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Three Sudden Cardiac Deaths Associated with Lyme Carditis — United States, November 2012–July 2013

Lyme disease* is a multisystem illness caused by *Borrelia burgdorferi*, a spirochete transmitted by certain species of *Ixodes* ticks. Approximately 30,000 confirmed and probable cases of Lyme disease were reported in the United States in 2012, primarily from high-incidence states in the Northeast (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont) and upper Midwest (Minnesota and Wisconsin) (*1,2*).† Common manifestations include cutaneous, neurologic, and rheumatologic signs and symptoms. Symptomatic infection of the heart is rare in recognized Lyme disease cases and usually resolves promptly with appropriate antibiotic therapy. Nonetheless, cardiac involvement occasionally can cause life-threatening cardiac conduction abnormalities. During November 2012–July 2013, one woman and two men (ranging in age from 26 to 38 years) from high-incidence Lyme disease states experienced sudden cardiac death and, on postmortem examination, were found to have evidence of Lyme carditis. The three deaths were investigated by the Connecticut Department of Public Health, Massachusetts Department of Public Health, New Hampshire Department of Public Health, New York State Department of Health, and CDC. Donated corneas from two decedents had been transplanted to three recipients before the diagnosis of Lyme disease was established, but no evidence of disease transmission was found. Although death from Lyme carditis is rare, it should be considered in cases of sudden cardiac death in patients from high-incidence Lyme disease regions. Reducing exposure to ticks is the best method for preventing Lyme disease and other tickborne infections.§

Case Reports and Public Health Investigation

Patient 1. In November 2012, a Massachusetts resident was found unresponsive in an automobile after it veered off the road. No evidence of traumatic injury was found. An electrocardiogram (EKG) performed by emergency responders showed no cardiac activity, and the patient was pronounced dead at a nearby hospital. The patient had no serious preexisting medical conditions. No rash was noted at autopsy, although some atherosclerosis was present. Interviews with next-of-kin revealed that the patient had described a nonspecific illness with malaise and muscle and joint pain during the 2 weeks

INSIDE

Continuing Education examination available at http://www.cdc.gov/mmwr/cme/conted_info.html#weekly.

*Additional information available at http://www.cdc.gov/lyme.
†Additional information regarding how many persons receive a diagnosis each year of Lyme disease is available at http://www.cdc.gov/lyme/faq/index.html#humancases.
§Additional information available at http://www.cdc.gov/lyme/prev/index.html.

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preceding death. The patient lived alone with a dog that was reported to have ticks frequently.

The decedent's corneas and skin, musculoskeletal, cardiac, and vascular tissues were recovered for potential transplantation. The heart was sent to tissue bank A for valve recovery. Microscopic examination of cardiac tissue found extensive myocarditis with mixed perivascular lymphoplasmacytic inflammation suggestive of Lyme carditis. A postmortem serum sample tested at CDC yielded serologic evidence of recent infection with *B. burgdorferi*, reacting strongly in both whole cell sonicate (WCS) and C6 enzyme immunoassay (EIA), and against all three scored bands (23 kDa, 39 kDa, and 41 kDa) by immunoglobulin M (IgM) Western blot. Western blot testing for immunoglobulin G (IgG) antibodies demonstrated reactivity against four of 10 scored bands (23 kDa, 39 kDa, 41 kDa, and 45 kDa); these serologic findings were consistent with early disseminated Lyme disease.

Histopathologic evaluation of postmortem tissues at CDC also was suggestive of Lyme pancarditis (Figure 1) and abundant spirochetes were observed by Warthin-Starry silver stain (Figure 2). Spirochetes also were detected in the myocardium by immunohistochemistry (IHC). Polymerase chain reaction (PCR) assays detected *B. burgdorferi* in extracts of formalin-fixed, paraffin-embedded heart tissue based on outer surface protein A, flagellin, and plasminogen-binding protein gene targets. No donor tissues were transplanted.

Patient 2. In July 2013, a New York state resident experienced chest pain and collapsed at home. Cardiopulmonary resuscitation was unsuccessful, and the patient was pronounced dead at a local hospital. The patient's past medical history included a diagnosis of Wolff-Parkinson-White syndrome, a cardiac conduction abnormality. The patient had no known tick contact or rash but was reported to be a hiker. Evidence of hypertensive and atherosclerotic cardiovascular disease was noted at autopsy. The decedent's corneas and skin, musculoskeletal, vascular, and cardiac tissue were recovered for potential transplantation. Examination of cardiac tissue at tissue bank A revealed moderate diffuse, perivascular lymphoplasmacytic pancarditis, similar to that seen in patient 1. Serologic testing at CDC was consistent with recent infection with *B. burgdorferi*; WCS and C6 EIAs were strongly reactive, IgM Western blot demonstrated strong reactivity to all three scored bands, and IgG Western blot demonstrated reactivity to four scored bands (23 kDa, 41 kDa, 58 kDa, and 66 kDa). Rare spirochetes were identified in cardiac tissue by Warthin-Starry silver stain and IHC; heart tissues tested positive for *B. burgdorferi* by PCR.

Before diagnosis of *B. burgdorferi* infection, the decedent's corneas were transplanted to two recipients. The transplanting physicians and cornea recipients subsequently were notified of the donor's infection. Neither recipient 1 nor recipient 2 reported signs or symptoms of Lyme disease or problems with the transplanted cornea. Both recipients elected to receive antibiotic therapy with doxycycline. None of the remaining donated tissues were transplanted.

Patient 3. In July 2013, a Connecticut resident collapsed while visiting New Hampshire and was pronounced dead at a

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FIGURE 1. Hematoxylin and eosin stain at 6.25X magnification demonstrating interstitial perivascular lymphoplasmacytic pancarditis in postmortem tissue of one of three patients whose death was associated with Lyme carditis — United States, 2013

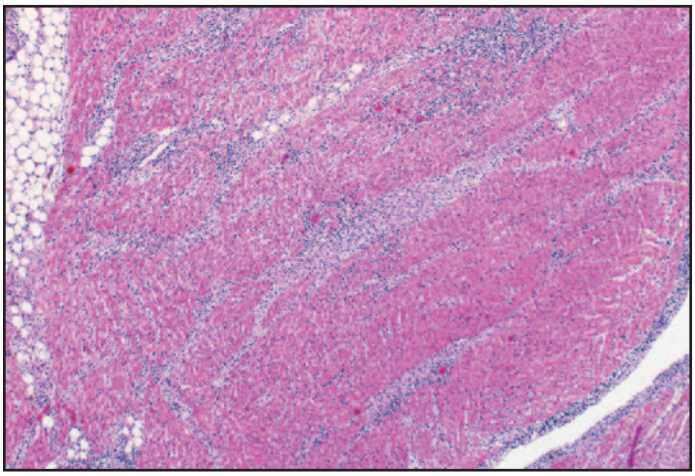
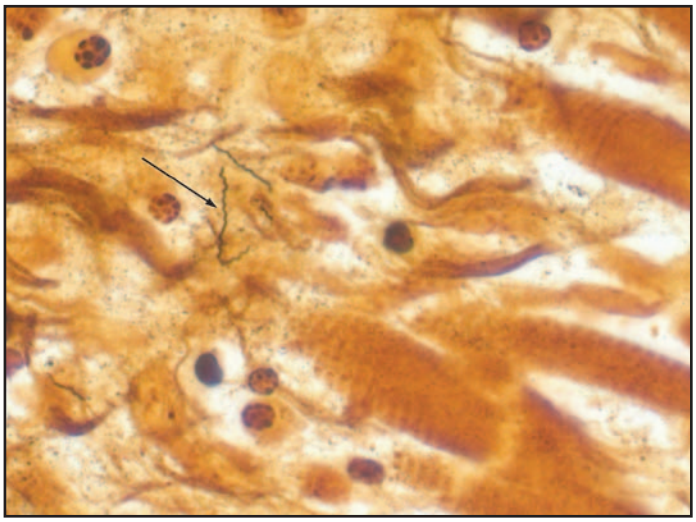


FIGURE 2. Warthin-Starry stain of cardiac tissue at 158X magnification demonstrating *Borrelia burgdorferi* spirochetes (arrow) in one of three patients whose death was associated with Lyme carditis — United States, 2013



local hospital. The patient had complained of episodic shortness of breath and anxiety during the 7–10 days before death. No rash, arthralgia, or neurologic symptoms were noted. A physician consulted 1 day before death prescribed clonazepam for anxiety; an EKG was not performed, nor were any antibiotics prescribed. The patient lived on a heavily wooded lot and had frequent tick exposure; there was no known history of cardiovascular disease. Autopsy revealed myocarditis, and the medical examiner submitted heart tissues to CDC for evaluation of suspected viral myocarditis. Corneas and skin were recovered for donation, and one cornea was transplanted to recipient 3. No other tissue was transplanted. Recipient 3 was examined 1 week after corneal transplant and was recovering as anticipated. Examination of heart tissues at CDC again demonstrated diffuse mixed perivascular lymphoplasmacytic pancarditis. Warthin-Starry stain revealed spirochetes in the myocardium, and IHC and PCR assays confirmed the spirochete as *B. burgdorferi*. WCS and C6 EIAs were positive, IgM Western blot was positive for all three scored bands, and IgG Western blot demonstrated reactivity to one scored band (41 kDa).

The eye bank was informed of the Lyme disease status of the donor and the recommendations for therapy. Before notification of the Lyme disease status of the donor, recipient 3 died of unrelated causes. No tissues or serum from recipient 3 were available for evaluation.

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Editorial Note

This report describes three cases of sudden cardiac death associated with Lyme carditis, with subsequent transplantation of corneas from two of the decedents into three recipients. Only rarely has death been attributed to Lyme carditis (*3*–*6*), and review of pathology reports at tissue bank A did not identify any additional confirmed cases among 20,000 cardiac specimens received since 2004. Whether the preexisting heart conditions found in two patients increased their risk for death is unclear.

What is already known on this topic?

Carditis with heart block is a known but uncommon complication of early disseminated Lyme disease that is generally treated effectively with appropriate antibiotic therapy. Four deaths from Lyme carditis have been reported.

What is added by this report?

This report describes three new cases of sudden cardiac death associated with Lyme carditis. The decedents were aged 26 to 38 years and lived in high-incidence Lyme disease areas.

What are the implications for public health practice?

Pathologists and medical examiners should be aware that Lyme carditis can be a cause of sudden cardiac death. All suspected cases of fatal Lyme carditis should be reported to state or local public health authorities, and the cases should be investigated. Physicians and health-care providers should ask patients with suspected Lyme disease about cardiac symptoms, and conversely, ask patients with acute, unexplained cardiac symptoms about possible tick exposure and symptoms of Lyme disease. Clinicians should encourage all patients to practice recommended tick bite prevention strategies.

Borrelia burgdorferi has been shown to affect all layers of the heart, but tends to spare the great vessels and heart valves (*7*). Inflammation is characteristically diffuse, perivascular, lymphohistiocytic, and plasma cell-rich. Spirochetes can be found within the myocardial cellular infiltrates; IHC and PCR testing can provide additional evidence of infection. Although Lyme carditis usually is present in conjunction with other features of the disease, such as erythema migrans, arthritis, or neurologic disease, it can be observed independently (*8*). The most common cardiac manifestation is atrioventricular block, which can fluctuate between first, second, and third degree (*7,8*). Second-degree or third-degree atrioventricular block occurs in approximately 0.8% of all Lyme disease cases reported to CDC (*2*). Symptoms of atrioventricular block, including lightheadedness, palpitations, shortness of breath, chest pain, and syncope can occur 4 days to 7 months after onset of disease, with a median of 21 days (*7,8*). With appropriate therapy (*9*), prognosis is excellent, and signs of cardiac involvement typically resolve within 1–6 weeks, depending on the degree of conduction disturbance (*10*). Some cases of complete heart block might require temporary pacing.

Although no cases of Lyme disease transmission through organ or tissue transplantation have been reported, the identification of organisms in tissue suggests the risk for transmission could exist. Ophthalmologic manifestations of Lyme disease are rare but can involve any of the ocular structures and occur during any stage of Lyme disease.¶ Given the rarity of ocular Lyme disease, and of corneal Lyme disease in particular, and the absence of ocular symptoms in the deceased patients, the need for antibiotics in this setting was equivocal. However, if administered, oral doxycycline would be expected to penetrate eye structures well.

Medical examiners and pathologists should be aware that Lyme carditis is a potential, albeit rare, cause for sudden cardiac death in persons from high-incidence Lyme disease areas. Diffuse, mixed perivascular lymphoplasmacytic infiltrates seen on pathologic examination of heart tissue from patients who have sudden cardiac death in high-incidence Lyme disease areas should prompt serologic evaluation for Lyme disease and further histopathologic examination for spirochetes, including IHC evaluation and PCR. Lyme disease is a nationally notifiable disease; all suspected cases of fatal Lyme carditis should be reported to state or local public health authorities, and the cases should be investigated.

Prompt recognition and early, appropriate therapy for Lyme disease is essential. Health-care providers should ask patients with suspected Lyme disease about cardiac symptoms and obtain an EKG if indicated. Conversely, they should ask patients with unexplained heart block about possible exposure to infected ticks. Health-care providers also should remind their patients of steps to prevent infection, including use of repellent, daily tick checks, prompt showering after potential exposure, and landscape management. The three deaths described in this report underscore the need for better methods of primary prevention of Lyme disease and other tickborne infections.

¶ Additional information available at http://www.sciencedirect.com/science/article/pii/S0161642099001281.

