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Human Case of Leptospirosis During a Canine Disease Outbreak — Wyoming, 2023

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Abstract

Leptospirosis is a zoonotic bacterial disease spread through the urine of infected animals; the typical incubation period is 5–14 days. In approximately 90% of human cases, illness is asymptomatic or mild, characterized by fever, chills, myalgia, nausea, vomiting, diarrhea, headache, calf pain, and conjunctival suffusion, but severe illness can progress to multiorgan dysfunction and death. Although Wyoming is considered a low-risk area for leptospirosis because of its cold and semiarid climate, the Wyoming Department of Health was notified of a probable human case in August 2023, the first reported in the state since 1983. The patient had occupational exposure to dogs but did not report other risk factors. The same week that the human patient's illness began, public health authorities received notification of an increase in canine leptospirosis cases. Public health authorities investigated to determine potential sources of infection, identify additional cases, and recommend control measures. After public health outreach activities were implemented, canine vaccination practices changed substantially in the affected city: a survey conducted after the outbreak revealed that all responding veterinary clinics in the affected city were recommending the vaccine more frequently to dog owners and reporting higher levels of owner compliance with vaccination recommendations. Increased vaccination coverage offers protection from leptospirosis for both dogs and persons exposed to them. Leptospirosis should be considered in the differential diagnosis of persons with occupational exposure to animals and clinically compatible signs and symptoms, including fever, chills, myalgia, nausea, vomiting, diarrhea, headache, calf pain, and conjunctival suffusion, irrespective of geographic location.

Introduction

Leptospirosis is an acute zoonotic bacterial illness characterized by fever, chills, myalgia, nausea, vomiting, diarrhea, headache, calf pain, and conjunctival suffusion (i.e., redness without inflammatory exudates). The incubation period is normally 5–14 days, and 90% of cases in humans are asymptomatic or result in mild, self-limited illness (*1*). However, severe illness can progress to multiorgan dysfunction and death. Factors associated with severe disease include high levels of leptospiremia, delayed antimicrobial treatment, infection with *Leptospira interrogans* serogroup *Icterohaemorrhagiae*, chronic hypertension, chronic alcoholism, and age ≥60 years (*2–4*). Oral antibiotics are the treatment of choice for mild illness; patients with severe cases might require hospitalization with intravenous antibiotics and aggressive supportive care (*1*). In August 2023, the Wyoming Department of Health (WDH) was notified of a human case of leptospirosis, the first case reported in the state since 1983 (*5*). Leptospirosis is more common in wet and warm regions, and Wyoming is typically considered a low-risk location because of its dry and semiarid climate (*6*).

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Investigation and Results

Data Source

WDH staff members reviewed medical records, interviewed the patient, and reviewed reportable conditions data* to monitor for additional cases. The office of the State Animal Health Official (SAHO) obtained histories for canine leptospirosis cases, reviewed veterinary records, and interviewed veterinary clinic staff members. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.†

Case Report

The patient reported initial signs and symptoms of body aches, fever, nausea, and sweating. Two days later, after briefly losing consciousness, the patient was treated in a hospital emergency department with atropine and intravenous fluids for vasovagal syncope and released. The illness worsened during the subsequent 2 days, and included symptoms of calf pain, shortness of breath, cough, headache, conjunctival hyperemia, lower extremity edema, lightheadedness, and reported "brain fog." The patient reported no exposure to common risk factors, including standing water or mud, or participation in activities such as traveling, hunting, and adventure sports. The only reported risk factor was occupational exposure to dogs.

After the first hospitalization, the patient learned about several canine leptospirosis cases from a colleague. The patient sought follow-up care with a primary health care provider on day 5 of illness and was hospitalized again on day 6 with signs of pleural effusion, hypoxemia, and acute kidney injury. The patient did not have a known connection to a canine case but was occupationally exposed to body fluids from multiple dogs, including three that died from unknown causes. Despite experiencing illness consistent with leptospirosis and communicating occupational risk to multiple health care providers, the patient did not receive testing until day 8 of illness, at which time immunoglobulin M antibodies to *Leptospira* sp. were detected.§ The patient began treatment with oral doxycycline (100 mg twice daily for 7 days) on day 11 of illness and improved sufficiently to be released 1 day later.

