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## 1.0 AUTHORITY

BC Public Health Act (2008). Available at  
[http://www.leg.bc.ca/38th4th/3rd\\_read/gov23-3.htm](http://www.leg.bc.ca/38th4th/3rd_read/gov23-3.htm)

## 2.0 GOAL

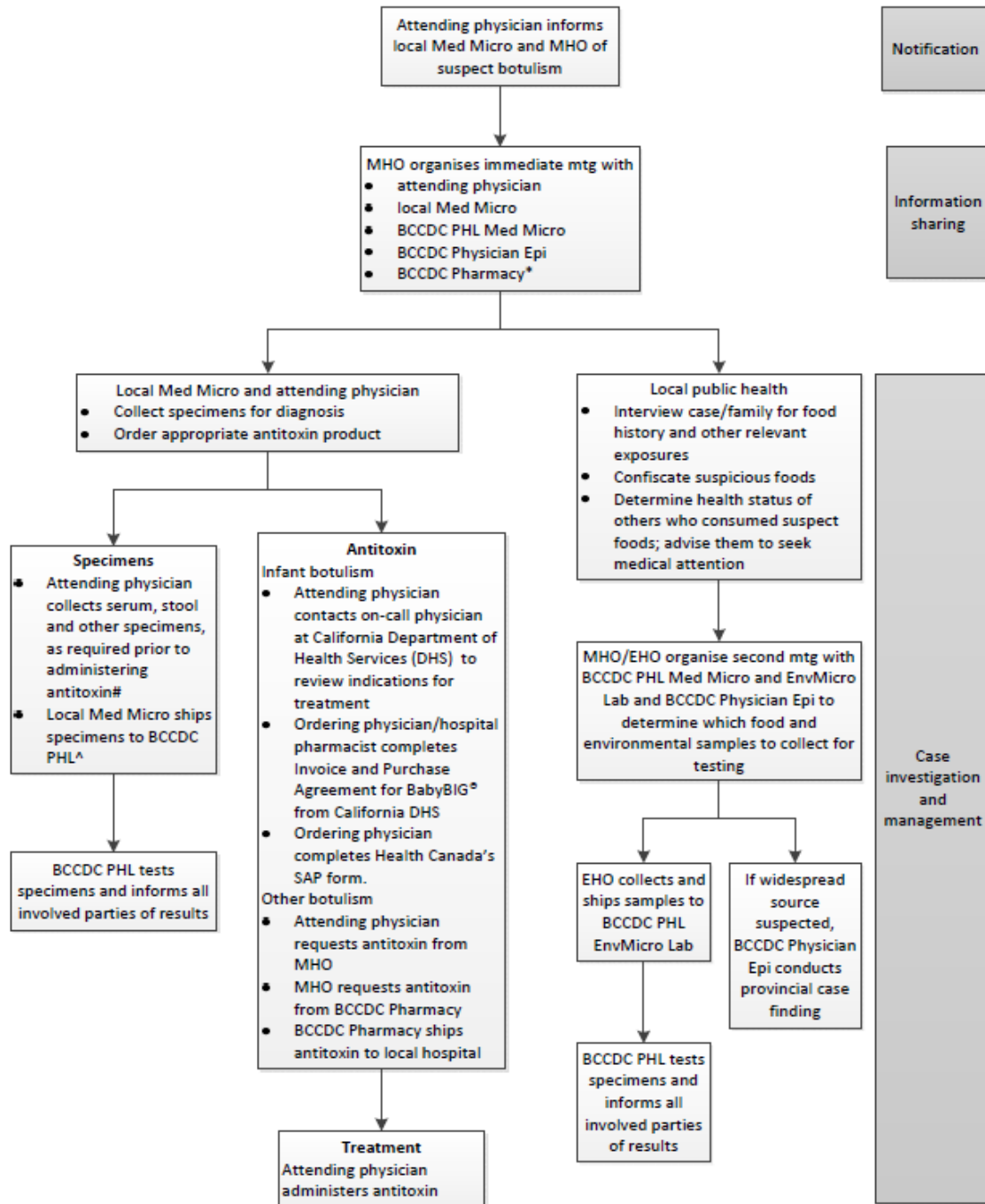
To prevent serious medical complications associated with botulism and to prevent further cases from occurring.

