

BOTULISM (NON-INFANT)

I. BOTULISM: DESCRIPTION AND EPIDEMIOLOGY

A. Overview

Botulism is a rare but serious illness characterized by descending flaccid paralysis and occurs when botulinum neurotoxin (BoNT) irreversibly binds to the neuromuscular junction. BoNT is produced by spore forming-*Clostridium spp.*, usually *C. botulinum*, and rarely other clostridial species. There are seven types of BoNT: A, B, C, D, E, F, and G. Human cases are most often caused by BoNT types A, B, E, and rarely F.

Botulism occurs in several forms, defined by the method of transmission:

- **Infant botulism:** Clostridial species colonize the immature gut and germinate, producing BoNT.
- **Foodborne botulism:** Pre-formed BoNT is ingested from contaminated foods.
- **Wound botulism:** Clostridial species colonize a wound and in anaerobic conditions germinate and produce BoNT; many cases are related to injection drug use (IDU), but wound botulism has also been associated with trauma, such as an open fracture.
- **Adult toxemia:** Clostridial species colonize the gut and germinate, producing BoNT, similar to infant botulism. Persons at risk for adult toxemia include those with recent antibiotic use, gastrointestinal surgery or other gastrointestinal abnormality; this is a very rare form of botulism.
- **Iatrogenic:** Systemic BoNT intoxication follows localized injection of commercial BoNT for cosmetic or clinical indications (e.g., with Botox, Myobloc, etc.); this is a very rare form of botulism.

In 2018, there were 242 cases of botulism reported to the U.S. Centers for Disease Control and Prevention (CDC); this included 162 infant, 61 wound, 18 foodborne, and 1 suspected adult toxemia. While infant botulism is the most commonly reported form of botulism in the United States, this guidance will focus on non-infant botulism; detailed information on infant botulism can be found at: [Infant Botulism Treatment and Prevention Program](http://www.infantbotulism.org) (www.infantbotulism.org).

BoNT is one of the deadliest toxins known, and a minute amount can cause illness. There is also concern that BoNT could be used as a bioterrorism agent and deliberate contamination of food, water, or even air could occur. Botulism should always be managed as a medical and public health emergency, and each case be investigated thoroughly.

B. Botulism in California

The California Department of Public Health (CDPH) Infectious Diseases Branch (IDB) investigates each reported case of botulism and assists in outbreak and cluster

investigations. California reports the highest number of wound botulism cases in the United States. From 2013 to 2019, an average of 26 cases of wound botulism per year were reported in California; the majority were related to injection drug use, specifically the use of black tar heroin (BTH), which is more commonly used on the West Coast. Additionally, from 2013 to 2019, 24 cases of foodborne botulism were reported, including several outbreaks. CDPH is available 24/7 to release botulism antitoxin (BAT) and authorize laboratory testing for all local health jurisdictions in California except for Los Angeles County (LAC) Department of Public Health (DPH), which manages botulism cases occurring in LAC residents.

C. Symptoms of Botulism

Botulism is characterized by an acute onset of symmetric, descending, rapidly progressing flaccid paralysis, typically beginning with cranial nerve involvement. Signs and symptoms include:

- Cranial nerve involvement, such as ptosis, diplopia, blurred vision, dry mouth dysarthria, difficulty swallowing, complaints of “thick tongue”;
- Progression of weakness/ paralysis, which is classically descending, symmetrical, and flaccid. Proximal muscle groups tend to be involved before distal muscles;
- Respiratory distress or failure due to weakness of respiratory muscles, resulting in shortness of breath, hypercapnia, and respiratory failure;
- Normal mentation (unless intoxicated); patients are generally alert and oriented; paresthesias (numbness, tingling) are usually not reported.
- Additionally, patients with foodborne botulism may present with nausea/vomiting and other gastrointestinal (GI) symptoms, though it is not known whether this is caused by botulinum toxin, other clostridial products, or nonclostridial substances related to food spoilage.

D. Diagnosis of Botulism

The initial diagnosis of botulism is based on clinical presentation. Treatment should not be delayed for laboratory confirmation, as available laboratory testing may take several days/weeks to finalize, and prognosis is greatly impacted by the early administration of antitoxin.

