Notification Timeline:

From Lab/Practitioner to Public Health: Immediate.

From Public Health to Ministry of Health: Within 24 hours.

Public Health Follow-up Timeline: Immediate.

Public Health Purpose for Notification of Botulism

- To minimize mortality and serious morbidity from botulism through timely access to botulism antitoxin
- To identify the risk to the public through source identification;
- To monitor the effectiveness of food safety programs;
- To make timely and evidence informed actions on outbreaks; and
- To support the communication to the public and medical community about risks of botulism.

Information

A confirmed case requires laboratory definitive evidence with clinical evidence **or, in the case of foodborne botulism,** clinical evidence and consumption of the same suspect food as an individual who has laboratory-confirmed botulism.

Table 1. Surveillance Case Definition[1] (Public Health Agency of Canada, 2008**)**

Confirmed Foodborne Botulism[1] (Either 1 or 2)	1. Laboratory confirmation of intoxication with clinical evidence:[1] • detection of botulinum toxin in serum, stool, gastric aspirate or food **OR** • isolation of *Clostridium botulinum* from stool or gastric aspirate. 2. Clinical evidence[1] and indication that the client ate the same suspect food as an individual with laboratory-confirmed botulism.

[1] Surveillance case definitions ensure uniform reporting to allow comparability of surveillance data. The definition is not intended to be used for clinical or laboratory diagnosis or management of cases.

Confirmed Wound Botulism[2]	Laboratory confirmation of infection: • laboratory 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 symptoms and no evidence of consumption of food contaminated with *C. botulinum.*
Confirmed Infant Botulism[3]	Laboratory confirmation with symptoms[3] compatible with botulism 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.
Confirmed Colonization Botulism	Laboratory confirmation with symptoms compatible with botulism in a patient aged 1 year or older 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: • detection of botulinum toxin in stool or serum **OR** • isolation of *C. botulinum* from the patient's stool or at autopsy.
Probable Case Foodborne Botulism	A probable case requires clinical evidence[1] and consumption of a suspect food item in the incubation period (12-48 hours).

Clinical Evidence

[1]**Foodborne:** Clinical illness is characterized by blurred vision, dry mouth and difficulty swallowing and speaking. Descending and symmetric paralysis may progress rapidly, often requiring respiratory support.

[2]**Wound:** Clinical illness is characterized by diplopia, blurred vision and bulbar weakness. Symmetric paralysis may progress rapidly.

[3]**Infant:** Clinical illness in infants is characterized by constipation, loss of appetite, weakness, altered cry and loss of head control.

Epidemiology and Occurrence

Under Construction

Additional Background Information

Causative Agent

The causative agent is *Clostridium botulinum* which is a spore-forming bacterium. It is a Gram-positive anaerobic bacillus. There are several strains of *C. botulinum* classified into types A-G based on the properties of the toxin formed. Most human cases of botulism are caused by types A, B, E and rarely F (Heymann, 2008).

Symptoms

Botulism is a severe neuroparalytic progressive disorder caused by the toxins produced by *Clostridium botulinum* (Heymann, 2022).

- The characteristic early symptoms and signs are marked fatigue, weakness and vertigo, usually followed by ptosis (drooping of eyelids), blurred or double vision, dry mouth, and difficulty in swallowing and speaking.
- Neurological symptoms always descend through the body: shoulders are first affected, then upper arms, lower arms, thighs, calves, etc. Paralysis is symmetric and may progress rapidly, often requiring respiratory support.
- Nausea, vomiting, constipation and abdominal swelling, and less commonly diarrhea, may occur.
- Symptoms of classic infant botulism (predominates in infants less than 6 months but can occur up to 12 months or age) include constipation followed by decreased movement, loss of facial movements and head control, poor feeding, weak cry, diminished gag reflex, ocular palsies, and progressive descending generalized weakness and decreased muscle tone (American Academy of Pediatrics, 2018).

Incubation Period

- The shorter the incubation period, the more severe the disease and the higher the case-fatality rate (Public Health Agency of Canada, 2011).
- Foodborne botulism: Neurological symptoms usually appear within 12 to 72 hours, but onset can range from 2 hours to 8 days after eating contaminated food (Heymann, 2022).

- Infant botulism: 3 to 30 days from the time of ingestion of spores (American Academy of Pediatrics, 2018).
- Wound botulism: incubation period is 4 to 14 days from time of injury until onset of symptoms (Heymann, 2022).

