Update on Progress in Selected Public Health Programs After the 2010 Earthquake and Cholera Epidemic — Haiti, 2014

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On January 12, 2010, an earthquake devastated Haiti’s infrastructure, killing an estimated 230,000 persons and displacing more than 1.5 million (1). Ten months later, Haiti experienced the beginning of the largest cholera epidemic ever reported in a single country (2). Immediately after the earthquake and at the start of the cholera epidemic, health priorities in Haiti included improvement of surveillance and laboratory capacity for addressing public health threats in the general population and targeted surveillance and provision of improved water and sanitation in camps for internally displaced persons. As part of a multi-sector, post-earthquake response in collaboration with the Government of Haiti and others, CDC focused on supporting the recovery, expansion, or establishment of several key health programs (3). This update reports progress in selected health programs, services, and systems in Haiti as of the end of 2014.

Human Immunodeficiency Virus Treatment

Although severely affected by the earthquake, human immunodeficiency virus (HIV) clinical services supported by the President’s Emergency Plan for AIDS Relief were restored quickly. For example, from October 1, 2008, to September 30, 2009, 44% (1,881 of 4,275) identified HIV-positive pregnant women received antiretroviral medicines to prevent HIV transmission to their children. This coverage fell to nearly 32% (1,115 of 3,563) the following year, which included the earthquake, but rebounded to 87% (4,783 of 5,502) (Figure) from October 2013 to September 2014. Similar recoveries occurred for other services, including antiretroviral therapy enrollment and screening of tuberculosis patients for HIV infection (4).

Immunization Cold Storage Capacity

To support immunization programs in Haiti, there was a critical need to improve cold storage capacity at central, regional, and peripheral levels. Compared with the immediate post-earthquake period, cold storage capacity at the central level has increased from 17,000 L to 32,500 L, allowing for sufficient vaccine storage capacity until 2018. To date, regional-level storage capacity has increased by 212% since 2010; at the peripheral level, 86% of institutions have refrigerators, with plans to reach 100% coverage of institutions with solar refrigerators over the next 3 years (5). Combined with other efforts, the improvements in cold chain capacity have facilitated the scale-up of measles-rubella vaccination (Figure) and the

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introduction of two vaccines into the routine immunization schedule: a pentavalent vaccine that protects children against five diseases (diphtheria, tetanus, pertussis [whooping cough], hepatitis B, and *Haemophilus influenzae* type b [Hib] disease) with one shot (2012) and rotavirus vaccine (2014).

**Lymphatic Filariasis Elimination**

The elimination of lymphatic filariasis in Haiti was at risk at the time of the earthquake because of a lack of campaigns to administer drugs to treat the disease in Port-au-Prince. Subsequently, with CDC support, Haiti achieved 93% national coverage for lymphatic filariasis mass drug administration (MDA) among at-risk persons, with approximately 8 million persons treated nationally, including 2.3 million in Port-au-Prince (4) (Figure). In all, 58% of communes in Haiti have completed five or more rounds of MDA. Currently, 13 evaluation units in the regions of Centre, Nippes, Nord, Nord Est, Nord Ouest, and Sud Est are eligible and scheduled for Transmission Assessment Surveys in 2015 to determine if MDA can be stopped (6). For the remaining regions, MDA will continue as needed, with metropolitan Port-au-Prince set to receive its fourth and fifth rounds of MDA in 2015 and 2016, respectively.

**Malaria Testing**

Elimination goals for malaria were predicated on a targeted “test and treat” approach; there was a need to expand diagnostics to move from treatment of clinically diagnosed malaria to the treatment of laboratory-confirmed cases. To reach this objective, in 2010 the malaria program approved a national policy for use of rapid diagnostic tests. As of March 2014, approximately 900 staff members from 214 institutions received training on new case management guidelines and approximately 300,000 rapid diagnostic tests were conducted, bringing Haiti closer to the malaria pre-elimination stage (7).

**Cholera Response**

Efforts to respond to and control the cholera epidemic ultimately contributed to a large decline from 352,033 cases in 2011 to 15,063 through October 2014, with annual case fatality rates consistently below the World Health Organization target of 1% since 2011 (8). Extremely weak water and sanitation infrastructure and services, which contributed to the rapid spread of cholera, have been addressed in rural areas by the hiring and training of more than 250 rural water and sanitation technicians. Of the more than 500 rural community-based piped water systems identified in a national survey, a chlorination program has been implemented in 107 (9). In Port-au-Prince, results from a CDC evaluation of the quality of water sold by private vendors indicated that the water was usually pathogen-free at the point of sale.

**Rabies Control**

Haiti has the highest incidence of human rabies in the Western Hemisphere, and a lack of rabies surveillance data has limited...
control efforts. An initiative of the Haitian Ministry of Health and CDC begun in July 2013 is addressing that deficiency. From July 2013 to June 2014, CDC and Haitian Ministry of Health staff members investigated 323 possible cases of canine rabies, with 27% found positive or probable. For the metropolitan Port-au-Prince area, this represented a 14-fold increase in the number of cases investigated compared with the same period in 2012, when only 23 cases were investigated (10).

Laboratory Diagnosis of Tuberculosis

Laboratory diagnostic capacity for tuberculosis has expanded from no site with fluorescent microscopy and one site with nucleic acid amplification equipment in 2010 to 25 sites with fluorescent microscopy and 12 sites with nucleic acid amplification capacity in 2014. This has contributed to improved detection and notification of cases of active tuberculosis; the World Health Organization estimates that the rate of detection of active tuberculosis cases in Haiti improved from 62% in 2010 (11) to 80% in 2013 (12).

Sentinel Surveillance for Notifiable Diseases

The national sentinel surveillance system (13) for notifiable diseases has expanded from 51 sites soon after the earthquake to 153 currently. The system has facilitated identification and investigations of immediately notifiable diseases, including vaccine-preventable diseases such as measles, rubella, and diphtheria. In addition, a system for enhanced laboratory-based surveillance strengthens analysis of predominant etiologies of acute febrile, respiratory, and diarrheal diseases, and meningitis.

Field Epidemiology Training

Since 2011, the Haitian field epidemiology training program has graduated 154 basic-level residents, 58 intermediate-level residents, and five advanced-level residents. These graduates have supported disease control efforts for a number of outbreaks, including cholera, dengue, and chikungunya, and have developed a national Ebola preparedness plan (14).

New Challenges and Priorities

Progress in Haiti remains fragile. For example, although there have been significant accomplishments and improvements in both rural and urban settings, there remains a great shortfall in the resources required for water and sanitation infrastructure and services to eliminate cholera in Haiti, as outlined in the country’s 10-year national plan (15). There has been slow and limited progress in restoring the physical health infrastructure. For many programs, the financial resources that were made available following the earthquake were needed simply to maintain key programs, with a focus on human resources and commodities; funding sources for ongoing, essential public health programs remain uncertain.