In addition to clinical findings of cranial nerve involvement and descending flaccid paralysis, risk factors for botulism should be elicited. Patients with:

- Wound botulism may provide a history of injection drug use, trauma including recent fracture, surgery, or have wounds or track marks. Not all patients with wound botulism, particularly injection drug users, had an apparent infected wound.
- Foodborne botulism may have a history of consumption of foods that are at risk of botulism contamination, such as home-canned/jarred/preserved foods, especially vegetables or meats that have higher pH (>4.6) and low sugar or salt levels.

- Adult toxemia may provide history of altered gut microbiota, gastrointestinal surgery, Meckel's diverticulum.
- Iatrogenic exposure may report recent injection with commercial botulism toxin for therapeutic or cosmetic reasons.

Detection of BoNT in serum, stool, wounds, gastric aspirate, or suspect food item is required for confirmation of botulism. This test is only available in select public health laboratories; in California, this includes the CDPH Microbial Diseases Laboratory (MDL) and the LAC Public Health Laboratory (PHL). At MDL and LAC PHL, BoNT is detected utilizing the mouse bioassay; at CDC, the matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF) is performed.

Wounds may be cultured and if *Clostridia spp.* are identified, CDPH will request the isolate for toxin testing.

For foodborne botulism, stool samples and food items suspicious for being the source may also be cultured and tested by CDPH MDL.

E. Transmission

Transmission occurs via ingestion of pre-formed BoNT, through the production of BoNT by *Clostridia* in a wound or the gastrointestinal tract, or from iatrogenic administration of BoNT. Botulism is not spread through person-to-person transmission.

F. Incubation Period

Foodborne botulism has an incubation period of 6 to 36 hours following ingestion of contaminated food but may be delayed up to 10 days. Wound botulism has an incubation period of 1 to 14 days from the development of the wound or injection with contaminated drug.

The incubation periods for adult toxemia and infant botulism are unknown.

Iatrogenic botulism symptoms may arise anywhere from a few days to several weeks following administration of BoNT.

G. Clinical Management

Botulism is a medical emergency and requires immediate and intensive supportive care with close monitoring of patient's neurologic and respiratory status.

The only specific therapy for botulism is the heptavalent botulism antitoxin (BAT), which is available through CDPH. BAT is an equine based therapy that does not reverse symptoms but can prevent further progression. BAT should be administered as soon as possible to maximize benefit, but even in cases where the disease was unrecognized for a prolonged period of time, there may be benefit to BAT administration, especially if the source of BoNT is ongoing (e.g., an abscess infected with *C. botulinum*) or if symptoms continue to progress. In cases where symptoms/paralysis seem stable, there

is likely less benefit. Therefore, discussion with IDB botulism subject matter experts (SMEs) should be expedited to determine if BAT should be released.

BAT contains equine derived antibody to the following BoNT types: A, B, C, D, E, F and G. Guidance for dosing and product administration is available in the package insert that accompanies the product and is available here: [Package Insert - Botulism Antitoxin Heptavalent \(A, B, C, D, E, F, G\) - \(Equine\)](http://www.fda.gov/media/85514/download) (www.fda.gov/media/85514/download)

II. COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS (CSTE) SURVEILLANCE CASE DEFINITIONS

The 2011 CSTE case definitions can be found on the [CDC National Notifiable Diseases Surveillance System \(NNDSS\) website](https://www.cdc.gov/nndss/). The definitions have slight differences depending on method of transmission. **Please note, that cases may still meet the probable case definition without a positive laboratory finding.**

[Botulism, Foodborne \(2011\)](#)

Clinical Description

Ingestion of botulinum toxin results in an illness of variable severity. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory Criteria for Diagnosis

- a. Detection of botulinum toxin in serum, stool, or patient's food, OR
- b. Isolation of *C. botulinum* from stool

Case Classification

Probable: A clinically compatible case with an epidemiologic link (e.g., ingestion of a home-canned food within the previous 48 hours).

Confirmed: 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.

[Botulism, Wound](#)

Clinical Description

An illness resulting from toxin produced by *C. botulinum* that has infected a wound. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory Criteria for Diagnosis

- a. Detection of botulinum toxin in serum, OR
- b. Isolation of *C. botulinum* from wound

Case Classification

Probable: A clinically compatible case in a patient who has no suspected exposure to contaminated food and who has either a history of fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms.