References

1. CDC. Notice to readers: final 2012 reports of nationally notifiable infectious diseases. MMWR 2013;62:669–82.
2. CDC. Surveillance for Lyme disease—United States, 1992–2006. MMWR 2008;57(No. SS-10):1–9.
3. Cary NR, Fox B, Wright DJ, Cutler SJ, Shapiro LM, Grace AA. Fatal Lyme carditis and endodermal heterotopia of the atrioventricular node. Postgrad Med J 1990;66:134–6.
4. Marcus LC, Steere AC, Duray PH, Anderson AE, Mahoney EB. Fatal pancarditis in a patient with coexistent Lyme disease and babesiosis. Demonstration of spirochetes in the myocardium. Ann Intern Med 1985;103:374–6.
5. Tavora F, Burke A, Li L, Franks TJ, Virmani R. Postmortem confirmation of Lyme carditis with polymerase chain reaction. Cardiovasc Pathol 2008;17:103–7.
6. Reimers CD, de Koning J, Neubert U, et al. *Borrelia burgdorferi* myositis: report of eight patients. J Neurol 1993;240:278–83.
7. Steere AC, Batsford WP, Weinberg M, et al. Lyme carditis: cardiac abnormalities of Lyme disease. Ann Intern Med 1980;93:8–16.
8. Fish AE, Pride YB, Pinto DS. Lyme carditis. Infect Dis Clin N Am 2008;22:275–88.
9. Wormser GP, Dattwyler RJ, Shapiro ED, et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America. Clin Infect Dis 2006;43:1089–134.
10. McAlister HF, Klementowicz PT, Andrews C, Fisher JD, Feld M, Furman S. Lyme carditis: an important cause of reversible heart block. Ann Intern Med 1989;1110:339–45.

Estimated Influenza Illnesses and Hospitalizations Averted by Influenza Vaccination — United States, 2012–13 Influenza Season

Influenza is associated with substantial morbidity and mortality each year in the United States. From 1976 to 2007, annual deaths from influenza ranged from approximately 3,300 to 49,000 (*1*). Vaccination against influenza has been recommended to prevent illness and related complications, and since 2010, the Advisory Committee on Immunization Practices has recommended that all persons aged ≥6 months be vaccinated against influenza each year (*2*). In 2013, CDC published a model to quantify the annual number of influenza-associated illnesses and hospitalizations averted by influenza vaccination during the 2006–11 influenza seasons (*3*). Using that model with 2012–13 influenza season vaccination coverage rates, influenza vaccine effectiveness, and influenza hospitalization rates, CDC estimated that vaccination resulted in 79,000 (17%) fewer hospitalizations during the 2012–13 influenza season than otherwise might have occurred. Based on estimates of the percentage of influenza illnesses that involve hospitalization or medical attention, vaccination also prevented approximately 6.6 million influenza illnesses and 3.2 million medically attended illnesses. Influenza vaccination during the 2012–13 season produced a substantial reduction in influenza-associated illness. However, fewer than half of persons aged ≥6 months were vaccinated. Higher vaccination rates would have resulted in prevention of a substantial number of additional cases and hospitalizations.

CDC used a model published in 2013 (*3*) to estimate an annual burden of influenza-associated outcomes prevented by influenza vaccination. All data inputs and estimates were stratified by age group: 6 months–4 years, 5–19 years, 20–64 years, and ≥65 years (Table 1). The disease burden during the 2012–13 influenza season was estimated in the following steps. First, laboratory-confirmed influenza-associated hospitalization rates were obtained from FluSurv-NET, a collaboration between CDC, the Emerging Infections Program Network, and selected health departments in 14 geographically distributed areas in the United States that conduct population-based surveillance. Hospitalization rates were adjusted for underreporting based on surveys conducted during the 2009 influenza pandemic; rates were increased by a factor of 2.74 for all age categories (*3*). Influenza illnesses were extrapolated from hospitalization data based on multipliers to reflect the percentage of ill persons who are hospitalized. Multipliers were age group–specific: 143.4 for 0–4 years; 364.7 for 5–19 years; 148.2 for 20–64 years, and 11.0 for ≥65 years. The percentage of ill persons who sought medical attention was estimated from the Behavioral Risk Factor Surveillance Survey (BRFSS) (*3*): 67% for persons aged 0–4 years; 51% for ages 5–19 years; 37% for ages 20–64 years, and 56% for ages ≥65 years. Second, 2012–13 vaccination coverage and vaccine effectiveness data were used to estimate the size of the susceptible population that was unprotected by vaccination and at risk of these outcomes. The rate of each outcome among susceptible persons was calculated as the number of estimated outcomes divided by the number of susceptible persons. This rate was then used to estimate the number of influenza-associated outcomes that would have occurred in a hypothetical, unvaccinated, susceptible population. Estimates of 2012–13 seasonal influenza vaccination coverage were based on self-report or parental report of vaccination status using data from the National Immunization Survey for children aged ≥6 months–17 years and BRFSS for adults aged ≥18 years,* and varied from 35.8 to 69.3, depending on the age group (Table 1). Vaccine effectiveness estimates were derived from the U.S. Influenza Vaccine Effectiveness (Flu VE) Network, a group of five academic institutions that conduct annual vaccine effectiveness studies, and varied from 32% among persons aged ≥65 years to 58% among children aged 6 months–4 years (*4*). Finally, the averted outcomes attributable to vaccination were estimated as the difference between outcomes in the hypothetical unvaccinated population and the observed population (*3*). The prevented fraction was calculated as the number of averted illnesses divided by the total illnesses that would have been expected in an unvaccinated population.

From October 2012 to May 2013, influenza vaccination resulted in an estimated 6.6 million (95% confidence interval [CI] = 4,011,725–10,551,756) fewer illnesses, 3.2 million (CI = 1,911,592–5,206,874) fewer medically attended illnesses, and 79,260 (CI = 39,530–136,744) fewer hospitalizations (Table 2). Overall, 17.3% (CI = 16.2%–18.0%) of adverse health outcomes associated with influenza were prevented. Although 29% of the averted illnesses and 39% of averted medically attended illnesses were among children aged 6 months–4 years and persons aged ≥65 years (two groups known to be at higher risk for complications), these two age groups accounted for 69% of averted hospitalizations. Vaccination had a substantial impact on averted hospitalizations in persons aged ≥65 years. Although persons aged ≥65 years accounted for 7% of the prevented illnesses and 8% of medically attended illnesses, 56% of all hospitalizations prevented were in those aged ≥65 years. If vaccination levels had reached the *Healthy People 2020*

* Methods for estimating season-specific influenza vaccination coverage and descriptions of National Immunization Survey and BRFSS data are available at http://www.cdc.gov/mmwr/pdf/ss/ss6204.pdf.

TABLE 1. Variables affecting impact of influenza vaccination, by age group — United States, 2012–13 influenza season

Age group (yrs)	Cumulative vaccine coverage (%)*		Vaccine effectiveness (%)†		Total population§	Cumulative hospitalization rate (per 100,000)¶	Estimated hospitalizations**		Estimated medically attended cases††		Estimated cases§§	
	%	(95% CI)	%	(95% CI)			No.	(95% CI)	No.	(95% CI)	No.	(95% CI)
6 mos–4	69.3	(67.8–70.8)	58.0	(40–71)	17,879,414	49.7	24,354	(15,224–38,206)	2,340,568	(1,466,829–3,701,433)	3,493,384	(2,183,709–5,480,282)
5–19	48.5	(47.6–49.4)	46.0	(32–57)	62,505,456	13.3	22,746	(14,172–35,852)	4,230,713	(2,612,263–6,656,229)	8,295,516	(5,168,531–13,075,561)
20–64	35.8	(35.2–36.4)	52.0	(43–60)	188,263,884	23.1	119,167	(78,995–177,656)	6,534,419	(4,292,193–9,776,843)	17,660,591	(11,707,096–26,328,640)
≥65	66.0	(65.2–66.8)	32.0	(0–56)	43,145,356	182.0	215,206	(142,909–316,950)	1,325,672	(871,647–1,968,414)	2,367,271	(1,572,003–3,486,454)
All ages	**44.7**	**(44.3–45.1)**	**51.0**	**(45–57)**	**311,794,110**	**42.0**	**381,474**	**(251,300–568,665)**	**14,431,371**	**(9,242,933–22,102,920)**	**31,816,763**	**(20,631,339–48,370,938)**

Abbreviation: CI = confidence interval.

* Season-cumulative vaccine overage rates calculated using data from the National Immunization Survey for children aged 6 months–17 years and from the Behavioral Risk Factor Surveillance System for adults aged ≥18 years. Model uses incremental monthly age-specific values. Estimates of the cumulative monthly proportion vaccinated through end of April of each season were developed using the Kaplan-Meier product limit method for receipt of most recent reported influenza vaccination. Negative lower 95% confidence intervals (CI) were revised to 0.

† Negative lower 95% CI intervals were revised to 0.

§ Calculated from U.S. Census Bureau annual estimates of the resident population by single year of age and sex for April 1, 2010 to July 1, 2012, available at http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2012_PEPSYASEXN&prodType=table.

¶ Season-cumulative hospitalization rates calculated using data from the CDC Influenza Hospitalization Surveillance Network (FluSurv-NET). Model uses month-specific and age-specific values.

** Estimated using FluSurv-NET hospitalization rates adjusted for underreporting. The underreporting adjustment multiplier was calculated during the 2009–10 pandemic season and was 2.74 across age categories (*3*).

†† Based on the estimated number of cases and outpatient medically attended ratios by age group (*3*).

§§ Based on the estimated number of hospitalizations and age-specific case-hospitalization ratios for persons aged <65 years, and using a case-hospitalization ratio of 11:1 for persons aged ≥65 years (*3*).

TABLE 2. Estimated number of influenza cases averted by vaccination and the associated fraction prevented, by age group — United States, 2012–13 influenza season

Age group (yrs)	Averted hospitalizations		Averted, medically attended cases		Averted cases		Fraction prevented	
	No.	(95% CI)	No.	(95% CI)	No.	(95% CI)	%	(95% CI)
0–4	10,216	(5,994–16,502)	981,851	(575,222–1,591,166)	1,465,450	(859,735–2,367,044)	29.6	(28.0–30.2)
5–19	4,770	(2,869–7,722)	887,256	(529,333–1,437,481)	1,739,717	(1,046,532–2,816,363)	17.3	(16.8–17.8)
20–64	19,813	(12,887–30,107)	1,086,409	(698,241–1,666,804)	2,936,241	(1,909,887–4,461,808)	14.3	(14.0–14.5)
≥65	44,460	(17,779–82,413)	273,876	(108,797–511,422)	489,065	(195,570–906,541)	17.1	(10.5–21.3)
All ages	**79,260**	**(39,530–136,744)**	**3,229,393**	**(1,911,592–5,206,874)**	**6,630,473**	**(4,011,725–10,551,756)**	**17.3**	**(16.2–18.0)**

Abbreviation: CI = confidence interval.

target of 70%, approximately 4.4 million illnesses, 1.8 million medically attended illnesses, and 30,000 additional hospitalizations might have been averted.

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Editorial Note

The 2012–13 influenza season was characterized as a moderately severe season, based on CDC influenza surveillance data.† During this season, rates of influenza-associated hospitalizations were 42.0 per 100,000 persons, compared with 7.7–23.4 per 100,000 during the previous three seasons. Among persons aged ≥65 years, hospitalization rates were three to seven times higher than rates observed for this age group during the previous three seasons. In addition, 169 influenza-associated pediatric deaths (deaths among persons aged <18 years) were reported to CDC, the highest number of reported deaths among this age group in a nonpandemic season since national reporting of influenza-associated pediatric deaths began in 2004. In this setting of a relatively high burden of severe disease, a 17% overall reduction in severe health outcomes resulted in a large number of prevented hospitalizations and medical visits for influenza that exceeded estimates of annual serious outcomes averted during influenza seasons from 2006 to 2011 (*3*). The fraction of outcomes averted was highest in children aged <5 years, among whom 30% of illness and hospitalizations were averted. The higher estimated prevented fraction in this group compared with older age groups was the result of higher vaccine coverage and vaccine effectiveness. Although vaccine

† National, regional, and state influenza surveillance data can be viewed at http://www.cdc.gov/flu/fluactivitysurv.htm.

effectiveness was lowest among persons aged ≥65 years, the relatively high vaccination coverage and high risk for severe outcomes resulted in substantial reductions in hospitalizations in this vulnerable group.

Fewer than half of persons in the United States are vaccinated each year (*5*), despite a recommendation for universal influenza vaccination for persons aged ≥6 months (*3*). Successful efforts to increase vaccination rates among all persons would increase the benefits of immunization programs on reducing illnesses. Strategies known to improve coverage should be encouraged. Those include ensuring that all those who visit a provider during the influenza season receive a vaccination recommendation and offer from their provider and using immunization information systems.[§]

Influenza vaccine effectiveness for the 2012–13 season was estimated to be 51% (CI = 45%–57%) (*6*), which is similar to estimates from recent seasons in the United States (*2,4,6,7*). Use of vaccines that are more effective would increase the number of averted illness and hospitalizations. However, despite a low measured vaccine effectiveness estimated to be 32% (CI = -5%–56%) among persons aged ≥65 years, vaccination likely produced substantial reductions in illness and hospitalizations because of the intensity of the 2012–13 epidemic and the relatively high vaccination coverage in this group compared with younger adults. Because most hospitalizations (*8*) and >90% of influenza deaths (*1*) occur in elderly persons, improving the ability of immunization programs to protect this vulnerable population will require vaccines with improved efficacy in elderly persons, along with continued efforts to increase vaccination rates. In 2010, a high-dose influenza vaccine (Fluzone HD, Sanofi Pasteur) was licensed for use in persons aged ≥65 years after prelicensure studies demonstrated superior immunogenicity compared with standard-dose vaccines (*9*). Final data from a recent efficacy trial are being analyzed.