Reservoir/Source

- *C. botulinum* spores are ubiquitous in soil including dust, soil, and sediments in streams, lakes and coastal waters throughout the world, and in the intestinal tract of animals, including fish (Heymann, 2022). Outbreaks of avian botulism have also occurred in wild fowl (Lindström, 2006).
- Spores are often found in agricultural products, including vegetables and honey (Heymann, 2022).
- The *C. botulinum* toxin is produced in anaerobic, low-acid environments such as those found in certain fermentation processes, and inadequately processed or canned foods. (Heymann, 2022)
- Recently identified sources include: homemade salsa, uneviscerated fish, baked potatoes wrapped in aluminum foil, cheese sauce, improperly handled commercial potpies, sautéed onions, minced garlic in oil, home-prepared pickled eggs, canned meat and fish, and home-prepared fermented tofu (Heymann, 2022).

Mode of Transmission (Heymann, 2022)

- Ingestion of foods in which the toxin is present.
- Wound botulism is acquired through the contamination by *C. botulinum* spores that produce toxin inside the wound which is then absorbed into the bloodstream. Most commonly associated with severe trauma or injection drug use.
- Intestinal botulism is through the ingestion of spores which germinate then release toxin.
- Person-to-person transmission does not occur.

Risk Groups/Risk Factors (Heymann, 2022)
Those at higher risk of acquiring disease include:

- Colonization botulism: Individuals > 1 of age with severely compromised gastrointestinal function or antimicrobial use.
- Wound botulism: Injection drug users.

Period of Communicability

There have been no reported cases of person-to-person transmission.

Specimen Collection and Transport

- Testing for botulism requires prior arrangement with the Microbiologist on-call at Roy Romanow Provincial Laboratory (RRPL), who can be reached at 306-798-1234.
- Refer to Attachment-Botulism Case Management and Reporting.
- Additional information on specimen collection is available from Botulism Reference Service for Canada[2].

[2] https://www.canada.ca/content/dam/hc-sc/documents/services/food-nutrition/legislation-guidelines/guidance-documents/botulism-guide-healthcare-professionals-2012/botulism-guide-healthcare-professionals.pdf

Treatment/Supportive Therapy

The primary care provider is responsible for the treatment and clinical management of cases in consultation with an infectious disease specialist and local Medical Health Officer (MHO). The following serves as a reference for the public health investigator:

Persons with botulism require immediate treatment. Antitoxin is most effective if given within 24 hours of the onset of symptoms therefore ***treatment must not await laboratory confirmation*** *(Public Health Agency of Canada, 2020). Refer to Testing section regarding completing specimen collection prior to treatment.*

- *Antitoxin for foodborne and wound botulism - treatment with equine-derived botulism antitoxin heptavalent (BAT) is recommended as soon as possible as it blocks the action of the toxin circulating in the blood and arrests the progression of paralysis. Refer to Attachment – Botulism Case Management and Reporting and Appendix D – Publicly Funded Medications for Chemoprophylaxis/ Treatment on how to access botulism antitoxin.*
- *Antitoxin for infant botulism – BabyBIG® is a human-derived botulism immune globulin indicated in the treatment of infant botulism for babies up to one year of age. It is deemed to be safer than equine-derived antitoxin because there are lower rates of hypersensitivity reactions and serum sickness associated with its administration. BAT may be administered as an alternate treatment option based on emerging safety data from international retrospective studies and case studies (Alberta Health, 2023; Heymann, 2022). Refer to Attachment – Botulism Case Management and Reporting which outlines the process that must be followed for timely acquisition of the BabyBIG® product.*

Public Health Investigation

I. Case

History

- Suspect foodborne exposure for adult and intestinal botulism. Food histories should include:
  - consumption of home canned or preserved items;
  - consumption of processed foods in which containers may have been bulging or had strange odours or tastes;
  - consumption of smoked wild meat (e.g., bear, moose); smoked fish, whale and seal meat;
  - consumption of fermented foods, particularly home fermets;
  - homemade salsa, uneviscerated fish, baked potatoes wrapped in aluminum foil, cheese sauce, improperly handled commercial potpies, sautéed onions, minced garlic in oil, home-prepared pickled eggs and home-prepared fermented tofu.
- For wound botulism, inquire about recent trauma/wounds (within 2 weeks) or history of injection drug use.
- For infant botulism, inquire specifically about history of ingestion of honey.
- Medical history related to gastrointestinal system function.
- All probable cases should be investigated to determine the source.

