptions aggregated at national or state levels can mask substantial vulnerability at the local level. Since exemptions cluster geographically (5,6), there might be smaller areas and schools where low levels of immunization could sustain ongoing measles transmission after importation from other countries.

Exemption levels continue to be low overall; however, these low levels are aggregated at the state level before they are reported to CDC. The reported exemptions could be for one or more required vaccines. It is unlikely that children with an exemption were completely unvaccinated. The 2005–2006 birth cohort matriculated into the school system during the 2011–12 school year, and their vaccination coverage was measured using data from the 2006–2009 National Immunization Surveys, which indicate that $<1\%$ of children had not received any vaccines (7). A study of school children with nonmedical exemptions found that 75% of these children had received at least one vaccine previously (8). The process of requesting an exemption might be related to exemption levels, with easier

What is already known on this topic?

Outbreaks of some vaccine-preventable diseases can occur despite generally high levels of vaccination coverage. To ensure that children entering school are protected from vaccine-preventable disease, kindergarten vaccination assessments are performed annually. These assessments monitor state and local levels of vaccination coverage and compliance with state vaccination requirements.

What is added by this report?

In 47 states and the District of Columbia, median vaccination coverage for three vaccines (diphtheria and tetanus toxoids and acellular pertussis; poliovirus; and hepatitis B) met the *Healthy People 2020* target of $\geq 95\%$. However, median coverage for measles, mumps, and rubella vaccine and varicella vaccine were $<95\%$. Exemption levels were low overall, but clusters of unvaccinated children might exist at the school or community level.

What are the implications for public health practice?

Although statewide levels of vaccination coverage are at or very near target levels, locally low vaccination coverage for extremely transmissible diseases such as measles remains a threat to public health. CDC will continue to support and build capacity to assist grantees in identification of local areas with low vaccination coverage or high exemption rates for further intervention.

standards for exemption being associated with higher levels of exemption (3).

Immunization Information Systems (IISs) used by 55 of the 64 grantees might be able to assist with tracking vaccinations, which can improve vaccination coverage (9), and might reduce the reporting burden on parents at school enrollment. Building links between education and public health departments through the use of the local IIS, where acceptable, can ease reporting burdens at the school level and provide state and local public health departments with an accessible tool to monitor vaccination coverage at the school level. In 2010, 52 grantees allowed schools to view records in their IIS, and 18 grantees allowed schools to update information in their IIS (CDC, unpublished data, 2012).

The findings in this report are subject to at least three limitations. First, these data are cross-sectional and generally collected at the start of the school year, although some states might collect later in the school year. Reports might not be updated as a child obtains the required vaccines or exemptions later in the school year. Vaccination and exemption status might not have been reported for every child. By grantee, the proportion of children not classified as either vaccinated or exempt for each individual vaccine was estimated to range from 0% to 29.1%. Second, the vaccines required and survey methods varied by state, although efforts to improve standardization are in progress. Finally, changes in school vaccination assessment reporting over time limit the ability to compare national trends over time.

In 2011, CDC conducted a study to determine best practices in monitoring school vaccination coverage and exemptions among kindergarteners to help meet the *Healthy People 2020* target of 51 grantees collecting kindergarten vaccination coverage in accordance with CDC minimum standards. Best practices included using systematic and standardized approaches to data collection and ensuring communication and partnership between schools and public health systems (CDC, unpublished data, 2012). The annual school vaccination assessment takes place at the local level and might involve school personnel at the time when they are busiest, at the start of a school year. Minimizing the burden on school staff, improving the ease of reporting vaccination coverage and exemption levels, and providing feedback to schools on their vaccination coverage and exemptions levels might help improve school vaccination coverage. Additionally, capturing school vaccination coverage in the local IIS can help ensure a timely response after an imported case of measles, allowing quick identification of those who are not fully vaccinated and need protection. Continued evaluation and understanding of the limitations of the school vaccination assessment reporting system will help identify and address existing limitations and improve the usefulness of the

system. Moreover, the ability to compare school vaccination rates across jurisdictions and over time will permit more effective program improvement efforts.

Assessing vaccination coverage compliance with local requirements and exemption levels as children enter kindergarten is essential for identifying and addressing areas of under-vaccination and reducing outbreaks of vaccine-preventable disease and accompanying morbidity and mortality (9). This report identifies some concerns at the state and national levels that should be investigated at the local level to ensure that the appropriate population protection for measles is maintained at each school to protect school children, their families, and the community.

