

Ontario Public Health Standards:  
Requirements for Programs, Services and Accountability

Infectious Disease Protocol

# **Appendix 1:**

## **Case Definitions and Disease-Specific Information**

### **Disease: Botulism**

Effective: May 2023

# Botulism

☒ Communicable

☐ Virulent

[Health Protection and Promotion Act \(HPPA\)](#)<sup>1</sup>

[Ontario Regulation \(O. Reg.\) 135/18 \(Designation of Diseases\)](#)<sup>2</sup>

## Provincial Reporting Requirements

☒ Confirmed case

☒ Probable case

☒ Suspect case

As per Requirement #3 of the “Reporting of Infectious Diseases” section of the *Infectious Diseases Protocol, 2018* (or as current), the minimum data elements to be reported for each case are specified in the following:

- [O. Reg. 569](#) (Reports) under the HPPA;
- The [iPHIS User Guides](#) published by Public Health Ontario (PHO); and
- Bulletins and directives issued by PHO.<sup>3,4</sup>

## Type of Surveillance

Case-by-case.

## Case Definition

### Confirmed Case

A confirmed case requires confirmatory laboratory evidence.

## Confirmed Case of Foodborne Botulism

Laboratory confirmation of intoxication with clinically compatible signs and symptoms:

- Detection of botulinum toxin in serum, stool, gastric aspirate or food;

**OR**

- Isolation of *Clostridium botulinum* (*C. botulinum*) from stool or gastric aspirate.

## Confirmed Case of Wound Botulism

Laboratory confirmation of infection with clinically compatible signs and symptoms:

- Detection of botulinum toxin in serum;

**OR**

- Isolation of *C. botulinum* from a wound;

**AND**

- Presence of a freshly infected wound in the 2 weeks before clinically compatible signs and symptoms **and** no evidence of consumption of food contaminated with *C. botulinum*.

## Confirmed Case of Intestinal/Colonization Botulism

Laboratory confirmation with clinically compatible signs and symptoms in a patient aged one year of age or older:

- Detection of botulinum toxin in stool or serum;

**OR**

- Isolation of *C. botulinum* from the patient's stool over a prolonged period of time or at autopsy.

## Confirmed Case of Infant Botulism

Laboratory confirmation with clinically compatible signs and symptoms in a person less than one year of age:

- Detection of botulinum toxin in stool or serum;

**OR**

- Isolation of *C. botulinum* from the patient's stool, or at autopsy.

## Probable Case

Clinically compatible signs and symptoms in a person with an epidemiologic link to a laboratory-confirmed case of foodborne botulism.

## Suspect Case

Clinical evidence strongly suggestive of botulism, as determined by a medical officer of health or attending physician, in the absence of laboratory confirmation or an epidemiologic link.

## Outbreak Case Definition

A single case of botulism, other than infant botulism, should be managed as if it was an outbreak (see Outbreak Management section). A single case of infant botulism does not need to be managed as such and should be managed as a sporadic case of botulism (see Case Management section). However, two or more cases of infant botulism should be managed as an outbreak.

The outbreak case definition varies with the outbreak under investigation. Please refer to the *Infectious Diseases Protocol, 2018* (or as current) for guidance in developing an outbreak case definition as needed.<sup>3</sup>

The outbreak case definitions are established to reflect the disease and circumstances of the outbreak under investigation. The outbreak case definitions

should be developed for each individual outbreak based on its characteristics, reviewed during the course of the outbreak, and modified, if necessary, to ensure that the majority of cases are captured by the definition. The case definitions should be created in consideration of the outbreak definitions.

Outbreak cases may be classified by levels of probability (*i.e.*, confirmed and/or probable).

## Clinical Information

### Clinical Evidence

**Foodborne/Wound/Intestinal:** Ingestion of botulinum toxin results in an illness of variable severity. Common symptoms are diplopia, blurred vision, bulbar weakness, dry mouth and difficulty swallowing and speaking. Descending and symmetric paralysis may progress rapidly, often requiring respiratory support.

**Infant:** Clinically compatible signs and symptoms in infants are characterized but not limited to the following: constipation, lethargy, loss of appetite, weakness, altered/weak cry, decreased gag reflex, ptosis, hypotonia and loss of head control.