The findings in this report are subject to at least six limitations. First, influenza vaccination coverage rates were derived from vaccination status reported by survey respondents, not vaccination records, and are subject to recall bias. Second, these rates are based on telephone surveys with relatively low response rates; therefore, selection bias might remain after weighting adjustments. Third, these surveys only cover the noninstitutionalized population. Fourth, estimates of the number of persons vaccinated based on these survey data exceeded the actual number of doses distributed, indicating coverage estimates used in this report overestimate averted illness resulting from vaccination (*5*). Fifth, the model only calculates outcomes directly averted by vaccination. If there is indirect protection from decreased exposure among unvaccinated persons in a partially vaccinated population (i.e., herd immunity), the model would underestimate the number of prevented illnesses. Also, although the impact of vaccination in preventing severe outcomes is most pronounced among persons aged ≥65 years, if vaccine effectiveness were lower among frail elderly persons, the model might have overestimated the effect in this group. Finally, adjustments for underreporting of influenza hospitalizations were based on studies conducted in 2009–10, as were the extrapolation of hospitalization rates to estimate rates of illness and medically attended illness. Because multipliers were calculated during a pandemic, if the ratio of hospitalizations to other outcomes or the underreporting of hospitalization rates were different in 2012–13 (e.g., through changes in health-seeking behaviors or testing practices), the model might have underestimated or overestimated the effect of vaccination.

Influenza vaccination prevents a substantial number of influenza-associated illnesses and hospitalizations. Although vaccines with increased effectiveness are needed, much can be done to maximize influenza prevention in the 2013–14 season.[¶] In particular, efforts to increase vaccination rates will further reduce the burden of influenza. Although the timing and intensity of influenza circulation for the 2013–14 season cannot be predicted, peak weeks of influenza have occurred in January through March in >90% of seasons during the past 20 years, and significant circulation can occur as late as May.

What is already known on this topic?

Influenza vaccination has been a central tool for influenza prevention in the United States for >50 years. In 2012, CDC estimated that annual influenza vaccination resulted in 1.1–5.0 million fewer cases and 7,700–40,400 fewer hospitalizations annually during the 2005–11 influenza seasons.

What is added by this report?

Using surveillance data, vaccination coverage survey data and vaccine effectiveness estimates collected during the 2012–13 influenza season, estimates of the impact of influenza vaccination for the most recent season were generated. Vaccination during that season resulted in an estimated 79,260 fewer hospitalizations, 6.6 million fewer cases of influenza, and 3.2 million fewer medically attended cases.

What are the implications for public health practice?

The study supports the importance of influenza vaccination, but highlights the need for increasing coverage rates and more effective vaccines; efforts to increase vaccination rates can further reduce the burden of influenza.

[§] Evidence-based strategies for improving vaccination coverage are described in the *Community Guide for Preventive Services*, available at http://www.thecommunityguide.org/index.html.

[¶] Full influenza immunization recommendations and a list of available vaccines are available at http://www.cdc.gov/flu/protect/vaccine/index.htm.

Therefore, vaccination should be offered now and as long as influenza continues to circulate.

References

1. CDC. Estimates of deaths associated with seasonal influenza—United States, 1976–2007. MMWR 2010;59:1057–62.
2. CDC. Prevention and control of seasonal influenza with vaccines. Recommendations of the Advisory Committee on Immunization Practices—United States, 2013–2014. MMWR 2013;62(No. RR-7).
3. Kostova D, Reed C, Finelli L, et al. Influenza illness and hospitalizations averted by influenza vaccination in the United States, 2005–2011. PloS One 2013;8:e66312.
4. Treanor JJ, Talbot HK, Ohmit SE, et al. Effectiveness of seasonal influenza vaccines in the United States during a season with circulation of all three vaccine strains. Clin Infect Dis 2012;55:951–9.
5. CDC. Flu vaccination coverage, United States, 2012–13 influenza season. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/flu/fluvaxview/coverage-1213estimates.htm.
6. CDC. Advisory Committee on Immunization Practices (ACIP): summary report, June 19–20, 2013. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-jun13.pdf.
7. Ohmit SE, Petrie JG, Malosh RE, et al. Influenza vaccine effectiveness in the community and the household. Clin Infect Dis 2013;56:1363–9.
8. Zhou H, Thompson WW, Viboud CG, et al. Hospitalizations associated with influenza and respiratory syncytial virus in the United States, 1993–2008. Clin Infect Dis 2012;54:1427–36.
9. Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ. Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. J Infect Dis 2009;200:172–80.

Seasonal Influenza Vaccination Coverage Among Women Who Delivered a Live-Born Infant — 21 States and New York City, 2009–10 and 2010–11 Influenza Seasons

Because influenza can be especially severe during pregnancy, the American College of Obstetricians and Gynecologists and the Advisory Committee on Immunization Practices recommend influenza vaccination for pregnant women (*1,2*). Pregnant women experience increased morbidity from influenza infection, and they were at increased risk for severe disease and mortality from 2009 influenza A(H1N1) pdm09 (pH1N1) pandemic virus infection (*3–5*). During the 2009–10 influenza season, CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) began collecting data on pregnant women's vaccination coverage, and 22 areas continued to collect it during the 2010–11 season (*6*). To estimate state-specific seasonal influenza vaccination coverage among pregnant women for the 2010–11 influenza season, the most recent data available, CDC analyzed data from women who delivered a live-born infant during September 2010–May 2011(N = 18,522). This report describes the results of that analysis, which indicated that, for the 2010–11 season, overall combined 53.6% were vaccinated (44.2% during pregnancy, 8.8% postpartum, and <1% with unknown time during pregnancy). Among those vaccinated during pregnancy, most were vaccinated during the second or third trimester. Wide state-to-state variation in vaccination coverage was observed, with a range of 32.6% to 75.9% and a median of 54.8%. Compared with the 2009–10 season, coverage was either the same or higher in all areas. Strategies that contributed to increased vaccination coverage need to be promoted.

CDC analyzed data from PRAMS,* an ongoing, population-based survey that collects data on a range of maternal behaviors and experiences before, during, and after pregnancy among women who recently delivered a live-born infant. The surveys take stratified random samples of 100–300 women with recent live births monthly from each state birth certificate registry. The selected mothers are mailed up to three questionnaires after delivery; those who do not respond by mail within 2 months are contacted by telephone, and up to 15 attempts are made to reach the women. For the 2010–11 season, 21 states and New York City (NYC) had seasonal influenza vaccination data available.† For this report, CDC analyzed data available on the 2010–11 influenza season from 21 states and NYC among women who had a live birth from September 1, 2010, through May 31, 2011, and responded to PRAMS (N = 18,522). For comparison, vaccination coverage data from the same areas for the 2009–10 season among women who had a live birth from September 1, 2009, through May 31, 2010 (N = 19,429), were also analyzed. The state median response rate was 69.6% (range: 53.7%–85.0%) for the 2009–10 season and 68.2% (range: 55.6%–81.1%) for the 2010–11 season.

Weighted PRAMS data for seasonal vaccination coverage for each of the two seasons were aggregated, and overall estimates of vaccination coverage by area and pregnancy status (pregnant or postpartum) were calculated. To assess the extent and magnitude of changes, the relative percentage point change between two seasons was calculated. Changes in vaccination coverage were reported for each state and NYC, along with information about places where the pregnant women received their vaccination. Women who did not obtain vaccinations were asked to provide reasons why, with the option to select more than one response. All estimates were weighted to adjust for complex survey design and nonresponse.

Seasonal influenza vaccination coverage among women with live births varied among the participating areas, and the median coverage among the states increased from 50.1% during the 2009–10 season to 54.8% in the 2010–11 season (Table 1). All states either maintained or increased their seasonal vaccination coverage from the 2009–10 to the 2010–11 season. Eight (36.4%) of the 22 participating areas reported a statistically significant increase. Areas with the highest percentage increases during the 2010–11 season were Louisiana (from 39.6% to 49.8%), Missouri (from 42.8% to 53.6%), and Washington (from 53.3% to 64.5%).

*Additional information is available at http://www.cdc.gov/prams.

†Questions on the PRAMS influenza supplement included the following: "Since September 2009, did you get a seasonal flu shot? This is different than the H1N1 flu shot." and "At any time during your most recent pregnancy, did a doctor, nurse, or other health-care worker offer you a seasonal flu shot or tell you to get one?" The question used to assess women's reasons for not getting flu shot included five items with a yes/no response format, and women could select more than one reason: "What were your reasons for not getting a seasonal flu shot during your most recent pregnancy? For each item, circle Y (yes) if it was a reason for you and N (no) if it was not: 1) My doctor didn't mention anything about a seasonal flu shot during my pregnancy; 2) I was worried about side effects of the seasonal flu shot for me; 3) I was worried that the seasonal flu shot might harm my baby; 4) I don't normally get a seasonal flu shot; and 5) other reason—please tell us."

TABLE 1. State-specific seasonal influenza vaccination coverage among women with live births — 21 states and New York City, Pregnancy Risk Assessment Monitoring System, 2009–10 and 2010–11 influenza seasons

State	2009–10 season			2010–11 season			Change between 2009–10 and 2010–11 seasons (%)†
	No.	%*	(95% CI)	No.	%*	(95% CI)	
Arkansas	1,055	46.7	(42.6–50.7)	438	46.2	(39.9–52.7)	-1.0
Georgia	614	29.9	(24.3–35.5)	783	32.6	(27.2–38.5)	9.1
Illinois§	1,071	47.1	(43.8–50.3)	1,076	54.1	(50.8–57.3)	14.9
Louisiana§	540	39.6	(34.4–44.8)	662	49.8	(45.1–54.5)	25.7
Maine	709	64.0	(59.9–68.0)	573	63.7	(59.0–68.2)	-0.3
Maryland	1,080	46.1	(41.6–50.7)	1,085	51.8	(47.1–56.5)	12.4
Massachusetts	996	67.5	(63.5–71.4)	1,158	70.9	(67.2–74.4)	5.1
Minnesota§	917	67.9	(64.6–71.1)	848	75.9	(72.6–79.0)	11.8
Missouri§	973	42.8	(39.1–46.6)	932	53.6	(49.8–57.3)	25.1
Nebraska§	1,198	65.4	(62.2–68.5)	901	73.5	(69.9–76.9)	12.5
New Jersey§	1,053	36.8	(33.6–40.0)	1,040	43.6	(40.3–46.9)	18.5
New York	693	54.7	(50.0–59.4)	756	55.5	(50.9–60.0)	1.5
New York City	894	45.9	(41.8–50.0)	985	45.3	(41.5–49.2)	-1.3
Oklahoma	1,432	49.1	(44.6–53.5)	1,221	50.3	(45.5–55.2)	2.6
Rhode Island§	821	63.7	(59.8–67.6)	865	71.7	(68.1–75.1)	12.5
Tennessee	650	41.2	(36.1–46.2)	457	47.2	(41.4–53.0)	14.6
Utah	1,124	57.8	(54.6–61.0)	1,061	57.2	(53.8–60.5)	-1.0
Vermont	742	66.3	(62.8–69.7)	742	65.3	(61.7–68.7)	-1.4
Virginia	318	51.2	(43.9–58.5)	390	58.8	(52.2–65.1)	14.9
Washington§	1,052	53.3	(49.2–57.3)	918	64.5	(60.4–68.3)	21.0
West Virginia	880	44.9	(40.8–48.9)	1,060	49.2	(45.5–53.0)	9.8
Wyoming	617	55.6	(51.0–60.2)	571	55.7	(50.8–60.4)	0.1
Median	*945*	*50.1*		*883*	*54.8*		*10.8*
Minimum	*318*	*29.9*		*390*	*32.6*		*-1.4*
Maximum	*1,432*	*67.9*		*1,221*	*75.9*		*25.7*

Abbreviation: CI = confidence interval.
* Weighted to adjust for complex survey design and nonresponse.
† Equals percentage in 2010–11 season minus percentage in 2009–10 season divided by percentage in 2009–10 season multiplied by 100.
§ States that had a statistically significant increase in influenza vaccination coverage in the 2010–11 season compared with the 2009–10 season based on nonoverlapping 95% CIs for the estimates for the two seasons.

For the 2010–11 season, the percentage of respondents who reported that their health-care provider recommended vaccination varied by area, ranging from 53.7% to 89.5% (median: 74.3%). Among those who received a provider recommendation or offer of vaccination, median vaccination coverage was 67.1%, ranging from 53.8% in Georgia to 81.9% in Nebraska; among those who did not receive a provider recommendation or offer of vaccination, median vaccination coverage was 18.6%, ranging from 4.0% in Tennessee to 42.4% in Minnesota. Provider recommendation or offer of vaccination was associated with higher influenza vaccination coverage across all areas.

For the 2010–11 season, overall 53.6% of women with live-births reported receiving vaccine, and a majority of these received it during pregnancy (83% [8,715 of 10,533]). Of the women who reported being vaccinated during pregnancy, 4.0% were vaccinated during the first trimester, 17.1% during the second trimester, and 14.4% during the third trimester; the rest were vaccinated during pregnancy, but the trimester could not be ascertained because of missing information. The most common place women reported receiving their influenza vaccination during pregnancy was at their obstetrician/gynecologist's office (49.3%), followed by the family doctor's office (14.2%), and work place or school (11.3%) (Table 2). Among women who received an influenza vaccination postpartum, the most common place they reported receiving their vaccination was at the hospital (50.6%), followed by family doctor's office (15.5%), and their obstetrician/gynecologist's office (10.5%). Among women who did not receive an influenza vaccination, 71.4% reported the reason was because they "don't normally get a flu shot," followed by being "worried about side effect for myself" (53.5%), and "worried that the flu shot might harm my baby" (48.7%) (Table 3). Approximately 41% of nonvaccinated women reported they did not obtain vaccinations because they were "not worried about getting sick from the flu," and 29% reported they "did not think the flu shot works" (Table 3).

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TABLE 2. Place where influenza vaccination was received among women with live births — 21 states and New York City, Pregnancy Risk Assessment Monitoring System, 2010–11 influenza season

Place of vaccination	During pregnancy			After delivery		
	Sample size	%*	(95% CI)	Sample size	%*	(95% CI)
Obstetrician/Gynecologist's office	4,132	49.3	(47.6–51.0)	198	10.5	(8.6–12.8)
Family doctor or other doctor's office	1,142	14.2	(13.0–15.4)	332	15.5	(13.2–18.2)
Health department or community clinic	687	8.5	(7.5–9.5)	157	7.2	(5.6–9.2)
Hospital	494	5.7	(5.0–6.5)	937	50.6	(47.0–54.2)
Pharmacy, drug store, or grocery store	628	9.1	(8.2–10.1)	124	8.3	(6.4–10.6)
Work place or school	996	11.3	(10.2–12.4)	90	5.0	(3.7–6.7)
Other place	203	2.1	(1.6–2.6)	64	2.9	(1.9–4.3)
Total	**8,282**			**1,902**		

Abbreviation: CI = confidence interval.
* Weighted to adjust for complex survey design and nonresponse.