Public Health Interventions

Assessment

- Assess for exposure source.
- Collect all suspected foods for appropriate testing and proper disposal.

Education

- Once stabilized, provide instructions to prevent future illness. See Prevention Measures.

Exclusion

- Because there is no person-to-person transmission, exclusion is not necessary.

Referrals

- Not applicable.

Immunization

- Vaccination against botulism is not routinely recommended or provided in Canada at this time.

Testing

- Ensure serum specimen collection is completed prior to antitoxin treatment as administration of antitoxin prior to withdrawal of blood will result in a negative assay (PHAC, 2008).
- Refer to Specimen Collection and Transport

II. Contacts/Contact Investigation

Contact Definition

- Botulism contacts only include persons with the same food history.
- All symptomatic contacts should be investigated to determine the source.

Public Health Interventions

Assessment

- Assess for exposure and signs and symptoms.

Education

- Individuals exposed should be informed of the disease, its characteristics, the nature of the risk. See Prevention Measures.

Exclusion

- As with cases, contacts do not have to be excluded.

Monitoring

- Contacts should self-monitor for signs and symptoms

Testing

- No specific tests for contacts.

Referrals

- Those people known to have eaten the suspected food should be referred to a physician for assessment, observation and consideration of gastric lavage if indicated.

Prophylaxis/Immunization

- None.

III. Environment

Child Care Centre Control Measures/Institutional Control Measures

- Care should be taken to reduce the possibility of ingesting improperly canned or preserved food. Home prepared foods are not permitted in food facilities, including childcare or institutional food facilities.
- Strictly follow safe food storage and preparation practices.
- Once a potential botulism case is identified all remaining food from the same source should be immediately collected, stored in sealed containers and submitted for testing. See Preventative Measures for discard and disinfection instructions.

Epidemic Measures

- In the case of a botulism outbreak there should be an immediate recall of implicated food and an immediate search for people who shared the suspected food (Government of Manitoba, 2001). If it is a commercially produced food, the Canadian Food Inspection Agency (CFIA) should be informed and possibly the Ministry of Agriculture, depending on the implicated food.
- Stool and food samples should be collected according to the procedure outlined in the specimen collection section and send to SDCL for testing. All other suspected food should be disposed of immediately.

Bioterrorism Considerations

Bioterrorism might be considered in any outbreak of botulism. The following features would be particularly suggestive:

- outbreak of a large number of cases of acute flaccid paralysis with prominent bulbar palsies;
- outbreak with an unusual botulinum toxin type (i.e., type C, D, F, or G, or type E toxin not acquired from an aquatic food);
- outbreak with a common geographic factor among cases (e.g., airport, work location) but without a common dietary exposure (i.e., features suggestive of an aerosol attack);
- multiple simultaneous outbreaks with no common source.

Note: A careful travel and activity history, as well as dietary history, should be taken in any suspected botulism outbreak. Patients should also be asked if they know of other persons with similar symptoms. Where no common dietary exposure can be identified

in cases that are temporally clustered, the possibility of inhalational botulism may be considered.

Prevention Measures

Refer to the Enteric Illness Introduction and General Considerations section of the manual that highlights topics for client education that should be considered as well as provides information on high-risk groups and activities.

- To proper discard any remaining suspected contaminated foods, after specimens have been collected and sent for testing, place foods in sealed container or sealed double bags and dispose in garbage (Centers for Disease Control and Prevention, 2019).
    - If there is a risk that garbage may come into human or animal contact, ensure food is made inedible or inaccessible.
- Any spills of the potentially contaminated product may be cleaned up with a bleach solution (1/4 cup 5% bleach in 2 cups water) and let sit on area for 15 minutes. (Heymann, 2022)
- Contaminated utensils should be disinfected after cleaning by soaking in bleach solution (as above) or by heating in boiling water (>85˚C) for at least 5 minutes (PHAC, 2011; Spickler, 2018).
- Discard sponges, cloths, rags, paper towels, and gloves that may have come into contact with contaminated food or containers with the food.
- Wash hand thoroughly after handling.

