Provider Responsibilities

1) Report suspected and confirmed cases of botulism to the local health department immediately. Your state and local public health agencies will coordinate with the Centers for Disease Control and Prevention (CDC) to procure antitoxin for cases of foodborne and wound botulism; and with the California Department of Health Services to procure botulinum immune globulin for infant botulism.

*Note:* Do NOT wait for laboratory confirmation to contact the health department and arrange for antitoxin. The decision to administer antitoxin must be made on clinical presentation. Antitoxin must be administered early in the course of illness to lessen the chance of severe outcomes.

2) Collaborate with public health authorities to obtain laboratory specimens for confirmation on cases of botulism.

3) Provide the necessary clinical information to the local health department for completion of the West Virginia Electronic Disease Surveillance System (WVEDSS) botulism form.

Use standard precautions with botulism patients.

Laboratory Responsibilities

1) Report suspected and confirmed cases of botulism immediately to the local health department by phone. Refer requests for testing immediately to the local health department or the Division of Infectious Disease Epidemiology (DIDE) at (304) 558-5358 ext 1.

Local Health Responsibilities

1) Prior to the occurrence of a botulism case:
   a) Educate employees about employee health: Botulism is NOT transmitted from one person to another. It is transmitted by ingestion of contaminated food or by inhalation (in a BT event). In a BT event, the environment could be contaminated with botulinium toxin; however, the toxin degrades rapidly (e.g., within 2 days) depending on weather conditions. Nonetheless, untrained personnel should NOT enter a presumed contaminated site until cleared by the appropriate Federal agencies.
   b) Assemble and train a BT epidemiologic response team: Periodically train and pre-drill individuals on the team in their respective responsibilities during an outbreak.
2) Educate health care providers and the public in the recognition and diagnosis of botulism.

3) Educate providers and laboratories to report suspected botulism infections to the local health department in the patient’s county of residence immediately.

4) When a suspected case of botulism is reported, the LHD should contact DIDE immediately (do not wait for lab confirmation to contact DIDE).
   a) **Treatment:** For a case of foodborne or wound botulism, DIDE will coordinate with CDC and the attending physician immediately to request release of botulinum antitoxin. In the case of infant botulism, DIDE will contact the California Department of Health Services immediately for release of infant botulism immune globulin.
   b) **Laboratory diagnosis:** DIDE will coordinate with clinical provider and the Office of Laboratory Services (OLS) immediately for information on laboratory confirmation.
   c) **Outbreak investigation:** In the event of an outbreak (>1 case of botulism), DIDE will assist with the investigation and coordinate with Federal authorities.

5) **Preliminary investigation and triage.** Once the connections have been made to obtain the needed antitoxin, the steps to investigation of a reported case of botulism are:
   a) **Confirm the diagnosis.** Review the case definition and determine if the case meets the case definition.
   b) **Do a preliminary epidemiological investigation.** Using the WVEDSS form, interview the case or a family member to identify risk factors for foodborne botulism, wound botulism or infant botulism.
   c) **Collect clinical laboratory specimens:** Collaborate with DIDE and the provider to obtain specimens for confirmatory testing.
   d) **IF A SUSPECT FOOD IS IDENTIFIED, SEIZE FOOD SAMPLES IMMEDIATELY!** Especially if the food is commercially distributed, it is an emergency to confirm or rule out the food item as a source. Consult with DIDE/OLS about testing immediately.
   e) If the source is not obvious or if there is more than one case. Contact DIDE for assistance in completing a more detailed epidemiological investigation.

6) The majority of cases identified are sporadic, however if preliminary investigation suggests an outbreak or a suspect or confirmed BT event:
   a) **Consult DIDE immediately.** Anticipate the need to collaborate with State and Federal public health officials and officials from other public health jurisdictions (state and local). For a BT event, collaboration with FBI will be needed.

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**Division of Infectious Disease Epidemiology**

350 Capitol Street, Room 125, Charleston, WV 25301-3715
Phone: 304.558.5358, ext 1  Fax: 304.558.6335  [www.dide.wv.gov](http://www.dide.wv.gov)
Answering Service: (304) 925-9946

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State Health Responsibilities

1) Facilitate communication between attending physician and appropriate agency to determine the necessity for the release of antitoxin for reported botulism cases. (CDC for foodborne or wound botulism and the California Department of Health for infant botulism.)