TABLE 3. Reasons for not receiving influenza vaccination among women with live births who did not receive an influenza vaccination — 21 states and New York City, Pregnancy Risk Assessment Monitoring System, 2010–11 influenza season

Reason*	Sample size	%†	(95% CI)
Doctor didn't mention it	6,957	26.7	(25.1–28.4)
Worried about side effect for myself	7,054	53.5	(51.6–55.3)
Worried that the flu shot might harm my baby	7,020	48.7	(46.9–50.6)
Not worried about getting sick from flu	6,910	40.7	(38.8–42.5)
Do not think the flu shot works	6,816	29.4	(27.7–31.1)
Don't normally get a flu shot	7,117	71.4	(69.7–73.0)
Other reason	5,117	22.1	(20.4–23.9)

Abbreviation: CI = confidence interval.
* Women were instructed to select all the applicable reasons they did not receive an influenza vaccination. A total of 7,898 women reported that they were not vaccinated. The sample sizes do not sum to the overall sample size because of missing response information.
† Weighted percentage.

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Editorial Note

Results from this study indicate that historically high seasonal influenza vaccination coverage levels among pregnant women achieved during the 2009–10 season were either maintained or increased during the 2010–11 season by the 21 participating states and NYC (*6,7*). Influenza vaccination of pregnant women was a focus of public health efforts during the 2009–10 season, with extensive collaborations and mobilization of resources among local, state, federal, and private sector entities. These efforts might have contributed to higher coverage during the 2009–10 season than was observed for previous seasons (*1,2,6–8*), and might also have contributed to sustained higher rates during the 2010–11 season.

The 2011 American College of Obstetricians and Gynecologist's recommendations for influenza vaccination of pregnant women and the updated Advisory Committee on Immunization Practices 2010 guidelines, which recommend vaccinations for anyone aged ≥6 months, might lead to further increases in coverage (*1–2*). As observed during the 2009–10 influenza season, the proportion of respondents who reported that their health-care providers offered or recommended influenza vaccination for 2010–11 varied substantially among states (*6*). This variation might relate to state-specific approaches to implementing vaccination efforts, differences in health-care delivery infrastructure, or variation in the proportion of pregnant women seeking vaccination. Among those who reported receiving the vaccination during pregnancy, nearly 50% received it from their obstetrician, and those who received it postpartum reported receiving it in the hospital. This information could be useful for guiding vaccination promotion strategies for pregnant and postpartum women.

Variation in vaccination coverage might also relate to differences in state-level policies on vaccine acquisition or distribution and in prevalence or strength of provider offer or recommendation for influenza vaccination in their practices, given that a high correlation was observed between provider recommendation and vaccination. For women who did not report being vaccinated during the 2010–11 season, although the reasons varied overall and by provider recommendation, worries about adverse effects of the influenza vaccine on the woman and her baby, in addition to not getting the flu vaccine as a normative behavior, predominated. In settings where pregnant and postpartum women seek care, continued efforts are needed to encourage providers to recommend and offer influenza vaccination to build on the gains in influenza vaccination coverage made during the 2009–10 and 2010–11 seasons (*6–8*).

The findings in this report are subject to at least five limitations. First, PRAMS data were available from only 21 states and NYC and might not be generalizable to all women with live births in the United States. For the same 21 states and cohort of pregnant women, PRAMS data compared with internet panel surveys showed similar coverage for the 2010–11

What is already known on this topic?

Historically the seasonal vaccination coverage for pregnant women was low, but vaccination rates increased during the 2009–10 season, when vaccination of pregnant women was a focus of public health efforts.

What is added by this report?

Among 21 states and New York City participating in the Pregnancy Risk Assessment Monitoring System, the median proportion of recently pregnant women who reported receiving a seasonal influenza vaccination during the 2010–11 influenza season was 54.8%, compared with 50.1% during the 2009–10 season. All participating states either maintained or increased influenza vaccination coverage among women with live births.

What are the implications for public health practice?

Further efforts are needed that recognize the substantial differences in vaccination rates among geographic areas and the importance of encouraging providers to address pregnant women's concerns about influenza vaccine safety and effectiveness and to offer influenza vaccination to them.

influenza season. Second, the cohort of women available for this analysis, who had live births during September 2010–May 2011, represents only a subset of all women who were pregnant during the influenza seasons. Third, because two influenza vaccines were available during 2009–10 influenza season (seasonal and pH1N1), recall bias might have occurred if women forgot which vaccine they received, leading to potential misclassification of the type of vaccine received. Fourth, because the response rates ranged from 53.7% to 85.0% by state over the two seasons (median: 69.6% for 2009–10 and 68.2% for 2010–11), the findings might be subject to response bias. Finally, mail and telephone respondents might have different demographic characteristics, and women who participated by telephone might have provided responses they perceived to be more socially desirable, although nonresponse analysis and weighting were used to evaluate and adjust for differential response rates between mothers with different characteristics in the PRAMS survey.

Based on the findings in this report, seasonal influenza vaccination coverage among women with live-births was higher overall during the 2010–11 influenza season than the 2009–10 season, and estimated coverage was the same as or higher in all 21 participating states and NYC. Despite the gains in coverage from 2009–10 season, 46% of women with live-births did not get vaccinated during the 2010–11 season. Further, among those who reported being vaccinated during pregnancy, a majority of vaccinations occurred during the latter part of pregnancy, which might suggest a need to reinforce messages about the safety of being vaccinated any time during pregnancy. These findings point to the need for continued education of health-care providers and pregnant women regarding the risk for severe illness and pregnancy-related complications from influenza to reduce the burden of influenza on pregnant women and their infants (*9,10*). These results indicate that providers need to understand the risks and potential barriers to vaccination during pregnancy and develop strategies to address these during encounters with women. Partnerships among various stakeholders at the state, federal, and local levels will be necessary to promote increased implementation of evidence-based vaccination promotion strategies (*10*).

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References

1. American College of Obstetricians and Gynecologists Committee on Obstetric Practice. ACOG committee opinion no. 468: influenza vaccination during pregnancy. Obstet Gynecol 2011;116:1006–7.
2. CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR 2010;59(No. RR-8).
3. Neuzil KM, Reed GW, Mitchel EF, Simonsen L, Griffin MR. Impact of influenza on acute cardio-pulmonary hospitalizations in pregnant women. Am J Epidemiol 1998;148:1094–102.
4. Naleway AL, Smith WJ, Mullooly JP. Delivering influenza vaccine to pregnant women. Epidemiol Rev 2006;28:47–53.
5. Jamieson DJ, Honein MA, Rasmussen SA, et al. H1N1 2009 influenza virus infection during pregnancy in the USA. Lancet 2009;374:451–8.
6. CDC. Influenza vaccination coverage among pregnant women—29 states and New York City, 2009–10 season. MMWR 2012;61:113–8.
7. Kennedy ED, Ahluwalia IB, Ding H, Lu PJ, Singleton JA, Bridges CB. Monitoring seasonal influenza vaccination coverage among pregnant women in the United States. Am J Obstet Gynecol 2012;207(3 Suppl):S9–16.
8. CDC. Influenza vaccination coverage among pregnant women—United States, 2010–11 influenza season. MMWR 2011;60:1078–82.
9. Moro PL, Broder K, Zheteyeva Y, et al. Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the vaccine adverse event reporting system, 1990–2009. Am J Obstet Gynecol 2011;204:146.e1–7.
10. CDC. Vaccinations to prevent diseases: universally recommended vaccinations. Community Guide systematic reviews. Atlanta, GA: US Department of Health and Human Services, CDC; 2011.

Progress in Immunization Information Systems — United States, 2012

Immunization information systems (IIS) are confidential, computerized, population-based systems that collect and consolidate vaccination data from vaccination providers that can be used in designing and sustaining effective immunization strategies (*1,2*). To monitor progress toward achieving IIS program goals, CDC annually surveys immunization program grantees using the IIS Annual Report (IISAR). Results from the 2012 IISAR, completed by 54 of 56 grantees, indicate that 86% (19.5 million) of U.S. children aged <6 years, and 25% (57.8 million) of U.S. adults participated in IIS. Eight of 12 minimum functional standards for IIS published by the National Vaccine Advisory Committee (NVAC) (*3,4*) have been met by ≥90% of grantees. During 2011–2012, progress was also made in meeting three additional functional standards, including the presence of core data element fields, timeliness of vaccine records, and Health Level 7 (HL7) messaging, and will be monitored in new functional standards for IIS published in 2013 (*5*). Several new and ongoing initiatives, including interoperability between IIS and electronic health records (i.e., ensuring systems can work together and exchange information), the use of IIS to support vaccine ordering and inventory management, the use of two-dimensional barcodes to record vaccination information (*1*), and collaboration with pharmacies, federal agencies, and other adult vaccination providers, will support further progress in meeting functional standards and enhance reporting of adult vaccinations to IIS.

Of the 56 immunization program grantees (50 states, five cities,* and the District of Columbia [DC]), 2012 IISAR data† were available for 54 grantees. DC did not report and New Hampshire was not eligible because it did not have an IIS in 2012. The self-administered survey asked about participation in IIS, data quality indicators, and IIS functionality (e.g., interoperability with electronic health records).

Child and Adult Participation in IIS

Child participation was defined as having two or more vaccinations for children aged <6 years documented in an IIS. Adult participation was defined as having one or more vaccinations administered to adults aged ≥19 years documented in an IIS. Participation was calculated by dividing the number of children or adults in an IIS who met their age group and vaccination criteria by the 2012 U.S. Census estimate of the same age group in the grantee's geographic area (*6*). National estimates were calculated by summing the number of children or adults reported to be participating and dividing by the U.S. Census estimate for the total population for that age group.

Nationally, 19.5 million U.S. children aged <6 years (86.2%) participated in an IIS in 2012. This child participation measure is used to track a *Healthy People 2020* objective (IID-18) to increase to 95% the proportion of children aged <6 years whose immunization records are in fully operational, population-based IIS (*7*). Child participation in IIS has increased steadily, from 63% in 2006 to 86% in 2012 (*1*). Of the 54 grantees with available data in 2012, 26 (48%) reported that ≥95% of children aged <6 years in their geographic area participated in their IIS (Figure 1). Nationally, 57.8 million U.S. adults aged ≥19 years (24.5%) participated in an IIS in 2012 (Figure 2). Two IIS did not collect immunization information for adults. The Connecticut IIS includes only children aged <6 years, and the Rhode Island IIS includes only persons aged <19 years. Adult participation in IIS among the remaining 52 grantees responding in 2012 ranged from 0.5% (Houston) to 85.4% (Minnesota).

Functional Standards for IIS

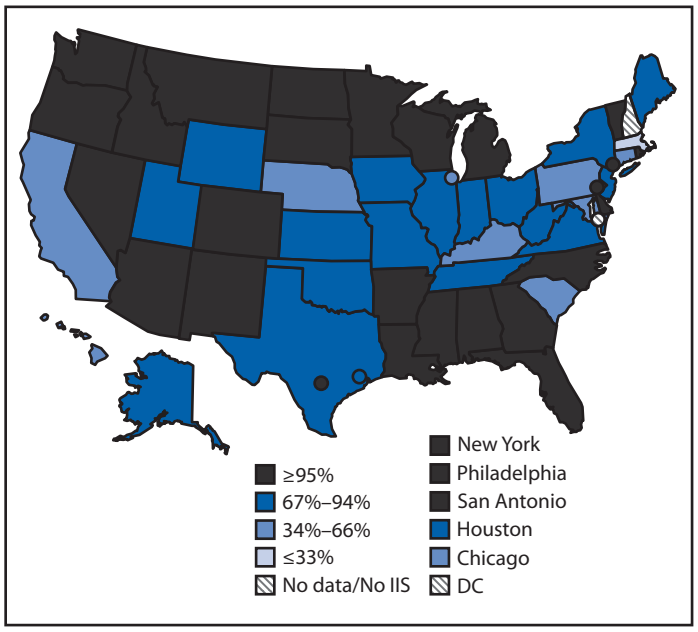
Functional standards for IIS were developed in 2001 and revised in 2007. The standards have been approved by NVAC (*3,4*) for assessing IIS progress in meeting minimum functionalities. Substantial progress has been made in meeting these functional standards since inception, and in 2012, eight of 12 functional standards had been met by ≥90% of grantees (Figure 3). Increases were observed during 2011–2012 in the percentage of grantees meeting three of the four remaining functional standards. The percentage of grantees meeting functional standard (FS) 1 (i.e., reporting the presence of fields in their IIS for 18 required NVAC core data elements) increased from 57% in 2011 to 65% in 2012. Completeness of core data elements has been reported on previously (*1*). The percentage of grantees meeting FS 4 (i.e., percentage of grantees who reported receiving and processing ≥70% of vaccine and other immunization encounter information within 30 days of vaccine administration) increased from 63% in 2011 to 76% in 2012. The percentage of grantees meeting FS 7 (i.e., meeting basic HL 7 functionality§) increased from 58% in 2011 to 77% in 2012. The percentage of grantees meeting more

* Chicago, Illinois; New York, New York; Philadelphia, Pennsylvania; Houston, Texas; and San Antonio, Texas.

† Additional information available at http://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/index.html.

