وقاية
هيئة الصحة العامة
PUBLIC HEALTH AUTHORITY

Guidelines for Foodborne Botulism (Clostridium Botulinum)

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Foodborne Botulism

Botulism is a rare, neurotoxin-mediated, life-threatening disease characterized by flaccid descending paralysis that begins with cranial nerve palsies and might progress to extremity weakness and respiratory failure.Botulinum neurotoxin, which inhibits acetylcholine release at the neuromuscular junction, is produced by the anaerobic, gram positive bacterium Clostridium botulinum. Food-borne botulism is usually caused by ingestion of potent neurotoxins, the botulinum toxins, formed in contaminated foods. Person to person transmission of botulism does not occur.

Case Definition

Clinical Description

Initially symptoms of foodborne botulism may include nausea, vomiting, abdominal cramps or diarrhea. Dry mouth, blurred vision, and diplopia are usually the earliest neurologic symptoms followed by dysphonia, dysarthria, dysphagia, and peripheral muscle weakness. These symptoms may extend to a descending symmetrical flaccid paralysis in an alert afebrile person. Constipation is a common symptom later in presentation.

Laboratory Criteria For Diagnosis

Detection of botulinum toxin in serum, stool, or patient's food, OR Isolation of Clostridium botulinum from stool.

Case Classification

- **Suspected**

A clinically compatible case with an epidemiological link (e.g., ingestion of a suspect food within the previous 48 hours).

- **Confirmed**

A clinically compatible case that is laboratory confirmed or that occurs among persons who ate the same food as persons who have laboratory-confirmed botulism.

Symptoms of food-borne botulism

Due to their neurotoxicity, botulinum toxins have an impact on the neurological system. The hallmark of foodborne botulism is a progressive, flaccid paralysis that may result in respiratory failure. Early signs and symptoms include extreme tiredness, weariness, and vertigo. These are often followed by dry mouth, impaired vision, and trouble speaking and swallowing. Constipation, diarrhea, vomiting, and edema in the abdomen are possible side effects. The condition might worsen to the point that weakness develops in the arms and neck, which then affects the lower body muscles and breathing muscles. Both a fever and unconsciousness are absent. Certain neurological diseases (e.g., Myasthenia gravis and Guillain-Barre Syndrome) have signs and symptoms that overlap with botulism.Although rare, symptoms such as fever, non-descending paralysis, and altered mental status have been reported.

The poison that the bacteria produces is what causes the symptoms rather than the bacterium itself. After exposure, symptoms often start to show up 12 to 36 hours later (with a minimum and maximum range of 4 hours to 8 days). Botulism is rare, but if it is not diagnosed and treated promptly (by giving antitoxin early on and providing extensive respiratory care), the death rate is significant. Five to ten percent of instances of the condition might be deadly. Respiratory failure without preceding neurologic deficits has rarely been reported as the presenting symptom.

Pathophysiology of Botulism

Botulinum neurotoxin enters the vascular circulation and is transported to peripheral cholinergic nerve terminals, including neuromuscular junctions , postganglionic parasympathetic nerve endings, and peripheral ganglia .It produces a clinical syndrome of cranial nerve palsies followed by descending symmetric flaccid paralysis of variable severity .

