Botulism

Section 1: ABOUT THE DISEASE

A. Etiologic Agent

Botulism is caused by exposure to a neurotoxin produced by *Clostridium botulinum*. *C. botulinum* is an anaerobic, spore-forming bacterium. The toxin is produced as the bacteria are multiplying; the bacteria multiply under anaerobic (no oxygen) and mildly acidic (generally pH>4) conditions. There are seven types of botulinum toxins (A–G), but human botulism is primarily caused by types A, B, and E.

B. Clinical Description

*C. botulinum* toxin is one of the most potent, lethal substances known. In humans, botulism occurs in one of three forms: foodborne botulism, wound botulism, and intestinal (infant and adult) botulism. There is a different site of toxin production for each of the forms, but they all share the flaccid paralysis that results from exposure to botulinum toxin.

| Foodborne Botulism | Foodborne botulism is a severe poisoning caused by the ingestion of pre-formed *C. botulinum* toxin. The clinical syndrome is dominated by neurologic signs and symptoms, including blurred or double vision, dysphagia, dry mouth, and muscle weakness. Symmetric, descending flaccid paralysis is classic for botulism. Generally, paralysis first affects the cranial nerves, followed by the upper extremities, the respiratory muscles, and finally, the lower extremities. Patients usually require ventilatory support, which is commonly needed for 2–8 weeks. The clinical symptoms are similar no matter which toxin type is responsible for the illness, but type A has been associated with a higher case-fatality rate than types B or E. In general, the case-fatality rate for foodborne botulism is 5–10%. Recovery may take months. |
| Wound Botulism | Wound botulism usually presents with the same clinical picture as foodborne botulism. In wound botulism, the organism multiplies in the wound and produces the toxin, which is then absorbed into the bloodstream. |
| Intestinal Botulism | Intestinal (previously called “infant”) botulism has a distinctly different clinical presentation than wound or foodborne botulism. In intestinal (infant) botulism, the *C. botulinum* spores are ingested, and the toxin is formed in the intestines. It is a rare disease, confined exclusively to infants <1 year of age and adults with gastrointestinal tract abnormalities or altered microflora (e.g., due to abdominal surgery or antibiotic treatment). The earliest clinical sign in infants is constipation, which is followed by poor feeding, decreased sucking, lethargy, listlessness, ptosis (drooping eyelids), difficulty swallowing, a weak cry, and lack of muscle tone, giving rise to the term “floppy baby syndrome.” In some cases, respiratory insufficiency and respiratory arrest may occur. Intestinal (infant) botulism presents with a wide range of severity, from mild illness to sudden death. Some studies suggest that intestinal (infant) botulism may be responsible for up to 5% of cases of Sudden Infant Death Syndrome (SIDS). Among hospitalized cases in the U.S., the case-fatality rate for intestinal botulism is <1%. |
C. Vectors and Reservoirs

*C. botulinum* spores are ubiquitous in soil worldwide. The spores can survive indefinitely in soil under almost any environmental condition. Spores are also found in marine sediment.

D. Modes of Transmission

Foodborne botulism is acquired by ingesting pre-formed toxin. This usually occurs as a result of ingesting food that has been inadequately processed and then inadequately prepared before being eaten. The most frequent source is home-canned foods, but outbreaks have also been attributed to baked potatoes in foil, minced garlic in oil, Alaskan salmon products, and sautéed onions held under a layer of butter. Tomato and similar food products, once thought to be a low-risk food due to a low pH, can no longer be dismissed as a potential vehicle because microenvironments in the food product can allow growth of *C. botulinum*. The toxin is destroyed by boiling.

Wound botulism occurs when wounds are contaminated with dirt or gravel containing botulism spores. Wound botulism has also been reported among chronic injection drug users.

Intestinal (infant and adult) botulism, which is the most common form of botulism in the U.S., occurs as a result of ingesting the spore form of the bacteria, which then goes on to germinate and produce toxins in the intestines. This can happen through ingestion of food, soil, or dust contaminated with botulinum spores. Honey often contains *C. botulinum* spores. Some cases of intestinal botulism have occurred in infants living in areas of construction and earth disruption.

E. Incubation Period

The incubation period is variable, but neurologic symptoms of foodborne botulism usually appear within 12–36 hours (ranging from 6 hours to 8 days) after eating contaminated food. The median incubation period for wound botulism is generally longer than the period for foodborne botulism, usually 7 days, with a range of 4–14 days. In general, the shorter the incubation period, the more severe the disease. The incubation period for intestinal botulism is unknown since it is usually not known when the spores were ingested.

