Health Canada Santé Canada

Botulism- Guide for healthcare professionals

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Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre :
Botulisme–Guide pour les professionnels de la santé

To obtain additional information, please contact:

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Address Locator 0900C2
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Healthcare workers should notify local and/or provincial public health authorities when a case of botulism is suspected. The *Botulism - Guide for Healthcare Professionals* document is for use by healthcare workers and facilities/organizations providing healthcare including hospitals and hospital pharmacies, community-based healthcare service providers and pre-hospital emergency services. The Botulism Reference Service for Canada receives specimens for testing from hospital and provincial laboratories.

Contact information

Botulism Reference Service for Canada:
Laboratory 613-957-0885 weekdays from 8:00 a.m. to 4:00 p.m.
Consultation for testing of clinical or food samples 613-296-1139 Weekdays from 8:00 a.m. to 4:00 p.m.

Samples must be received Monday to Friday between 9:00am and 4:00pm. Do not submit specimens that may arrive on a weekend or holiday, or after regular working hours

Please print and complete the BRS requisition for diagnostic tests and include it in your sample's shipment.

Please ship samples by courier to:

Botulism Reference Service
Health Canada, Banting Research Centre
251 Sir Frederick Banting Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9
Special Access Programme: 613-941-2108

Please provide us with your tracking number by phone as soon as shipment is confirmed.

It is the sender's responsibility to ensure the samples arrive at the correct location. Since some air couriers only ship as far as the Ottawa airport, you may be required to arrange for a courier company to pick up the samples from the airport and deliver them to our facility.

Botulism is a rare neuroparalytic disease caused by a neurotoxin that is produced by the bacterium *Clostridium botulinum*. Botulism develops if a person ingests the toxin or if the organism grows in the intestines or wounds and toxin is released. There are four main forms of botulism: foodborne, infant, adult intestinal colonization and wound.

Foodborne botulism results from the ingestion of preformed neurotoxin in food or drink. In foodborne botulism, symptoms generally begin 12 to 36 hours after eating contaminated food, but can also occur as early as six hours or as late as 10 days. Symptoms may initially include vomiting and/or diarrhea and are followed by one or more of: ptosis (drooping of eyelids), visual disturbance, dilated and fixed pupils, dysphagia (difficulty in swallowing), dry mouth and dysphonia (difficulty speaking). These symptoms may extend to a descending symmetrical flaccid paralysis in an alert afebrile person. Constipation is a common symptom later in presentation. The case-fatality rate is approximately 5%.

Infant botulism affects infants under the age of one with most cases occurring between six weeks and six months old. This form of botulism results from ingestion of spores that germinate in the intestine and produce bacteria that release toxin. Clinical symptoms start with constipation and may include loss of appetite, generalized weakness, weak cry, weak suck, ptosis, sluggishly reactive pupils, disconjugate gaze, blunted facial expression, drooling, decreased anal sphincter tone, hypotonia and a significant loss of head control.

Adult intestinal colonization botulism results when *C. botulinum* germinates and produces toxin in the digestive system. This form of botulism affects adults who have altered gastrointestinal anatomy and microflora caused by a previous history of intestinal surgery, inflammatory bowel disease, or exposure to antimicrobial agents. The symptoms observed are similar to foodborne botulism.

Wound botulism results when a wound becomes infected with *C. botulinum* and toxin is produced. The incubation period for wound botulism is longer, averaging about 10 days. This form of botulism exhibits similar symptoms as foodborne botulism (except there is no vomiting and/or diarrhea). The presence of a wound is also useful to note. Wound botulism cases may result from contamination of wounds by soil or gravel, or injection of illicit intravenous drugs.

Laboratory confirmation

Laboratory confirmation of foodborne botulism is made by demonstration of botulinum toxin in serum, stool, gastric aspirate or incriminated food, or isolation of *C. botulinum* from stool or gastric aspirate. Identification of organisms in a suspected food is helpful but not diagnostic because *C. botulinum* spores are ubiquitous in the environment. Individuals may be diagnosed with foodborne botulism if they consumed a food item linked to a laboratory confirmed botulism case. The diagnosis of intestinal botulism is established by identification of *C. botulinum* organisms and/or toxin in a patient's feces over an extended period of several days or weeks, combined with the lack of a toxic food. Wound botulism is diagnosed by evidence of

a wound combined with detection of toxin in serum or isolation of *C. botulinum* from a wound culture. Differential diagnoses of botulism include Guillain-Barré syndrome, stroke, and myasthenia gravis.