As the focus of the response has naturally shifted from addressing short-term crises to long-term needs, new challenges and priorities have emerged. However, the link between immediate problems (e.g., cholera) and structural issues (e.g., weak water and sanitation systems) is clear, and the two need to be addressed in tandem. Failure to consider the long-term context in the immediate aftermath of an emergency (e.g., local human capacity to sustain a program) might jeopardize hard-won public health gains over time. Nonetheless, Haiti has seen substantial progress in key health indicators in just 5 years and might serve as a model for other resource-limited countries recovering from natural or manmade disasters, including countries prioritized under the global health security agenda and those recovering from the West African Ebola epidemic (16,17). Additional information related to activities supported by CDC in Haiti is available at http://www.cdc.gov/global-health/countries/haiti and via Twitter at @CDCHaiti.

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References


Hypothermia is defined as a core body temperature of <95°F (<35°C) and is caused by environmental exposure, drug intoxication, or metabolic or nervous system dysfunction. Exposure to cold is a leading cause of weather-related mortality and is responsible for approximately twice the number of deaths annually as exposure to heat in the United States (1). To understand the risk factors for hypothermia-related death and improve prevention efforts, during January 1–April 30, 2014, a period of record low temperatures, the Wisconsin Division of Public Health began active surveillance for hypothermia. Suspected hypothermia-related deaths were reported by coroners or medical examiners and identified in death records. Hypothermia was confirmed as the cause of death by review of death investigation narratives. This report describes three selected cases of hypothermia-related deaths in Wisconsin and summarizes characteristics of all cases that occurred in the state during the period of active surveillance. A summary of hypothermia-related deaths for the United States during 2003–2013 also is presented for comparison and to assess national mortality trends. Hypothermia continues to be an important cause of weather-related death. Key risk factors include drug intoxication, mental illness, and social isolation. State and local health agencies might need to focus outreach on vulnerable populations and target interventions for groups at highest risk for death.

Case Reports

Case 1. In January 2014, a man aged 25 years was found frozen to death one block from his home. The decedent had been healthy previously and had no known medical conditions. Ambient temperature at the estimated time of death was -8°F (-22°C). Death investigation concluded that he had been dropped off at the wrong residence after leaving a tavern. His blood alcohol level was 230 mg/dL (intoxication is legally defined as ≥80 mg/dL in all states), and cause of death was environmental hypothermia with a contributing cause of alcohol intoxication.

Case 2. In February 2014, a deceased woman aged 59 years was found outside in her driveway 72 hours after last contact with a friend. She lived alone and had multiple comorbid conditions, including type 2 diabetes, chronic obstructive pulmonary disease, and spinal stenosis. Ambient temperature at the estimated time of death was 6°F (-14°C). The death investigation concluded that she likely fell and sustained minor injuries. Although she was wearing suitable clothing for the weather, she was unable to stand because of impaired mobility. The cause of death was environmental hypothermia.

Case 3. In March 2014, a deceased man aged 63 years was found in a snow-covered field. The decedent had a history of advanced Parkinson’s disease and lived alone. Family members reported that he had been unable to care for himself completely, and neighbors noted he had a tendency to wander outdoors. He had last spoken with his family 36 hours before discovery of his body. Core body temperature was 42°F (6°C), and the ambient temperature at time of discovery was 35°F (2°C). The decedent was wearing only jeans, a short-sleeve shirt, shoes, and gloves. Autopsy and death investigation concluded the cause of death was environmental hypothermia.

Wisconsin, 2014

During January–April 2014, a total of 27 hypothermia-related deaths occurred in Wisconsin, all of which were investigated by a coroner or medical examiner. Eighteen (67%) decedents were male; decedents’ median age was 66 years (range = 25–95 years). Autopsies were performed on 14 (52%) decedents, and toxicology was performed for nine (33%). Of those nine, six (67%) were positive for alcohol, and one (11%) was positive for both a prescription opioid and delta-9-tetrahydrocannabinol (the principal psychoactive ingredient of cannabis). Eighteen (67%) bodies were discovered outdoors, and the median outside temperature at the estimated time of death was 6°F (-15°C), with a range of -14°F to 35°F (-26°C to 2°C). Four (15%) of the decedents who were discovered indoors resided in homes with unused or nonfunctional furnaces. Coroner and medical examiner investigations revealed that five (19%) decedents had a history of mental illness. Fifteen (56%) lived alone, and two (7%) had been homeless.

United States, 2003–2013

Hypothermia-related deaths for the United States overall were obtained from CDC’s multiple cause of death files and were defined as any death with an underlying or contributing cause of death from exposure to excessive natural cold (International Classification of Diseases, 10th Revision [ICD-10] code X.31). A total of 13,419 deaths occurred during the period, with unadjusted annual rates ranging from 0.3 to 0.5 per 100,000 persons. There was a statistically significant increase in rates over the period (chi-square for trend; p<0.01).
Males accounted for 9,050 (67%) decedents. Rates of death were highest among persons of advanced age; mean death rates during the 10-year period for males and females aged ≥65 years were 1.8 and 1.1 per 100,000 population, respectively (Figure). A total of 1,391 (10%) decedents had alcohol or drug poisoning (ICD-10 codes X.40–45, Y.10–15, or E.10) as a contributing cause of death.

Discussion

Hypothermia is a preventable cause of death that begins when core body temperature decreases to <95°F (<35°C). Initial symptoms include shivering and cool extremities. As hypothermia worsens, symptoms progress to confusion, loss of fine motor skills, and amnesia (2). Continued heat loss without adequate rewarming can result in hypotension, impaired respiration, cardiac arrhythmias, and death (2).

This report highlights previously identified risk factors for fatal hypothermia, including advanced age, male sex, drug intoxication, homelessness, and mental illness. Older persons have impaired heat generation and often multiple comorbidities that increase the risk for death (3). Substance and alcohol abuse can contribute to hypothermia by blunting physiologic responses to cold and can lead to prolonged exposure caused by impaired judgment. A review of Wisconsin hypothermia-related deaths revealed that approximately half of decedents lived alone, which can lead to substantial delays in treatment if persons are incapacitated by injury or illness.

Prompt recognition of the signs and symptoms of hypothermia is necessary for reducing mortality. Patients should be rewarmed by using external warming (e.g., blankets or forced heated air) for mild hypothermia and internal warming methods (e.g., body cavity lavage) for severe hypothermia. In the event of cardiac arrest, cardiopulmonary resuscitation should be performed during rewarming in accordance with published guidelines (4).

Greater awareness of severe weather events and the need for emergency and disaster response has led to increased public health attention to weather-related response planning (5). One of the most visible components of such plans is the opening of publically available warming shelters when extreme cold is expected. However, this report suggests that state and local health agencies also might need to focus more on public education, communication networks to reach the most vulnerable persons, and targeted interventions for groups at risk (e.g., older persons, homeless, and those living alone). Educational materials should emphasize the rapidity with which hypothermia can occur, review the warning signs of hypothermia, and outline ways to reduce risk (e.g., wearing suitable clothing, avoiding hazardous weather situations, and preparing for such emergencies as motor vehicle breakdowns and power outages). Emphasizing how alcohol consumption and certain drugs increase the risk for cold-related injuries and hypothermia also might be helpful.

What is already known on this topic?
Exposure to extreme cold is a leading cause of preventable weather-related mortality in the United States. Risks for hypothermia-related death include advanced age, mental illness, male sex, and drug intoxication.