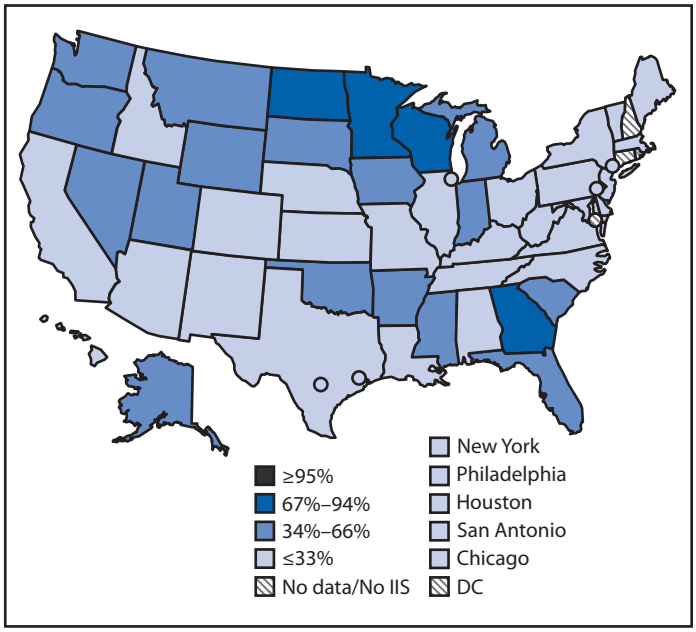
§ HL7 is the industry standard to exchange patient information electronically between IIS and electronic medical record systems. Basic HL7 functionality is defined as receiving VXU and sending ACK message types for either HL7 v.2.3.1 or v.2.5.1.

FIGURE 1. Percentage of children aged <6 years participating in an immunization information system (IIS)* — United States, five cities,† and the District of Columbia (DC), 2012



* Child participation is defined as having two or more vaccinations for children aged <6 years documented in the IIS. National child participation = 86%.
† Chicago, Illinois; New York, New York; Philadelphia, Pennsylvania; Houston, Texas; and San Antonio, Texas.

FIGURE 2. Percentage of adults aged ≥19 years participating in an immunization information system (IIS)* — United States, five cities,† and the District of Columbia (DC), 2012



* Adult participation is defined as having one or more vaccinations administered to adults aged ≥19 years documented in an IIS. National adult participation = 25%.
† Chicago, Illinois; New York, New York; Philadelphia, Pennsylvania; Houston, Texas; and San Antonio, Texas.

advanced HL7 functionality¶ increased from 35% in 2011 to 37% in 2012. In 2012, 37% (19) of grantees were sending and receiving any HL7 v.2.5.1 messages, an increase from 17.3% (9) of grantees in 2011. The percentage of grantees meeting FS 2 (i.e., reporting the establishment of a birth record within an average time of ≤6 weeks) decreased from 85% in 2011 to 84% in 2012. This slight decline occurred because three grantees who previously met the functional standard in 2011 reported a decrease in timeliness in 2012 resulting from their acceptance of larger amounts of data, which slowed processing times; however, two grantees achieved the functional standard in 2012 who had not previously.

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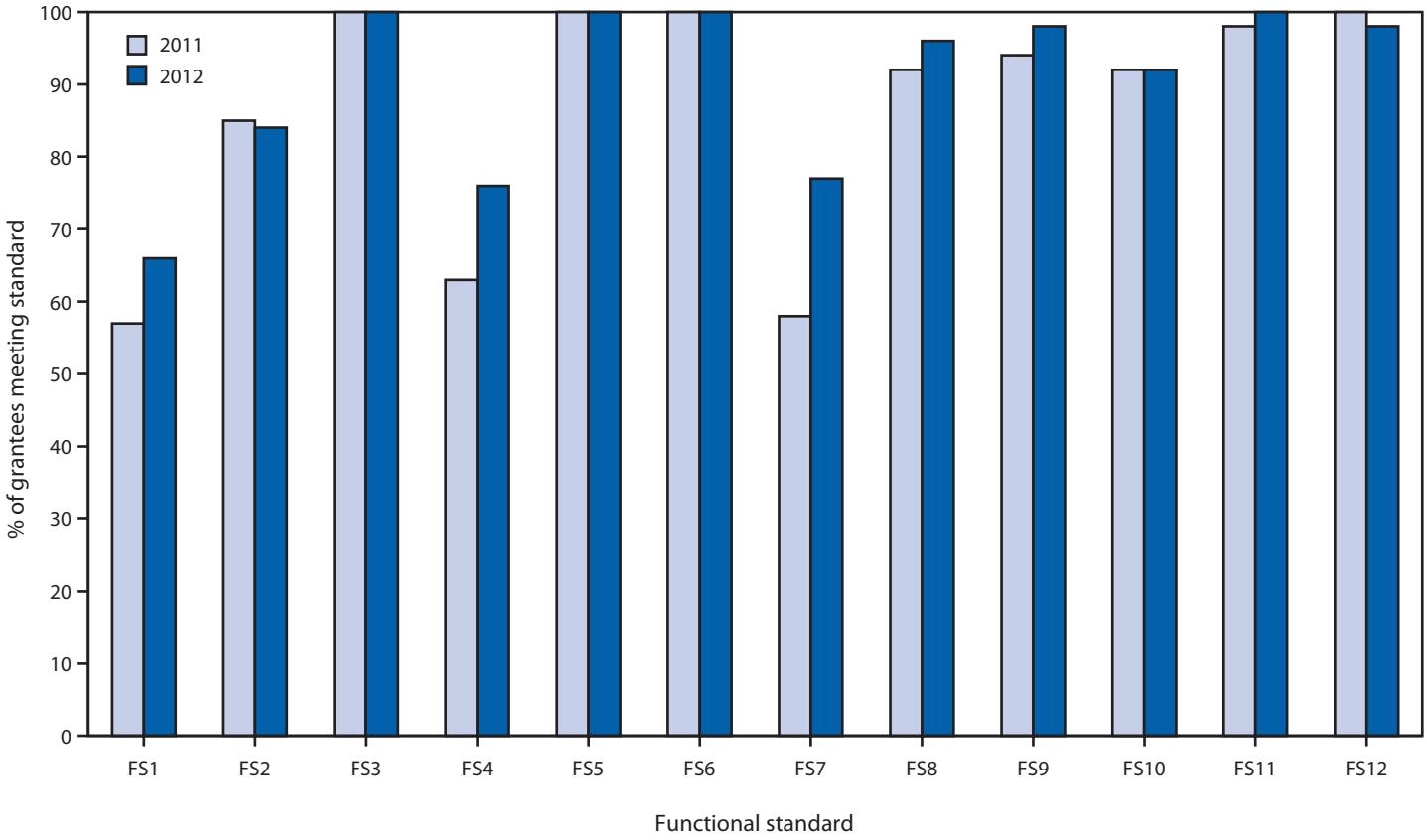
Editorial Note

Child participation in IIS increased steadily from 2006 to 2012, reaching 86%; adult participation, however, only reached 25% in 2012. Eight of 12 IIS functional standards were met by ≥90% of grantees in 2012. Increases in grantees meeting minimum functional standards for IIS data quality and interoperability, including the presence of core data element fields, timeliness for vaccination records, and HL7 messaging functionality, also have been demonstrated from 2011 to 2012, although challenges remain for IIS to reach their full potential in these areas, and for improving the timeliness of birth records in IIS.

Historically, the primary focus of IIS and immunization programs has been pediatric populations. This focus was warranted because of the increasing complexity of the routine pediatric immunization schedule, mobility of children among different providers resulting in vaccination record scattering (*8*) that makes tracking and catch-up immunization challenging, and the role of the IIS in supporting the Vaccines for Children program through ordering and inventory management, report generation, and vaccine accountability. Nevertheless, interest is growing in ensuring that adult populations are included and vaccinations tracked in IIS. Adults are vaccinated by multiple and diverse providers, beyond traditional health-care providers (e.g., pharmacies, retail clinics, and subspecialists), and consolidated adult vaccination records maintained by IIS could play an instrumental role in providing clinical point-of-care support and population-level immunization coverage,

¶ Advanced HL7 functionality is defined as the percentage of grantees who received VXQ and sent VXR and QCK message types for v.2.3.1 and received QBP and sent RSP message types for v.2.5.1.

FIGURE 3. Percentage of immunization program grantees meeting National Vaccine Advisory Committee (NVAC) functional standards (FS) for immunization information systems (IIS),* United States, 2011 and 2012



* The standards include FS1: presence of a field for data collection of all 18 required NVAC core data elements; FS2: establishment of a newborn birth record within an average time of 6 weeks or less; FS3: ability to access patients' immunization information from the IIS during a patient encounter; FS4: receiving and processing ≥70% of vaccine and other immunization encounter information within 30 days of vaccine administration; FS5: implementation of a written confidentiality policy; FS6: implementation of a written security policy; FS7: meeting basic Health Level 7 messaging functionality; FS8: presence of forecasting algorithm; FS9: ability to run reminder and recall notifications; FS10: ability to produce immunization coverage reports by providers, age groups, and geographic areas upon request; FS11: ability to produce official immunization records; and FS12: presence of a patient-level de-duplication algorithm. Additional information available at http://www.cdc.gov/vaccines/programs/iis/func-stds-2001.html.

particularly in special circumstances such as tracking doses administered during an influenza pandemic.

Currently, 53 of 56 immunization program grantees have IIS with lifespan systems, yet adult participation in IIS remains low. Challenges to increase adult participation in IIS include 1) identifying and enrolling the diverse providers that serve adults, 2) a lack of adult immunization reporting mandates in many grantees' jurisdictions, and 3) competing priorities for state and local immunization programs. To support increased adult provider participation in IIS, CDC is supporting several new initiatives, including partnering with the Veterans Administration, the Indian Health Service, and federal occupational health clinics; providing supplemental funding to IIS Sentinel Sites to support adult provider enrollment and completeness of adult data in IIS as part of pandemic preparedness; and collaborating with the American Immunization Registry Association to better understand barriers and opportunities for pharmacy reporting to IIS. CDC also has initiated the Clinical Decision Support for Immunization (CDSi) project for the adult vaccine schedule, which will provide a single, authoritative, software-independent foundation for development and maintenance of evaluation and forecast systems (*9*).** By capturing Advisory Committee on Immunization Practices (ACIP) recommendations for adult vaccination in an unambiguous manner, it will improve the uniform representation of vaccination decision guidelines, and the ability to automate vaccine evaluation and forecasting (*9*). CDSi for the childhood schedule was completed in October 2012 and has already proven successful in clarifying ACIP recommendations and designing new and existing computer systems.

** Evaluation describes the process of determining if a vaccination has been given at the right time, in the right amount, and with the right product. Forecasting involves recommending when the next dose of a vaccine should be given, based on a patient's history and the guidelines described in the immunization schedule.

What is already known on this topic?

In 2011, 84% of U.S. children aged <6 years (19.2 million) participated in immunization information systems (IIS).

What is added by this report?

In 2012, 86% of U.S. children aged <6 years participated in IIS. Adult participation (25%) in IIS lags behind. Eight of 12 minimum functional standards for IIS published by the National Vaccine Advisory Committee have been met by ≥90% grantees, but gaps still exist in meeting Health Level 7 (HL7) interoperability and some data quality standards.

What are the implications for public health practice?

To realize the full benefits of IIS, progress is needed to reach lifespan participation in IIS, advanced bidirectional HL7 messaging between IIS and electronic health records, and improved data quality in IIS. Initiatives designed to increase adult participation in IIS, and promote HL7 messaging and electronic health records use among providers, are expected to support progress in these areas.

In addition to capturing the complete population of children and adults within each IIS jurisdiction, IIS must maintain and enhance system functionality to ensure that data quality is high, protect the confidentiality of data, and serve multiple stakeholders. Although IIS have made great strides in implementing functional standards, progress can still be made in areas such as timeliness of record submission, completeness of core data elements, and HL7 functionality. Several ongoing and new initiatives are expected to support these functional standards, including the use of IIS to support vaccine ordering and inventory management, the use of two-dimensional barcodes to record vaccination information, and interoperability between IIS and electronic health records (*1*). Implementation of stage 2 meaningful use criteria for the Medicare and Medicaid electronic health record incentive program (*10*), emphasizing use of HL7 version 2.5.1 and promotion of successful, ongoing submission from providers to IIS, is expected to increase child and adult participation in IIS and improve data quality in IIS, including completeness and timeliness of records. Stage 2 implementation was scheduled to launch in October 2013 for hospitals and January 2014 for providers.

The findings in this report are subject to at least two limitations. First, although CDC provides guidance to grantees to validate IISAR responses, data are self-reported and self-validated, which might result in overestimation or underestimation of participation rates. Second, because two of the 56 grantees did not report data during the period studied, the percentage of grantees meeting each of the functional standards might be higher or lower than calculated.

New functional standards for IIS for 2013–2017 have been developed by CDC through a consensus process involving input from IIS managers and technical experts nationwide (*5*). Those standards are intended to lay a framework for the development of IIS through 2017, and supersede the minimum functional standards for registries adopted by NVAC in 2001. These new functional standards encompass areas within the old functional standards where progress is still being achieved, including timeliness of records submission, completion of core data elements, and HL7 interoperability standards. They also include new areas, such as supporting the Vaccines for Children program and state vaccine purchase programs through vaccine inventory functions and capture of program eligibility at the dose-level, and enhanced data quality through patient- and vaccine-level de-duplication. Grantees meeting and exceeding these new functional standards will lead the way in realizing and demonstrating the full potential of IIS.