Reports of Increase in Canine Leptospirosis Cases

The day of the patient's illness onset, a local veterinary clinic diagnosed leptospirosis in three dogs. Canine leptospirosis is rarely diagnosed in Wyoming and is not a reportable disease in the state. However, the veterinarian was concerned that the cases represented an increase in morbidity and therefore, reported the cases to SAHO.

* The National Electronic Disease Surveillance System for Wyoming was used to monitor for additional cases.

† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

§ The patient received a diagnosis based on a qualitative immunoblot test. https://ltd.aruplab.com/Tests/Pub/0055233

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SAHO requested that veterinary clinics statewide voluntarily report canine leptospirosis cases, and during August–October 2023, a total of 13 canine cases were reported. Veterinary records and interviews with veterinary clinic staff members indicated that the ill dogs had nonspecific signs and symptoms, including vomiting, lethargy, and decreased appetite. All the ill dogs experienced azotemia (increased levels of blood urea nitrogen and serum creatinine, resulting from kidney injury) and four were euthanized or died of severe disease. Three dogs met confirmed leptospirosis case criteria and 10 met probable case criteria[¶] (*6*). Because none of the deceased dogs associated with the patient had been tested for leptospirosis, they were not among the dogs with confirmed or probable cases.

Veterinary records indicated that canine cases were geographically dispersed throughout the city where the patient worked. Five affected dogs were epidemiologically linked to the same boarding kennel during August–September. One additional dog was potentially exposed through ingestion of standing water. Seven dogs could not be linked to high-risk activities or locations. However, wet conditions might contribute to increased environmental persistence of *Leptospira*, and the affected region experienced nearly double its average precipitation during the 3 months preceding the outbreak (*6*,*7*), suggesting that dogs might have been exposed in the general environment.

Three ill dogs received microagglutination testing results demonstrating high antibody titers (≥1:800) to vaccine-preventable serovars. However, none of the dogs affected during this outbreak was up to date on leptospirosis vaccination.

Public Health Response

Case Surveillance

WDH conducted interviews with close contacts and work colleagues of the patient and SAHO conducted interviews with staff members at facilities visited by infected dogs. No additional human cases were reported or identified through interviews.

[¶] A probable case meets the clinical criteria and one or more supportive laboratory criteria. Clinical criteria for dogs include the onset of systemic illness within the previous 2 weeks (nonspecific fever, lethargy, polyuria, polydipsia, or clinical suspicion of acute kidney injury with or without clinical signs of leptospirosis) and two or more clinicopathologic abnormalities suggestive of a leptospirosis diagnosis. Supportive laboratory criteria for dogs include *Leptospira* microagglutination titer ≥800, detection of immunoglobulin M anti-*Leptospira* antibodies, detection of pathogenic leptospires in urine using a nucleic acid amplification test, or isolation of *Leptospira* from a clinical specimen by a reference laboratory. A confirmed case meets the clinical criteria and one or more confirmatory laboratory criteria (fourfold or higher acute to convalescent increase in *Leptospira* agglutination titer at a single laboratory, detection of pathogenic leptospires in blood using a nucleic acid amplification test, or isolation of *Leptospira* from a clinical specimen by a reference laboratory).