What is added by this report?
During January–April 2014, a total of 27 hypothermia-related deaths occurred in Wisconsin. Eighteen decedents were male; median age was 66 years (range = 25–95 years). Six of nine tested for alcohol were positive. Eighteen bodies were discovered outdoors. Investigations revealed that five decedents had a history of mental illness, 15 lived alone, and two had been homeless. Rates of hypothermia-related deaths in the United States increased during 2003–2012.

What are the implications for public health practice?
Social isolation can be an important factor in hypothermia-related mortality. State and local health agencies might need to target public education and interventions at socially isolated groups, including older persons, the homeless, and those living alone.

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In August 2014, PulseNet, the national molecular subtyping network for foodborne disease surveillance, detected a multistate cluster of *Salmonella enterica* serotype Newport infections with an indistinguishable pulse-field gel electrophoresis (PFGE) pattern (*Xba*I PFGE pattern JJPX01.0061).* Outbreaks of illnesses associated with this PFGE pattern have previously been linked to consumption of tomatoes harvested from Virginia’s Eastern Shore in the Delmarva region and have not been linked to cucumbers or other produce items (1). To identify the contaminated food and find the source of the contamination, CDC, state and local health and agriculture departments and laboratories, and the Food and Drug Administration (FDA) conducted epidemiologic, traceback, and laboratory investigations. A total of 275 patients in 29 states and the District of Columbia were identified, with illness onsets occurring during May 20–September 30, 2014. Whole genome sequencing (WGS), a highly discriminating subtyping method, was used to further characterize PFGE pattern JJPX01.0061 isolates. Epidemiologic, microbiologic, and product traceback evidence suggests that cucumbers were a source of *Salmonella* Newport infections in this outbreak. The epidemiologic link to a novel outbreak vehicle suggests an environmental reservoir for *Salmonella* in the Delmarva region that should be identified and mitigated to prevent future outbreaks.

**Epidemiologic Investigation**

A case was defined as infection with *Salmonella* Newport with PFGE pattern JJPX01.0061 (the outbreak strain) in a person with illness onset occurring during May 20–September 30, 2014. Initial interviews of ill persons conducted by state and local health officials found that travel to the Delmarva region during the incubation period was commonly reported. A structured, focused supplemental questionnaire was developed to collect detailed information on travel and exposure to restaurants, seafood, fruit, and produce, including tomatoes, in the 7 days before illness onset. Exposure frequencies were compared with the 2006–2007 FoodNet Population Survey, in which healthy persons reported foods consumed in the week before interview.† Information also was collected on illness subclusters, defined as two or more unrelated ill persons who reported eating at the same restaurant, attending the same event, or shopping at the same grocery store in the week before becoming ill.

A total of 275 cases were reported from 29 states and the District of Columbia (Figure 1). An additional 18 suspected cases not meeting the case definition were excluded from the analysis because they were found to be temporal outliers and unlikely to be related. Illness onset dates ranged from May 25 to September 29, 2014 (Figure 2). Median age of patients was 42 years (range = <1–90 years); 66% (174 of 265) were female. Thirty-four percent (48 of 141) were hospitalized; one death was reported in an elderly man with bacteremia. A total of 101 patients were interviewed using the supplemental questionnaire about exposures in the week before illness onset. This questionnaire focused on leafy greens and tomatoes and contained smaller sections on fruit, vegetables, and seafood common to the Delmarva region. Many patients were unreachable and did not receive the supplemental questionnaire. Sixty-two percent (49 of 79) of respondents reported eating cucumbers in the week before becoming ill. Patients were significantly more likely to report consuming cucumbers compared with respondents in the 2006–2007 FoodNet Population Survey, both for national year-round cucumber consumption (46.9%}

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*Additional information available at http://www.cdc.gov/pulsenet.
†Additional information available at http://www.cdc.gov/foodnet/studies/population-surveys.html.
[p=0.002]) and for cucumber consumption in Maryland during the month of July (54.9% [p=0.04]). The proportion of ill persons who reported eating tomatoes, leafy greens, or any other item on the supplemental questionnaire was not significantly higher than expected compared with findings from the FoodNet Population Survey.

**Traceback investigation**

Officials in Maryland, Delaware, and New York worked with their FDA district offices and FDA and U.S. Department of Agriculture foodborne outbreak rapid response teams to conduct an informational (i.e., nonregulatory) traceback from retail establishments in these states to identify a point of distribution convergence for produce items (i.e., cucumbers, leafy greens, and tomatoes) consumed in nine of 12 subclusters. Each of eight establishments in Maryland and Delaware received cucumbers from a single major distributor. Preliminary traceback from the distributor to several brokers identified a common grower on Maryland’s Eastern Shore in the Delmarva region. Traceback from a New York subcluster led to a different distribution chain than in Maryland and Delaware. Officials from the Maryland Department of Agriculture, the Maryland rapid response team, and the FDA Baltimore District Office visited the Maryland farm. Officials collected 48 environmental samples from areas where cucumbers were grown, harvested, and packed. Sediment and manure samples were taken from the farm. No samples yielded *Salmonella*; however, sampling was performed several months after the harvest. Records and interviews indicated that the farm applied poultry litter approximately 120 days before harvest, but it was not available for testing.

**Laboratory investigation**

Twelve distinct illness subclusters were identified across four states, ranging in size from two to six cases. WGS was performed on 58 clinical isolates by state health departments, FDA, and CDC laboratories to further characterize the genetic relatedness of bacteria isolated from patients. Phylogenetic analysis revealed a primary group of highly related clinical isolates from cases in Delaware, Maryland, Ohio, Pennsylvania, and Virginia (median single nucleotide polymorphism distance = 26 [97.5% confidence interval = 1–37]). An additional group of highly related isolates from patients in New York was also identified, but this group was distinct from the primary

**FIGURE 2. Number of persons (N = 275) infected with the outbreak strain of *Salmonella* Newport, by estimated date of illness onset — United States, May 20–September 30, 2014**

![Graph showing number of persons infected with *Salmonella* Newport by estimated date of illness onset from May 20 to September 30, 2014.](image-url)
What is already known on this topic?

*Salmonella* is the most common bacterial cause of foodborne disease in the United States and results in the highest number of hospitalizations and deaths among foodborne pathogens. *Salmonella* Newport has historically been a common cause of tomato-associated outbreaks in the United States. The Virginia Eastern Shore in the Delmarva region has been the site of multiple outbreaks of *Salmonella* Newport infection in recent years.

What is added by this report?

In August 2014, a multistate cluster of *Salmonella enterica* serotype Newport infections with an indistinguishable pulse-field gel electrophoresis (PFGE) pattern (XbaI PFGE pattern JJPX01.0061) was detected, involving 275 patients in 29 states and the District of Columbia with illness onsets occurring during May 20 and September 30. Epidemiologic, product traceback, and laboratory evidence implicated cucumbers. Whole genome sequencing, used to subtype the isolates, and the traceback investigation suggested that some, but not all, of the contaminated cucumbers were from a farm in Maryland. No *Salmonella* was isolated from environmental samples taken at the farm.

What are the implications for public health practice?

The epidemiologic link to a novel outbreak vehicle from the Delmarva region, cucumbers, suggests an environmental reservoir for *Salmonella* that might also include both the Virginia and Maryland portions of the Delmarva region. Federal, state, and local public health and regulatory authorities should focus on identifying and mitigating this potential environmental reservoir to prevent future outbreaks.