2) Immediately (within 4 hours) notify the CDC Emergency Operations Center (EOC) of any case of foodborne botulism, clusters or outbreaks of infant botulism, intentional or suspected intentional release, or any case of unknown etiology.

3) Prompt and complete reporting of botulism cases to the CDC through WVEDSS

4) Provide technical expertise and consultation regarding surveillance, investigation, control measures and prevention of botulism

5) Notify CDC of suspected outbreaks identified in West Virginia and assist local health jurisdictions in obtaining the knowledge and resources necessary for investigation of a botulism outbreak.

6) Summarize surveillance data for cases of botulism on an annual basis

7) If preliminary investigation suggests an outbreak or a suspect or confirmed BT event, proceed as follows:
   a) Anticipate the need to collaborate with State and Federal public health officials and officials from other public health jurisdictions (state and local). For a BT event, collaboration with FBI will be needed.
   b) Case Finding:
      i) Develop a working case definition: Develop a working case definition for the outbreak investigation. After the outbreak has been identified, a working case definition may be considered as follows: 1) a confirmed case of botulism (according to the CDC definition), 2) a clinically confirmed case of botulism after laboratory confirmation of exposure to \textit{C. botulinum} or botulinum toxin, or 3) a clinically confirmed case of botulism while laboratory confirmation of \textit{C. botulinum} is pending, and the individual is epi-linked to a previous confirmed case.
      ii) Begin enhanced passive surveillance: Immediately begin enhanced passive surveillance as needed with health care providers and laboratories in the county. (1) Educate health care providers and the public in the recognition and diagnosis of botulism. (2) Educate providers and laboratories to immediately report possible botulism infections that meet the 'Working Case Definition' to the local health department in the patient's county of residence.
      iii) Prepare for active surveillance: If necessary, alert the regional epidemiologist and be prepared to expand active surveillance throughout the region, e.g., be prepared...
to interview providers and patients, and review/abstract patient records.

iv) **Confirm new cases:** Receive and screen reports of suspected cases, and confirm new cases.

v) **Develop line list of cases:** Develop a line listing of all clinically and laboratory confirmed cases. Use the line list to manage the work related to the outbreak. Record information on:

   (1) Case ID number (use this number to link to other databases),
   (2) Name,
   (3) Age, date of birth,
   (4) Location (hospital, clinic, home),
   (5) Date and time of onset of symptoms,
   (6) Classification of case (confirmed, pending, ruled out, suspected, clinically confirmed, and laboratory confirmed),
   (7) Laboratory confirmation status (confirmed, negative, pending),
   (8) Status of clinical information (complete or incomplete), and
   (9) Status of exposure information (complete or incomplete).

vi) Maintain the line listing of cases up to date as new information becomes available.

c) **Assist with development of a risk factor/exposure data base:** For large outbreaks, this activity requires the leadership of an epidemiologist experienced in outbreak investigation and study design. The basic steps are:

i) **Perform descriptive epidemiology to guide hypothesis generation.**

ii) **Perform detailed open-ended interviews with a sample of 8-10 ill persons to further develop hypotheses.** Use the WVEDSS form, modified as appropriate to guide the open-ended inquiry.

iii) **Design and implement appropriate epidemiological / laboratory / environmental studies to test / confirm / refine hypotheses.**

iv) **Establish control measures as guided by the results of the investigation and continue surveillance to evaluate the effectiveness of control measures.**

   (1) **Eliminate any continuing source of exposure.** Botulism is a major public health emergency. Any implicated commercial food item must be removed from circulation immediately.

   (2) **Identify exposed population:**

      (a) **Definition of an exposed individual:** An exposed individual will be a person who shared or possibly shared airspace that was contaminated by *Clostridium Botulinum*, or ingested contaminated food or water.

      (b) **Develop a line listing of all persons possibly exposed.** Record each person’s exposure risk based upon proximity to exposure.
(c) Surveillance of exposed population: Assure that all exposed individuals are contacted within 24 hours. For large populations, alert the public through media announcements. Conduct surveillance of all exposed individuals for 8 days.

(3) Prevention and control:
(a) Management of exposed persons: Because of the short incubation period, exposed individuals should be kept under surveillance and treated with antitoxin when botulism symptoms are first identified.
(b) Treatment of Cases: Recommend to the State Health Commissioner that cases should be recommended for treatment with antitoxin according to current guidelines (See treatment section).

Disease Control Objectives
To identify and investigate outbreaks at the earliest possible time, so that control measures can be instituted rapidly.