This will be accomplished by:

- Rapid and coordinated communication between clinicians, public health, pharmacy and laboratory,
- Rapid availability of antitoxin,
- Laboratory processes for testing of appropriate specimens,
- Prompt confiscation of food(s) felt to be implicated, especially foods eaten within the last two to three days,
- Medical consideration of other possible causes that could produce a similar symptomatology, and
- Meticulous supportive care, particularly respiratory and nutritional.

### 3.0 BOTULISM FLOW CHART

The flow chart describes public health actions to be taken when notified of a case of botulism.



\* If case is infant botulism, no need to involve BCCDC Pharmacy  
# Do not withhold antitoxin pending results  
^ If patient requires transfer from a remote site during weekend, local Med Micro and BCCDC Med Micro discuss optimal sample transport strategy

**4.0 CASE IDENTIFICATION**

**4.1 Confirm the diagnosis**

	<b>Definition</b>	<b>Reportable</b>
<b>Foodborne botulism</b>		
<b>Confirmed case</b>	Laboratory confirmation of intoxication with clinical evidence❶: <ul style="list-style-type: none"> <li>• Detection of botulinum toxin in serum, stool, gastric aspirate or food</li> <li style="text-align: center;">OR</li> <li>• Isolation of <i>C. botulinum</i> from stool or gastric aspirate</li> <li style="text-align: center;">OR</li> </ul> Clinical evidence❶ and indication that the client ate the same suspect food as an individual with laboratory-confirmed botulism.	Yes
<b>Probable case</b>	Clinical evidence❶ AND Consumption of a suspect food item in the incubation period (12 – 48 hours)	Yes
<b>Wound botulism</b>		
<b>Confirmed case</b>	Laboratory confirmation of infection: <ul style="list-style-type: none"> <li>• Detection of botulinum toxin in serum</li> <li style="text-align: center;">OR</li> <li>• Isolation of <i>C. botulinum</i> from a wound</li> <li style="text-align: center;">AND</li> </ul> Presence of freshly infected wound in the 2 weeks before symptoms and no evidence of consumption of food contaminated with <i>C. botulinum</i>	Yes
<b>Infant botulism</b>		
<b>Confirmed case</b>	Laboratory confirmation with symptoms compatible with botulism❷ in a person < one year of age: <ul style="list-style-type: none"> <li>• Detection of botulinum toxin in stool or serum</li> <li style="text-align: center;">OR</li> <li>• Isolation of <i>C. botulinum</i> from the patient's stool, or at autopsy</li> </ul>	Yes
<b>Adult colonization botulism</b>		
<b>Confirmed case</b>	Laboratory confirmation with symptoms compatible with botulism❶ in a patient ≥ one year of age with severely compromised gastrointestinal tract functioning (i.e., abnormal bowel) due to various diseases such as colitis, or intestinal bypass procedures, or in association with other conditions that may create local or widespread disruption in the normal intestinal flora: <ul style="list-style-type: none"> <li>• Detection of botulinum toxin in stool or serum</li> <li style="text-align: center;">OR</li> <li>• Isolation of <i>C. botulinum</i> from the patient's stool, or at autopsy</li> </ul>	Yes

❶Clinical evidence of foodborne botulism includes: blurred vision; dry mouth and difficulty swallowing and speaking; and descending symmetric paralysis that may progress rapidly.

❷Clinical evidence of infant botulism includes: constipation; loss of appetite; altered cry; and loss of head control.

## 5.0 CASE MANAGEMENT

### 5.1 Notification and Information Sharing

When botulism is suspected, the attending physician or local medical microbiologist should immediately inform the local Medical Health Officer (MHO).

The MHO will coordinate a brief meeting as soon as possible with the local Medical Microbiologist and attending physician as well as the BCCDC Medical Microbiologist, Physician Epidemiologist and pharmacist, if applicable. The objective is to coordinate next steps required for rapid diagnosis, access to antitoxin and initiation of the public health investigation. The diagnostic work-up of the patient and treatment details are not in scope. The partners will also establish a process for ongoing communication.