Diagnosis

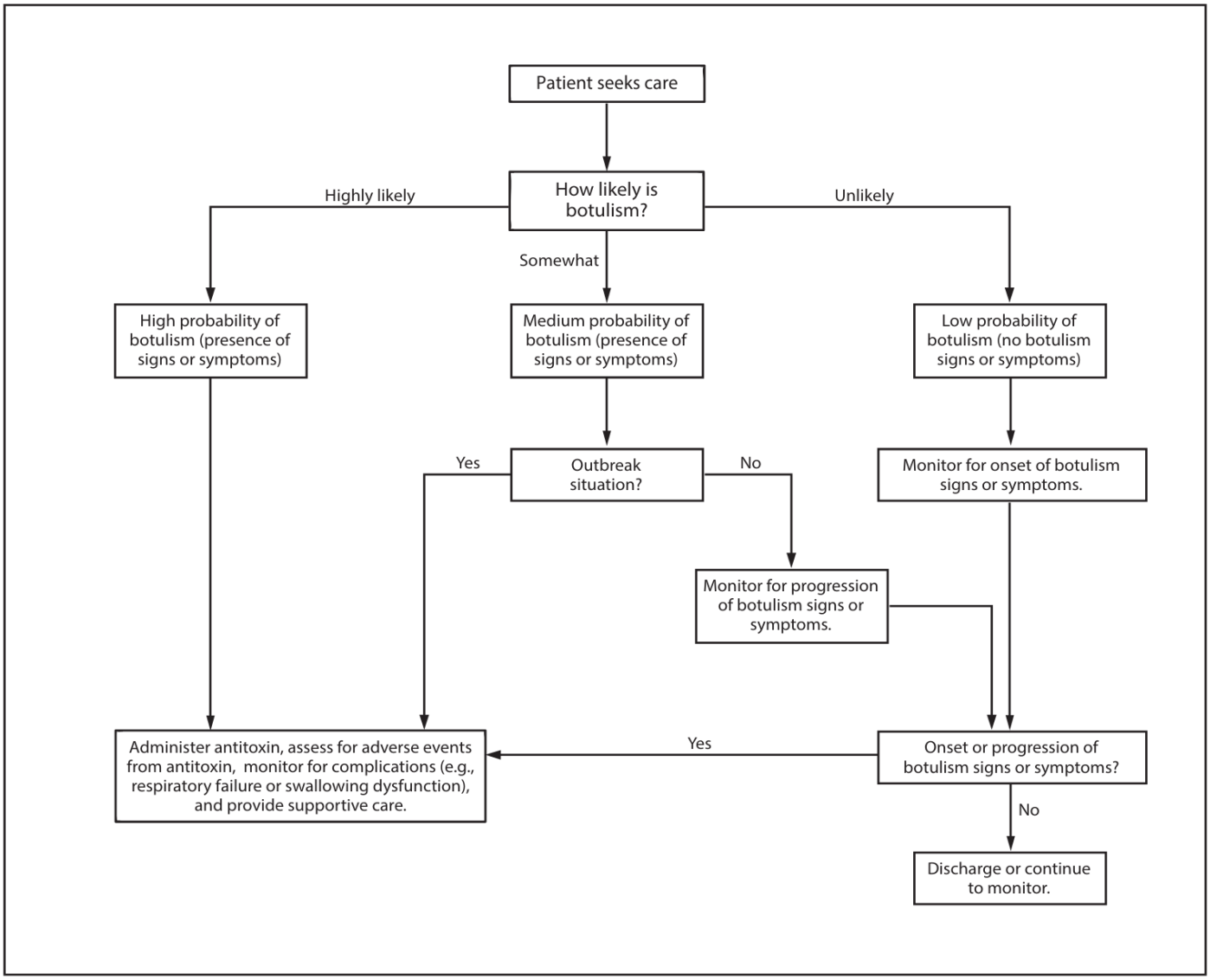
Diagnosis is usually based on clinical history and clinical examination followed by laboratory confirmation including demonstrating the presence of botulinum toxin in serum, stool or food, or a culture of C. botulinum from stool, wound or food. Misdiagnosis of botulism sometimes occurs as it is often confused with stroke, Guillain-Barré syndrome, or myasthenia gravis (Figure 1).

Challenges in the Diagnosis of foodborne Botulism

The reasons for initial failure to diagnose botulism in subsequently confirmed cases has been investigated most productively in outbreaks, in which cases initially misdiagnosed were eventually identified by outbreak investigators.

Outbreak investigations in which some botulism cases were only identified after the patients had been discharged with alternative diagnoses highlight the potential for delayed or missed diagnoses. The diagnostic challenges resulting from the variations in the spectrum of signs and symptoms of botulism were highlighted in the delayed recognition of a large food-borne botulism outbreak, in which some patients initially received diagnoses of myasthenia gravis, stroke, or psychiatric disorders.

FIGURE 1. Assessing patients with known or possible exposure to botulinum toxin in conventional and contingency settings*



* When assessing the likelihood of botulism, consider clinical criteria and available epidemiologic data. Classify patients into a botulism likelihood category per the clinician's judgement. Additional information on clinical criteria is available (Rao AK, Lin NH, Griese SE, Chatham-Stephens K, Badell ML, Sobel J. Clinical criteria to trigger suspicion for botulism: an evidence-based tool to facilitate timely recognition of suspected cases during sporadic events and outbreaks. Clin Infect Dis 2017;66[suppl_1]:S38–S42).

Source: US.CDC, 2021 Clinical Guidelines for Diagnosis and Treatment of Botulism (3)

Treatment:

Botulinum Antitoxin should be administered as soon as possible after a clinical diagnosis. Early administration is effective in reducing mortality rates. Severe botulism cases require supportive treatment, especially mechanical ventilation, which may be required for weeks or even months. Antibiotics are not required (except in the case of wound botulism).

Antitoxin heptavalent antidote:

Timing:
Antitoxin should be given as early as possible as soon as presumptive clinical diagnosis of botulism is made, and it should not be delayed until laboratory confirmation.
BAT should be administered even if the patient progresses to complete paralysis and requires ventilation as long as patient symptoms started less than 7 days ago.