References

1. CDC. Progress in immunization information systems—United States, 2011. MMWR 2013;62:48–51.
2. Community Preventive Services Task Force. Universally recommended vaccinations: immunization information systems. In: Guide to Community Preventive Services. Atlanta, GA: Community Preventive Services Task Force; 2010. Available at http://www.thecommunityguide.org/vaccines/universally/imminfosystems.html.
3. National Immunization Program Technical Working Group. 2001 minimum functional standards for registries. Atlanta, GA: National Immunization Program Technical Working Group; 2011. Available at http://www.cdc.gov/vaccines/programs/iis/func-stds.html.
4. National Vaccine Advisory Committee. Immunization information systems: National Vaccine Advisory Committee (NVAC) progress report. Atlanta, GA: National Vaccine Advisory Committee; 2007. Available at http://www.hhs.gov/nvpo/nvac/reports/index.html.
5. CDC. Immunization information system functional standards, 2013–2017. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. Available at http://www.cdc.gov/vaccines/programs/iis/func-stds.html.
6. US Census Bureau. State single year of age and sex population estimates: April 1, 2010 to July 1, 2012–resident. Washington, DC: US Census Bureau; 2012. Available at http://www.census.gov/popest/data/state/asrh/2012/index.html.
7. US Department of Health and Human Services. Healthy people 2020. Washington, DC: US Department of Health and Human Services; 2010. Available at http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=23.
8. Smith PJ, Stevenson J. Racial/ethnic disparities in vaccination coverage by 19 months of age: an evaluation of the impact of missing data resulting from record scattering. Stat Med 2008;27:4107–18.
9. CDC. Clinical Decision Support for Immunization (CDSi): logic specification for ACIP. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html.
10. Centers for Medicare & Medicaid Services. 45 CFR Part 170. Medicare and Medicaid Programs; Electronic Health Record Incentive Program—stage 2. Federal Register 2012;77:53968–4162.

Progress Toward Poliomyelitis Eradication — Nigeria, January 2012–September 2013

Transmission of wild poliovirus (WPV) has never been interrupted in Afghanistan, Pakistan, and Nigeria, and since 2003, Nigeria has been a reservoir for WPV reintroduction to 25 polio-free countries (*1–3*). In 2012, the Nigerian government activated an emergency operations center and implemented a national emergency action plan to eradicate polio (*2,4*). The 2013 revision of this plan prioritized 1) improving quality of supplemental immunization activities (SIAs), 2) implementing strategies to reach underserved populations, 3) adopting special approaches in security-compromised areas, 4) improving outbreak response, 5) enhancing routine immunization and activities implemented between SIAs, and 6) strengthening surveillance. This report summarizes polio eradication activities in Nigeria during January 2012–September 2013 and updates previous reports (*2,5–7*). During January–September 2013, 49 polio cases were reported from 26 local government areas (LGAs) in nine states in Nigeria, compared with 101 cases reported from 70 LGAs in 13 states during the same period in 2012. For all of 2012, a total of 122 cases were reported. No WPV type 3 (WPV3) cases have been reported since November 2012. For the first time ever, in 2013, no polio cases of any type have been detected in the northwest of Nigeria; however, transmission continues in Kano and states in the northeast. Despite considerable progress, 24 LGAs in 2012 and seven LGAs in 2013 reported two or more cases; WPV continues to circulate in eight LGAs that had cases in 2012. Efforts to interrupt transmission remain impeded by insecurity, anti–polio-vaccine sentiment, and chronically poor SIA implementation in selected areas. Improvement of SIA quality and effective outbreak response will be needed to interrupt WPV transmission in 2014.

Vaccination Activities

Increasing routine immunization coverage is a key polio eradication strategy. Reported administrative vaccine data indicate that national coverage with 3 doses of trivalent oral polio vaccine (OPV3) increased from 73% in 2012 to 84% during January–September 2013. Among children aged 6–35 months with nonpolio acute flaccid paralysis (AFP), the proportion with a dose history of ≥4 OPV doses, nationwide, increased from 75% in 2012 to 87% in 2013.

Fifteen SIAs* were implemented during January 2012–September 2013; four national rounds of SIAs used trivalent (type 1, type 2, and type 3) oral polio vaccine (OPV), and 11 subnational rounds used bivalent (type 1 and type 3) OPV in high-risk northern states. Vaccination rounds in January and June 2013 were limited in scope, focusing on persistently poor-performing areas and on states with recent polio cases. In February 2013, Nigeria's polio eradication program suffered setbacks when 13 health workers were targeted and killed in separate attacks in Borno and Kano, resulting in suspension of an SIA and cancelation of the follow-up round. Terrorist attacks had further negative impact on planned SIAs in Yobe and Borno, and some SIAs were repeatedly missed in both states. Borno participated in seven of the eight scheduled SIAs in 2013. When Borno was included, a substantial proportion (37%–55%) of the 27 LGAs did not take part, and some SIAs were of poor quality, as indicated by postcampaign lot quality assurance sampling (LQAS) surveys. To extend reach, OPV vaccination was added to several subnational campaigns with other vaccinations in 2013, including campaigns with measles and serogroup A meningococcal conjugate vaccines (*4*).

SIA quality in LGAs is assessed through LQAS surveys using a four-category pass/fail scheme based on the proportion of children with a finger mark (indicating they received OPV during the SIA) (*2*).† During February 2012–September 2013, the number of LGAs conducting LQAS among the 11 high-risk states§ increased from 87 to 168. During February 2012–September 2013, the proportion of LGAs conducting LQAS in the 11 high-risk states with SIA assessments meeting the ≥90%

* Mass campaigns conducted for a brief period (days to weeks) in which 1 dose of OPV is administered to all children aged <5 years, regardless of vaccination history. Campaigns can be conducted nationally or in portions of the country.

† A clustered LQAS methodology is used to assess SIA quality by sampling the target population of children at the LGA level and documenting finger markings indicative of OPV receipt. A sample is drawn from six wards (geopolitical subunits) within the LGA, with 10 children in a single settlement selected at random from each sampled ward, yielding a sample of 60 children per LGA. SIAs in the LGAs are classified into one of four quality categories based on the number of unmarked children found: 0–3, tested range >90.0% (high pass); 4–8, tested range 80.0%–89.9%, (pass); 9–19, tested range ≥60.0%–79.9% (unacceptable); and >19, tested range <60.0% (fail). A detailed description of the methodology is available at http://www.polioeradication.org/portals/0/document/research/opvdelivery/lqas.pdf.

§ Bauchi, Borno, Jigawa, Kaduna, Kano, Katsina, Kebbi, Niger, Sokoto, Yobe, and Zamfara.

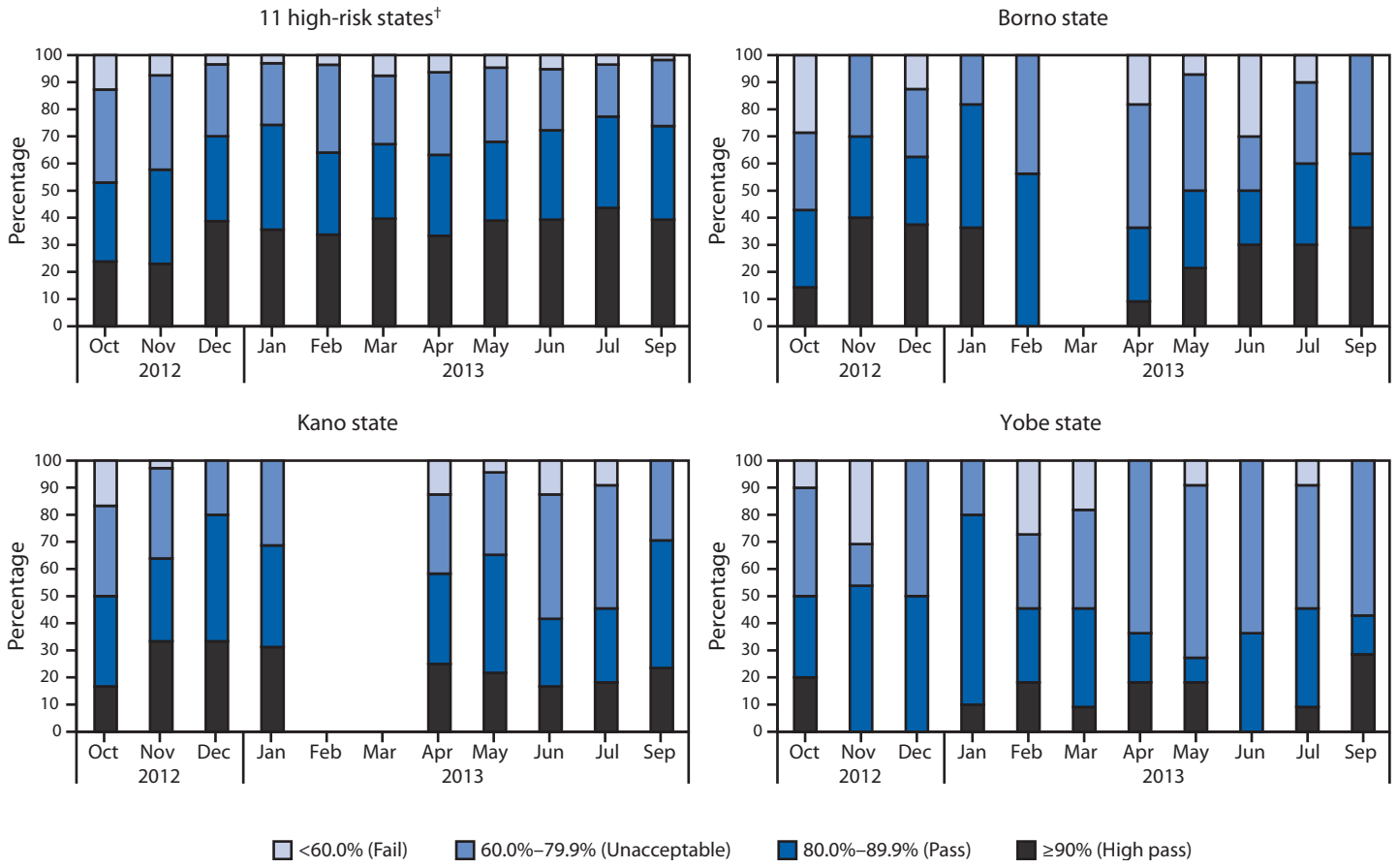
range increased from 7% to 39%, and the proportion at the 80%–89% range increased from 9% to 35%. The proportion of LGAs at the 60%–79% range decreased from 43% to 24%, and the proportion at the <60% range declined from 40% to 2%. As noted, some LGAs in Borno and Yobe did not conduct any SIAs during this period because of insecurity. In addition, during October 2012–February 2013, when SIAs were held, less overall improvement was noted in these states suggesting insecurity negatively impacted quality. This also was noted in Kano, where LQAs results decreased for several SIAs after February 2013, when polio workers were attacked (Figure 1).

Poliovirus Surveillance

A nonpolio AFP rate of ≥2 cases per 100,000 children aged <15 years and collection of adequate stool specimens in ≥80% of AFP cases are key performance indicators for AFP surveillance. In 2013, the nonpolio AFP rate was 8.8 cases per 100,000, and 86.5% of AFP cases had adequate stool specimens collected, although these indicators decreased slightly from 2012. The proportion of high-risk states that met both indicators increased from 82% in 2012 to 91% in 2013. Within these states, the proportion of LGAs meeting both requirements increased from 67% in 2012 to 75% in 2013.

AFP surveillance is supplemented by environmental surveillance, for which sewage samples taken every 4–5 weeks are tested for polioviruses. Environmental surveillance in Nigeria was expanded from three sites in 2011 in Kano to 19 sites in 2013: Borno (three sites), Kaduna (two), Kano (three), Lagos (five), Sokoto (four), and the Federal Capital Territory (FCT) (two). During January–September 2013, WPV type 1 (WPV1) was identified in three positive sewage samples (one from Kano in a sample collected in February and two from Sokoto samples collected in March and April). In 2012, WPV1 was identified in two positive sewage samples from Kano (September and October), whereas Sokoto had 16 WPV1

FIGURE 1. Percentage of local government areas with indicated quality category from lot quality assurance sampling (LQAS*) surveys assessing supplementary immunization activities, by month— northern Nigeria, October 2012–September 2013



* LQAS surveys are used to assess the quality of polio supplemental immunization activities (SIAs) in local government areas, using a four-category pass/fail scheme based on the proportion of children with a finger mark indicating they had received oral polio vaccine during the SIA.
† Bauchi, Borno, Jigawa, Kaduna, Kano, Katsina, Kebbi, Niger, Sokoto, Yobe, and Zamfara.

positive sewage samples through September 30, 2012, and none during October–December 2012.

Wild Poliovirus Incidence

The number of WPV cases in Nigeria increased from 62 in 2011 to 122 in 2012. From January to September in 2012, a total of 101 cases were reported, compared with 49 cases reported during the same period in 2013 (as of November 27, 2013). These case counts remain higher than 2010 levels, when 21 cases were reported through September (*2*). No WPV3 cases have been reported in Nigeria since November 2012 (Figure 2). Early in 2013, cases were reported in previously unaffected LGAs in the north central states of Nassarawa, Niger, and FCT. More recently, WPV transmission shifted geographically from the northwest part of the country to the northeast (Figure 3). Forty-two of 49 cases in 2013 (86%) were reported from Borno (16 cases), Kano (13), Yobe (seven), and Bauchi (six). Compared with 2012, the number of affected states declined from 13 to nine, and the number of affected LGAs dropped from 70 to 26. Eight cases of circulating vaccine-derived poliovirus type 2 (cVDPV2) were reported in 2012 and one cVDPV2 case has been reported in 2013 (onset of paralysis on June 6).

As poliovirus circulation declines in reservoir communities, the genetic diversity of poliovirus isolates also declines. The number of genetic clusters[¶] circulating in 2013 will be determined in early 2014 based on genetic analysis of all 2013 cases. Two genetic clusters present in 2012 also have been found in 2013. In 2011, 11 WPV1 clusters were circulating; eight continued to circulate in 2012. Partial genomic sequence analysis also is used to assess surveillance sensitivity; a nucleotide difference of ≥1.5% in the coding region of the major capsid protein, VP1, from the closest matching sequences of previously identified isolates indicate gaps in surveillance with >1 year of undetected virus circulation (*1,8*). Of 100 WPV cases detected during January–September 2012, 13 (13%) had less genetic linkage than expected with sensitive AFP surveillance, compared with eight (16%) of the 49 cases detected in 2013.