Education

- Honey should not be given to children under one year of age.
- Education of the public in safe handling of food. Refer to Appendix F. For example:
    - Do not use food from damaged or bulging containers.
    - Foods with unusual odours and tastes should not be eaten or “taste-tested.”
    - Proper storage is one of the keys to food safety. Refrigeration slows down most bacterial growth. Set the refrigerator temperature at or below 4°C/40°F.

- Storing food in non-airtight containers and at 4°C or lower will stop or slow the growth of the bacterium.
- Educate those concerned with home canning regarding the proper time, pressure and temperature required to destroy spores. See Home canning safety from Health Canada.
- Educate those concerned with home fermented foods. See Fermented Foods Guidance

- Take precautions with home-prepared foods stored in oil (e.g., vegetables, herbs and spices). If these products are prepared using fresh ingredients, they must be kept refrigerated (<4°C) and for no more than 10 days.
  - If the above products are purchased from fairs, farmers' markets, roadside stands or have been received as a gift and prepared more than a week ago, discard them.

Revisions

Date	Change
June 2024	• Formatted into new chapter template. • Added BAT as an alternative treatment option for infant botulism. • Notification Timeline- updated from Public Health to Ministry of Health to "Within 24 hours" to align with case management sheet (previously "Immediately"). • Symptoms- updated to include ptosis and double vision. Infant botulism updated with constipation. • Additional Background Information- general updates included in this section. • Incubation period- updated foodborne botulism to 12 to 72 hours (previously 12 to 36 hours) with range 2 hours to 8 days; added infant botulism and wound botulism. • Specimen Collection and Transport- removed detailed information and added "Additional information on specimen collection is available from Botulism Reference Service for Canada". • Public Health Investigation- general updates included in this section. • Environment- general updates included in this section. • Added Prevention Measures section. • Updated References
April 2018	• Clarified the purpose for notification of cases to public health

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PANORAMA

Botulism Routine Questionnaire - August 2018

Record type:
Record ID:
Record Name:

In this form the answers (Yes, Probably, No, and Don't know) are from the perspective of the person being interviewed. "Probably" can be used if the client thinks he/she may have eaten this food or usually eats this food, but is unsure if it was eaten during the period in question.

Diet and Allergies

Show/Hide

Are you a vegetarian?
- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Not asked

Do you have any food Allergies / avoidances / special diet?
- ◯ Yes
- ◯ No
- ◯ Don't know
- ◯ Not asked

If yes, specify details

Food Exposures

Show/Hide

In the 8 days prior to onset, did you eat…

Any smoked salmon/fish?
- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know
- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any fermented fish eggs?
- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know

PANORAMA

- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any seafood (e.g. fish in oil, fermented fish)?

- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know
- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any smoked meat?

- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know
- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any fermented meat?

- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know
- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any salted fish/meat?

- ◯ Yes
- ◯ Probably
- ◯ No
- ◯ Don't know
- ◯ None of the Above

If yes, specify details (E.g., where consumed, type, brand, location)

Any home canned products?	◯ Yes ◯ Probably ◯ No ◯ Don't know ◯ None of the Above
If yes, specify details (E.g., where consumed, type, brand, location)	
Any flavoured oils (e.g. garlic oil)?	◯ Yes ◯ Probably ◯ No ◯ Don't know ◯ None of the Above
If yes, specify details (E.g., where consumed, type, brand, location)	
Any honey?	◯ Yes ◯ Probably ◯ No ◯ Don't know ◯ None of the Above
If yes, specify details (E.g., where consumed, type, brand, location)	
Any other weaning foods?	◯ Yes ◯ Probably ◯ No ◯ Don't know ◯ None of the Above
If yes, specify details (E.g., where consumed, type, brand, location)	

Any bottled vegetable/fruit juice?	◯ Yes ◯ Probably ◯ No ◯ Don't know ◯ None of the Above
If yes, specify details (E.g., where consumed, type, brand, location)	

Social Functions Show/Hide

In the 8 days prior to onset, did you attend any social functions (e.g. parties, weddings, showers, potlucks, community events)?	◯ Yes ◯ No ◯ Don't know ◯ Not asked

Click the Add button to add social event/function details

Add

Restaurants Show/Hide

In the 8 days prior to onset, did you attend any restaurants (including take-out, cafeteria, bakery, deli, kiosk)?	◯ Yes ◯ No ◯ Don't know ◯ Not asked

Click the Add button to add restaurant details

Add

Grocery Stores Show/Hide

In the past 8 days prior to onset, did you visit grocery stores for foods consumed during the incubation period?	◯ Yes ◯ No ◯ Don't know ◯ Not asked

Click the Add button to add grocery store details

Add

Loyalty card/store issued card (for outbreak investigation only)

Show/Hide

This section is only for use in some specific outbreak situations, with client consent. It is not a routine question for sporadic cases.

