LOUISIANA DEPARTMENT OF HEALTH Public Health	**Louisiana Health Alert Message 24-3: Adverse Effects Linked to Counterfeit or Mishandled Botox Injections**
Origination Date: August 13, 2024	**Revision Dates (List All Revision Dates):**

Louisiana Health Alert Message 24-3: Adverse Effects Linked to Counterfeit or Mishandled Botox Injections

The Louisiana Department of Health (LDH) is issuing this Health Alert Network (HAN) Health Advisory **to alert clinicians about risks of counterfeit or mishandled botulinum toxin (commonly called "Botox") injections. In August 2024, one suspected reaction was reported in Louisiana.**

CDC, several state and local health departments, and the U.S. Food and Drug Administration (FDA) investigated reports of harmful reactions among people who received injections of counterfeit or mishandled botulinum toxin. As of June 24, 2024, a total of 17 people from 9 states have reported harmful reactions after receiving injections with counterfeit products, products from unverified sources, or from individuals who were not following state or local requirements.

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 should consider the possibility of adverse effects from botulinum toxin injections in patients presenting with localized paralysis.

Summary for healthcare providers:

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 the LDH Infectious Disease Epidemiology Section (IDEpi) 24/7 clinician hotline: 800-256-2748.**
- If consultation with IDEpi supports botulism, request antitoxin and begin treatment as soon as it is available. **Do not wait for laboratory confirmation to begin treatment**.
    - **Botulism antitoxin is provided for free by the US government.**

Clinician reporting

- A suspected case of botulism is a **clinical and public health emergency**. Suspected botulism cases should be reported immediately to the **LDH Infectious Disease Epidemiology Section (IDEpi) 24/7 clinician hotline: 800-256-2748**.
- 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.

Additional Information for healthcare providers:

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 June 24, 2024, a total of 17 people from 9 states have reported harmful reactions after receiving injections with counterfeit products, products from unverified sources, or from individuals who were not following state or local requirements. More information about the counterfeit products may be found on FDA's website.

The 17 people included in this investigation had reactions on dates ranging from November 4, 2023, through April 11, 2024. States that reported these reactions included California (2), Colorado (1), Florida (1), Illinois (2), Kentucky (1), New Jersey (1), New York (3), Tennessee (3), and Texas (3).

People reported experiencing

- Blurry vision and double vision

- Drooping eyelids
- Difficulty swallowing
- Dry mouth
- Slurred speech
- Difficulty breathing
- Fatigue
- Generalized weakness

Overall, 13 (76%) people were hospitalized and 6 (35%) were treated with botulism antitoxin because of concerns that the botulinum toxin could have spread beyond the injection site. Among 7 people tested for botulism, all had negative results.
All reports came from people identifying as female, ranging in age from 25 to 67 years, with a median age of 43 years. Fifteen (88%) people reported receiving botulinum toxin injections for cosmetic purposes.
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.

For More Information

- CDC: Harmful Reactions Linked to Counterfeit “Botox” or Mishandled Botulinum Toxin Injections
- FDA: Counterfeit Version of Botox Found in Multiple States
- FDA’s MedWatch Safety Information and Adverse Event Reporting Program
- Information for Health Professionals on Botulism | CDC
- About Botulism | CDC
- Injection Safety | CDC

References

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2. Rao AK, Sobel J, Chatham-Stephens K, Luquez C. Clinical Guidelines for Diagnosis and Treatment of Botulism, 2021. *MMWR Recomm Rep*. 2021;70(No. RR-2):1–30. doi:15585/mmwr.rr7002a1
3. Rao AK, Lin NH, Jackson KA, Mody RK, Griffin PM. Clinical Characteristics and Ancillary Test Results Among Patients With Botulism — United States, 2002–2015. *Clin Infect Dis*. 2018;66(suppl_1):S4–S10. doi:1093/cid/cix935