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Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012

On August 22, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

Permanent tattoos have become increasingly common, with 21% of adults in the United States reporting having at least one tattoo (1). On rare occasions, outbreaks of nontuberculous mycobacterial (NTM) skin infections have been reported after tattooing (2,3). In January 2012, public health officials in New York received reports of *Mycobacterium chelonae* skin infections in 14 New York residents who received tattoos during September–December 2011. All infections were associated with use of the same nationally distributed, prediluted gray ink manufactured by company A. CDC disseminated an Epi-X public health alert to identify additional tattoo-associated NTM skin infections; previously identified cases were reported from three states (Washington, Iowa, and Colorado). Public health investigations by CDC, state and local health departments, and the Food and Drug Administration (FDA) found NTM contamination in tattoo inks used in two of five identified clusters. All infected persons were exposed to one of four different brands of ink. NTM contamination of inks can occur during the manufacturing process as a result of using contaminated ingredients or poor manufacturing practices, or when inks are diluted with nonsterile water by tattoo artists. No specific FDA regulatory requirement explicitly provides that tattoo inks must be sterile. However, CDC recommends that ink manufacturers ensure ink is sterile and that tattoo artists avoid contamination of ink through dilution with nonsterile water. Consumers also should be aware of the health risks associated with getting an intradermal tattoo.

On January 4, 2012, the Monroe County (New York) Department of Public Health began an outbreak investigation after receiving a report of a person with a persistent papular rash beginning 1 week after being tattooed by an artist in October 2011; *M. chelonae* was isolated from a skin biopsy. Since May 2011, the artist had been using company A prediluted gray ink. Using a list of customers provided by the artist, a total of 19 infections were identified, including 14 confirmed with *M. chelonae*.

All infected persons had been tattooed with company A prediluted gray ink. The tattoo artist said he had not diluted the ink before use, and a review of his practices did not reveal other potential sources of contamination. *M. chelonae* was isolated from tissue specimens, and from one opened and one

unopened bottle of company A prediluted gray ink. Pulsed-field gel electrophoresis (PFGE) patterns of 11 available patient isolates and an unopened bottle of company A prediluted gray ink were indistinguishable; the *M. chelonae* isolate from the opened ink bottle showed $\geq 95\%$ genetic relatedness to the other isolates. Water and environmental samples collected at the manufacturing company and tattoo parlor were negative for *M. chelonae*.

Company A prediluted gray ink was a nationally distributed product. To identify additional tattoo-related NTM infections not limited to exposure to any particular brand of ink, case finding was initiated February 15, 2012, through Epi-X using the following case definitions: 1) a *possible case* was defined as persistent inflammatory reaction (i.e., redness, swelling, or nodules) localized within the margins of a new tattoo on a person between May 1, 2011, and February 10, 2012; 2) a *probable case* was defined as a possible case with evidence of an NTM infection by histopathology or clinical response to treatment; 3) a *confirmed case* was defined as a possible case with NTM cultured from a wound or skin biopsy. The New York cluster included 14 confirmed and four probable cases, and one possible case. An investigation by Public Health – Seattle & King County, Washington, identified five confirmed and 26 possible cases. Confirmed cases also were reported from Iowa (two) and Colorado (one) (Table). Among 22 confirmed cases, 63.6% involved men, and the median age of persons in the 22 cases was 33.5 years (range: 20–48 years).

Cases identified in Washington were associated with two clusters, and the initial two cases from patients with recent tattoos were reported by clinicians to local public health authorities. The first, Washington cluster 1, had three confirmed *Mycobacterium abscessus* cases and 24 possible cases in persons tattooed with black ink from company B. Water and environmental samples collected from company B did not grow NTM, but the company reported receiving complaints of unusually long-lasting skin reactions in clients tattooed with company B black ink from 35 customers in 19 states between August 2011 and March 2012. Customer identifiers were not available to CDC for follow-up. Two *M. abscessus* clinical isolates from Washington cluster 1 were indistinguishable by PFGE, but NTM was not recovered from samples of brand B ink. The second Washington cluster had two confirmed cases of *M. chelonae* and two possible cases associated with company C gray ink. One clinical isolate from Washington

TABLE. Characteristics of nontuberculous mycobacteria (NTM) tattoo-associated skin infection clusters — multiple states, 2011–2012