Has the client given consent (written or verbal)?

- ◯ Yes
- ◯ No
- ◯ Not applicable

Loyalty card details (names and numbers)

Interviewer Details and Notes

Show/Hide

Interviewer Name

Interview date: 9/26/2018

Any special notes regarding this interview

Orbeon Forms Orbeon Forms 4.9.0.201505052329 CE

Section 1 – Initial Notification:

Attending Physician Immediately notifies the Local Medical Health Officer (MHO)

- Botulism is a Reportable Disease in Saskatchewan under the Disease Control Regulations of *The Public Health Act, 1994*
- Botulism (suspected and confirmed cases) must be reported immediately to the local MHO. See Appendix E - Contact Information for Regional Health Authorities and First Nations Inuit Health and Northern Inter-Tribal Health Authority.
- The MHO must be also advised if a food item is the suspected source of the illness.

Local MHO must notify the Saskatchewan Ministry of Health

Botulism (suspected and confirmed cases) must be reported as per Appendix A within 24 hours.

Send notification emails to:
cdc@health.gov.sk.ca
and
OCHMO@health.gov.sk.ca

The following information must be reported immediately to the Ministry of Health:

a. name of the patient,
b. date of birth (or age if DOB is not known),
c. onset date,
d. address and current location of the case, and
e. current health status of the case.

Additional information is to be shared with the Ministry as details become available.

Attending Physician notifies Botulism Reference Service (BRS) for Canada to:

- discuss the clinical presentation of the suspect case in order to support the diagnosis;
- obtain advice on the appropriate submission of laboratory specimens (see Section 2 - Specimen Collection) prior to administering treatment.

During Work Hours: 613-957-0902
After-Hours, Weekends and Holidays: 613-296-1139

The local MHO should follow-up with the BRS and the physician to facilitate coordinated communication and follow-up.

Section 2 – Specimen Collection:

The BRS will provide recommendations of specimen collection (clinical and food).

Obtain the appropriate laboratory specimens and forward the specimens to the BRS for Canada.

- A good case history should be obtained to support the diagnosis.
- Public Health coordinates collection of food specimens.
- Attending physician coordinates collection of clinical specimens.

Prior to sending clinical specimens, the attending physician must call the BRS to make arrangements for transporting clinical specimens for laboratory analysis.

During Work Hours: 613-957-0902
After-Hours, Weekends and Holidays: 613-296-1139

Samples must be sent by courier (not Canada Post) to:

Laboratory Services
Botulism Reference Service
Health Products and Food Branch
Health Canada, Banting Research Centre
251 Sir Frederick Banting Driveway
Tunney's Pasture, Postal Locator 2204A2
Ottawa ON K1A 0K9
Telephone: 613-957-0902
Fax: 613-941-0280

NOTE – Specimens should be forwarded to the Roy Romanow Provincial Laboratory (RRPL) who will forward the specimens to the BRS and will ensure specimens meet transporting standards prior to shipment. Please contact RRPL for additional information on shipping of specimens.

Section 3 – Accessing Botulism Antitoxin (BAT)

For treatment of botulism cases in those 1 year of age and older **or,** as an alternate to BabyBIG®, in infants less than 1 year of age (see Section 4).

Access botulism antitoxin (BAT) from the Ministry of Health as outlined in Appendix D – Publicly Funded Medications for Chemoprophylaxis/Treatment. Consultation must occur with the local MHO. BAT is stocked at the Roy Romanow Provincial Laboratory (RRPL) provincial vaccine depot.

NOTE: A blood sample (as suggested by the BRS) should be collected to identify the *C. botulinum* type before antitoxin is administered; **antitoxin should not be withheld pending test results however:**

- One vial of BAT should be administered as soon as possible.
- RRPL staff will arrange for the shipment of the product.
- A product monograph and directions for administration will be included with the product.

Section 4 – Accessing BabyBIG®

For botulism cases in infants less than 1 year of age, obtain infant botulism immune globulin (BabyBIG®). BabyBIG® is the preferred product for this age group, however BAT may be provided as an alternate treatment (see Section 3).