Disease Prevention Objectives
Prevent cases of botulism by education of the general public about the causes and prevention of:
1) Foodborne botulism, (e.g. use of commercially canned goods and adequate home canning techniques).
2) Infant botulism, (e.g., appropriate feeding of infants).
3) Wound botulism (e.g. needle use, appropriate wound care).

Disease Surveillance Objectives
To identify and characterize cases of botulism at the earliest possible time so that further cases can be prevented.

Public Health Significance
Botulism is a very serious but rare illness. Three forms of naturally occurring human botulism exist: foodborne, wound, and infant botulism. All forms result from absorption of botulinum toxin into the circulation from either a mucosal surface (gut, lung) or a wound. Wound botulism and infant botulism are infectious diseases that result from production of botulinum toxin by *C. botulinum* either in damaged tissue or in the intestinal lumen, respectively. Neither would
Botulism Surveillance Protocol

result from intentional use of botulinum toxin. Foodborne botulism could occur from intentional or unintentional exposure, while inhalational botulism is only known to occur by intentional exposure. Iatrogenic botulism resulting from an over dosage of botulinum toxin administered for cosmetic purposes has also been reported.

Historically, the majority of botulism cases have been traced to home-processed foods such as home-canned vegetables, fruits, and meat products. Outbreaks have been associated with commercially canned or processed products such as chili sauce, carrot juice, foil wrapped baked potatoes held at room temperature, sautéed onions, garlic in oil, inadequately eviscerated fish, yogurt, cream cheese and jarred peanuts.

With recognition of the threat posed by bioterrorism, public health officials must also be prepared to recognize botulism outbreaks due to intentional causes. Botulism was first weaponized in the mid-20th century and could be disseminated by airborne or foodborne routes. The cause of a botulism outbreak should be carefully and quickly determined by an epidemiologic and law enforcement investigation.

**Clinical Description**

All forms of human botulism display virtually identical neurological signs. Botulism is an acute, afebrile, symmetric, descending flaccid paralysis that always begins in bulbar musculature. It is not possible to have botulism without having multiple cranial nerve palsies.

Patients with botulism typically present with difficulty seeing, speaking, and/or swallowing. Prominent neurologic findings in all forms of botulism include ptosis, blurred vision, often enlarged or sluggishly reactive pupils, and the “4 Ds” (diplopia, dysarthria, dysphonia, and dysphagia). The mouth may appear dry and the pharynx injected because of peripheral parasympathetic cholinergic blockade. Sensory changes are not observed except for infrequent circumoral and peripheral paresthesias from hyperventilation as a patient becomes frightened by onset of paralysis.

As paralysis extends beyond bulbar musculature, loss of head control, hypotonia, and generalized weakness become prominent. Dysphagia and loss of the protective gag reflex may require intubation and mechanical ventilation. Deep tendon reflexes may be present initially but diminish or disappear in the ensuing days, and constipation may occur. In untreated persons, death results from airway obstruction (pharyngeal and upper airway muscle paralysis) and inadequate tidal volume (diaphragmatic and accessory respiratory muscle paralysis).
Botulism

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In foodborne botulism, neurological signs may be preceded by abdominal cramps, nausea, vomiting, constipation or diarrhea. Disease manifestations are similar regardless of botulinum toxin type. However, the extent and pace of paralysis may vary considerably among patients. Some patients may be mildly affected while others may be so paralyzed that they appear comatose and require months of ventilatory support. The rapidity of onset and the severity of paralysis depend on the amount of toxin absorbed into the circulation. The toxin does not penetrate brain parenchyma, so patients are not confused or obtunded. However, they often appear lethargic and have communication difficulties because of bulbar palsies.

Etiologic Agent
Botulism is caused by toxins produced by Clostridium botulinum, a gram-positive, spore forming rod. C. botulinum spores can survive indefinitely under essentially any environmental conditions— even boiling. Spore germination resulting in bacterial growth and toxin production occurs only in low oxygen, non-acidic conditions. Botulinum toxins are temperature sensitive and are inactivated by heating to 85°C (185°F) for 5 minutes. However, in order to kill C. botulinum spores, higher temperatures (>120°C or 250°F) which are achieved under pressure (e.g., in an autoclave or a properly functioning home pressure cooker) are required.

