

HEALTH ALERT NETWORK | HEALTH ADVISORY | April 23, 2024

Adverse Effects Linked to Counterfeit or Mishandled Botulinum Toxin Injections in the United States

North Dakota Department of Health and Human Services (HHS) is providing this information from the Centers for Disease Control and Prevention (CDC) regarding adverse effects linked to counterfeit or mishandled botulinum toxin reported in 11 states. Federal, state, and local partners are investigating clusters of 22 people in 11 U.S. states reporting adverse effects after receiving injections with counterfeit botulinum toxin or injections. These injections were administered by unlicensed or untrained individuals or in non-healthcare settings, such as homes or spas.

As of April 18, 2024, California, Colorado, Florida, Illinois, Kentucky, Nebraska, New Jersey, New York City, Tennessee, Texas, and Washington have reported people with adverse effects after having received a botulinum toxin injection. Symptom onset dates ranged from November 4, 2023, to March 31, 2024. Among all 22 people, symptoms began a median of 3 days after exposures (range from 0 to 20 days). Their symptoms included those near the injection site (e.g., blurred vision and ptosis after facial injection), dry mouth, slurred speech, shortness of breath, fatigue, and generalized weakness. Of the 20 people with information available, 11 (55%) symptomatic people were hospitalized. Six of 22 received botulism antitoxin to treat suspected botulism. Seven people underwent botulinum toxin testing to determine pretense of circulating botulinum toxin to support diagnosis of botulism. Results were negative for six symptomatic people and pending one result. A negative test may not rule out botulism as levels of the toxin may have fallen below detectable levels. None of the 22 cases met the case definition for botulism and none of them have died.

Illnesses with botulism is rare but can sometimes be fatal. Initial botulism symptoms may include double or blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and difficulty breathing. Descending, symmetrical muscle weakness that progresses over hours to days may follow the previous symptoms. Any botulism toxin circulating in the blood can be neutralized by administration of a botulism antitoxin. It is important that the antitoxin be administered early in the course of disease. Administration of the antitoxin as early as possible can prevent the progression of paralysis and further complications. Consider the possibility of adverse effects from botulinum toxin injections in the differential diagnosis if the patient presents with localized paralysis near the injection site. It is also important to be aware of symptom overlap between the presentation of the localized adverse effects from injection of botulinum toxin and early symptoms of botulism. In order to help distinguish between early botulism symptoms from localized adverse effects, assess for symmetry of cranial nerve palsies and their progression, followed by descending symmetric flaccid paralysis. If these conditions are met, then suspicions should be raised for botulism.

Botulism is a notifiable disease in North Dakota. Healthcare professionals and clinical laboratories

should report all suspect cases with history of recent botulinum toxin injections to HHS as soon as possible. HHS will assist in coordinating testing of the patient once other illnesses have been ruled out. Reports can be made by calling 701-328-2378 or 800-472-2180.

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
April 23, 2024, 11:00 AM ET
CDCHAN-00507

Adverse Effects Linked to Counterfeit or Mishandled Botulinum Toxin Injections

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to alert clinicians about risks of counterfeit or mishandled botulinum toxin injections. CDC, the U.S. Food and Drug Administration (FDA), and state and local partners are investigating clusters of 22 people in 11 U.S. states reporting adverse effects after receiving injections with counterfeit botulinum toxin or injections administered by unlicensed or untrained individuals or in non-healthcare settings, such as homes or spas. Eleven patients were hospitalized, and none have died. When botulinum toxin diffuses around the injection site, it can result in adverse effects. Botulism is the disease caused by botulinum toxin circulating in the blood and producing effects remotely from the injection site. There may be symptom overlap between the presentation of localized adverse effects from injection of botulinum toxin, especially in the head and neck, and the early symptoms of botulism. Information about the botulinum toxin injection (e.g., dose) can help distinguish between botulism and localized adverse effects but is challenging to obtain for counterfeit products. Clinicians and health departments should consider the possibility of adverse effects from botulinum toxin injections in patients presenting with localized paralysis. Clinicians should immediately contact their state, tribal, local, or territorial health department if they suspect botulism.

Background

Botulism is a rare and sometimes fatal illness caused by botulinum toxin. Initial botulism symptoms may include double or blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and difficulty breathing. These symptoms may be followed by a descending, symmetric muscle weakness that progresses over hours to days. Administration of botulism antitoxin can neutralize toxin circulating in the blood; therefore, treating botulism patients with botulism antitoxin early in the course of disease can prevent the progression of paralysis and consequent complications. Administration of antitoxin is not indicated for local effects of low-dose injections of botulinum toxin preparations, because the low doses of injected toxin are not likely to reach circulation or produce botulism with its life-threatening manifestations.

Some localized paralytic effects, resulting from diffusion of the toxin around the injection site, are expected from botulinum toxin administration. Most individuals with localized symptoms (e.g., dysphagia after injection to the neck) following low-dose cosmetic or therapeutic injections using FDA-approved products will not require treatment with botulism antitoxin. Iatrogenic botulism can occur after cosmetic or therapeutic injections of botulinum toxin when the toxin circulates in the blood and produces effects remotely from the injection site. Iatrogenic botulism is rare; the most recent laboratory-confirmed domestic case occurred in 2017.