Control Activities

WDH alerted local health care providers about the outbreak to encourage prompt testing of persons with clinically compatible signs and symptoms, such as fever, chills, myalgia, nausea, vomiting, diarrhea, headache, calf pain, or conjunctival suffusion. SAHO notified veterinary clinics and boarding facilities. WDH and SAHO also inspected the epidemiologically linked boarding kennel to evaluate vaccination policies, quarantine procedures, and cleaning and disinfection protocols. Although the facility required vaccination of boarded dogs against multiple diseases, it did not require vaccination against leptospirosis. Recommendations for preventing disease transmission were provided, including requiring leptospirosis vaccination for all dogs, eliminating standing water, following appropriate cleaning and disinfection protocols, isolating ill dogs, and using best practices for personal protective equipment.[**]

Public Outreach

WDH published a news release[††] and conducted interviews with media outlets to notify the public of the outbreak. SAHO provided materials to veterinary clinics and boarding facilities to educate staff members and dog owners. An educational webinar for veterinary professionals was conducted by SAHO, WDH, and subject matter experts.

Assessment of Changes in Canine Vaccination Practices

As part of the public health response, a survey was distributed to veterinary clinics throughout Wyoming to assess changes in canine leptospirosis vaccination rates during October 2022–January 2023 (preoutbreak) and October 2023–January 2024 (postoutbreak). Six of 10 clinics in the affected city and eight clinics in rural counties responded.

After public health outreach, 100% of clinics from the affected city that responded reported recommending the vaccine more frequently to dog owners after the outbreak (to 80.0% of owners compared with 8.3% before the outbreak). Clinic staff members also reported higher owner compliance with vaccination recommendations, estimating that the proportion of dog owners agreeing to leptospirosis vaccination increased from approximately one third (32.5%) to approximately one half (51.5%). After the outbreak, clinics reported administering leptospirosis vaccines to 33.1% of dogs seen for routine vaccination appointments, which is an increase from the previous year, when only 5.4% of dogs seen for routine vaccination appointments received leptospirosis vaccines.

[**] https://www.nasphv.org/Documents/VeterinaryStandardPrecautions.pdf
[††] https://health.wyo.gov/rare-bacterial-infections-reported-in-wyoming/

Responding rural clinics reported recommending vaccination more frequently than did clinics in the affected city: approximately 50%–60% of dogs in rural clinics were reported as vaccinated both pre- and postoutbreak. These clinics also reported higher owner compliance: seven of eight rural clinics estimated that 90%–100% of clients agreed to leptospirosis vaccination for their dog when it was recommended. No leptospirosis cases were reported from rural counties during the outbreak, and just one rural clinic reported updating its vaccination protocol, changing from dog lifestyle–based recommendations to recommending vaccination of all dogs.

Discussion

Although prevalent in temperate and tropical climates, leptospirosis has also occurred in areas with less conducive environmental conditions (*6*). Recent canine outbreaks have been reported in arid and semiarid parts of the United States, including in California and Arizona (*6*).

Canine and cattle vaccines for preventing leptospirosis are available in the United States, but human vaccines are not. Initial vaccination of dogs requires 2 doses, administered 2–4 weeks apart, with annual boosters to maintain immunity. Historically, vaccination was only recommended for dogs considered to be at increased risk for infection, based on geographic location or participation in activities that might expose them to infected animal urine. Geographically, Appalachia is considered the highest-risk region for canine leptospirosis in the contiguous United States; the upper Midwest and central Texas are also considered to be at increased risk (*8*). Lifestyle factors considered to increase dogs' risk for exposure include contact with livestock or wildlife, time spent in kennel environments, and participation in activities that expose them to standing water or mud such as roaming farmland, hunting, hiking, or swimming (*6*,*9*). However, because of illness severity and zoonotic potential, consensus in the veterinary community is shifting to recommendation of vaccination for all dogs, and shortly after this outbreak ended, revised guidelines were published recommending that all dogs be vaccinated against leptospirosis, regardless of lifestyle or geographic location (*6*,*10*). The canine vaccine available in the United States covers four serovars: Canicola, Grippotyphosa, Icterohaemorrhagiae, and Pomona (*6*).