See [Appendix 1](#) for contact information.

- BCCDC Pharmacy is not involved in the case of infant botulism treated with BabyBIG which is obtained directly from the California Department of Health.
- BCCDC Pharmacy must consult with BCCDC Physician Epidemiologist or Physician On-Call prior to releasing botulism antitoxin for use in non-infant cases.
- The local MHO and Medical Microbiologist must consult with the BCCDC Medical Microbiologist to discuss specimens required and shipment for testing.
- The First Nations Health Authority will be invited to participate if the suspect case is Indigenous.

### 5.2 Laboratory investigation

The MHO, local Medical Microbiologist and other attending physician should discuss testing with the BCCDC Public Health Laboratory (PHL) Medical Microbiologist early to ensure ordering of mice for the bioassay as well as adequate and rapid shipment of specimens to the BCCDC PHL Environmental Microbiology Program. This can occur during the initial coordination meeting or beforehand.

Lab requisition forms can be obtained from the eLab Handbook at <http://www.elabhandbook.info/PHSA/Default.aspx> . Indicate Botulism Testing, STAT and “Attention: Frankie Tsang” on all associated requisitions.

Collect the following specimens: (\*= preferred specimen):

- **Foodborne botulism**
  - 15 mL of serum for toxin bioassay (within 3 days of ingestion of suspect food)\*
  - 25 - 50 gm of stool for culture and toxin bioassay\*
  - 100 mL of vomitus or gastric aspirate for culture and toxin bioassay
  - 200 gm of suspect foods for culture and toxin bioassay
  
- **Wound botulism**
  - wound exudate for culture\*
  - 15 mL serum for toxin bioassay
  
- **Infant botulism**
  - Send all available stool; 25 gm of stool or enema (without preservatives) for culture and toxin bioassay is preferred (pooled stool or enema samples are also acceptable)\*
  - 200gm of suspect food
  - At least 3 mL of serum for toxin bioassay (toxin rarely found in serum in infant cases); 10-30 mL of serum is preferred
  
- **Adult colonization botulism**
  - At least 25 gm of stool for culture and toxin bioassay
  - 15 mL of serum for toxin bioassay
  
- **Fatal case**
  - autopsy material (especially liver and contents of gut), at least 100gm

In some situations, other specimens may be collected and tested (e.g., food or environmental specimens in cases of infant botulism). Further information on botulism testing is available in the eLab Handbook at <http://www.elabhandbook.info/PHSA/Default.aspx>

### 5.3 Treatment

**Collect serum for identification of specific toxin prior to administering antitoxin.**

If wound botulism: debride wound, establish drainage, and give antibiotics. Antibiotics are not effective against toxins but may be used to treat secondary infections.

### ***Botulism Antitoxin***

**Initiate treatment as soon as possible. Do not wait for laboratory confirmation if clinical suspicion is strong.** Antitoxin cannot reverse the effects of the disease but can prevent further paralysis, and prompt treatment is associated with significant reductions in length of ICU and hospital stay.

BabyBIG® is a human plasma derived product and may be the preferred product for treatment of infant cases caused by types A and B. BAT Botulism Antitoxin Heptavalent is indicated for use in all age groups; it is indicated for infants when botulism is not due to types A or B. Details on availability of these products is contained in the product-specific sections below.

#### **5.3.1 Botulism Immune Globulin, IV (BIG-IV); (BabyBIG®) for treatment of infant cases of botulism due to type A or B**

BabyBIG® is not approved for use in Canada and is not stocked at BCCDC. The use of BabyBIG® in Canada must be approved through the Special Access Program, Health Canada. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada for the treatment patients with serious or life-threatening conditions.

The treating physician must complete the Special Access Request Form A available here:

<http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-droques/index-eng.php>

and submit by fax immediately (613) 941-3194. To avoid delays, all sections of the form must be completed accurately and it is recommended to follow-up with a phone call to the SAP office at (613) 941-2108 (24/7 line). If the case presents on a weeknight, weekend or holiday, the SAP on-call officer can be reached by telephone at this same telephone number (press 2). The treating physician should be prepared to provide the information required on the SAP Request Form to the on-call officer. Following administration of BabyBIG®, reporting of use must be submitted to Health Canada using Follow-up Form C at the same web link shown above.