BabyBIG® is a human-derived botulism immune globulin indicated in the treatment of infant botulism for infants less than one year of age. It is deemed to be safer than equine-derived BAT because there are lower rates of hypersensitivity reactions and serum sickness associated with its administration.

The California Department of Public Health, Infant Botulism Treatment and Prevention Program (IBTPP), is the supplier of BabyBIG® and does not permit pre-orders of their product. **The attending physician must place a request with IBTPP and Health Canada (through SAP) to access BabyBIG®.**

The Ministry of Health will reimburse the Saskatchewan Health Authority (SHA) for the product cost, as well as the transportation cost from California.

Steps to access BabyBIG®:

NOTE: If assistance is required during weekday business hours to navigate access to BabyBIG®, please contact the Ministry of Health Population Health Branch at 306-787-8847 and ask to speak to a Public Health Nursing Consultant.

1. **The attending physician must consult with the local MHO** for authorization to access BabyBIG®.

2. **Request permission to import BabyBIG® through SAP.**

   a. **The attending physician must complete SAP Form A[1] 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.
   b. If the 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 attending physician should be prepared to provide the information required on the Special Access Request Form A to the on-call officer and then follow-up on the next business day with a copy of the completed form.
   c. SAP must authorize the California Department of Public Health, IBTPP to ship the BabyBIG® to the hospital.

   For further information on the SAP, please refer to their website at http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf1_pasf1-eng.php.

3. **Request shipment of BabyBIG® from California Department of Public Health**

   a. BabyBIG® is only authorized for shipment by the IBTPP on-call physician who must be contacted by the patient's attending physician to discuss the clinical situation.
   b. An IBTPP on-call physician can be reached 24 hours a day, 7 days a week at **510-231-7600**.
   c. **Before BabyBIG is released for shipment, IBTPP must receive**:

[1] Access on SAP website under 'For a patient-specific request': http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf3_pasf3-eng.php

- the signed **International Invoice and Purchase Agreement** (IPA) for BabyBIG®document;
- medical records submitted either electronically or by fax that include documentation of the patient's weight;
- the import permit authorization letter from the requesting country's Medicines Regulatory Agency (i.e., SAP); and
- written permission to utilize the hospital's international courier account, and the contact information for someone at the hospital who can facilitate the shipment, if needed.

For additional information on BabyBIG® and the requirements prior to shipment of BabyBIG®, contact the IBTPP at 510-231-7600 or refer to the IBTPP International Inquires webpage: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/IBTPP_International_Inquiries.aspx

After treatment with BabyBIG®, the attending physician must complete Special Access Request Form C – Patient Follow-up Form[2] and fax to 306-787-9576 or email to cdc@health.gov.sk.ca.

The Ministry of Health must forward the information provided on Form C to SAP for the purpose of notifying Health Canada of the product administration.

For reimbursement for the payment of BabyBIG®, the SHA shall submit an invoice with the following documents attached to the address noted below:

- International Invoice and Purchase Agreement (IPA) for BabyBIG® - State of California – Health and Human Services Agency
- Completed SAP Form C

Director of Health Promotion and Central Policy Support Unit
Population Health Branch
3475 Albert Street
Regina SK S4S 6X6
Fax: 306-787-9576
cdc@health.gov.sk.ca

[2] Found under 'Follow up form' on SAP website: http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf3_pasf3-eng.php

Revisions

Date	Change
June 2024	• Revised Ministry of Health contact notification: added OCMHO email and removed phone numbers. • Initial notification- added reference to Appendix E. • Added BAT as an alternative treatment option for infant botulism. • Clarified steps to access BAT: available at RRPL and no longer obtained through SAP. • Clarified steps to access BabyBIG®. • Updated flow charts BabyBIG® and BAT access flowcharts.

References

Please note that this information is subject to change. The following sources contain additional information:

Heymann, D. L. (Ed.). (2022). *Control of communicable diseases manual* (21st ed.). Washington, DC: American Public Health Association.