State	No. of cases			Mycobacterium species identified	Tattoo ink supplier and type		Note
	Confirmed	Probable	Possible		Company	Ink	
New York	14	4	1	<i>M. chelonae</i>	A	Prediluted gray	Clinical and company A ink isolates indistinguishable
Washington	3	0	24	<i>M. abscessus</i>	B	Black	No NTM isolated from company B ink
Washington	2	0	2	<i>M. chelonae</i>	C	Gray	Clinical and company C ink isolates unrelated
Iowa	2	0	0	<i>M. chelonae</i>	C	Black	Available clinical isolates from Iowa cluster and Washington cluster 2 were indistinguishable
Colorado	1	0	0	<i>M. chelonae</i>	D	Black	Clinical isolate was unrelated to New York or Washington isolates, no NTM isolated from ink

cluster 2 was available for testing. A sample from an opened bottle of company C gray ink grew *M. chelonae*, which was unrelated to the Washington cluster 2 clinical isolate and was unrelated to New York isolates, based on PFGE patterns. Reviews of tattoo practices at the parlors associated with the clusters did not reveal other potential sources of contamination.

The Iowa Department of Public Health reported two confirmed *M. chelonae* cases. Patients were tattooed with black ink from company C. PFGE testing showed that two clinical isolates from Iowa and the clinical isolate from Washington cluster 2 were indistinguishable from each other, but unrelated to New York isolates. Ink and environmental samples were not available for testing.

The Colorado Department of Public Health and Environment reported one confirmed case of *M. chelonae* infection. PFGE testing showed that this strain was unrelated to any of the clinical and ink isolates identified in other clusters. Artists at the Colorado tattoo parlor reported using distilled or reverse osmosis water to dilute company D black ink. Although used for tattooing, the ink was labeled as a drawing ink, and specified as not indicated for tattooing. The artist rinsed needles with distilled or reverse osmosis water when switching colors of ink on the same client. An unopened bottle of company D black drawing ink, reverse osmosis water samples, and environmental samples were tested, but NTM were not recovered.

In March and April 2012, FDA conducted inspections of company A and company B ink manufacturing sites. Ingredients used in the manufacture of tattoo inks at those sites included a wide range of pigments, carrier solutions, and diluents, including distilled water in some formulations. Samples of unopened ink bottles, ink ingredients, environmental samples, distilled water, and tap water were tested at CDC and did not yield NTM.

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Editorial Note

This report describes cases of tattoo-associated NTM skin infections in four states. The use of ink contaminated before distribution or just before tattooing likely led to infections in each of the reported clusters. In the New York cluster, NTM isolates from clinical specimens, and unopened containers of company A prediluted gray ink were indistinguishable. In Washington cluster 2 and the Iowa cluster, intrinsic contamination of company C gray ink was indicated by indistinguishable *M. chelonae* clinical isolates from infected tattoo lesions, with no other common exposure except the brand of ink used for tattooing. NTM isolates matching cases were not cultured from any other brand of ink; however, whether the ink samples tested were from the same batches of inks used in the cases could not be determined.

The frequency of NTM skin and soft tissue infections occurring subsequent to tattooing is not known, but these events have been reported previously, and dilution of inks with nonsterile water during tattooing was implicated (3–6). Tattoo-associated NTM infections can range from mild inflammation (e.g., rash, papules, or nodules) to severe abscesses requiring

What is already known on this topic?

Outbreaks of tattoo-associated nontuberculous mycobacterial (NTM) skin infections are reported infrequently. Dilution of tattoo inks with nonsterile water during tattooing has been implicated as a potential source of infection.

What is added by this report?

Investigations of 22 cases of tattoo-associated NTM skin infections in four states that occurred during 2011–2012 found contamination of ink with NTM before use. NTM contamination can occur during the manufacturing process as a result of using contaminated ingredients or as a result of dilution with nonsterile water by the tattoo artist before use.

What are the implications for public health practice?

This report highlights the risk for tattoo-associated NTM skin infections resulting from use of contaminated inks or nonsterile water for ink dilution. To prevent infection, CDC recommends that only sterile ink products and sterile water should be used and appropriate hygienic practices should be followed when tattooing.

extensive and multiple surgical debridements. NTM infections are difficult to treat and can require a minimum of 4 months of treatment with a combination of two or more antibiotics. Physicians who encounter persistent papular rashes or nodules localized to newly tattooed areas should consider the possibility of an NTM infection.

Contamination of tattoo inks can occur during the manufacturing process and might persist if steps are not taken to eliminate harmful microbial contaminants in the finished product. A cross-sectional laboratory survey in 2010 of 58 unopened ink bottles from different manufacturers identified intrinsic contamination with a variety of organisms in 10% of these inks (7), but did not test for the presence of NTMs.