Health care providers should consider leptospirosis in the differential diagnosis when evaluating patients with clinically compatible illness, and inquire about occupational exposure to animals, even in historically low-risk areas. Although the patient described in this report was at increased occupational risk and demonstrated clinically compatible illness, testing was delayed because leptospirosis prevalence in the area was historically low, and the diagnosis was not considered. Early treatment can reduce disease severity and duration, and initiation of antibiotic therapy is recommended when disease is suspected, even if diagnostic test results are pending (*1*).

Summary

What is already known about this topic?

Leptospirosis, a zoonotic bacterial disease that results from contact with body fluids of infected animals, occurs worldwide and can lead to severe illness in humans and animals.

What is added by this report?

A case of human leptospirosis was reported in Wyoming, a historically low-incidence state with a cold and semiarid climate considered to lower the probability for disease emergence. Coordination by human- and animal-focused public health agencies facilitated epidemiologic linkage of the case to a canine outbreak through occupational exposure.

What are the implications for public health practice?

Leptospirosis should be considered in the differential diagnosis of persons with occupational exposure to animals and clinically compatible signs and symptoms, including fever, chills, myalgia, nausea, vomiting, diarrhea, headache, calf pain, and conjunctival suffusion, irrespective of geographic location.

Implications for Public Health Practice

A spillover event (transmission from animal to human) likely occurred in this outbreak, illustrating the importance of One Health[§§] (i.e., a human, animal, and environmental approach) collaboration when responding to zoonotic diseases. Environmental exposure likely occurred in approximately one half of the canine cases, highlighting the need to prepare for unusually warm or wet seasons. Although many states consider human leptospirosis a reportable condition, few require notification for canine cases. The early alert by a local veterinarian of an increase in canine cases facilitated rapid investigation and interventions by public health authorities, underscoring the importance of trust between public health officials and clinical practitioners. Efforts to raise awareness of animal and human cases in this outbreak led to increased rates of canine vaccination in the affected community. Vaccination of animals can aid in controlling outbreaks and preventing spillover of leptospirosis.

[§§] https://www.cdc.gov/one-health/

Acknowledgments

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Notes from the Field

Respiratory Viral Panel as an Early Diagnostic Tool for Neonatal Enterovirus Infection — San Diego, California 2023

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Enterovirus infections in neonates can result in high morbidity and mortality. In 2023, a cluster of neonatal enterovirus cases associated with Coxsackie B4 and B5 occurred in San Diego, California.

Summary

What is already known about this topic?

Enterovirus infections can cause severe disease in neonates.

What is added by this report?

In 2023, a cluster of neonatal enterovirus infections initially suspected to be echovirus 11, but subsequently identified as Coxsackie B4 and B5 infections, occurred in San Diego, California. Respiratory panel polymerase chain reaction (PCR) testing for rhinovirus-enterovirus facilitated diagnosis of enterovirus infection in these infants.

What are the implications for public health practice?

Coxsackie virus as well as echovirus can cause severe disease in neonates. Respiratory virus panel PCR testing in neonates can be a useful diagnostic tool for enterovirus sepsis evaluations.

Investigation and Outcomes

During June–October 2023, five cases of neonatal enterovirus infection were identified at Rady Children's Hospital in San Diego, California. The authors were granted a waiver of individual authorization for use of protected health information by the University of California San Diego Institutional Review Board. All five cases were initially suspected to be caused by enterovirus based on characteristic clinical presentations during enterovirus seasons and supported by positive rhinovirus-enterovirus (RhV-EV) results from respiratory virus panel (RVP) testing of nasopharyngeal specimens, performed within 1 day of symptom onset. Reports of severe neonatal enterovirus disease from Europe linked to a new variant of echovirus 11 caused concern (*1*). Four of the five patients' plasma also tested positive for enterovirus by reverse transcription–polymerase chain reaction (RT-PCR). Results of RT-PCR testing of cerebrospinal fluid (CSF) for enterovirus were positive for two patients. Four infants had thrombocytopenia, and three had hepatitis with coagulopathy. Serum ferritin levels were elevated in three neonates. One neonate experienced seizures as the initial sign and subsequently developed pancytopenia with suspected, but unconfirmed, viral-induced hemophagocytic lymphohistiocytosis. The most severely affected patient, an infant aged 5 days, whose mother experienced a febrile illness during delivery diagnosed as chorioamnionitis, developed multiorgan failure. The infant received multiple immune globulin intravenous (IGIV) doses, the investigational antiviral drug pocapavir* (*2*), and maternal convalescent plasma; however, the infant did not survive. Four of the five infants received IGIV therapy. Mothers of three of the infants received a diagnosis of chorioamnionitis before delivery, and the mother of the remaining two infants (twins) was reportedly evaluated for postpartum fever and received a diagnosis of endometritis.