### Clinical Presentation

For information on clinical presentations in case investigations refer to the Ministry of Health's (ministry) document [Botulism – Guide for Healthcare Professionals](#) (2022 or as current).<sup>5</sup>

There are three main forms of botulism depending on the mode of transmission: foodborne, wound, and intestinal (infant and adult) botulism. All forms cause flaccid paralysis as a result from the botulinum neurotoxin.<sup>6</sup>

Foodborne botulism is a severe intoxication resulting from ingestion of preformed toxin present in contaminated food. Most individuals develop the following symptoms: nausea, vomiting, diarrhea, constipation, fatigue, weakness, dizziness, blurred or double vision, dysphasia, and dry mouth may occur. Acute bilateral cranial nerve impairment and descending weakness or paralysis characterize the

illness. Most people recover if diagnosed and treated quickly, but recovery may take months and some have residual weakness.<sup>6,7</sup>

Wound botulism occurs when spores penetrate an open wound and produce the toxin in an anaerobic environment. Symptoms are similar to food borne botulism but may take up to two weeks to appear.<sup>6</sup>

Intestinal (infant and adult colonization) botulism occurs following spore ingestion, subsequent outgrowth and in-vivo toxin production in the intestine; it affects children under one year but can also affect adults who have altered intestinal microflora because of antimicrobial use or because of bowel abnormalities.<sup>6</sup> Clinical symptoms in infants include constipation, loss of appetite, poor suck, weakness, lethargy, altered cry, and a striking loss of head control known as “floppy head”.<sup>6</sup>

Other forms of botulism include iatrogenic and inhalational. Iatrogenic botulism is caused by accidental overdose of botulinum toxin that is injected for cosmetic or other indications (e.g. neuromuscular disorders). Inhalational botulism is the result of inhaling aerosolized botulinum neurotoxin. Clinical manifestations are similar to other forms of botulism.<sup>6</sup>

## Laboratory Evidence

### Laboratory Confirmation

Any of the following will constitute a confirmed case of botulism:

- Detection of botulinum toxin, with or without culture;
- Isolation of *C. botulinum* from stool or gastric aspirate.

### Approved/Validated Tests

- Standard culture for *C. botulinum* with demonstration of neurotoxin where neurotoxin is detected in culture supernatant using mouse bioassay.
- *C. botulinum* neurotoxin mouse bioassay.

## Indications and Limitations

- *C. botulinum* neurotoxin may not be detectable in serum. Administration of antitoxin prior to withdrawal of blood will result in a negative assay.
- Two other species of the genus, *Clostridium baratii* and *Clostridium butyricum*, may produce the neurotoxin and should be entered as a case.
- Culture without toxin assay by mouse bioassay is not useful. Group I *C. botulinum* cannot be distinguished from *Clostridium sporogenes* without toxin assay.
- Isolates and/or clinical specimens should be referred to Health Canada's National Botulism Reference Service in Ottawa.
- Enzyme immunoassay (EIA) for botulinum toxin is not as sensitive as the mouse bioassay and therefore should not replace the mouse bioassay for neurotoxin detection in clinical specimens; consideration should also be given to cultures using PCR targeted to detect the neurotoxin genes.

For further information about human diagnostic testing, contact the Public Health Ontario Laboratories or refer to the [Public Health Ontario Laboratory Services](#).

Identification of organisms in suspected food is helpful but not diagnostic because *C. botulinum* spores are ubiquitous. The diagnosis may be accepted in a person with the clinical syndrome who had consumed food incriminated in a laboratory-confirmed case.<sup>6</sup>

Diagnosis is made in collaboration with Health Canada's National Botulism Reference Service in Ottawa. The Botulism Reference Service office can be reached during working hours at 613-957-0902. Guidance on the collection and transportation of specimens to the national laboratory can be found in [Government of Canada's Botulism – Guide for Healthcare Professionals](#).

Also refer to the ministry's document [Botulism Guide for Healthcare Professionals](#) (2022 or as current).<sup>5</sup>

## Case Management

In addition to the requirements set out in the Requirement #2 of the “Management of Infectious Diseases – Sporadic Cases” and “Investigation and Management of Infectious Diseases Outbreaks” sections of the *Infectious Diseases Protocol, 2018* (or as current), the board of health shall investigate cases and suspected exposures in collaboration with the attending physician, PHO, the Botulism Reference Service (BRS) in Ottawa, as well as with the Public Health Agency of Canada (PHAC).<sup>3</sup> If required, notification of the Canadian Food Inspection Agency (CFIA) will be made in collaboration with the PHO and PHAC, as well as decisions for any other communication and or notification that are required.