Discussion

The epidemiologic data, traceback investigations, and whole genome sequencing all support the hypothesis that cucumbers were a likely source of *Salmonella* Newport infections in this outbreak. Cucumbers were the only food eaten by patients significantly more often than expected. Traceback investigations performed using invoices from illness subclusters in Maryland and Delaware identified a common grower of cucumbers in the Delmarva region. This is the first multistate outbreak of *Salmonella* Newport implicating a fresh produce item grown in the Delmarva region other than tomatoes. Historically, *Salmonella* Newport outbreaks associated with this PFGE pattern have been linked to red round tomatoes grown on Virginia’s Eastern Shore. These outbreaks occurred in 2002 (333 persons), 2005 (72 persons), 2006 (115 persons), and 2007 (65 persons), with an additional suspected outbreak in 2010 (51 persons) (1). A definitive contamination source has not been found, and *Salmonella* Newport has not been isolated directly from any Delmarva region tomatoes. Wildlife have been evaluated as a possible source of contamination, but fecal specimens from deer, turtles, and birds have been negative and do not support the hypothesis that animals are a source (2). Other serotypes of *Salmonella* have been linked to cucumbers; most recently an outbreak of *Salmonella* Saintpaul infections was linked to imported cucumbers from Mexico in 2013 (3).

Investigating illness subclusters can provide critical clues about the source of an outbreak. Informational traceback can support the epidemiologic investigation by quickly assessing the plausibility of one or more vehicles as the source of the outbreak. Informational traceback generally can be completed much more quickly than regulatory traceback, which requires the collection of specific types of records, such as receipts, invoices, and bills of lading, at each step of the distribution chain. In this investigation, the informational traceback quickly provided a critical clue that suggested cucumbers were a likely source in the outbreak.

Consultation with independent industry experts early in an outbreak investigation also can provide important clues to help focus the investigation on certain suspected foods. Because of the suspicion that this outbreak was caused by a novel vehicle for this *Salmonella* Newport PFGE pattern, an industry consultation was held on September 11, 2014, with three independent experts from the produce industry to obtain information regarding cucumber harvesting and distribution on the Delmarva region. The consultants provided information regarding crop production and distribution practices that also helped assess the plausibility of cucumbers as an outbreak vehicle.

Advanced molecular detection methods, including WGS, might improve discrimination of subclusters during outbreak investigations. WGS data from the subclusters in this investigation demonstrated a phylogenetic link between clinical isolates from the eight Maryland and Delaware subclusters, in addition to differentiating these clusters from a subcluster in New York. The significance of this differentiation remains unclear at this time but might suggest that some of the illnesses in New York were not related to consumption of cucumbers from the Delmarva region. This is also supported by the informational traceback from the New York establishment, which led to a different distribution chain than those of the Maryland and Delaware establishments.

The findings in this report are subject to at least two limitations. First, no case-control study was performed because illness...
subclusters were small. Second, not all patients in the subclusters were systematically asked about cucumber consumption.

This outbreak supports the continued evaluation of farm practices by FDA as a part of the development of a Produce Safety Rule. These evaluations include conducting a risk assessment and working with the U.S. Department of Agriculture and other stakeholders. It also includes performing research to strengthen scientific support for determining appropriate intervals between application of raw manure fertilizer and harvest. The Maryland Department of Agriculture plans additional assessments in the Delmarva region before the 2015 planting season to determine whether additional or alternative “best practices” can be implemented.

Given the typical shelf life of cucumbers is 10–14 days, cucumbers from the implicated grower are no longer available for purchase or in person’s homes. Consumers and retailers should always follow safe produce handling recommendations. Cucumbers, like all produce, should be washed thoroughly, scrubbed with a clean produce brush before peeling or cutting, and refrigerated as soon as possible to prevent multiplication of bacteria such as *Salmonella*.

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**References**

Hepatitis A virus (HAV) infections among persons with developmental disabilities living in institutions were common in the past, but with improvements in care and fewer persons institutionalized, the number of HAV infections has declined in these institutions (1). However, residents in institutions are still vulnerable if they have not been vaccinated. On April 24, 2013, a resident of a group home (GH) for adults with developmental disabilities in southeast Michigan (GH-A) was diagnosed with hepatitis A and died 2 days later of fulminant liver failure. Four weeks later, a second GH-A resident was diagnosed with hepatitis A. None of the GH-A residents or staff had been vaccinated against hepatitis A. Over the next 3 months, six more cases of hepatitis A were diagnosed in residents in four other Michigan GHs. Three local health departments were involved in case investigation and management, including administration of postexposure prophylaxis (PEP). Serum specimens from seven cases were found to have an identical strain of HAV genotype 1A. This report describes the outbreak investigation, the challenges of timely delivery of PEP for hepatitis A, and the need for preexposure vaccination against hepatitis A for adults living or working in GHs for the disabled.

The Michigan Department of Human Services licenses approximately 200 and 170 GHs for adults with developmental disabilities in Oakland and Macomb Counties, respectively. GHs, owned and operated by various companies, provide 24-hour care and supervision for up to six residents, who share rooms and bathrooms. Residents have developmental and/or physical disabilities; some are nonverbal or minimally communicative, and some require assistance with toileting. The average staff-to-resident ratio is 2:1. Residents attend various programs at off-site work sites (WSs) including vocational centers for the disabled, a restaurant, and hotel, where they have contact with off-site workers and residents from other GHs or private homes.

After the hepatitis A diagnosis in a GH-A resident, the Oakland County Health Division (OCHD) began an investigation on April 24, 2013, to identify the source of infection and to prevent HAV transmission to other residents and staff. For purposes of this investigation, a confirmed case of hepatitis A was a case meeting the Council of State and Territorial Epidemiologists case definition for acute hepatitis A (http://wwwn.cdc.gov/nndss) in a person who resided or worked at an adult GH or WS during April 16–September 18, 2013.

A second case in GH-A was diagnosed May 16, 2013, in a person who attended WS-A (Table 1). At a second Oakland County group home (GH-B), three cases were reported among residents, with illness onset dates of May 17 (case 3), May 28 (case 5), and May 29 (case 6) (Figure 1). Case 4, in a resident of GH-C who attended WS-B in Macomb County, was diagnosed on May 26, 2013. Patients 3 and 4 had no previous contact with patients 1 or 2. Patients 3 and 4 attended WS-B, and patients 5 and 6 attended WS-C and WS-D, respectively. A health care worker (HCW-1), who was employed at GH-A, GH-B, and WS-B, was identified as a common link for the first six cases. HCW-1 did not report any symptoms and had not previously received the hepatitis A vaccine. Five cases were in residents of the GHs where HCW-1 worked, and HCW-1 cared for patient 4 while at WS-B (Figure 2).

At a fourth GH (GH-D) in Oakland County, patient 7 became symptomatic on July 5, 2013. A fifth GH (GH-E) reported case 8, in a resident with an approximate illness onset date of July 23, 2013. Patients 7 and 8 had no direct contact with any previous patient, nor did they attend the same WS. However, two GH-D residents (one was the roommate of case 7) attended WS-B where they were likely exposed to patients 3 or 4 or both. Two GH-E residents worked at WS-D, the same vocational center that patient 6 attended. Patient 8 attended a special needs camp in Tuscola County during June 30–July 12, 2013. The camp and Tuscola County Health Department were notified on July 25, 2013, of the potential exposure to other campers and camp staff.