Blood, CSF, and respiratory specimens were sent to the California Department of Public Health Center for Laboratory Sciences Viral and Rickettsial Disease Laboratory for virus identification,† in coordination with the County of San Diego. Coxsackie B5 was identified in three specimens and Coxsackie B4 in one. Plasma from the fifth patient tested positive for enterovirus by RT-PCR; however, the viral copy number was too low for further identification (Table).

Preliminary Conclusions and Actions

Enterovirus infection can be life-threatening in the early neonatal period. At the time of this cluster, countries in Europe were reporting echovirus 11 infection in neonates (*1*). Coxsackie B4 and B5, but not echovirus 11, were identified among the patients described in this report. In a review of clinical characteristics of severe neonatal enterovirus infections during 2000–2020 (*3*), in cases where virus serotype was known, 82.7% of cases resulted from Coxsackie B viruses and 16.7% from echoviruses. Data from the U.S. National Enterovirus Surveillance System (*4*) showed that Coxsackie B viruses and echoviruses were also the most common groups of enteroviruses reported among U.S. neonates.

Maternal illness is reported in association with neonatal enterovirus infection and is a likely source of infection for infants with early illness (*3*,*5*). Details of maternal symptoms in this cluster of patients were not available for review; however,

* Pocapavir was obtained through ViroDefense, Inc. and the Food and Drug Administration expanded access program.

† https://journals.asm.org/doi/10.1128/jcm.00542-06

TABLE. Pertinent laboratory values* and clinical features of neonatal patients with enterovirus infection — San Diego, California, 2023

Characteristic	Patient A	B	C	D	E
Sex	Male	Male	Female	Male	Female
Age at symptom onset, days	9	6	5	6	5
Gestational age, wks	36	36	38	40	35
Initial symptoms	Respiratory distress and poor feeding	Poor feeding and seizures	Poor feeding	Fever and respiratory distress	Poor feeding and decreased tone
AST / ALT (U/L)	104 / 17†	970 / 367§	1,608 / 318§	69 / 26†	4,215 / 564¶
Ferritin (ng/mL)	Not done	112,984§	98,999§	Not done	>100,000¶
Platelet count (× 1,000/μL)	64§	6§	20§	227†	8¶
PT / INR ratio	Not done	33.6 / 3.1§	18.9 / 1.5§	Not done	60.3 / 5.3¶
Antiviral therapy	None	IGIV	IGIV	IGIV	IGIV, pocapavir, MCP
Outcome	Survived	Survived, seizures	Survived	Survived	Deceased
EV type identified	Coxsackie B5	Coxsackie B5	Coxsackie B4	Copy number too low for detection	Coxsackie B5

Abbreviations: ALT = alanine transaminase; AST = aspartate aminotransferase; EV = enterovirus; IGIV = immunoglobulin intravenous; INR = international normalized ratio; MCP = maternal convalescent plasma; PT = prothrombin time.

* The most abnormal values identified for each category are presented; laboratory testing for patients A, D, and E was performed at different hospitals.

† Reference values: AST = 17–184 U/L; ALT not established for age ≤28 days; platelet count = 150,000–450,000/μL.