Confirmed: 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 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms.

[Botulism, Other](#)

Clinical Description

See Botulism, Foodborne.

Laboratory Criteria for Diagnosis

- a. Detection of botulinum toxin in a clinical specimen, OR
- b. Isolation of *C. botulinum* from clinical specimen

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed in a patient aged greater than or equal to 1 year who has no history of ingestion of suspect food and has no wounds.

III. CASE SURVEILLANCE, INVESTIGATION, REPORTING

A. Purpose of Surveillance, and Investigation, and Reporting

- To identify botulism cases and provide BAT as early as possible for improved outcome; even a single botulism case is considered to be a medical emergency.
- To identify botulism outbreaks; two or more cases that are epi-linked should immediately be investigated as an outbreak and should be considered public health emergencies. Additionally, it is important to rule out bioterrorism in these situations.
- To interrupt potential sources of ongoing transmission.
- To detect and monitor epidemiologic trends.

- To better understand the epidemiology of botulism in California and to use this information to develop targeted interventions to decrease illness.

B. Local Health Department (LHD) General Case Investigation Recommendations

- Healthcare providers are required to report suspected botulism cases immediately to the LHD. Begin the case investigation as soon as a suspected botulism case is reported from a healthcare provider (please see **Appendix A**).
- Assess the likelihood of botulism in the suspected case.
 - Determine if signs/symptoms consistent with botulism are present; cranial nerve palsies are the sine qua non of botulism; botulism without cranial nerve symptoms have not been reported.
 - Collect information about potential exposures and risk factors; history of IDU, recent wound, or consumption of high-risk foods would increase the likelihood of botulism.
- If botulism is suspected, or if additional consultation is needed, immediately contact the CDPH IDB (510-620-3434) during business hours and ask for the botulism subject matter expert (SME). After hours, call the Division of Communicable Disease (DCDC) Duty Officer of the Day (DOD) or the CDPH Duty Officer (916-328-3605) for BAT release and testing approval for suspected botulism patients who are residents of all California jurisdictions except for LAC. For suspected botulism patients who are LAC residents, contact LAC DPH (213-974-1234).
 - The IDB botulism SME or DCDC DOD will review the patient's presentation and history with the clinical team and authorize the release of BAT from the nearest quarantine station (Los Angeles or San Francisco International Airport). The IDB botulism SME or DCDC DOD will include the LHD in an email summary of the case presentation and completed actions (e.g., BAT release), and include the preliminary botulism worksheet and CDPH Botulism Case Report Form (CRF).
- It is the responsibility of the LHD to finalize the Botulism CRF and work with the clinical team and hospital to confirm that the patient received the BAT, appropriate specimens were collected for testing, and risk factors were reviewed.
- Follow up with the hospital laboratory to ensure that an adequate volume (at least 15 ccs) of non-hemolyzed **pre-treatment** serum was collected from the patient, and that other specimens (e.g., stool, wound) were collected if indicated. These specimens should be refrigerated and not frozen and forwarded to the local public health laboratory (LPHL). Post-treatment serum will not be tested. For further diagnostic testing guidance, see the [MDL Adult Botulism Diagnostic Testing webpage](#).
- Alert your LPHL that specimens for botulism testing are expected from the treating hospital. Once received, the LPHL should promptly forward the specimens to MDL.
- Interview patients or their proxies as soon as possible using the CDPH Botulism CRF (**III. C. LHD Reporting**). The sooner a patient or family member is

interviewed, the better the recall of food or other exposures and identification of others who may be at risk. Though most cases of wound and foodborne botulism in California are sporadic, it is critical to identify other persons who may be at risk from a shared food item or contaminated lot of drugs.

- Immediate investigation is required for suspected foodborne botulism cases, especially if the suspected source is a commercial food source. If foodborne botulism is suspected, or type of botulism is unknown, interview the patient using the Suspect Foodborne or Unknown Botulism Case Interview Form (**Appendix B**).
- For foodborne botulism, conduct a home (or commercial establishment) visit and inspection, preferably within 24 hours. The CDPH Food and Drug Branch Rapid Response Team (FDB RRT) is available 24/7 for consultation. Use the Home Inspection Guide for Suspected Botulism (**Appendix C**).