Additional case follow-up may include:

- The collection of food histories 2-3 days prior to symptom onset (including: when consumed, where obtained);
- History of other risk behaviours or exposures (e.g. site and date of injury, illicit drug use);
- The collection of food samples of suspected sources of intoxication for laboratory analysis using appropriate media, sampling techniques and routine practices for the handling of suspect food; and

Coordinate food and clinical specimen collection (as appropriate), and communicate with the Botulism Reference Service in Ottawa at tel. # 613-957-0902. Guidance on the collection and transportation of specimens to the national Botulism Reference Service laboratory can be found in the [Government of Canada Botulism – Guide for Healthcare Professionals](#).

Botulism may also be used as a bioterrorism agent. If bioterrorism is suspected, the Provincial Emergency Operations Centre (PEOC) will be activated to coordinate and direct the province's response under the [Emergency Management and Civil Protection Act](#).<sup>8</sup>

**Note:** Given the potential for the appearance of botulism cases to signal a bioterrorism incident, investigation and follow-up may involve notification of law



enforcement. If tampering, sabotage, or bioterrorism is suspected, the health unit shall immediately notify their local police service and the Health System Emergency Management Branch (HSEMB) Health Care Provider Hotline at 1-866-212-2272.. A bioterrorism event would trigger activation of the provincial emergency operations centre, including the HSEMB of the ministry and relevant health emergency response plans, as well as those additional ministries with responsibilities for security, law enforcement, or other relevant areas of concern, as identified in the [Emergency Management and Civil Protection Act](#) and associated Order in Council. The [Ministry Emergency Response Plan \(MERP\)](#) provides information on how the ministry would respond to a health emergency.<sup>8,9</sup> Any requests for federal supplies of medical countermeasures for a botulism bioterrorism incident must be made through HSEMB. The Provincial Emergency Operations Centre (PEOC) can be contacted by email at [EOCOperations.MOH@ontario.ca](mailto:EOCOperations.MOH@ontario.ca).

## **Treatment:**

Immediate medical treatment is required; do not await laboratory confirmation. Although Emergent BioSolutions® Botulinum Antitoxin (BAT) is generally used for adult cases, there is a recommended dose for infants less than 1 year of age in the product monograph. Botulinum Antitoxin (BAT) can be accessed through the Office of the Chief Medical Officer of Health, Public Health during business hours by calling 416-327-7392. After-hours and on weekends and holidays please call the ministry's Health Care Provider Hotline at 1-866-212-2272.

BabyBig® is indicated for the treatment of infant botulism in infants under one year of age. BabyBig® is not approved for sale in Canada and is only available from the California Department of Public Health. Treating clinicians must obtain approval for use of BabyBig® through Health Canada's Special Access Programme (SAP). The ministry supports clinicians in the ordering and use of BabyBIG® due to the lack of evidence for use of BAT in infant cases as per the product monograph.

For more information on placing a request for BAT or BabyBIG® refer to the ministry's document [Botulism Guide for Healthcare Professionals](#) (2022 or as current).<sup>5</sup>

## Contact Management (foodborne botulism only)

Contacts are managed as part of the outbreak as per the *Infectious Diseases Protocol, 2018* (or as current).<sup>3</sup> People who are known to have eaten contaminated food or who have shared a likely exposure should be advised to consult with their health care provider for assessment and/or treatment.

## Outbreak Management

Please see the *Infectious Diseases Protocol, 2018* (or as current) for the public health management of outbreaks or clusters in order to identify the source of illness.<sup>3</sup>

Given the severity and rarity of botulism, one case of botulism (or two or more cases of infant botulism) should be treated as if it was an outbreak and should be **managed with great urgency** (with the exception of a single case of infant botulism, which should be managed as a sporadic case of botulism). Foodborne botulism outbreaks should be managed according to the [Ontario's Foodborne Illness Outbreak Response Protocol, 2020 \(ON-FIOP\)](#) (or as current); and will include the Botulism Reference Service and the attending physician(s) in order to handle the unique laboratory testing needs and urgency of a botulism outbreak.<sup>10</sup>

# Prevention and Control Measures

## Personal Prevention Measures

### Foodborne botulism:

- Practice safe food preparation and canning processes. For more information on safe home canning practices, please see Health Canada's website [Food Safety Tips for Home Canning](#).
- Refrigerate foods stored in oil (e.g. oils infused with garlic, herbs, and vegetables).
- Follow storage and shelf-life recommendations on food labels.
- Avoid consumption of canned or bottled foods that are dented, leaking or have bulging ends, or it is suspected they have been tampered with.<sup>11</sup>

### Wound botulism:

- Avoid injection of illicit drugs; and
- Seek prompt medical attention for infected wounds.<sup>12</sup>

### Infant botulism:

- Do not feed honey to infants less than one year of age.