F. Period of Communicability or Infectious Period

No instances of person-to-person spread have ever been documented for botulism.

G. Epidemiology

Botulism occurs worldwide as sporadic cases and as family and general outbreaks. Since 1973 in the U.S., a median of 24 cases of foodborne botulism, 3 cases of wound botulism, and 71 cases of intestinal (mostly infant) botulism have been reported annually to the Centers for Disease Control and Prevention (CDC). Since 1994, the use of black tar heroin by injection drug users has been associated with an increase in the number of cases of wound botulism.

H. Bioterrorist Potential

*C. botulinum* toxins are listed by the CDC as Category A bioterrorist agents. If acquired and properly disseminated, botulinum toxin could cause a serious public health challenge in terms of ability to limit the number of casualties and to control repercussions of such an attack.
Section 2: REPORTING CRITERIA AND LABORATORY TESTING

A. What to Report to the Massachusetts Department of Public Health (MDPH)

Report any suspicion of botulism that is called to your attention. This could take the form of a health care provider or laboratory inquiring about botulism or botulism testing. Also report any suspected exposure to *C. botulinum* that could represent bioterrorism.

Since laboratory testing to confirm botulism is only performed at the MDPH State Laboratory Institute (SLI), the local board of health (LBOH) will not receive a report of a confirmed case of botulism without the knowledge of the MDPH Division of Epidemiology and Immunization.

*Note: See Section 3C for information on how to report a case.*

B. Laboratory Testing Services Available

The SLI Enteric Laboratory will test clinical specimens for the presence of both *C. botulinum* and botulinum toxin only if epidemiologically and clinically indicated. Prior approval for testing must be obtained from the MDPH Division of Epidemiology & Immunization at (617) 983-6800 or (888) 658-2850. The most reliable method for identifying toxin is the mouse neutralization test. In addition, at the time of this printing, the SLI Enteric Laboratory is validating the diffusion-in-gel enzyme-linked immunosorbent assay (DIG-ELISA) procedure for use as an initial screening test for toxin.

For more information on testing and specimen submission, call the SLI Enteric Laboratory at (617) 983-6609.

The SLI Food Microbiology Laboratory will test food specimens for the presence of *C. botulinum* and/or toxin, if epidemiologically indicated. For more information, call the SLI Food Microbiology Laboratory at (617) 983-6610.

Section 3: REPORTING RESPONSIBILITIES AND CASE INVESTIGATION

A. Purpose of Surveillance and Reporting

- To assist in the diagnosis and treatment of potential cases.
- To identify sources of public health concern (e.g., a commercially-distributed food product), and to stop transmission from such a source.
- To classify reported cases properly as foodborne, intestinal, or wound botulism.
- To identify cases and clusters of human illness that may be associated with a bioterrorist event.
B. Laboratory and Health Care Provider Reporting Requirements

Botulism is reportable to the LBOH. The MDPH requests that health care providers immediately report to the LBOH in the community where the case is diagnosed, all confirmed or suspect cases of botulism, as defined by the reporting criteria in Section 2A.

Due to the rarity and potential severity of botulism, the MDPH requests that information about any suspect or known case of botulism, or any suspected exposure that may be bioterrorist in nature, be immediately reported to the LBOH in the community where the case is suspected or diagnosed. If this is not possible, call the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850 (anytime of day or night). Since botulism testing is only available at the SLI or the CDC, the MDPH must be informed to approve appropriate testing.

C. Local Board of Health (LBOH) Reporting and Follow-Up Responsibilities

Reporting Requirements

MDPH regulations (105 CMR 300.000) stipulate that botulism is reportable to the LBOH and that each LBOH must report any case of botulism or suspect case of botulism, as defined by the reporting criteria in Section 2A. Cases should be reported to the MDPH Bureau of Communicable Disease Control, Office of Integrated Surveillance and Informatics Services (ISIS) using an official MDPH Generic Disease Case Report Form (found at the end of this chapter). Please refer to the Local Board of Health Reporting Timeline at the end of this manual's Introduction section for information on prioritization and timeliness requirements of reporting and case investigation.

Note: The LBOH will not receive notification of confirmed cases without the knowledge of the MDPH Division of Epidemiology and Immunization since confirmatory testing is only available at the SLI and the CDC. However, the LBOH could be the initial recipient of a report of a suspect case.