§ Reference values: AST = 32–162 U/L; ALT = 5–33 U/L; ferritin = 100–717 ng/mL (age 0–14 days), 14–647 ng/mL (age 15 days–6 months); platelet count = 140,000–440,000/μL; PT = 12.3–15.3 sec; INR = 0.86–1.14.

¶ Reference values: AST = 0–32 U/L; ALT = 0–33 U/L; ferritin = 150–973 ng/mL; platelet count = 220,000–450,000/μL (age 0–7 days), 230,000-600,000/μl (age 8 days–6 months); PT = 9.7–12.5 sec; INR = no reference values for patients not receiving anticoagulation therapy.

symptoms attributed to chorioamnionitis and endometritis might also have been due to maternal enterovirus infection.

Detection of rhinovirus-enterovirus among the five patients at illness onset, despite absence of upper respiratory tract symptoms, led to high suspicion of enterovirus and thus a targeted neonatal sepsis workup. Timely RVP testing is not always performed for neonates. If rapid on-site enterovirus-specific RT-PCR testing is not available, including nasopharyngeal RVP testing as part of the neonatal sepsis workup, particularly during summer and fall, could facilitate diagnosis of neonatal enterovirus infection. Timely identification facilitates optimal clinical management for the infant, which might include receipt of IGIV and possibly antiviral medication.

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Notes from the Field

Illnesses After Administration of Presumed Counterfeit Botulinum Toxin in Nonmedical Settings — Tennessee and New York City, March 2024

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Botulinum neurotoxin (BoNT) products are considered safe for cosmetic use when administered in clinical settings, although potential spread of BoNT around the injection site can result in local, transient neurological effects (e.g., ptosis or diplopia) (*1*). In March 2024, clinicians notified the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) and Tennessee Department of Health (TDH) of illnesses after presumed cosmetic BoNT injections. A multistate investigation, which included the Food and Drug Administration (FDA) and CDC, sought to characterize these illnesses and identify implicated BoNT products.

Investigation and Outcomes

Health department staff members interviewed patients and reviewed medical records to obtain information about patients' signs and symptoms, health care encounters, and exposure to BoNT products. Product information was shared with FDA. TDH Division of Laboratory Services tested patient specimens for BoNT.* This activity was reviewed by CDC, deemed not research, and conducted consistent with applicable federal law and CDC policy.†

NYC DOHMH identified three patients, and TDH identified four (including one Kentucky resident who was admitted to a Tennessee hospital). All patients were women, aged 26–55 years (median age = 48 years). Reported signs and symptoms included ptosis, dry mouth, dysphagia, shortness of breath, and weakness (Table), with onset during February 23–March 7, 2024. All patients sought health care for their illness; four were hospitalized, and two were monitored in intensive care units. None required intubation. CDC's Botulism Consultation Service determined that botulinum antitoxin was not indicated for any of the seven patients.§ All patients reported receiving cosmetic BoNT injections in

* Patient stool was tested for *Clostridium botulinum* toxin genes A–G by polymerase chain reaction and, if test results were negative, testing was repeated 5 days later after culture enrichment. Patient serum was tested using mouse bioassay.

† 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

§ CDC's Botulism Consultation Service provides consultation for health departments and clinicians and releases botulinum antitoxin when indicated. For the cases described in this report, antitoxin was not released because some patients' signs and symptoms were consistent with transient effects of toxin, or signs of neurologic injury were not ongoing or progressing. In addition, >10 days had passed for all patients since onset of symptoms, at which point antitoxin would offer minimal benefit, because botulinum toxin was unlikely to be circulating in the blood.