Botulinum toxin is produced as the bacteria are multiplying. There are 7 types of botulinum toxin, designated by the letters A-G. Only types A, B, E, and rarely F are known to cause human disease. Most cases of infant botulism have been caused by Type A or B. Type E outbreaks are usually related to fish, seafood and meat from marine animals. Type G has been isolated from soil and autopsy specimens but an etiologic role in botulism has not been established.

Botulinum toxins are the most potent toxins known to exist. A few nanograms of the toxin can cause illness. The toxin is heat-labile and can be inactivated by boiling.

Reservoir
C. botulinum spores are widely distributed in nature and are commonly found in soil worldwide, in agricultural products, the intestines of animals, and in the gills and viscera of fish.

Mode of Transmission
Foodborne botulism
Foodborne botulism is caused by ingestion of preformed toxin in foods. Typically, implicated foods have been low acid, home-canned foods that were not heated adequately during
canning. A growing proportion of implicated foods have been cultural delicacies prepared by traditional methods, such as fermented fish heads (among Alaska Natives). Rarely, commercial products are implicated, usually after some breakdown in standard canning procedures. Examples of implicated foods include:

- home-canned asparagus, beans, and other vegetables (including low-acid tomatoes), usually canned by the water-bath method;
- fish that has been improperly canned, dried, and/or stored;
- sausage or other prepared meats that are improperly processed (inadequate sodium nitrite) and improperly stored;
- commercially processed canned chili sauce;
- chopped garlic in oil;
- baked potatoes in foil;
- among Alaska Natives, traditional foods including fermented (putrefied) whale blubber, salmon heads, salmon eggs, and other delicacies.

**Intestinal or 'Infant' Botulism**

The most common form of botulism is infant botulism. It occurs when *C. botulinum* spores, ingested in food or soil, germinate in a gut that does not have a mature flora. Botulinum toxin is then produced by the bacteria growing in the intestine. Most cases occur in infants <3 months old. Adult cases of intestinal botulism have very rarely been reported, in adults with GI illness that may predispose to enteric colonization.

**Wound Botulism**

Wound botulism results from a local *C. botulinum* infection of damaged tissue at a wound site, with low oxygen conditions. As with intestinal botulism, the toxin is produced *in situ* and disseminated in the blood. Wound botulism is the rarest form of naturally occurring botulism. It is most commonly associated with people who inject “black tar” heroin.

**Inhalational Botulism**

Inhalational botulism is not a naturally occurring disease and is only known to occur through deliberate aerosolization of pre-formed botulinum toxin.

**Iatrogenic Botulism**

Iatrogenic botulism is caused by an overdose of botulinum toxin injected for cosmetic or therapeutic purposes.
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Incubation Period
Symptoms of foodborne botulism usually begin within 12-72 hours but could be seen as early as 2 hours and as late as 8 days after ingesting the toxin. The time of onset of inhalational botulism cannot be stated with certainty because so few cases are known. The three known human cases of inhalational botulism had onset of symptoms approximately 72 hours after exposure to an unknown but probably small amount of re-aerosolized toxin.

Period of Communicability
There is no person to person transmission of botulism.

Outbreak Recognition
Historically, the majority of botulism cases have been traced to home-processed foods such as home-canned vegetables, fruits, and meat products. Previous outbreaks have been associated with commercially canned or processed products such as chili sauce, carrot juice, garlic in oil, and inadequately eviscerated fish. In 2011, an outbreak occurred among inmates of a prison facility after consumption of an illicit homemade alcohol known as pruno. The principal ingredients are fruit, sugar, and water, but many items including root vegetables, are sometimes added, depending on the availability of foods in prison. A baked potato saved from a meal served weeks earlier and added to the pruno was the suspected source of C. botulinum.

Outbreak recognition and investigation requires timely and complete epidemiological investigation (risk factors, food history, history of exposures, etc.) paired with timely and complete laboratory investigation. A careful travel history and activity history, as well as dietary history, should be taken in any suspected botulism outbreak. Patients should be asked if they know of other persons with similar symptoms.

An outbreak of botulism with the following characteristics should raise suspicion of a bioterrorist event:

• Outbreak of a large number of cases of acute flaccid paralysis with prominent bulbar palsies
• Outbreak of an unusual botulinum toxin type (i.e. type C, D, F, or G, or type E toxin)
• Outbreak with a common geographic factor among cases (e.g. Airport, work location) but without a common dietary exposure (i.e., features suggestive aerosol attack)
• Multiple simultaneous outbreaks with no common source
Laboratory Testing
A toxin neutralization bioassay in mice is used to detect botulinum toxin in stool, serum, gastric aspirate, or suspect foods. Stool the preferred specimen. Testing cannot be done by clinical laboratories and must be coordinated through public health. Call the local health department or DIDE at (304) 558-5358, ext 1 to arrange for testing.