Genomic sequence analysis indicated that the cVDPV2 case identified in Borno in 2013 was closely related to a cVDPV2 lineage that had circulated in Chad in 2012 and spread to neighboring countries such as Cameroon and Niger. In addition, sequence analysis indicated that WPV1 isolates from environmental samples in Sokoto in March and April 2013 were not of the same cluster circulating in the area in 2012, but rather were related to a cluster circulating in other states.

[¶] VP1, the ~900 nucleotide major capsid protein of WPV, is sequenced on all WPV isolates globally to assess viral transmission. Genetic clusters consist of WPV isolates with >95% VP1 nucleotide identity.

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Editorial Note

Considerable progress has been made in Nigeria toward polio eradication. As of late November 2013, no WPV 3 cases had been reported for more than a year; the geographic extent of WPV transmission appears to no longer include the western-most states, and the number of WPV cases reported through September 2013 (49) was half that reported during the same period in 2012 (101). Despite these successes, continued WPV1 transmission in Nigeria is a threat to global polio eradication and must be addressed urgently, particularly as the country enters the relatively low WPV transmission season (November–April).

Several strategies are being employed to improve program performance and address specific constraints in LGAs defined as high-risk by SIA evaluation data (LQAS) and statistical modeling. To address anti–polio vaccination sentiment and the threat of violence, social and community mobilization activities provide opportunities for community leaders to engage and become advocates for the protection of children against the acquisition of poliovirus. To enhance community engagement where noncompliance has been particularly high, >1,000 polio survivors work to raise risk perception, and health camps (temporary mobile health service stations) are held during SIAs to address unmet primary health-care needs. Approximately 200 community outreach workers have engaged with religious leaders and Koranic school teachers in high-risk LGAs to further enhance community support. Additionally, several strategies are used to enhance campaign performance including: 1) interagency "management support teams" deployed at the ward level to assist in the supervision of SIA activities; 2) "management and accountability officers" who monitor funding expenditures and increase local accountability; and 3) global postitioning system (GPS) tracking that is used to improve microplanning and track vaccination teams during SIAs.

FIGURE 2. Number of cases of wild poliovirus type 1 (WPV1), wild poliovirus type 3 (WPV3), and vaccine-derived poliovirus type 2 (VDPV2), by month — Nigeria, January 2011–September 2013

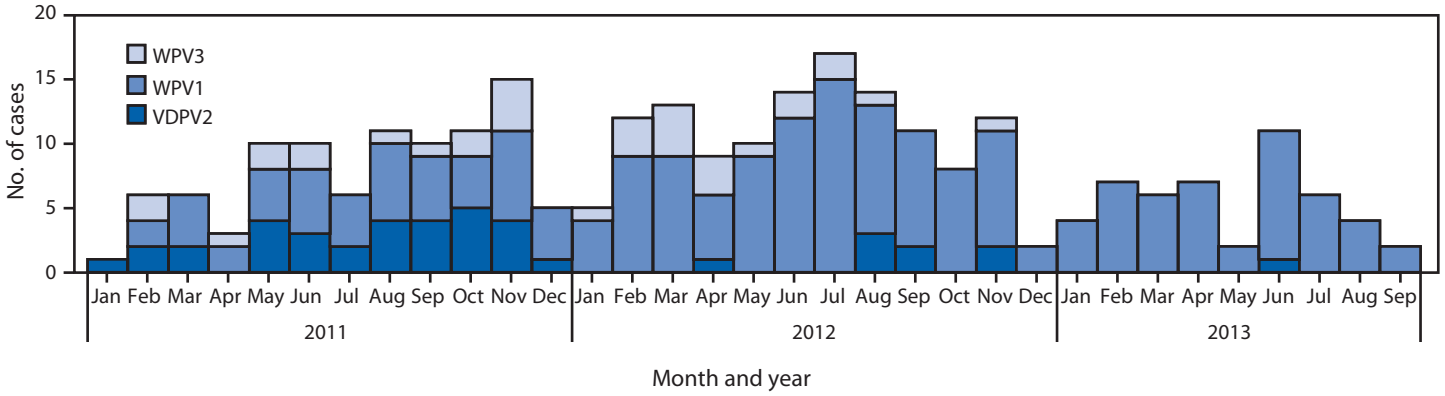
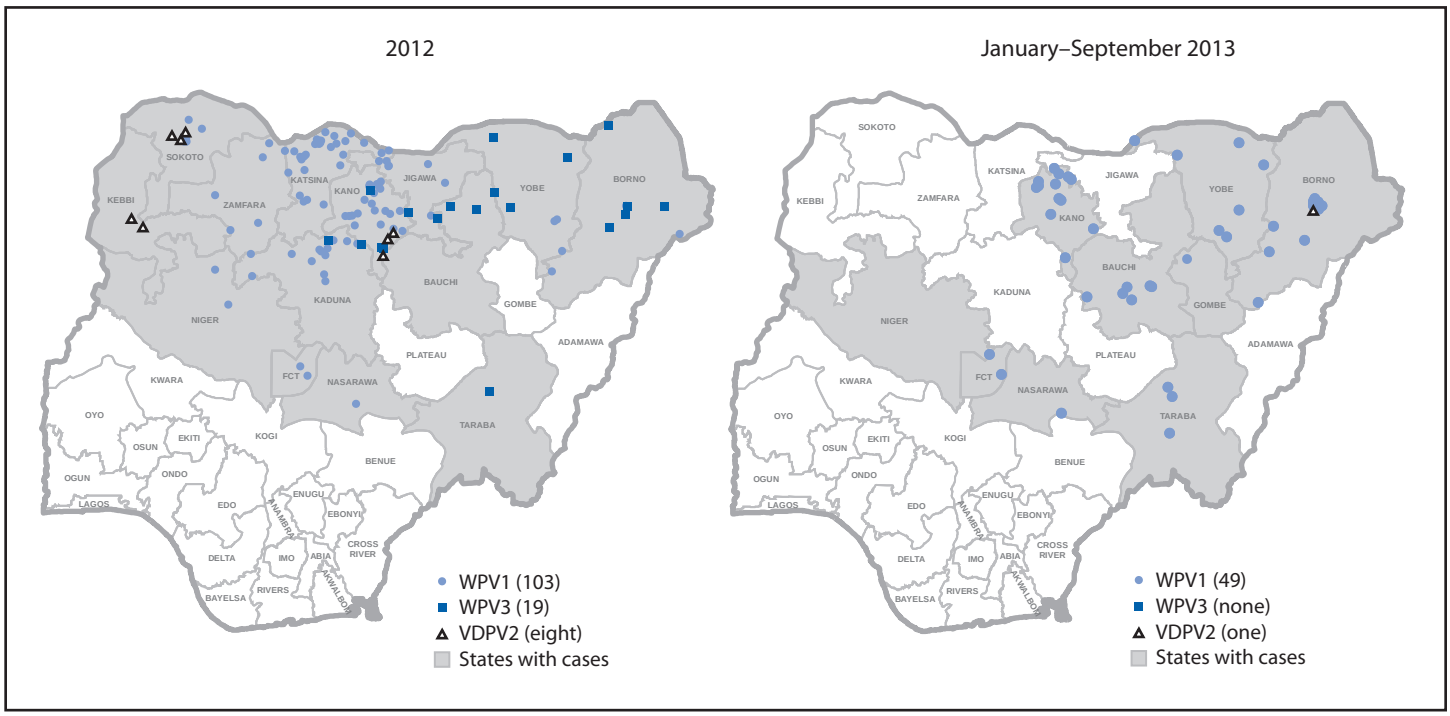


FIGURE 3. Distribution of cases of wild poliovirus type 1 (WPV1), wild poliovirus type 3 (WPV3), and vaccine-derived poliovirus type 2 (VDPV2), by month — Nigeria, 2012 and January–September 2013*



* Each dot represents one WPV case placed at random within a local government area boundary.

Nigeria experienced setbacks in 2013, including continued low SIA quality in specific areas and states, the targeted killing of polio workers, and high levels of insecurity in the northeast. Despite increased political commitment and accountability in Kano, persistently poor performing LGAs remain throughout much of the state. Activities taken to address the substantial immunity gap among children living in security-compromised areas of Borno where SIAs could not be conducted include 1) mobile vaccination teams, 2) intensified routine infant immunization and other health services, 3) shortened intervals between OPV doses, 4) health camps coupled with intensified community engagement, and 5) vaccination posts placed at state and LGA borders to vaccinate children in transit. In addition, operational funds and prepositioned vaccine stocks are being provided so that SIAs can be organized quickly and implemented when windows of opportunity open for safe deployment of vaccination teams.

What is already known on this topic?

Nigeria is the only country in Africa where wild poliovirus (WPV) transmission has never been interrupted and has served as a reservoir for polio outbreaks throughout the last decade. Low routine immunization coverage, poor quality supplemental immunization activities (SIA), and anti–polio-vaccination sentiment have historically provided opportunities for continued virus transmission throughout the northern part of the country. To address ongoing WPV transmission, the Nigerian government restructured the national polio response in 2012 and increased efforts to reach missed children through routine immunization and improved SIA.

What is added by this report?

During January–September 2013, 49 polio cases were reported from 26 local government areas (LGAs) in nine states, compared with 101 cases reported from 70 LGAs in 13 states during the same period in 2012. No cases have been detected in the most northwestern states for the first time ever, but transmission continues in Kano and states in the northeast where high levels of insecurity, violence targeting polio workers early in 2013, and continued suboptimal SIA planning continue to impede progress. In addition, there are indications of substantial surveillance gaps that need to be addressed.

What are the implications for public health practice?

Global polio eradication efforts have long been challenged by WPV circulation in Nigeria. Unless further improvements are made in improved SIA quality and effective outbreak response, there is considerable risk of not interrupting WPV transmission in 2014. A comprehensive immunization strategy and improvements in campaign implementation will be needed to reach all unimmunized children while increasing community demand for routine vaccination.

Despite the setbacks, Nigeria has made considerable progress toward polio eradication in the last 18 months. Successful interruption of WPV transmission will depend on a sustained focus on the issues raised and effective outbreak response. Virologic analysis revealed that substantial gaps remain in AFP surveillance, which must be strengthened to further pinpoint poliovirus circulation. Enhanced AFP surveillance, along with environmental surveillance, can subsequently document that transmission is interrupted when cases are no longer detected.

Acknowledgments

Kimberly A. Porter, Brian Kaplan, Kristin Brown, Daniel Tom-Aba, Rosa C. Norman.

References

1. Independent Monitoring Board of the Global Polio Eradication Initiative. Eighth report. London, England: Independent Monitoring Board; 2013. Available at http://www.polioeradication.org/aboutus/governance/independentmonitoringboard/reports.aspx.
2. CDC. Progress toward poliomyelitis eradication—Nigeria, January 2011–September 2012. MMWR 2012;61:899–904.
3. CDC. Progress toward interruption of wild poliovirus transmission—worldwide, January 2011–March 2012. MMWR 2012;61:353–7.
4. National Primary Healthcare Development Agency. Nigeria polio eradication emergency plan 2013. Abuja, Nigeria; 2013. Available at http://www.polioeradication.org/Portals/0/Document/Aboutus/Governance/IMB/9IMBMeeting/4.2_9IMB.pdf.
5. CDC. Progress toward poliomyelitis eradication—Afghanistan and Pakistan, January 2011–August 2012. MMWR 2012;61:790–5.
6. CDC. Progress toward poliomyelitis eradication—Nigeria, January 2010–June 2011. MMWR 2011;60:1053–7.
7. CDC. Progress toward global polio eradication—Africa, 2011. MMWR 2012;61:190–4.
8. Burns CC, Jorba J, Bukbuk D, et al. Multiple independent emergences of type 2 vaccine-derived poliovirus during a large outbreak in northern Nigeria. J Virol 2013;87:4907–22.

Extent and Effects of Recurrent Shortages of Purified-Protein Derivative Tuberculin Skin Test Antigen Solutions — United States, 2013

Two purified-protein derivative (PPD) tuberculin skin test (TST) antigen solutions are approved by the U.S. Food and Drug Administration (FDA): Tubersol (Sanofi Pasteur Limited) and Aplisol (JHP Pharmaceuticals, LLC). Tubersol was out of production in late 2012 through April 2013 (*1*). Shortages of Aplisol have resulted from increased demand as practitioners have sought a substitute for Tubersol. Tubersol production resumed in May 2013, and supplies had been nearly restored by early June. However, in mid-July, state tuberculosis (TB) control officials notified CDC of difficulty obtaining Tubersol and Aplisol. Sanofi Pasteur notified FDA of a temporary delay in the availability of tuberculin in the 10-dose and 50-dose presentations. In mid-October, the 10-dose presentation was being returned to market, on allocation, which means that historical purchasing practices determine the amount that customers are allotted. In late October, the 50-dose presentation was being returned to market, also on allocation, one vial per historical customer per month. Supplies are forecast to approach normal during January 2014, after distributors have restored their supply chains. A compensatory surge in testing after deferment of testing during the periods of shortage might cause further temporary instability of supplies. In mid-August 2013, officials in 29 of 52 U.S. jurisdictions noted a shortage of at least one PPD TST antigen solution in health departments to the extent that it interrupted activities. This report includes a summary of the extent and effects of the shortages and a reiteration of advice on how to adapt to them.

Two kinds of immunologic tests are used for detecting *Mycobacterium tuberculosis* infection: TSTs* and interferon-γ release assay (IGRA) blood tests (*2*). The indications for using these tests are the same, although one or the other test is preferred for certain populations (e.g., TST is preferred for children aged <5 years) (*2*). These preferences could play a role in setting priorities when one of the methods is unavailable. Together, these tests are the only means for detecting latent *M. tuberculosis* infection, and they contribute to diagnosing active TB disease. When findings such as chest radiography and mycobacterial cultures are sufficient for confirming or excluding the diagnosis of TB disease, the results from TST or IGRA might be unnecessary. However, most TB cases in the United States are diagnosed with an array of diagnostic findings, including results from TST or IGRA. When TB disease is strongly suspected, specific treatment should be started, regardless of results from these tests.