Dose:
Adults:

- In Adults, administer 1 single-use vial diluted 1:10 in NS via IV infusion starting at rate of 0.5 mL/min; may double rate every 30 minutes, if tolerated; MAX infusion rate 2 mL/min; MAX dose, 1 vial. Do not administer a second dose as it is not beneficial, please contact public health authority if you believe a second dose is needed.

Pediatrics:

- (1 to younger than 17 years, 10 to 14 kg) Administer 20% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 15 to 19 kg) Administer 30% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 20 to 24 kg) Administer 40% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 25 to 29 kg) Administer 50% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min

- (1 to younger than 17 years, 30 to 34 kg) Administer 60% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 35 to 39 kg) Administer 65% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 40 to 44 kg) Administer 70% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 45 to 49 kg) Administer 75% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (1 to younger than 17 years, 50 to 54 kg) Administer 80% of 1 vial diluted 1:10 in NS via IV infusion starting at rate of 0.01 mL/kg/min; may increase rate by 0.01 mL/kg/min every 30 minutes if tolerated; MAX infusion rate 0.03 mL/kg/min or adult infusion rate of 2 mL/min
- (17 years or older OR 55 kg or greater) Administer 1 single-use vial diluted 1:10 in NS via IV infusion starting at rate of 0.5 mL/min; may double rate every 30 minutes, if tolerated; MAX infusion rate 2 mL/min; MAX dose, 1 vial

Key points for Clinicians:

- Be aware of the spectrum of signs and symptoms of botulism, ranging from limited cranial nerve palsies (e.g., ptosis) to respiratory failure and complete extremity paralysis.
- Be aware that the repiratory system might be compromised early in the illness, when respiratory muscles (e.g., diaphragm) are unaffected but the upper airway is compromised from paresis of cranial nerve muscles, resulting in pharyngeal collapse or pooling of secretions.

Recommendations:

- Consider botulism when myasthenia gravis or Guillain- Barré syndrome are suspected and in a patient with unexplained symmetric cranial nerve palsies, with or without paresis of other muscles.

- Conduct thorough ,serial neurologic examinations to detect the neurologic deficits of botulism and their progression.
- If botulism is suspected, immediately contact the local or state health department's emergency on-call staff to arrange an emergency expert clinical consultation and, when indicated, request botulinum antitoxin.

Notifications Events and Diseases:

Notification will be through the Health Electronic Surveillance Network (HESN Plus) and phone or email to the higher authority of the region/ Province.

When to notify: Immediately
MAP: Attending physician when suspected/diagnosed
MRP: Unit/department head assigned for public health reporting

Procedure for arranging testing at the Public Health Laboratory

- When a patient with suspected case is identified, PHL should be notified and direct contact with the PHL is essential to arrange receipt of specimens and obtain advice on specimen collection, safe packaging and transport.
- Label each specimen container with the patient's ID number, HESN requisition number, and the date the sample was collected.
- In HESN you can register the case and for test requested and for the distention you select public Health Authority.

Type of samples:

A. 50 g of Stool samples in an appropriate container
B. 25 mL Gastric contents, aspirate or vomitus
C. If stool samples is difficult to collect, High rectal washout can be collected
D. 15 ml Serum sample (Serum should be collected before giving antitoxin)

Transport of specimens to the Public Health Laboratory

- Samples should be identified as an Infectious Substances.
- Place the specimens in a tightly sealed, watertight primary container, such as leak-proof screw-cap plastic container.
- On the outside of the secondary container, attach the specimen labels and other relevant information.
- Place the second container in a secure box for shipment

- Arrange shipping with the courier and make sure that shipping services apply the regulations for transporting biological specimens
- Samples can be shipped free of charge via the courier, SMSA, following appropriate regulations. The courier service is available for sample transportation and pickup locations throughout the country for collection of samples . Specimens pick up can be requested from SMSA at the following number (8006149999)

- Shipment addressed to:

  Public Health Laboratory , Public health Authority, Al Aarid, Riyadh. phl@pha.gov.sa

References

1. World Health Organization, Botulism, 2023. URL https://www.who.int/news-room/fact-sheets/detail/botulism
2. Information for Health Professionals | Botulism | US.CDC. URL https://www.cdc.gov/botulism/health-professional.html
3. Botulism (Clostridium botulinum) 2011 Case Definition US.CDC. URL https://ndc.services.cdc.gov/case-definitions/botulism-2011
4. Clinical Guidelines for Diagnosis and Treatment of Botulism, US.CDC 2021 URL https://www.cdc.gov/mmwr/volumes/70/rr/rr7002a1.htm