Public Health Agency of Canada. (n.d.). *Botulism.* Retrieved January, 2024 from https://www.canada.ca/en/public-health/services/diseases/botulism.html

Centers for Disease Control and Prevention. (n.d.) *Emergency Preparedness and Response: Botulism*. Retrieved May, 2014 from http://emergency.cdc.gov/agent/botulism/

Botulism Case Management and Reporting

NOTE: Many of these steps occur at the same time in order to provide timely response to support botulism cases

Section 1 - Initial Notification

Section 2 - Specimen Collection

Clinical specimen pathway | Food specimen pathway

Section 3 - Accessing Botulism Antitoxin (BAT)

Patient 1 year or older (or infant < 1 year receiving BAT as alternate to BabyBIG)

- Goes to Dr. with symptoms of Botulism

Physician

- Clinical assessment suspect Botulism
- Notify BRS
- Notify local MHO by phone
- Provide clinical specimens based on BRS recommendations.
- Collect clinical specimens and send to RRPL
- Receive results
- Notify local MHO of positive results
- Provide food history and food samples to Public Health based on BRS recommendations.
- Complete BRS form & return to BRS & copy to Public Health
- Request BAT from MHO
- Administer BAT ASAP
- Information Updates

Local Public Health Medical Health Office (MHO)

- Notify MoH by phone and email
- Conduct investigation
- Follow-up with BRS
- Notify MoH
- Collect food samples in coordination with patient and BRS
- Receive results
- Notify MoH
- Request BAT from RRPL by phone
- Facilitate Info collection from physician and relay to MoH

Ministry of Health (MoH)
cdc@health.gov.sk.ca
OCMHO@health.gov.sk.ca

- Ensure BAT supply available at RRPL – await further information/request for BAT
- Notify PHAC
- Receive updates

Roy Romanow Provincial Laboratory (RRPL)
After hours BAT access (on-call manager): 1-306-540-3458

- RRPL test/forward specimens
- Send BAT to hospital ASAP

Botulism Reference Service (BRS)
613-957-0902
After hours: 613-296-1139

- Provide recommendations on specimen collection (clinical & food) & send form to physician to be completed
- Conduct test
- Send results to Physician (clinical)
- Send results to Public Health (food)
- Receive form

Public Health Agency of Canada (PHAC)

- Activate Foodborne Illness Outbreak Response Protocol (FIORP) as necessary

Last updated: June 28, 2024

Botulism Case Management and Reporting

NOTE: Many of these steps occur at the same time in order to provide timely response to support botulism cases

Section 1 - Initial Notification

Section 2 - Specimen Collection

Clinical specimen pathway Food specimen pathway

Section 3 - Accessing BabyBIG/Payment

Patient: less Infants than 1 year

Goes to Dr. with symptoms of Botulism

Physician

Clinical assessment suspect Botulism

Notify BRS

Notify local MHO by phone

Provide clinical specimens as per BRS recommendations

Provide food history and food samples to Public Health as per BRS recommendations

Collect clinical specimens and send to RRPL

Receive results

Notify local MHO of positive results

Complete BRS form & return to BRS & copy to Public Health

Receive authorization

Request BabyBIG from CDPH

Request BabyBIG access by fax using SAP Form "A"

SHA forwards payment to Calfornia

Administer BabyBIG ASAP

Information Updates

Report BabyBIG use on SAP Form "C" & send with CDPH invoice to MoH

Local Public Health Medical Health Officer (MHO)

Notify MoH by phone and email

Conduct investigation

Follow-up with BRS

Notify MoH

Collect food samples in coordination with patient and BRS

Receive results

Notify MoH

Authorize request for BabyBIG

Facilitate Info collection from physician and relay to MoH

Ministry of Health (MoH) cdc@health.gov.sk.ca and OCMHO@health.gov.sk.ca

Provide information on steps to access BabyBIG® as needed; await further information

Notify PHAC

Send Completed Form "C" to SAP

Reimburse SHA for BabyBIG

Roy Romanow Provincial Laboratory (RRPL)

RRPL test/ forward specimens

Botulism Reference Service (BRS)
Lab: 613-957-0885
Consult for testing samples (clinical/food): 613-296-1139 M-F 8am-4pm

Provide recommendations on specimen collection (clinical & food) & send form to physician to be completed

Conduct test

Send results to Physician (clinical)

Send results to Public Health (food)

Health Canada Special Access Program (SAP)
Fax: 613-941-3194
Phone: 613-941-2108

Authorize access from CDPH

Public Health Agency of Canada (PHAC)

Activate Foodborne Illness Outbreak Response Protocol (FIORP) as necessary

California Department of Public Health
(CDPH) 510-231-7600

Authorizes BabyBIG release

Ship to hospital

Last revised: June 28, 2024