Many NTM species (e.g., *M. abscessus* and *M. chelonae*) are found in water, so the addition of nonsterile water to ink during its manufacture or at its point of use could lead to contamination with NTM (3–5), and potentially result in infections. In addition, a common misconception is that distilled and reverse osmosis water are sterile (8), leading to the mistaken assumption that these products are acceptable for diluting tattoo inks. Dilution of inks with nonsterile water or other ingredients at the point of use might lead to product contamination. Dilution of ink also will dilute preservatives, if present, and make them less effective.

Under the Federal Food, Drug, and Cosmetic Act, tattoo inks are considered to be cosmetics, and the pigments used in the inks are color additives requiring premarket approval (9). No specific FDA regulatory requirement explicitly provides that tattoo inks must be sterile. However, intradermal introduction of nonsterile substances, such as tattoo ink, can pose a health risk and is a public health concern.

The practice of tattooing may be regulated by local jurisdictions (9). Such regulations generally have required blood-borne pathogens training and the use of hygienic practice during tattooing. A few local jurisdictions, such as Los Angeles County (10), have issued requirements that sterile water be used in tattoo ink dilution.

The findings in this report are subject to at least the following limitation. Because on-site investigations took place months after cases were reported, potentially contaminated batches and ingredients, such as distilled water and pigments, were not available for testing. Similarly, water sources used for the manufacture of inks or for ink dilution when patients were tattooed were not available.

Because tattoo inks are injected intradermally, CDC recommends that ink manufacturers be held to higher product safety standards, which should include production of sterile inks. In addition, tattoo artists should 1) avoid using products not intended for use in tattooing; 2) avoid ink dilution before tattooing, and if dilution is needed, use only sterile water; 3) avoid use of nonsterile water to rinse equipment (e.g., needles) during tattoo placement; and 4) follow aseptic techniques during tattooing (e.g., hand hygiene and use of disposable gloves). To reduce their risk for infection, consumers should 1) use tattoo parlors registered by local jurisdictions; 2) request inks that are manufactured specifically for tattoos; 3) ensure that tattoo artists follow appropriate hygienic practices; 4) be aware of the potential for infection following tattooing, and seek medical advice if persistent skin problems occur; and 5) notify the tattoo artist and FDA's MedWatch program* if they experience an adverse event.

* Additional information available at <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>.

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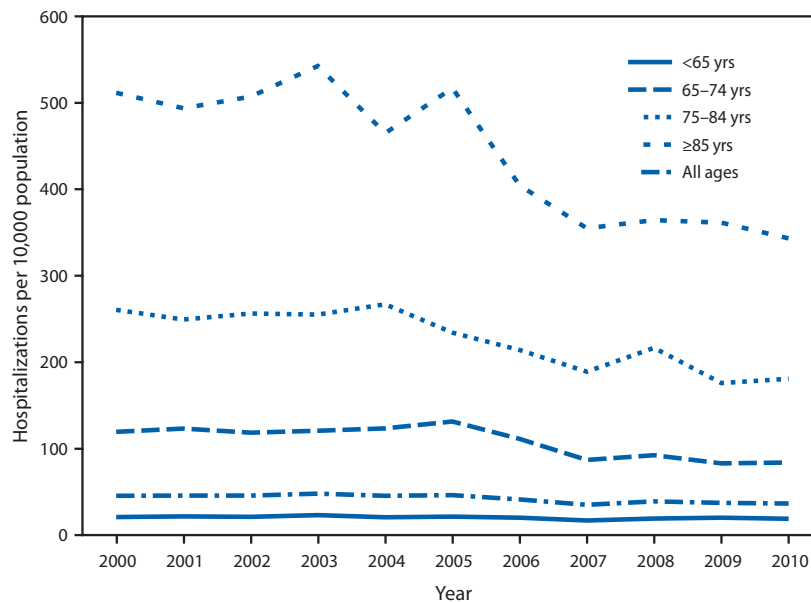
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QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Rate* of Hospitalization for Pneumonia, by Age Group — National Hospital Discharge Survey, United States, 2000–2010



* Per 10,000 population. Hospitalization for pneumonia is defined as a first-listed diagnosis on the medical record of 480-486, as coded according to the *International Classification of Diseases, Ninth Revision, Clinical Modification*. Rates were calculated using U.S. Census Bureau 2000-based postcensal civilian population estimates.

From 2000 to 2010, the hospitalization rate for pneumonia decreased by 20% for the total population. The rate decreased 30% among those aged 65–74 years, 31% among those aged 75–84 years, and 33% among those aged ≥85 years. Throughout the period, the rate of hospitalization for the <65 years age group was substantially lower than the rate for any other age group.

Source: National Hospital Discharge Survey, 2000–2010. Available at <http://www.cdc.gov/nchs/nhds.htm>.

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