Eight GH residents in five adult GHs in Oakland and Macomb Counties developed hepatitis A (Table 1). None of the residents and only eight (14%) of 57 HCWs in the five group homes had previously received hepatitis A vaccine. Illness onset dates ranged from April 16 to July 23, 2013. Ages of patients ranged from 42 to 61 years, with an average age of 48 years (median age = 48 years). Seven of the eight patients were male; three of the five homes housed only males. GH attack rates, calculated as the number of cases per home divided by the number of susceptible GH residents, ranged...
from 16.7% to 60.0% among the five homes; the attack rate among susceptible residents in all five homes was 27.6%. At GH-A and GH-B, where HCW-1 worked, the attack rates were 33.3% and 60.0%, respectively. After the occurrence of case 8, no further hepatitis A cases were detected among contacts.

No common food source was identified among the five group homes. Because a multistate hepatitis A outbreak was occurring concurrently that implicated a frozen berry product, GH managers were asked if frozen berries were consumed; none were. No staff reported any symptoms or previous diagnosis with hepatitis A. It was noted that HCW-1 did not always use gloves when assisting residents with toileting. Serum from seven of the eight patients was found to have the same HAV genotype 1A strain, sharing the identical VP1/P2B genomic sequence.

Of the 261 contacts who warranted PEP, 225 (86.2%) were confirmed to have received immunoglobulin (IG) or hepatitis A vaccine or both (Table 2).

### Discussion

Since 2006, the Advisory Committee on Immunization Practices (ACIP) has recommended routine vaccination against hepatitis A for all children at age 1 year (1), but its current recommendations for adults do not include residence in an institution or GH as an indication for vaccine (3). The 2006 ACIP recommendations note that in the past, HAV infection has been highly endemic in institutions for persons with developmental disabilities (1). However, because fewer persons have been institutionalized and conditions in institutions have improved, the incidence and prevalence of HAV infection have decreased, although outbreaks can occur in these settings (1). Disabled adults are now typically cared for in group homes, where residents live in close quarters and are often incontinent and nonverbal. These factors, as well as lack of contact precautions and hand washing might have contributed to the spread of HAV in this outbreak, similar to how transmission among diapered children in daycare settings was linked to community outbreaks of HAV infection during the prevaccine era (1). Moreover, after the introduction of hepatitis A vaccine in 1996, the age-specific patterns of disease have shifted to include an increasing proportion of susceptible adolescents and adults because of less exposure to infected children (4). Thus, the unvaccinated adult population in group homes is at high risk for HAV infection.

ACIP hepatitis A vaccine PEP recommendations were followed in this outbreak (2). Vaccine was used if IG was not available. Local public health workers partnered with two hospitals at clinics set up to provide PEP. Public health workers also

---

**TABLE 1. Epidemiologic and clinical summary of hepatitis A cases among residents of group homes — Michigan, April–July 2013**

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Group home</th>
<th>Work site</th>
<th>Age (yrs)</th>
<th>Sex</th>
<th>Illness onset date</th>
<th>Date of diagnosis</th>
<th>Clinical/Laboratory results</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>None</td>
<td>48</td>
<td>M</td>
<td>4/16</td>
<td>4/24</td>
<td>IgM anti-HAV+; ALT 2,525 U/dL; AST 4,530 U/dl</td>
<td>Yellow sclera, dark urine</td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>A</td>
<td>45</td>
<td>M</td>
<td>5/4</td>
<td>5/16</td>
<td>IgM anti-HAV+; ALT 436 U/dl; AST 175 U/dl</td>
<td>Lethargic, chalky stools, dark urine, diarrhea, jaundice</td>
</tr>
<tr>
<td>3</td>
<td>B</td>
<td>B</td>
<td>47</td>
<td>M</td>
<td>5/17</td>
<td>5/21 by clinical laboratory; 5/31 confirmed by MDCH laboratory</td>
<td>IgM anti-HAV+; ALT 693 U/dl; AST 118 U/dl</td>
<td>Painless jaundice, no other symptoms</td>
</tr>
<tr>
<td>4</td>
<td>C</td>
<td>B</td>
<td>49</td>
<td>M</td>
<td>5/23</td>
<td>5/26</td>
<td>IgM anti-HAV+; ALT 1,314 U/dl; AST 463</td>
<td>Weak, difficulty standing</td>
</tr>
<tr>
<td>5</td>
<td>B</td>
<td>C</td>
<td>42</td>
<td>M</td>
<td>5/28</td>
<td>5/29</td>
<td>IgM anti-HAV+; ALT 4,946 U/dl; AST 4,521 U/dl</td>
<td>Jaundice, dark urine, decreased appetite</td>
</tr>
<tr>
<td>6</td>
<td>B</td>
<td>D</td>
<td>49</td>
<td>M</td>
<td>5/29</td>
<td>5/30</td>
<td>IgM anti-HAV+; ALT 1,419 U/dl; AST 792 U/dl</td>
<td>Abdominal pain, decreased appetite</td>
</tr>
<tr>
<td>7</td>
<td>D</td>
<td>E</td>
<td>45</td>
<td>M</td>
<td>7/5</td>
<td>7/10</td>
<td>IgM anti-HAV+; ALT 2,434 U/dl; AST 2,082 U/dl</td>
<td>Nausea, vomiting, orange urine, jaundice</td>
</tr>
<tr>
<td>8</td>
<td>E</td>
<td>F</td>
<td>61</td>
<td>F</td>
<td>7/23</td>
<td>7/25</td>
<td>IgM anti-HAV+; ALT 1,291 U/dl; AST 980 U/dl</td>
<td>Jaundice</td>
</tr>
</tbody>
</table>

**Abbreviations:** IgM = immunoglobulin M; HAV = hepatitis A virus; ALT = alanine aminotransferase; AST = aspartate aminotransferase; MDCH = Michigan Department of Community Health.
FIGURE 2. Schematic of the suspected route of transmission of hepatitis A virus among residents of group homes and their work sites — Michigan, April–July 2013

Abbreviations: GH = group home; WS = work site; PEP = postexposure prophylaxis; CR = co-resident; HCW = health care worker.
administered vaccine at county clinics and at WS-F. Some staff and residents received PEP from their health care providers. OCHD notified neighboring counties of potential exposures in residents of GHs or in attendees at WSs within their respective counties. Vaccinations of contacts were verified through state and county immunization databases, or OCHD followed up with providers to confirm that PEP had been administered.