The SAP will authorize the California Department of Health Services to ship the BabyBIG® to the hospital. The treating physician must contact the on-call physician at California State Health Department, available 24 hours, 7 days a week, year round, at (510) 231-7600, to obtain the product. The attending physician may also call this resource in advance of making a decision to treat if they wish to discuss indications for treatment.

Alternately, the attending physician can arrange to transfer the patient to the closest US hospital that has the capability to administer BabyBIG®.

Human-derived botulism immune globulin (BabyBIG®) is indicated in infant botulism cases caused by type A or B, the neurotoxins most implicated in infant botulism. BabyBIG® is indicated and provided only for treatment of infants under one year of age.

BabyBIG® is derived from pooled adult plasma from persons immunized with pentavalent botulinum toxoid who have high titres of antibody against neurotoxins type A and B. In laboratory-confirmed infant botulism cases, BabyBIG® neutralizes circulating A and B toxins and so decreases the duration of hospitalization, mechanical ventilation, and tube feedings.

The BabyBIG® dose is 1.0 mL/kg (50 mg/kg), given as a single intravenous infusion. The product monograph for BabyBIG® which contains additional details required for use and safety is available at

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm089339.htm>

The antibodies present in BabyBIG® may interfere with the infant's response to live vaccines. For more information regarding the recommended interval between receipt of BabyBIG® and administration of live vaccines, refer to the BC Communicable Disease Control Manual, Chapter 2, [Immunization](#), Part 1 – Immunization Schedules.

### **5.3.2 BAT, Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G) – (Equine) Sterile solution or injection, Emergent Biosolutions (formerly Cangene Corporation) (for individuals of all ages)**

A limited supply of the heptavalent product is stored at BCCDC in Vancouver; the release of this product can be secured by contacting the BCCDC on-call clinician who will authorize the BCCDC pharmacist to release and ship the product to the hospital.

The heptavalent product is **equine-derived** and made from equine plasma. It is approved for use in all age groups. Prior to administering this product, assess whether the patient is at increased risk of a hypersensitivity reaction to equine protein (i.e., history of previous allergic reaction to equine protein, history of repeated use of antitoxin products). Consider skin sensitivity testing for such patients prior to administration of the treatment dose and concurrent administration of a medication to treat anaphylactic shock. Increased risk of allergic reaction is not a contraindication to administration of botulism antitoxin.

The treating physician/ hospital must comply with reporting requirements on the use of the product back to BCCDC.



This heptavalent product is for serotypes A, B, C, D, E, F and G antitoxin. Each single-use vial, regardless of size or fill volume, contains a minimum potency of:

- 4,500 Units (U) for serotype A antitoxin
- 3,300 U for serotype B antitoxin
- 3,000 U for serotype C antitoxin
- 600 U for serotype D antitoxin
- 5,100 U for serotype E antitoxin
- 3,000 U for serotype F antitoxin
- 600 U for serotype G antitoxin

Dosage by age is recommended in the product monograph for three age groups: infants < 1 year old, 1 to 16 years of age, and 17 years and older.

Refer to the product monograph for details of dosing and administration including Pediatric Dosing Guide for BAT based on Salisbury Rule:

<https://emergentbiosolutions.com/sites/default/files/inline-files/BAT%20Product%20Monograph%20-%20English.pdf>

The product is given intravenously by slow infusion after dilution 1:10 in normal saline.

### 5.3.3 Antibiotics

**Antibiotics** are not recommended in the treatment of botulism. Lysis of *C. botulinum* theoretically could increase the amount of toxin available for absorption. Aminoglycoside agents potentiate the paralytic effects of the toxin and should be avoided.

## 6.0 OUTBREAK MANAGEMENT

In foodborne botulism, one case is considered an outbreak. Infant botulism outbreaks rarely occur.

Early ascertainment and notification of the BCCDC of the potential for more cases is needed in order to secure sufficient inventory of antitoxin. The provincial supply is sufficient only for sporadic cases.