Federal support

The management of a suspected botulism case involves healthcare professionals, and provincial and federal public health officials. The federal management involves Health Canada's Botulism Reference Service (BRS) for Canada and may involve the Health Canada Special Access Programme (SAP).

The BRS for Canada, established in 1974, provides the following support:

- Assists physicians and Provincial Departments of Health when botulism is suspected;
- Examines suspect foods and clinical specimens submitted by hospital and provincial laboratories for analysis;
- Rapidly alerts responsible agencies when commercial foods are involved;
- Maintains reference cultures of *C. botulinum*; and
- Liaises with centres that have similar interests and responsibilities in Canada and abroad.

The SAP considers requests for non-marketed drugs from practitioners treating patients with serious and/or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada.

The procedure for healthcare workers and facilities/organizations providing healthcare, varies between provinces. Please check with the office of the Chief Medical Officer of Health for the provincial reporting requirements.

Laboratory investigation

The following provides information on submitting laboratory specimens to the BRS in Ottawa. A member of the BRS may be contacted when a case of botulism is suspected to:

- Discuss the clinical presentation of the suspect case of botulism in order to support the diagnosis; and
- Make arrangements for transporting suspect food and clinical specimens to Ottawa for laboratory analysis.

Clinical specimens must be obtained prior to administering botulism antitoxin. Food samples may be leftovers or unopened containers. For commercial foods, retrieve the label, the manufacturer's lot number, codes embossed on the can or package, etc.

Suitable clinical specimens for analyses include:

- Faecal samples (approximately 10 g if available);
- Enema fluid;
- Gastric contents (adjusted to approximately pH 6.0 with 1N NaOH, if possible);
- Serum (from 20 ml of blood collected before administration of antitoxin); and
- For suspected infant botulism, the essential material for analysis is the infant's faeces. As constipation is a common symptom, the soiled parts of diapers, a rectal swab, 2 ml of serum or a combination of samples may be submitted if necessary.

After collecting the sample, but prior to shipping, ensure the sample is kept in a refrigerator at 4°C. Ship specimens in a watertight primary receptacle, in a watertight secondary container, with sufficient absorbent material between the two containers to absorb the entire contents of the primary receptacle[1]. The preferred method of preserving the material is by cooling rather than freezing (i.e., by including commercial cooling packs in the parcel). Please print and complete the BRS requisition for diagnostic tests and include it in your sample's shipment. After the specimen is shipped, inform BRS of the expected delivery time. See the contact information at the beginning of this document.

Botulism antitoxin

Therapeutic botulism antitoxin is approved for treatment of cases of botulism in Canada.

- BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)] made by Emergent BioSolutions Canada Inc. (formerly Cangene Corporation)

The therapeutic antitoxin specifically for infant botulism is not approved for use in Canada and is currently only available via the SAP.

- BabyBIG®, Botulism Immune Globulin Intravenous (Human) (BIG-IV) for pediatric patients under the age of one year, accessed from the Infant Botulism Treatment and Prevention Program (IBTPP) at the California Department of Public Health (CDPH).

The BAT ® product is kept on hand throughout the country, either at a provincial depot or by the Public Health Agency of Canada's National Emergency Stockpile System (NESS).

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[1]Samples that may contain botulinum neurotoxin and/or viable organisms (including spores) should be shipped using the Transportation of Dangerous Goods instruction TC-125-1B.

Should BabyBIG® be required, it must be requested on a per patient basis from the California Department of Health Services Infant Botulism Treatment and Prevention Program at 510-231-7600.

The producers of BabyBIG® do not permit pre-orders of their product; therefore, the requesting physician must also submit a request with the SAP to gain access:

- The physician must complete a SAP request form - FORM A and fax it immediately to 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.
- If a case presents on a weeknight, weekend or holiday, the SAP on-call officer can be reached by telephone at 613-941-2108 (press 0). The requesting physician should be prepared to provide the information from the form to the on-call officer and then follow-up on the next business day with a copy the completed form. The SAP will authorize the California Department of Health Services to ship BabyBIG® to the hospital.

The SAP will then authorize the California Department of Health Services to ship the BabyBIG® to the hospital.

References

- Ontario - Ministry of Health and Long-Term Care Staff, Public Health Division
- Canada's Food-borne Illness Outbreak Response Protocol (FIORP) 2010: To guide a multi-jurisdictional response