Although ACIP recommendations were followed in this outbreak, PEP administration was not without challenges. In Michigan, local health departments are responsible for having a hepatitis A outbreak response plan that pre-identifies sources of hepatitis A vaccine and IG in the community. In this outbreak, although on-hand IG supplies at the pre-identified hospitals expedited administration of PEP, they were not sufficient to provide PEP for such a large cohort. However, hospital pharmacies were able to respond quickly, order IG and vaccine, and received shipments overnight from their suppliers. It is likely that because of the rapid public health response this hepatitis A outbreak in group homes involved only five of 370 homes in the two affected counties. Before the outbreak, the estimated hepatitis A vaccination coverage rate among staff and residents in the affected homes was only 6%, which is thought to be typical of vaccination coverage in other homes in the two counties. Thus, the risk for substantial

### TABLE 2. Number of persons who received postexposure prophylaxis (PEP) and date of PEP among group home and work site contacts of persons with hepatitis A infection* — Michigan, April–July 2013

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Group home</th>
<th>Work site</th>
<th>No. of group home contacts</th>
<th>Group home contacts who received PEP</th>
<th>PEP dates at group homes</th>
<th>No. of work site contacts</th>
<th>Work site contacts who received PEP</th>
<th>PEP dates at work sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>None</td>
<td>18</td>
<td>18 (100)</td>
<td>Vaccine: 4/29–5/3, 5/15; IG: 5/17</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>A</td>
<td>18</td>
<td>18 (100)</td>
<td>Vaccine: 4/29–5/3, 5/15; IG: 5/17</td>
<td>12</td>
<td>8 (66.7)</td>
<td>6/10</td>
</tr>
<tr>
<td>3</td>
<td>B</td>
<td>B</td>
<td>19</td>
<td>13 (68.4)</td>
<td>5/31–6/6</td>
<td>55</td>
<td>53 (96.4)</td>
<td>5/31–6/6</td>
</tr>
<tr>
<td>4</td>
<td>C</td>
<td>B</td>
<td>14 (2 previously vaccinated)</td>
<td>14 (100)</td>
<td>6/3–6/24</td>
<td>55</td>
<td>53 (96.4)</td>
<td>5/31–6/6</td>
</tr>
<tr>
<td>5</td>
<td>B</td>
<td>C</td>
<td>19</td>
<td>13 (68.4)</td>
<td>5/31–6/6</td>
<td>4</td>
<td>4 (100)</td>
<td>6/5–6/11</td>
</tr>
<tr>
<td>6</td>
<td>B</td>
<td>D</td>
<td>19</td>
<td>13 (68.4)</td>
<td>5/31–6/6</td>
<td>57</td>
<td>46 (80.7)</td>
<td>6/1–6/17</td>
</tr>
<tr>
<td>7</td>
<td>D</td>
<td>E</td>
<td>13 (2 previously vaccinated)</td>
<td>13 (100)</td>
<td>7/11–7/15 (2 received PEP at work site on 6/6)</td>
<td>10</td>
<td>5 (50)</td>
<td>7/15–7/19</td>
</tr>
<tr>
<td>8</td>
<td>E</td>
<td>F</td>
<td>13 (1 previously vaccinated)</td>
<td>12 (92.3)</td>
<td>7/30–8/2 (2 received PEP at work site on 6/10)</td>
<td>45</td>
<td>39 (86.7)</td>
<td>7/29–7/31</td>
</tr>
<tr>
<td>Camp</td>
<td></td>
<td></td>
<td>70 staff and 89 campers from group home and private residences in 16 counties in Michigan</td>
<td>None†</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Abbreviations:** IG = immunoglobulin; N/A = not applicable.

* Persons vaccinated against hepatitis A before the outbreak were not included among those needing PEP.

† 14-day period for effective PEP expired on day of notification about case. Campers were notified.

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**What is already known on this topic?**

Hepatitis A virus (HAV) infections among persons with developmental disabilities living in institutions were common in the past. With improvements in care and fewer persons institutionalized, the number of HAV infections has declined in these institutions. However, residents in institutions are still vulnerable if they have not been vaccinated.

**What is added by this report?**

During April–July 2013, eight residents of five group homes for adults with disabilities in Michigan were diagnosed with hepatitis A, and one died; none had been vaccinated against hepatitis A. Serum from seven of the eight was found to have HAV genotype IA strain, sharing the identical VP1/P2B genomic sequence. Of the 261 contacts who warranted postexposure prophylaxis, 86.2% received either the recommended immunoglobulin, hepatitis A vaccine, or both.

**What are the implications for public health practice?**

This outbreak report highlights the risk for HAV infection among adults living or working in small group home settings for the disabled and the public health resources needed to respond to outbreaks in these settings. A public health response plan for hepatitis A outbreaks should include pre-identification of sources of immunoglobulin and hepatitis A vaccine. Routine vaccination of residents and staff of the group homes might have prevented this outbreak and the costs of containing it.
spread was high. This outbreak raises the question of whether adult residents and staff of group homes, in light of increasing adult susceptibility, should be considered a high risk group for HAV transmission and a group for whom pre-exposure vaccination should be recommended.

When case 8 was detected, the 14-day window for effective PEP had passed, and PEP was not recommended to campers and camp staff at the special needs camp. Tuscola County Health Department provided education information on July 26, 2013, for approximately 70 staff working at the camp. Campers who attended during June 30–July 12 were notified of their potential exposure and told to seek medical attention if they developed symptoms suggestive of HAV infection.

In the United States, the most common risk factor identified for HAV infection is travel (5). However, a risk factor for HAV infection is unknown in 35%–85% of U.S. cases, depending on the surveillance source (6). Similarly, the initial source of the infection in this outbreak has not been identified. However, given the multiple sites of employment and lack of hand hygiene of HCW-1, it is plausible that HCW-1 played a role in transmitting the virus among cases 1 to 6. The connection to the outbreak for cases 7 and 8 is more indirect. The two residents of GH-D and the two residents of GH-E, who had exposures to confirmed hepatitis A cases at WS-B and WS-D, respectively, might have introduced HAV into their group homes. Almost all (94%) residents and staff in the Michigan GHs and WSs were unvaccinated against hepatitis A and thus were susceptible.

Several public health actions were undertaken to prevent further transmission of HAV, including education on proper hand hygiene and glove use, cancellation of outings (overnight camp), and administration of PEP. Because the staff at the facilities had multiple roles, such as preparing food and assisting residents with their toileting, OCHD asked GHs to bring in outside staff for food preparation. Contacts (defined as co-residents and staff at five GHs and seven WSs who had direct contact with hepatitis A cases) were evaluated by local public health providers for PEP with IG, hepatitis A vaccine, or both.

The findings in this report are subject to at least two limitations. First, the immune status of residents and contacts before onset of this outbreak is not known. Second, only symptomatic cases of HAV infection were identified and diagnosed. Some residents with mild illness might not have been recognized because some of the residents are nonverbal.

This outbreak report highlights the risk for HAV infection among adults living or working in small group home settings for the disabled and the public health resources needed to respond to outbreaks in these settings. A public health response plan for hepatitis A outbreaks should include pre-identification of sources of IG and hepatitis A vaccine. Routine vaccination of residents and staff of the GHs might have prevented this outbreak and the costs of containing it.

Acknowledgments

Katherine Arends, Sally Bidol, Tim Bolen, Jay Fiedler, Jim Collins, Jevon McFadden, Corinne Miller, Michigan Department of Community Health. Ann Hepfer, Tuscola County Health Department.