## Infection Prevention and Control Strategies

Refer to [PHO's website](#) to search for the most up-to-date information on Infection Prevention and Control (IPAC).

## Disease Characteristics

**Aetiologic Agent** - Botulinum toxin is produced by *Clostridium botulinum* (*C. botulinum*), which is a gram-positive, spore-forming obligate anaerobic bacillus.<sup>6,13</sup>

**Modes of Transmission** - Foodborne botulism is transmitted by the ingestion of improperly prepared, stored or cooked food containing the toxin. The foods most

often implicated are lightly preserved foods (such as smoked and salted fish) and in inadequately processed, home-preserved foods (including fruits, vegetables, and herbs in oil) that are low in sugar, salt, and acid.<sup>6</sup>

Wound botulism results from contamination of traumatized tissue by *C. botulinum* spores that germinate and produce toxin inside the wound; spores may originate in soil.<sup>6</sup> The majority of wound botulism occurs among injection drug users who subcutaneously inject illicit drugs that may be contaminated with *C. botulinum* spores.<sup>12</sup>

Intestinal (infant and adult) botulism is typically associated with the ingestion of spores that germinate and produce toxin in the colon that may be present in sources including: soil, dust, unpasteurized honey, and peanut butter.<sup>6</sup>

**Incubation Period** – In foodborne botulism neurological symptoms usually appear within 12 to 36 hours after ingestion of contaminated food, or up to several days after eating contaminated food. The shorter the incubation period, the more severe the disease and the higher the case-fatality rate.<sup>6,13</sup>

For wound botulism, the incubation period is generally 4 to 14 days.<sup>6</sup>

The incubation period of intestinal botulism in infants is estimated to be up to 30 days, but for adults is unknown since the precise time of spore ingestion often cannot be determined.<sup>6</sup>

**Period of Communicability** - No instance of secondary person-to-person transmission has been documented despite excretion of *C. botulinum* toxin and organisms in the feces of intestinal (infant) and foodborne botulism cases.<sup>6</sup>

**Reservoir** - *C. botulinum* spores are ubiquitous in soil worldwide; are frequently recovered from agricultural products, including honey and produce, and are also found in dust, soil, marine sediments, and in the intestinal tract of animals, including fish,<sup>6</sup>

**Host Susceptibility and Resistance** - Susceptibility is general. Adults with anatomical or functional bowel abnormalities leading to altered intestinal flora (unintentionally altered by antibiotic treatment for other purposes) may be predisposed to intestinal botulism.<sup>6</sup> Injection drug users are more susceptible to

wound botulism.<sup>12</sup>

Please refer to [PHO's Reportable Disease Trends in Ontario](#) reporting tool and other reports for the most up-to-date information on infectious disease trends in Ontario.

For additional national and international epidemiological information, please refer to the Public Health Agency of Canada and the World Health Organization.

## Comments

- One case is considered an outbreak (except for infant botulism).
- Note that infants under the age of one can also be diagnosed with foodborne botulism if the illness is due to toxin in the food.
- Botulism toxin can be inhaled or ingested through water. These cases must also be reported.

## References

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## Case Definition Sources

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## Document History

Revision Date	Document Section	Description of Revisions
March 2022	Entire Document	New template. Appendix A and B merged. No material content changes.
March 2022	Epidemiology: Occurrence section	Removed.
March 2022	ICD Codes	Removed.

<b>Revision Date</b>	<b>Document Section</b>	<b>Description of Revisions</b>
March 2022	Entire document	Removed reference to the Botulism Reference Service having afterhours service and linked to Health Canada's guidance for specimen collection and transportation.
May 2022	Case Management	Addition of considerations when BabyBIG is requested for ordering through SAP.
May 2022	Treatment and Document History	Addition of considerations when BabyBIG is requested for ordering through SAP.
October 2022	Treatment and Document History	Addition of considerations when BabyBIG is requested for ordering through SAP.
March 2023	Bioterrorism	Addition of bioterrorism guidelines.
May 2023	Case Management	Addition of contact information.