In mid-August 2013, during their routine assessments of the 68 TB control programs that are funded by federal cooperative agreements, program consultants at CDC's Division of Tuberculosis Elimination inquired about shortages of PPD TST antigen solutions. The officials in 52 jurisdictions (76%), including 43 states, two unincorporated territories (Puerto Rico and the U.S. Virgin Islands), and seven cities (Houston, Texas; Los Angeles, California; New York, New York; Philadelphia, Pennsylvania; San Francisco, California; San Diego, California, and the District of Columbia) shared updates. These jurisdictions accounted for 93% of the TB cases reported in the United States in 2012 (*3*). Officials in 29 jurisdictions (56%) reported shortages of PPD TST antigen solutions in health departments (10 Tubersol only, four Aplisol only, and 15 both) to the extent that routine activities were being threatened or had been curtailed. When comparing the shortages in August with those in early June, immediately before Tubersol supplies had become available again, officials in 13 of these 29 jurisdictions described the shortages in health departments as more severe in August; in seven, they described the shortages as similar; in six, they described the shortages as less severe; and in three, they were unsure about the comparison. Officials in 40 jurisdictions (77%) reported that they had been alerted about shortages by health-care providers in a non–public-health sector (19 Tubersol only, one Aplisol only, and 20 both). In four of the 23 jurisdictions that were not experiencing shortages at health departments, some routine testing practices (e.g., screening of matriculating students) were suspended preemptively. Use of IGRAs was being increased in 12 jurisdictions in response to shortages. The number of jurisdictions that have been less affected because of preshortage reliance on IGRAs is unknown.

To address shortages of PPD TST antigen solutions, CDC has recommended any of three general approaches: 1) substitute IGRA blood tests for TSTs (*2*); 2) allocate TST supplies to priority indications, as determined by public health authorities (*4*); and 3) substitute Aplisol for Tubersol for skin testing, which depends on Aplisol availability (*1*).

Some surveillance programs for institutional or occupational TB infection control rely on routine serial TST or IGRA. For these indications, switching products or methods should be undertaken cautiously. Serial changes in test results become difficult to interpret, because the apparent conversions of

*Additional information about TSTs available at http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm.

results from negative to positive or reversions from positive to negative could be caused by inherent interproduct or intermethod variability (*2,5*). In settings with a low likelihood of *M. tuberculosis* exposure, the deferment of routine serial testing should be considered in consultation with public health and occupational health authorities.

Up-to-date information about shortages of biologic products, including PPD TST antigen solutions, is available from FDA online at http://www.fda.gov/biologicsbloodvaccines/safetyavailability/shortages/ucm351921.htm.

Reported by

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References

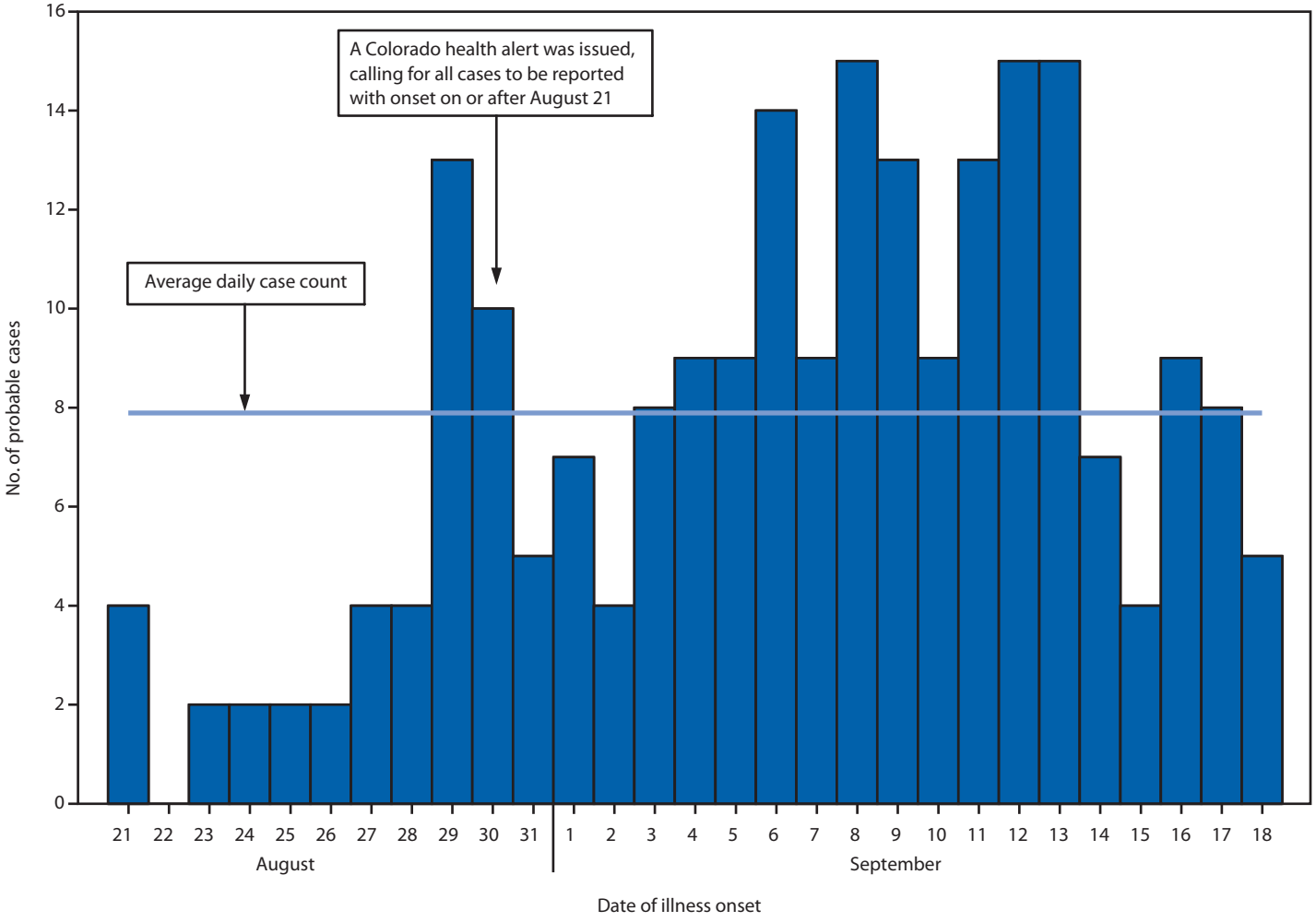
1. CDC. National shortage of purified-protein derivative tuberculin products. MMWR 2013;62:312.
2. CDC. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection—United States, 2010. MMWR 2010;59(No. RR-5).
3. CDC. Reported tuberculosis in the United States, 2012. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/tb/statistics/reports/2012/pdf/report2012.pdf.
4. CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000;49(No. RR-6).
5. CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR 2005;54(No. RR-17).

Notes from the Field

Severe Illness Associated with Reported Use of Synthetic Marijuana — Colorado, August–September 2013

On August 30, 2013, the Colorado Department of Public Health and Environment (CDPHE) was notified by several hospitals of an increase in the number of patients visiting their emergency departments (EDs) with altered mental status after using synthetic marijuana. Synthetic marijuana is dried plant material sprayed with various synthetic cannabinoids and smoked as an alternative to smoking marijuana. In response to the increase in ED visits associated with the use of synthetic marijuana, CDPHE asked all Colorado EDs to report through EMResource (a web-based reporting system) any patients examined on or after August 21 with altered mental status after use of a synthetic marijuana product. Serum and urine specimens from patients also were requested. On September 8, CDPHE, with the assistance of CDC, began an epidemiologic investigation to characterize the outbreak, determine the active substance and source of the synthetic marijuana product, and prevent further morbidity and mortality. Investigators reviewed ED visit reports submitted through EMResource and medical charts. A probable case was defined as any illness resulting in a visit to a Colorado ED during August 21–September 18, 2013, by a patient with suspected synthetic marijuana use in the 24 hours preceding illness onset. Of 263 patient visits reported to CDPHE through EMResource (214) and other means, such as e-mail and fax (49), a total of 221 (84%) represented probable cases (Figure).

FIGURE. Number of probable cases (n = 221) of severe illness associated with use of synthetic marijuana, by date of illness onset — Colorado, August 21–September 18, 2013



Among the 221 probable cases, abstracted medical records from a convenience sample of 127 (58%) patients were used for descriptive study. Median age of the 127 patients was 26 years (range: 13–60 years), and 101 (80%) were male. Clinical signs and symptoms included systolic blood pressure >120 mmHg in 81 (64%), heart rate >100 beats per minute in 73 (57%), somnolence in 45 (35%), aggressive or violent behavior in 40 (32%), agitation in 40 (32%), and confusion in 32 (25%).

Of the 127 patients, a total of 111 (87%) were treated and discharged from the ED. Sixteen (13%) were admitted, 10 of whom were admitted to an intensive care unit. No deaths were reported among the 127 patients. All 127 patients were reported from EDs in the Denver metropolitan area (99) or Colorado Springs (28).

Brand names of synthetic marijuana products that investigators determined had been used by the patients included Black Mamba, Crazy Monkey, Crazy Clown, Dead Man Walking, Funky Monkey, Sexy Monkey, SinX, Spice, TenX, Twilight, and 3X. Patients also identified two convenience stores, one "head shop," and one gas station as sources of synthetic marijuana products involved in this outbreak. These stores subsequently were closed by Colorado law enforcement officials. To alert the public to the outbreak, CDPHE released messages regarding the dangers of synthetic marijuana via social media and the news media. The investigation provided geographic and demographic information that enabled CDPHE to focus the messaging toward teens and young men in certain geographic areas.

Although the clinical features observed in patients were consistent with synthetic marijuana exposure described in the medical literature (*2,3*), no standard laboratory tests are available to confirm synthetic marijuana intoxication. Currently, CDPHE is coordinating with the Colorado Bureau of Investigation to determine whether two new variants of synthetic marijuana, ADBICA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide) and ADB-PINACA (N-(1-amino-3,3-dimethy-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide), that were found in products seized by the Colorado Bureau of Investigation shortly before the outbreak, contributed to the illnesses.

ADB-PINACA was linked to a similar outbreak in Georgia in August 2013 (*4*). The public should be aware of the potential dangers of synthetic marijuana use, and EDs and public health departments should remain vigilant for reports of adverse health effects from synthetic marijuana use so that they can detect outbreaks more readily and monitor the effectiveness of prevention efforts.

Reported by

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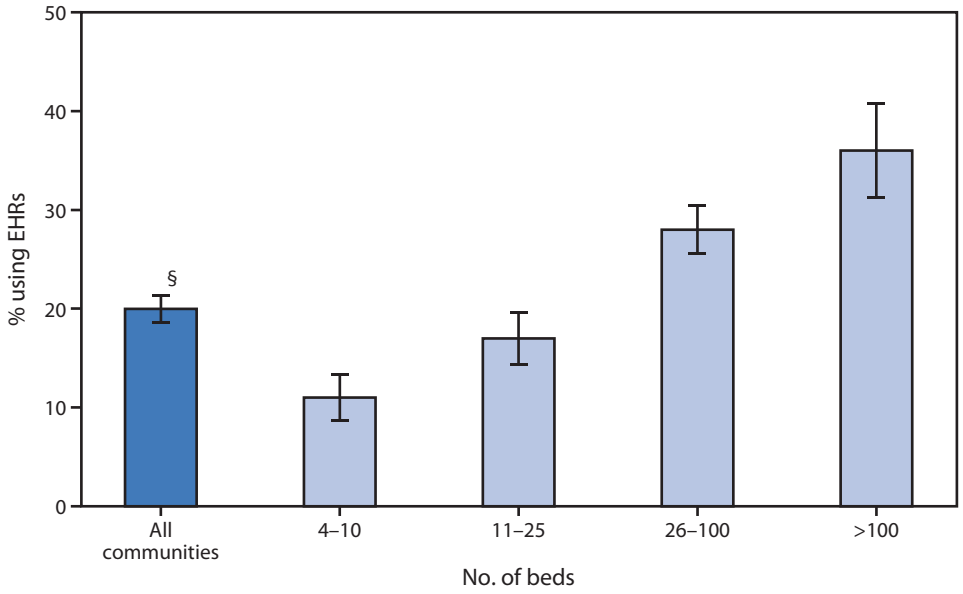
References

1. CDC. Acute kidney injury associated with synthetic cannabinoid use—multiple states, 2012. MMWR 2013;62:93–8.
2. Hoyte CO, Jacob J, Monte AA, Al-Jumaan M, Bronstein AC, Heard KJ. A characterization of synthetic cannabinoid exposures reported to the National Poison Data System in 2010. Ann Emerg Med 2012;60:435–8.
3. Every-Palmer S. Synthetic cannabinoid JWH-018 and psychosis: an explorative study. Drug Alcohol Depend 2011;117:152–7.
4. CDC. Notes from the field: severe illness associated with synthetic cannabinoid use—Brunswick, Georgia, 2013. MMWR 2013;62:939.

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage of Residential Care Communities* Using Electronic Health Records (EHRs),† by Number of Beds — National Study of Long-Term Care Providers, United States, 2012



* Assisted living and similar communities (e.g., personal care homes, adult care homes, board and care homes, and adult foster care). Residential care communities with missing data were excluded.
† Participating administrators and directors were asked, "An electronic health record is a computerized version of the resident's health and personal information used in the management of the resident's health care. Other than for accounting or billing purposes, does this residential care community use electronic health records?"
§ 95% confidence interval.

In 2012, 20% of residential care communities used EHRs. Greater proportions of communities with larger numbers of beds used EHRs compared with communities with fewer beds. Communities with >100 beds (36%) were more than three times as likely as communities with 4–10 beds (11%) to use EHRs.

Source: National Study of Long-Term Care Providers, 2012. Available at http://www.cdc.gov/nchs/nsltcp.htm.

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