TABLE. Characteristics of illnesses after administration of presumed counterfeit botulinum toxin in nonmedical settings — Tennessee and New York City, February–March 2024

Characteristic	No. (column %) Tennessee n = 4	New York City n = 3	Total N = 7
Age, yrs, median (range)	43 (39–48)	51 (26–55)	**48 (26–55)**
Sex			
Female	4 (100)	3 (100)	**7 (100)**
First sign or symptom*			
Ptosis	4 (100)	1 (33)	**5 (71)**
Diplopia	1 (100)	2 (67)	**3 (43)**
Headache	2 (50)	0 (—)	**2 (28)**
Weakness	2 (50)	0 (—)	**2 (28)**
Blurred vision	0 (—)	1 (33)	**1 (14)**
Signs and symptoms*			
Ptosis	4 (100)	3 (100)	**7 (100)**
Dry mouth	4 (100)	3 (100)	**7 (100)**
Dysphagia	4 (100)	3 (100)	**7 (100)**
Shortness of breath	4 (100)	3 (100)	**7 (100)**
Weakness	4 (100)	3 (100)	**7 (100)**
Blurred vision	4 (100)	2 (67)	**6 (86)**
Diplopia	3 (75)	3 (100)	**6 (86)**
Change in voice or hoarseness	4 (100)	2 (67)	**6 (86)**
Paresthesia	4 (100)	2 (67)	**6 (86)**
Fatigue	4 (100)	0 (—)	**4 (57)**
Nausea	3 (75)	0 (—)	**3 (43)**
Vomiting	2 (50)	0 (—)	**2 (29)**
Urinary retention or incontinence	2 (50)	0 (—)	**2 (29)**
Drooling or pooling of secretions	0 (—)	2 (67)	**2 (29)**
Thick tongue	1 (25)	0 (—)	**1 (14)**
Slurred speech	1 (25)	0 (—)	**1 (14)**
Health care encounter*	4 (100)	3 (100)	**7 (100)**
Admitted to a hospital	2 (50)	2 (67)	**4 (57)**
Admitted to intensive care unit	1 (25)	1 (33)	**2 (29)**
Mechanical ventilation	0 (—)	0 (—)	**0 (—)**
Injection site*			
Face (e.g., forehead or glabella)	4 (100)	3 (100)	**7 (100)**
Neck	0 (—)	2 (67)	**3 (43)**
Trapezius	0 (—)	1 (33)	**1 (14)**
Axillae	0 (—)	1 (33)	**1 (14)**
Injection setting			
Residence	4 (100)	2 (67)	**6 (86)**
Cosmetic spa	0 (—)	1 (33)	**1 (14)**

* Some persons reported multiple signs or symptoms, health care encounter types, or injection sites.

nonmedical settings a median of 3 days (range = 2–20 days) before symptom onset. Serum and stool specimens collected from two patients approximately 3 weeks after symptom onset tested negative for BoNT, likely because of the interval between symptom onset and specimen collection.

The three Tennessee residents and the Kentucky resident received injections of presumed BoNT in a nonmedical residential setting from a relative of one of the recipients, who was not licensed to administer these injections. FDA determined that the BoNT product administered to those four persons was counterfeit.[¶] The three NYC patients had no epidemiologic links to one another or to the Tennessee and Kentucky patients. The three NYC residents also received injections of presumed BoNT in separate nonmedical settings, with administration by an unlicensed person confirmed for one resident and suspected for two. Product information was not available; however, one person reported paying less than U.S. wholesale acquisition cost for the administered product, and another reported that the product had been purchased overseas.

Preliminary Conclusions and Actions

Seven persons experienced illness consistent with local and possible distant spread of BoNT after injection of presumed counterfeit BoNT product by unlicensed persons in nonmedical settings. Severe and potentially fatal illnesses associated with unlicensed product and off-label BoNT use have been reported (*2*,*3*). This investigation did not determine why these illnesses occurred after cosmetic BoNT injections; potential reasons might include use of counterfeit BoNT, which might be more potent or contain harmful additional ingredients or higher susceptibility to BoNT effects among some persons. Further studies are needed to describe the clinical spectrum of cosmetic BoNT injection effects (e.g., severity of signs and symptoms).