Case Investigation

The most important thing a LBOH can do upon learning of a suspect case of botulism, or any suspected exposure that may be bioterrorist in nature, is to immediately call the MDPH Division of Epidemiology and Immunization, any time of day or night, at (617) 983-6800 and (888) 658-2850.

1. Case investigation of botulism in Massachusetts residents will be directed by the MDPH Division of Epidemiology and Immunization. If a bioterrorist event is suspected, the MDPH and other response authorities will work closely with the LBOH and will provide instructions/information on how to proceed.
2. Following immediate notification of the MDPH, the LBOH may be asked to assist in investigating any case(s) of botulism. Use the guidelines listed on the next page to assist in the investigation.
3. Determine type of botulism: Foodborne botulism is a true medical and public health emergency and should be investigated as such. Intestinal (infant) and wound botulism do not require the same urgency in investigation. Therefore, it is essential to determine which illness is occurring.
Foodborne Botulism

The source of the intoxication and other potentially exposed persons must be identified. The case must be interviewed concerning possible food sources. In most cases, this information will need to be obtained from family members or from other close contacts, since the case will most likely not be in a condition to be interviewed. Use the MDPH Foodborne Illness Complaint Worksheet (found at the end of this chapter) to facilitate recording more information pertinent to foodborne transmission. Please call the MDPH Center for Environmental Health, Food Protection Program (FPP) at (617) 983-6712 for assistance in determining possible food sources. Use the following guidelines to assist in the investigation:

a. Identify all home-canned foods eaten during the week prior to symptoms. The most suspect foods are those eaten less than two days before onset and those that were not eaten by other well persons. Keep in mind that some cases may experience less severe symptoms with a later onset than the case.

b. Identify all commercially canned foods eaten during the week prior to the onset of illness. For implicated foods, determine the brand, manufacturer, package size, lot number, and place and date of purchase.

c. Identify all sausage and other preserved meats eaten during the week prior to onset of illness. Meat products that have not been adequately refrigerated are also suspect.

d. Identify all smoked or otherwise preserved fish eaten during the week before onset of symptoms.

e. Identify other potentially exposed persons. Other persons who have eaten implicated food must be reached as soon as possible and advised to seek health care immediately. Depending on the time of ingestion, other exposed persons might be candidates for treatment with purgatives, and at the very least, should be under close medical supervision.

   i. Obtain the name, address, and telephone number of every person who may have eaten the suspect food item.

   ii. Obtain the name, address, and telephone number of every person who may have the suspect home-processed food in his or her possession.

f. Remove implicated food items from the environment for testing. The FPP, at (617) 983-6712, will coordinate pick-up and testing of food samples. If a commercial product is suspected, the FPP will also coordinate follow-up with relevant outside agencies.

Wound botulism

No follow-up required.

Intestinal botulism

For infant cases, ask caretakers about honey consumption. Otherwise, extensive epidemiological follow-up is not usually required. Education should be provided regarding prevention.

4. Botulism Testing: In all suspect cases of botulism, a determination is made by the MDPH Division of Epidemiology and Immunization and the case’s health care provider, based on available clinical and epidemiological data, about the appropriateness of botulism testing. Arrangements will then be made for the submission of appropriate specimens.

5. Botulism Antitoxin: Antitoxin therapy is only administered to adult patients with foodborne or wound botulism. Antitoxin is a horse serum product and may cause serum sickness in approximately 20% of treated persons.
Antitoxin is not indicated in cases of infant botulism. The health care provider, in consultation with the MDPH Division of Epidemiology and Immunization, must determine the need for antitoxin therapy. The CDC must release and approve its use. If needed, antitoxin will be immediately flown into the nearest airport. The LBOH should be prepared to assist with logistical arrangements. The decision to administer antitoxin must be made immediately. The longer the wait to administer antitoxin, the less effective it will be. Since testing for the presence of toxin or bacteria in clinical specimens can take many days, the decision to administer antitoxin cannot wait for testing to confirm the intoxication.

6. Botulinal immune globulin (BIG): BIG is available for the treatment of intestinal botulism in infants under a Food and Drug Administration (FDA)-approved open-label investigational new drug (IND) license of the California Department of Health Services.

7. Institution of disease control measures is an integral part of case investigation. It is the responsibility of the LBOH to understand, and if necessary, institute the control guidelines listed in Section 4.

Section 4:

CONTROLLING FURTHER SPREAD

A. Isolation and Quarantine Requirements (*105 CMR 300.200*)

*Minimum Period of Isolation of Patient*
No restrictions.