References

On February 13, 2015, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

On January 5, 2015, the California Department of Public Health (CDPH) was notified about a suspected measles case. The patient was a hospitalized, unvaccinated child, aged 11 years with rash onset on December 28. The only notable travel history during the exposure period was a visit to one of two adjacent Disney theme parks located in Orange County, California. On the same day, CDPH received reports of four additional suspected measles cases in California residents and two in Utah residents, all of whom reported visiting one or both Disney theme parks during December 17–20. By January 7, seven California measles cases had been confirmed, and CDPH issued a press release and an Epidemic Information Exchange (Epi-X) notification to other states regarding this outbreak. Measles transmission is ongoing (Figure).

As of February 11, a total of 125 measles cases with rash occurring during December 28, 2014–February 8, 2015, had been confirmed in U.S. residents connected with this outbreak. Of these, 110 patients were California residents. Thirty-nine (35%) of the California patients visited one or both of the two Disney theme parks during December 17–20, where they are thought to have been exposed to measles, 37 have an unknown exposure source (34%), and 34 (31%) are secondary cases. Among the 34 secondary cases, 26 were household or close contacts, and eight were exposed in a community setting. Five (5%) of the California patients reported being in one or both of the two Disney theme parks during their exposure period outside of December 17–20, but their source of infection is unknown. In addition, 15 cases linked to the two Disney theme parks have been reported in seven other states: Arizona (seven), Colorado (one), Nebraska (one), Oregon (one), Utah (three), and Washington (two), as well as linked cases reported in two neighboring countries, Mexico (one) and Canada (10).

Among the 110 California patients, 49 (45%) were unvaccinated; five (5%) had 1 dose of measles-containing vaccine, seven (6%) had 2 doses, one (1%) had 3 doses, 47 (43%) had unknown or undocumented vaccination status, and one (1%) had immunoglobulin G seropositivity documented, which indicates prior vaccination or measles infection at an undetermined time. Twelve of the unvaccinated patients were infants too young to be vaccinated. Among the 37 remaining vaccine-eligible patients, 28 (67%) were intentionally unvaccinated because of personal beliefs, and one was on an alternative plan for vaccination. Among the 28 intentionally unvaccinated patients, 18 were children (aged <18 years), and 10 were adults. Patients range in age from 6 weeks to 70 years; the median age is 22 years. Among the 84 patients with known hospitalization status, 17 (20%) were hospitalized.

The source of the initial Disney theme park exposure has not been identified. Specimens from 30 California patients were genotyped; all were measles genotype B3, which has caused a large outbreak recently in the Philippines, but has also been detected in at least 14 countries and at least six U.S. states in the last 6 months (1).

Annual attendance at Disney theme parks in California is estimated at 24 million (2), including many international visitors from countries where measles is endemic. The December holiday season coincides with the exposure period of interest. Since 2011, six confirmed measles cases have been reported to CDPH in persons whose notable exposure was to large theme parks that attract international tourists. International travel to countries where measles is endemic is a well-known risk factor for measles, and measles importations continue to occur in the United States; the number of measles cases reported to CDC is updated weekly at http://www.cdc.gov/measles/cases-outbreaks.html. However, U.S. residents also can be exposed to measles in the United States at venues with large numbers of international visitors, such as other tourist attractions and airports. This outbreak illustrates the continued importance of ensuring high measles vaccination coverage in the United States.

Acknowledgments

FIGURE. Number of confirmed measles cases (N = 110),* by date of rash onset — California, December 2014–February 2015

* Reported to the California Department of Public Health as of February 11, 2015.

1California Department of Public Health (Corresponding author: Jennifer Zipprich, jennifer.zipprich@cdph.ca.gov, 510-620-3848)

References


Notes from the Field

Fatal Gastrointestinal Mucormycosis in a Premature Infant Associated with a Contaminated Dietary Supplement — Connecticut, 2014

Snigdha Vallabhaneni, MD1, Tiffany A. Walker, MD1, Shawn R. Lockhart, PhD1, Dianna Ng, MD2, Infectious Diseases Pathology Branch1, Tom Chiller, MD1, Richard Melchreit, MD3, Mary E. Brandt, PhD1, Rachel M. Smith, MD3 (Author affiliations at end of text)

In October 2014, a hospital in Connecticut notified CDC and the Connecticut Department of Public Health of a fatal case of gastrointestinal mucormycosis in a preterm infant. The infant, born at 29 weeks’ gestation and weighing 1,400 grams (about 3 pounds), had developed signs and symptoms initially consistent with necrotizing enterocolitis approximately 1 week after birth. Exploratory laparotomy revealed complete ischemia of the gastrointestinal tract from the esophagus to the rectum; a portion of necrotic cecum was sent for microscopic examination. Following surgery, the infant developed multiple areas of vascular occlusion, including a large clot in the aorta, findings not usually associated with necrotizing enterocolitis. The infant died soon after. Histopathology results from the resected cecum revealed an angioinvasive fungal infection consistent with mucormycosis. Gastrointestinal mucormycosis is an extremely rare fungal infection caused by mold in the order Mucorales. It occurs predominantly in low birth weight infants, patients with diarrhea and malnutrition, and those receiving peritoneal dialysis; mortality is 85% (1). Local investigation revealed that the infant had received a dietary supplement, ABC Dophilus Powder, for 7 days, beginning on day 1 of life.

Unopened bottles of ABC Dophilus Powder from the lot received by the infant were cultured by the hospital microbiology laboratory; the samples yielded Rhizopus species, a mold capable of causing mucormycosis. CDC later confirmed these isolates as Rhizopus oryzae. Immunohistochemical staining of the cecum tissue block locally and at CDC was positive for mucormycetes. Sequencing of fungal DNA recovered from the tissue block by CDC identified the fungus as Rhizopus oryzae, the same species of fungus recovered from the unopened dietary supplement.

CDC, the Food and Drug Administration (FDA), and the Connecticut Departments of Health and Consumer Protection initiated an investigation. ABC Dophilus Powder, manufactured by Solgar, Inc., Leonia, New Jersey, is a dietary supplement intended to contain three live bacterial species: Bifidobacterium lactis, Streptococcus thermophilus, and Lactobacillus rhamnosus and is advertised as having probiotic effects. The dietary supplement is marketed specifically for infants and children, is available without a prescription, and is distributed widely through both wholesale and retail channels in the United States and abroad. On November 14, 2014, Solgar Inc., issued a recall (2) of several product lots, including the one fed to the infant. CDC issued public health warnings (3) advising customers and consumers not to use ABC Dophilus Powder while the investigation was ongoing.

CDC initiated intensive case-finding efforts through several large clinician, laboratory, and public health networks for infants with gastrointestinal mucormycosis or for unexplained infant deaths following receipt of Solgar ABC Dophilus. No additional cases of gastrointestinal mucormycosis in neonates have been identified to date. Case-finding also was conducted by hospital staff members in the neonatal intensive care unit that had cared for the infant; no additional infections were identified.