Search for potential food sources, collect for testing, and discard any remaining suspect foods.

Conduct active case finding for other people who may have eaten the suspect food. No isolation or quarantine of cases is necessary.

The Botulism Follow-Up Form may be used to assist with outbreak management. The form is available at [http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Forms/Epid/Enterics/Botulism\\_Case\\_Report\\_Form.pdf](http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Forms/Epid/Enterics/Botulism_Case_Report_Form.pdf)

## 7.0 FOOD SOURCE INVESTIGATION

### 7.1 Authorisation and process for testing of suspect foods

All food testing must be discussed with, and approved by, the BCCDC PHL Medical Microbiologist.

Prior to sampling and testing, a brief meeting should be held between the MHO, EHO, BCCDC PHL and BCCDC Physician Epidemiologist to plan appropriate food testing. See [Appendix 1](#) for contact information.

Use gloves when confiscating or collecting food. Collect 200gm of each of the suspect foods for culture and toxin bioassay. Put sample in sterile container and complete all parts of the BCCDC PHL Environmental Microbiology requisition form from the eLab Handbook at <http://www.elabhandbook.info/PHSA/Default.aspx>.

### 7.2 Foodborne botulism

Investigate the case's food source with particular attention to foods eaten within the two or three days prior to symptom onset. In recent years in BC, foods having led to botulism include home canned, preserved or fermented foods. Use the botulism surveillance form as a guide.

Confiscate **all** suspicious foods in order to prevent other cases. Hold them until testing is determined.

Determine the health status of other household members and other individuals who may have consumed the suspected food. Advise other individuals who may have consumed the suspected food to seek medical attention immediately.

### 7.3 Infant botulism

Infant botulism occurs in infants with immature digestive tracts exposed to *C. botulinum* spores which sporulate in the gut. Sources of spores include contaminated soil or dust and solid foods or formula. The only food which has been implicated in several infant botulism cases is honey.

Most infants are exposed to botulism spores on a regular basis but only a few develop illness. In the majority of cases, it will be difficult to implicate a specific source and laboratory testing is rarely successful.

## 8.0 MANAGEMENT OF CONTACTS AND PERSONS WHO CONSUMED THE SAME SUSPECT FOODS

People who are known to have eaten from incriminated food should be purged with cathartics, given gastric lavage and high enema. **Note:** these measures should not be used for infant botulism.

Ensure these people are kept under close medical supervision.

Educate regarding safe practices in food preparation and home canning methods.

Despite excretion of *C. botulinum* toxin and organisms at high levels in the feces of infant and adult colonization botulism patients for weeks to months after onset of illness, no instance of secondary person to person transmission has been documented. Hence, isolation is not required.

### 8.1 Management of other persons who consumed the same sources of suspect foods

Immunoprophylaxis for asymptomatic people who have consumed the same food as an individual with botulism or food with probable or confirmed botulism toxin contamination is not recommended; the available products have not been licensed for this use and there is risk of serum sickness and hypersensitivity reactions associated with equine serum antitoxin administration (AAP 2018).

Attempts may be made to remove contaminated food still in the gut by inducing vomiting or by use of enemas.

Symptom watch and rapid management of symptomatic exposed people are recommended.

## 9.0 REPORTING

Report the case to BCCDC immediately (the same day) to arrange the shipment of antitoxin. Report the case(s) of botulism in the electronic public health information system within one business day.

Complete the BC Botulism Follow-Up Form available at [http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Forms/Epid/Enterics/Botulism\\_Case\\_Report\\_Form.pdf](http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Forms/Epid/Enterics/Botulism_Case_Report_Form.pdf) and within Panorama.

The physician prescribing BabyBIG® must complete Health Canada's Special Access Program form available at: [http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-droques/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-droques/index_e.html)

## 10.0 CLINICAL DESCRIPTION

Botulism is a severe neuromuscular disorder caused by toxins A through F produced by *Clostridium botulinum*. Types A, B, E, and rarely F cause human botulism. There are four clinical forms of botulism: foodborne, wound, infant, and adult colonization. The site of toxin production is different for each of the forms but all share the symmetrical descending flaccid paralysis that results from botulinum neurotoxin. No immunity develops even following severe disease.