*Minimum Period of Quarantine of Contacts*
No restrictions.

B. Protection of Contacts of a Case
None.

C. Managing Special Situations

*Reported Incidence Is Higher Than Usual/Outbreak Suspected*
Any case of botulism is considered an outbreak and must be investigated to determine the source of infection and the mode of transmission. See Section 3C for the proper response to a suspect or confirmed case of botulism.

*Note: Refer to the MDPH Foodborne Illness Investigation and Control Reference Manual for comprehensive information on investigating foodborne illness complaints and outbreaks. Copies of this manual have been made available to LBOH. It can also be located on the MDPH website in PDF format at www.mass.gov/dph/fpp/refman.htm. For the most recent changes to the Massachusetts Food Code, contact the FPP at (617) 983-6712 or through the MDPH website at www.mass.gov/dph/fpp.*

If a bioterrorist event is suspected, the MDPH and other response authorities will work closely with the LBOH and will provide instructions/information on how to proceed.
D. Preventive Measures

Personal Preventive Measures/Education

To avoid future exposures, recommend that individuals:

- Be educated about the proper time, pressure, and temperature required to destroy spores, if they are interested in home-canning and other preservation techniques. More information can be obtained from the FPP.
- Not open bulging containers and not eat or even “taste-test” foods with off odors.
- Not feed honey to children <1 year old.

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**ADDITIONAL INFORMATION**

The following is the formal CDC surveillance case definition for botulism. It is provided for your information only and should not affect the investigation or reporting of a case that fulfills the criteria in Section 2A of this chapter. (The CDC and the MDPH use the CDC case definitions to maintain uniform standards for national reporting.) For reporting to the MDPH, always use the criteria outlined in Section 2A.

*Note: The most up-to-date CDC case definitions are available on the CDC website at [www.cdc.gov/epo/dphp/casedef/case_definitions.htm](http://www.cdc.gov/epo/dphp/casedef/case_definitions.htm).*

**Laboratory Criteria For Diagnosis**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foodborne</td>
<td>Detection of botulinum toxin in serum, stool, or patient’s food, or isolation of <em>C. botulinum</em> from stool.</td>
</tr>
<tr>
<td>Infant</td>
<td>Detection of botulinum toxin in stool or serum, or isolation of <em>C. botulinum</em> from stool.</td>
</tr>
<tr>
<td>Wound</td>
<td>Detection of botulinum toxin in serum, or isolation of <em>C. botulinum</em> from a wound.</td>
</tr>
<tr>
<td>Other</td>
<td>Detection of botulinum toxin in a clinical specimen, or isolation of <em>C. botulinum</em> from a clinical specimen.</td>
</tr>
</tbody>
</table>
Confirmed Case Definition

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foodborne</td>
<td>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 (see Laboratory Criteria section for more information).</td>
</tr>
<tr>
<td>Infant</td>
<td>A clinically compatible case that is laboratory-confirmed occurring in a child aged &lt;1 year.</td>
</tr>
<tr>
<td>Wound</td>
<td>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 two weeks before onset of symptoms.</td>
</tr>
<tr>
<td>Other</td>
<td>A clinically compatible case that is laboratory-confirmed in a patient aged ≥1 year who has no history of ingestion of suspect food and has no wounds.</td>
</tr>
</tbody>
</table>

REFERENCES


CDC. Case Definitions for Infectious Conditions Under Public Health Surveillance. MMWR. 1997; 46(RR-10).


MDPH. Regulation 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements. MDPH, Promulgated November 4, 2005.


FORMS & WORKSHEETS

Botulism
LBOH Action Steps

This form does not need to be submitted to the MDPH with the case report form. It is for LBOH use and is meant as a quick-reference guide to botulism case investigation activities.

LBOH staff should follow these steps when botulism is suspected or confirmed in the community. For more detailed information, including disease epidemiology, reporting, case investigation, and follow-up, refer to the preceding chapter.

- Immediately notify the MDPH Division of Epidemiology and Immunization at (617) 983-6800 or (888) 658-2850 to report any suspect or known case(s) of botulism.
- Obtain laboratory confirmation.
- For foodborne botulism case(s), identify and remove any suspect food item(s).
- Submit suspect food(s) to the SLI for testing.
- Identify other potentially exposed persons.
- Fill out the case report form (attach laboratory results).
- Send the completed case report form (with laboratory results) to the MDPH Bureau of Communicable Disease Control, Office of Integrated Surveillance and Informatics Services (ISIS).