Health care providers should ask patients with symptoms of botulism about recent BoNT injections and, if botulism is suspected, immediately contact their local or state health departments.[**] Health departments should investigate reports of possible botulism and, if indicated, consult CDC regarding antitoxin release and notify other federal agencies to identify and remove counterfeit BoNT products from the market. BoNT injections should be administered only by licensed and trained providers using recommended doses of FDA-approved products.

Summary

What is already known about this topic?

Administration of botulinum toxin for cosmetic reasons is considered safe in clinical settings, although it can cause transient effects near the injection site.

What is added by this report?

During March 2024, seven women experienced illness after receiving botulinum toxin injections in nonmedical settings; four were hospitalized. At least four patients had received counterfeit product.

What are the implications for public health practice?

Botulinum toxin injections should be administered by licensed and trained providers using recommended doses of Food and Drug Administration–approved products, preferably in a licensed or accredited health care setting. Clinicians who see patients with suspected botulism should immediately contact their state or local public health department.

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[¶] The person who administered the presumed botulinum toxin product provided product photographs. After communication with the manufacturer, FDA determined the product was counterfeit. Packaging claimed to contain 150 units of "Botulinum Toxin Type A" (brand name "Botox") manufactured by a company that only manufactures 50-unit, 100-unit, and 200-unit vials of Botox. Manufacturing location in Ireland was misspelled on the packaging. The batch number on the vial label (C3709C3) belonged to a legitimate 100-unit strength batch that expired in August 2017.

[**] Symptoms of botulism can include ptosis, blurred and double vision, voice changes, dry mouth, drooling or pooling of secretions, dysphagia, shortness of breath, muscle weakness, and fatigue. The most severe signs of botulism include descending paralysis and respiratory failure.

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Erratum

Vol. 73, No. 21

The report "Early Safety Findings Among Persons Aged ≥60 Years Who Received a Respiratory Syncytial Virus Vaccine — United States, May 3, 2023–April 14, 2024" contained several errors.

On page 489, the sixth sentence in the Abstract should have read, "Reporting rates of GBS after RSV vaccination in VAERS (**4.4** and **1.8** reports per million doses of Abrysvo and Arexvy vaccine administered, respectively) were higher than estimated expected background rates in a vaccinated population."

On page 489, the fourth complete sentence in the second column should have read, "Estimated VAERS GBS reporting rates after RSV vaccination were **4.4** and **1.8** reports per million administered doses of Pfizer and GSK vaccines, respectively."

On page 490, the final sentence beginning in the second column should have read, "During May 3, 2023–April 14, 2024, VAERS received and processed 3,200 reports of adverse events among persons aged ≥60 years who reported receiving an RSV vaccine (Table 3),[†††] including **2,193** (**68.5**%) for GSK vaccine, **919** (**28.7**%) for Pfizer, and 88 (2.8%) for which the vaccine manufacturer was unknown."

On page 492, the first complete sentence should have read, "Among the 28 reports of GBS after vaccination that met case definition, **13** (**46.4**%) were after GSK vaccine (**1.8** reports per 1 million doses administered), and **15** (**53.6**%) were after Pfizer vaccine (**4.4** reports per 1 million doses administered)."

On page 492, the third sentence in the second column should have read, "Using VAERS data, estimated GBS reporting rates after RSV vaccination among persons aged ≥60 years were **4.4** and **1.8** reports per million doses of Pfizer and GSK vaccine administered, respectively."

On page 493, in Table 3, the total participants for GSK should have read **2,193**, and the total participants for Pfizer should have read **919**. Under "Events among serious reports," the GSK number and percentage should have read **167** (**7.6**), and the Pfizer number and percentage should have read **98** (**10.7**). Under "Guillain-Barré syndrome," the GSK number should have read **18**, and the Pfizer number should have read **19**.

On page 494, in the Summary, the sentence under "What is added by this report?" should have read, "Findings are consistent with those from trials; reports of GBS (**4.4** and **1.8** reports per million doses of Abrysvo and Arexvy vaccine administered, respectively) were more common than expected background rates.

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