Dietary supplements thought to have probiotic effects have been reported to reduce the incidence of necrotizing enterocolitis and all-cause mortality in preterm infants (4), although there are concerns that the safety of the products has not been adequately documented (5). The benefits of these supplements also are being studied with a variety of other medical conditions. However, dietary supplements such as ABC Dophilus Powder are not regulated as drugs by the FDA. Therefore, these products are not subject to FDA’s premarket review and approval requirements for safety and effectiveness, nor to the rigorous manufacturing and testing standards for drugs. Rather, dietary supplements are regulated by FDA as foods with good manufacturing practice requirements specific to the commodity. Following the investigation, on December 9, 2014, FDA issued a letter encouraging health care providers who use dietary supplements containing live bacteria or yeast as drugs (including to treat or prevent medical conditions) to submit an Investigational New Drug Application to FDA for review (6). Because these products continue to be used in vulnerable populations, such as preterm infants, care must be taken to ensure the delivery of safe products to health care consumers.

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References
Notes from the Field

Use of Unvalidated Urine Mycotoxin Tests for the Clinical Diagnosis of Illness — United States, 2014
Melody Kawamoto, MD1, Elena Page, MD1
(Author affiliations at end of text)

In February 2014, CDC’s National Institute for Occupational Safety and Health received a request for a health hazard evaluation from a union representative in an office building. A female employee reported the onset of symptoms involving multiple organ systems upon returning to work after a prolonged absence. The employee searched the Internet for descriptions of symptoms matching hers, found a laboratory offering “toxic mold testing” direct to consumers, and submitted a urine sample, despite the absence of musty odors and signs of fungal growth in her office. The laboratory reported “positive” concentrations of two mycotoxins: ochratoxin at 2.8 parts per billion (ppb) and tricothecenes at 0.4 ppb. The laboratory cutoff for “positive” was ≥2.0 ppb for ochratoxin and ≥0.2 ppb for tricothecenes. The interpretation accompanying the laboratory report said the results “revealed that you have an unusual level of that mycotoxin(s) present in your body.”

The laboratory referred the employee to a clinic specializing in “medical treatment for mold exposure and mold illness,” where she was examined, diagnosed with mold toxicity, and prescribed an antifungal medication. Antifungal medications are used to treat fungal infections, not illnesses caused by toxins produced by fungi. Also prescribed were dietary modification (eating only canned chicken and white rice for 3 days) and several nonstandard medical treatments (e.g., bowel evacuation or hydrocolonic irrigation, cupping therapy, and ionic nasal spray).

Two consultants, one hired by the building manager and one by the employee, carried out destructive testing (removal of drywall, carpet, and ceiling tiles) in the employee’s office. No evidence of water damage or significant fungal growth was found. The cost to the building manager exceeded $25,000. The employee remained convinced that mold exposure occurred in the workplace. Some coworkers, aware of the destructive testing and the urine mycotoxin testing, began to attribute nonspecific symptoms to workplace mold exposures.

The laboratory mentioned its Clinical Laboratory Improvement Amendments (CLIA) certification on its reports and noted that the urine mycotoxin testing was not approved by the Food and Drug Administration (FDA). CLIA regulations require any laboratory that performs testing on patient specimens to have an appropriate CLIA certificate and to meet applicable quality and analytic standards to ensure accurate and reliable test results.* CLIA regulations, however, do not address the clinical validity of testing (i.e., the accuracy with which the test identifies, measures, or predicts a patient’s clinical status).† FDA clearance or approval of a test provides assurance that the test has adequate analytical and clinical validation and that it is safe and effective.§ There is no FDA-approved test for mycotoxins in human urine.

During the past 10 years, CDC’s National Institute for Occupational Safety and Health has received many requests for workplace evaluations based on the results of unvalidated laboratory tests purported to diagnose occupational and environmental illnesses caused by exposure to fungi (including molds). Using unvalidated laboratory tests to diagnose work-related illness can lead to misinformation and fear in the workplace; incorrect diagnoses; unnecessary, inappropriate, and potentially harmful medical interventions; and unnecessary or inappropriate environmental and occupational evaluations (1,2).

Mycotoxins are metabolites of some fungi that can cause illness in humans and animals, primarily after ingestion of contaminated foods. Low levels of mycotoxins are found in many foods; therefore, mycotoxins are found in the urine of healthy persons (3,4). Mycotoxin levels that predict disease have not been established. Urine mycotoxin tests are not approved by FDA for accuracy or for clinical use.

CDC does not recommend biologic testing of persons who work or live in water-damaged buildings nor routine environmental sampling for mold (5,6). To identify possible mold contamination, visual inspection is the first step. To inspect the interior of walls and other difficult-to-examine spaces, a borescope can be inserted through a small hole. Moisture meters can measure moisture in building materials such as carpet, wallboard, wood, brick, and concrete. Identification and elimination of sources of moisture and cleaning or replacement of contaminated materials is essential.

Persons using direct-to-consumer laboratory tests that have not been approved by FDA for diagnostic purposes and their health care providers need to understand that these tests might not be valid or clinically useful. Additional information about molds and their health effects is available at http://www.cdc.gov/mold/faqs.htm#mold.

† Additional information available at 42 U.S.C. §263a; 42 CFR Part 493.
§ Additional information available at 21 U.S.C. §§360c, 360e and 21 CFR 814.20, 860.7.
References


5. CDC. Mold prevention strategies and possible health effects in the aftermath of hurricanes and major floods. MMWR Recomm Rep 2006;55(No. RR-08).

Errata

Vol. 64, No. 5

In the report, “Notes from the Field: Prevalence of Risk Factors for Suicide Among Veterinarians — United States, 2014,” an error occurred in the author affiliations. The author list and the author affiliations should read as follows:

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Vol. 64, No. 4

In the report “Mortality Among Blacks or African Americans with HIV Infection — United States, 2008–2012,” the second sentence on page 84 should read, “The report evaluates all-cause mortality in persons living with HIV and does not measure mortality resulting from HIV.”
**QuickStats**

**FROM THE NATIONAL CENTER FOR HEALTH STATISTICS**

**Percentage of Men Aged 25–74 Years Who Consume ≥15 Alcoholic Drinks Per Week,* by Age Group and Veteran Status† — National Health Interview Survey, United States, 2011–2013.§**

* Defined as having consumed at least 12 alcoholic drinks (of any type) in lifetime, and in the last year consuming on average ≥15 alcoholic drinks per week.
† Veterans are those who have ever served on active duty in the U.S. Armed Forces, military reserves, or National Guard but are not now on full-time active duty with the armed forces. During 2011–2013, veterans accounted for 18% of the male population aged 25–74 years, ranging from 6% among men aged 25–34 years to 45% for those aged 65–74 years.
§ Estimates are based on household interviews of a sample of the noninstitutionalized U.S. civilian population and are derived from the National Health Interview Survey sample adult component.
¶ 95% confidence interval.

During 2011–2013, male veterans aged 25–74 years were more likely to consume an average of ≥15 alcoholic drinks per week in the last year (“heavy drinking”) compared with nonveterans (7% versus 5%). Among men aged 25–34 years, the proportion of veterans who were heavy drinkers was 9%, higher than the 6% observed in nonveterans. Similarly, veterans were more likely than nonveterans to be heavy drinkers among men aged 55–64 years (7% versus 5%) and men aged 65–74 years (7% versus 4%). There was no significant difference in the proportion of veterans compared with nonveterans who were heavy drinkers among men aged 35–44 years or men aged 45–54 years.


**Reported by:** Carla E. Zelaya, PhD, vdn3@cdc.gov, 301-458-4164; Renee M. Gindi, PhD.