Case Definition

FOODBORNE BOTULISM
Clinical Description: An illness of variable severity. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory Criteria: Detection of botulinum toxin in serum, stool, or patient's food, OR Isolation of *Clostridium botulinum* from stool

Case Classification
Probable: A clinically compatible case with an epidemiologic link (e.g., ingestion of a home-canned 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

INFANT BOTULISM
Clinical Description: An illness of infants, characterized by constipation, poor feeding, and "failure to thrive" that may be followed by progressive weakness, impaired respiration, and death

Laboratory Criteria: Detection of botulinum toxin in stool or serum, OR Isolation of *Clostridium botulinum* from stool

Case Classification
Confirmed: A clinically compatible case that is laboratory-confirmed, occurring in a child aged less than 1 year

WOUND BOTULISM
Clinical Description: An illness resulting from toxin produced by *Clostridium botulinum* that has infected a wound. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.
Laboratory Criteria: Detection of botulinum toxin in serum, OR Isolation of *Clostridium botulinum* from wound

Case Classification

*Probable:* A clinically compatible case in a patient who has no suspected exposure to contaminated food and who has either a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms

*Confirmed:* A clinically compatible case that is laboratory confirmed in a patient who has no suspected exposure to contaminated food and who has a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms

Preventive Interventions

- Effective processing and preparation of commercially canned and preserved foods can prevent this disease.
- Educate the public on the proper use of all canned goods. Botulinum toxin is destroyed by high temperatures. Persons who eat home-canned foods should consider boiling the food for 10 minutes before eating it to ensure safety. Instructions on safe home canning can be obtained from the county extension services or from the US Department of Agriculture.
- Children less than 12 months old should not be fed honey. Honey is safe for persons 1 year of age and older.
- Wound botulism can be prevented by promptly seeking medical care for infected wounds and not by using injectable street drugs.
- In the event of an intentional aerosolization of *C. botulinum*, proper personal protective equipment, including clothing and respirator use, must be employed by all personnel entering a *C. botulinum* exposure zone. Only experienced and fully equipped personnel should enter the exposure zone until safety can be assured.
- *C. botulinum* toxin degrades rapidly in the environment with substantial degradation occurring by 2 days after aerosolization. Contaminated surfaces should be cleansed with 0.1% hypochlorite bleach solution if they cannot be avoided for the hours to days required for natural degradation.

Treatment

The mortality and sequelae associated with botulism have diminished with contemporary therapy. Despite this increase in survival, the paralysis of botulism can persist for weeks to months with concurrent requirements for fluid and nutritional support, assisted ventilation, and...
treatment of complications. The mainstays of therapy are meticulous intensive care unit support, with mechanical ventilation if needed, and administration of antitoxin. Timely antitoxin administration may arrest the progression of paralysis and decrease the duration of illness.

For cases of foodborne, wound, or iatrogenic botulinum, antitoxin is available from the CDC via state and local health departments. The heptavalent botulinum antitoxin (HBAT) contains equine-derived antibody to the seven known botulinum toxin types (A--G). Antitoxin should be administered as soon as the diagnosis is suspected and before confirmatory laboratory results are available. Antitoxin will prevent further paralysis, but will not reverse existing neurological defects.

**Infant botulism** is treated with BabyBIG®, Botulism Immune Globulin Intravenous (Human) (BIG-IV) available through the Infant Botulism Treatment and Prevention Program of the California Department of Health. BIG-IV is approved by the U.S. Food and Drug Administration for the treatment of infant botulism types A and B, and a controlled trial demonstrated reduction in hospitalization from 5.7 to 2.6 weeks in infants receiving BIG-IV compared to controls.

**Surveillance Indicators**

1) Time from diagnosis to notification of public health.
2) Proportion of investigations with complete demographic information.
3) Proportion of cases with known laboratory confirmation.
4) Proportion of cases with complete risk factor investigation.
5) Proportion of cases severity information (e.g. death, sequelae)
References


3) Centers for Disease Control and Prevention. Investigational heptavalent botulinum antitoxin (HBAT) to replace licensed botulinum antitoxin AB and investigational botulinum antitoxin E. MMWR, 2010;59(10):299


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