**Foodborne botulism:** This is a severe intoxication resulting from ingestion of preformed toxin present in contaminated food.

Acute bilateral cranial nerve impairment and descending weakness or paralysis characterizes the illness. Visual difficulty (blurred or double vision), dysphagia and dry mouth are often the first complaints. These symptoms may extend to a symmetrical flaccid paralysis in a paradoxically alert person. Vomiting and constipation or diarrhea may be present initially. Fever is absent unless a complicating infection occurs. The case-fatality rate is 5% - 10%. Recovery may take months.

**Wound botulism:** This form occurs when botulism spores get into an open wound and reproduce in an anaerobic environment. Symptoms are similar to the foodborne form but may take up to 2 weeks to appear. Clinical illness is characterized by double or blurred vision and bulbar weakness. Symmetric paralysis may progress rapidly.

**Infant botulism:** This form occurs when botulism spores are ingested, germinate in the gut and release toxin. It affects infants younger than one year of age and often occurs around the time of introduction of solid foods. The majority of cases occur in infants under the age of 6 months. It is preceded by or begins with constipation and is manifested as lethargy, poor feeding, weak cry, cranial nerve palsies (diminished gag reflex, ptosis and ocular palsies), progressive descending generalized weakness, hypotonia and hypoventilation. Respiratory arrest and death can occur. It is nearly always caused by botulism toxin type A or B. For more information about infant botulism, refer to <http://www.infantbotulism.org/>

**Adult colonization botulism:** This form affects older children and adults who have altered GI anatomy or function and microflora which allows the germination of ingested *C. botulinum* spores. It is very rarely encountered. Clinical presentation is similar to foodborne botulism. Recurring symptoms and relapse during antitoxin treatment may be observed due to ongoing intraluminal production of toxin.

## 10.1 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 canned food (vegetables and fruits), home preserved foods, smoked fish, fermented fish eggs and seal meat.

**Wound botulism** results from contamination of traumatized tissue by *C. botulinum* that grows in the wound and produces toxin locally. It occurs almost exclusively among injection drug users, particularly users of black tar heroin through “skin-popping” (i.e., injection of the black tar heroin into tissues, as opposed to veins).

**Infant and adult colonization botulism** result from ingestion of spores that germinate and produce toxin in the gut. Although most infants are exposed to botulism spores, only a minority develop infant botulism which may be due to a perturbation in the immature gut flora. Ingestion of honey is a known risk factor for infant botulism but only accounts for a small proportion of cases. Other foods like herbal tea and ingestion of contaminated soil or dust in an environment where soil/dust is being disturbed may also be sources.

Inhalational (through intentional or accidental release) and iatrogenic (through therapeutic uses) botulism can also occur, but extremely rarely.

## 10.2 Incubation periods

**Foodborne botulism:** neurologic symptoms usually appear within 12-36 hours, but may range from 6 hours to 8 days. The shorter the incubation period, the more severe the disease and the higher the case-fatality rate.

**Wound botulism:** onset of symptoms usually occurs 4-14 days after injury.

**Infant botulism:** cannot be determined for most cases but believed to be 3-30 days from the time of exposure to the spore-containing material.

**Adult colonization botulism:** unknown since the precise time of spore ingestion is often unknown.

## 11.0 EPIDEMIOLOGY

Between 2009 and 2018 in BC, there were 0-2 botulism cases reported per year for a total of 7 cases in this 10 year time period. Four were cases of infant botulism with no source identified and the other three were adults who had consumed suspect or contaminated foods.

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### 13.0 APPENDIX 1

Contact information for botulism investigation and management

<b>Contact</b>	<b>Daytime</b>	<b>After hours</b>
BCCDC Medical Microbiologist on call	604-661-7033	
BCCDC Public Health Lab Environmental Microbiology Program	604-707-2620	
BCCDC Physician Epidemiologist	604-707-2510	604-875-2161
BCCDC Pharmacy	604-707-2582	604-875-2161
California Department of Health		510-231-7600
Health Canada Special Access Program		613-941-2108