As of April 18, 2024, 22 people with adverse effects have been reported in California, Colorado, Florida, Illinois, Kentucky, Nebraska, New Jersey, New York City, Tennessee, Texas, and Washington. Symptom onset dates ranged from November 4, 2023, to March 31, 2024. All symptomatic people were females aged 25 to 59 years. All reported receiving botulinum toxin injections by unlicensed or untrained individuals or in non-healthcare settings, including homes or spas. Most (20, 91%) reported receiving botulinum toxin injections for cosmetic purposes.

Among all 22 people, symptoms began a median of 3 days after exposure (range 0 to 20 days) and included symptoms near the injection site (e.g., blurred vision and ptosis after facial injection), dry mouth,

slurred speech, shortness of breath, fatigue, and generalized weakness. Of 20 people with information available, 11 (55%) symptomatic people were hospitalized. Six of the 22 symptomatic people received botulism antitoxin to treat suspected botulism. Seven symptomatic people underwent botulinum toxin testing to determine if they had circulating botulinum toxin, which would support a diagnosis of botulism; results were negative for six symptomatic people and are pending for one symptomatic person. Negative results do not rule out botulism as levels of toxin in serum may have fallen below the limit of detection of laboratory tests. None of the 22 symptomatic people met the [case definition for botulism](#), and none have died.

These adverse events have been linked to improper procurement and administration of botulinum toxin. Botulinum toxin should be administered only by licensed providers, using only recommended doses of FDA-approved botulinum toxin, preferably in a licensed or accredited healthcare setting. Providers should be trained in the proper administration of botulinum toxin, practicing in accordance with state and local requirements.

More information about the counterfeit products [may be found on FDA's website](#).

Recommendations for Clinicians

Diagnosis, consultation, and treatment

- Consider the possibility of adverse effects from botulinum toxin injections, including those given for cosmetic reasons, in patients presenting with localized paralysis near the injection site.
 - Ask patients about history of botulinum toxin injections, including the dose.
- Be aware of symptom overlap between the presentation of localized adverse effects from injection of botulinum toxin and the early symptoms of botulism. To help distinguish early botulism symptoms from localized adverse effects:
 - Assess for symmetry of cranial nerve palsies; symmetric cranial nerve palsies are expected with botulism.
 - Assess for progression of cranial nerve palsies, possibly followed by a descending symmetric flaccid paralysis. These should raise suspicion for botulism.
- **If botulism is suspected, call your [health department](#) immediately** for consultation. Health departments and health care providers can contact the CDC clinical botulism service 24/7 at 770-488-7100.
- If public health clinical consultation supports botulism, request antitoxin and begin treatment as soon as it is available. **Do not wait for laboratory confirmation to begin treatment.**

Clinician reporting

- A suspected case of botulism is a clinical and public health emergency. Suspected botulism cases should be reported immediately to the [24-hour emergency contact of your health department](#).
- Report adverse events related to the use of any medications, including suspected counterfeit medications, to FDA's [MedWatch Safety Information and Adverse Event Reporting Program](#).

Counseling patients

- Counsel patients who report using or being interested in using botulinum toxin about potential adverse effects.
- Advise patients to receive injections only from licensed providers who are trained in proper administration of FDA-approved botulinum toxin products, preferably in a licensed or accredited healthcare setting.

Recommendations for Laboratories

- Diagnostic testing for suspected botulism may be done through the [CDC National Botulism Laboratory](#) or state public health laboratories.
- Laboratory confirmation of botulism is done by demonstrating the presence of botulinum toxin in serum through either mouse bioassay or mass spectrometry.
- Testing varies by state. Contact the CDC clinical botulism service (available 24/7 at 770-488-7100) or your state health department for further guidance on submitting clinical specimens for testing.

Recommendations for Public Health Professionals

- Health departments should contact the CDC clinical botulism service 24/7 at 770-488-7100 for consultation and antitoxin release.
- Health departments should report botulism cases to CDC through the [National Notifiable Diseases Surveillance System \(NNDSS\)](#).
- Contact bot surveillance@cdc.gov for information on how to report adverse effects following administration of unverified or counterfeit botulinum toxin products, by unlicensed or untrained individuals, or in non-healthcare settings such as homes or spas.

Recommendations for the Public

- Get injections only from licensed and trained professionals in licensed or accredited healthcare settings.
- If you are concerned that you or someone you know might have [symptoms of botulism](#), including trouble swallowing or breathing, see your doctor or go **immediately** to the emergency room. **Do not wait.**
- Report suspected counterfeit botulinum toxin products to FDA at 800-551-3989 or through FDA's [form for reporting suspected criminal activity](#).
- Report harmful reactions related to the use of any medications, including suspected counterfeit medications, to FDA's [MedWatch Safety Information and Adverse Event Reporting Program](#).

For More Information

- [CDC: Harmful Reactions Linked to Counterfeit “Botox” or Mishandled Botulinum Toxin Injections](#)
- [FDA: Counterfeit Version of Botox Found in Multiple States](#)
- [Information for Health Professionals on Botulism | CDC](#)
- [About Botulism | CDC](#)
- [Preventing Botulism | CDC](#)
- [Injection Safety | CDC](#)

References

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