C. LHD Reporting

Botulism Reporting Overview

Botulism is reportable in California by clinicians, laboratories, and local health officers by Title 17 California Code of Regulations, 2500, 2505, and 2502.

- As of January 2020, the CDPH public-facing website has been updated to remove documents that are not compliant with the new requirements of Section 508 of the Rehabilitation Act of 1973. Therefore, some documents intended primarily for LHDs and not the general public, such as case report forms, have been moved to the CalREDIE Document Repository under the CDPH tab of the ribbon in the CalREDIE application. This includes the Botulism CRF (CDPH 8547).
- The IDB Botulism SME or DCDC DOD will fill out the preliminary information in the Botulism CRF. **It is the responsibility of the LHD to complete the form with any updated information and transfer this information into CalREDIE.**
- Enter the patient information into CalREDIE upon notification of the case by the clinical laboratory or healthcare provider. Select “Botulism, Foodborne”, “Botulism, Wound”, “Botulism, Other” as “Disease Being Reported”.
- Complete at a minimum the fields necessary to correctly classify a botulism case:
 - The presence of clinically compatible symptoms;
 - The presence or absence of wounds;
 - Risk factor history including injection drug use, suspicious food items, iatrogenic or other toxin exposures,
 - Epidemiologic links to other confirmed or suspected cases;
 - Presence of BoNT in serum, stool, gastric aspirate, wound, or suspected food item;
 - Presence of BoNT producing-organisms in stool, wound, or gastric aspirate;
 - If testing was negative or not done, please indicate accordingly;

- As a reminder, proper completion of the demographics section provides valuable information on priority groups to target for potential interventions.
- Upload copies of medical records including the admissions history and physical, neurology and infectious disease consult notes, and discharge summary if possible into the Electronic Filing Cabinet in CalREDIE.
- For jurisdictions that do not submit via CalREDIE, confidential morbidity report (CMR) and case report data must still be provided, including the information requested in the forms provided on the CDPH website. Please submit the CDPH form 8547 (Botulism) within one week of completion.
 - Jurisdictions that do not submit via CalREDIE may contact IDB for the botulism case report form (CDPH 8547) if needed.
- A summary of key steps to investigating suspect botulism cases may be found in **Figure 1 Suspected Botulism Step-by-Step Guide**.

Reporting Outbreaks and Clusters:

Report suspected botulism outbreaks, including wound botulism clusters, immediately to CDPH via telephone. See **IV. D. Special Situations**.

D. Laboratory Considerations/MDL Resources

Detection of BoNT in serum, stool, wounds, or gastric aspirate or suspect food item is required for confirmation of botulism and is only available in select public health laboratories; in California, this includes the CDPH MDL and LAC PHL (see **I. D. Diagnosis of Botulism**). Botulism testing will only occur after consultation with the Botulism SME. Please see [MDL Adult Botulism Diagnostic Testing](#) for further guidance.

CDPH will not authorize testing without treatment (with rare exceptions):

- It may take several weeks for the final test results.
- Depending on timing of serum or other specimen collection, the amount of circulating BoNT, and other factors, testing may be negative despite a compatible syndrome. Clinical management is based on presentation compatible with botulism, not on testing results.
- The earlier BAT is administered, the more effective it is in preventing the progression of illness and shortening the duration.
- Therefore, with very rare exceptions such as patient history of anaphylaxis to BAT, resolution of patient’s symptoms, or prolonged complete paralysis (indicating that exposure occurred several weeks prior and therefore all BoNT has already bound irreversibly at the neuromuscular junction), CDPH will not authorize testing without release of BAT.

Specimens Collection Procedures:

- Detailed information about adult botulism diagnostic testing can be found on the [MDL Adult Botulism Diagnostic Testing webpage](#).

- Prior to administration of BAT, a 15mL serum specimen must be collected from all patients with suspected botulism. At least 15 mL of serum is required for MDL to perform this test.
- Pre-treatment serum is the most important test to detect circulating BoNT in the patient.
- If foodborne botulism is suspected, stool will be cultured for the presence of BoNT-producing organisms.
 - Feces: 10-25 grams solid stool – or – if solid stool cannot be obtained, 20 ml of rectal wash that must contain visible feces.
- Additional specimens may be requested depending on the clinical picture.
- All specimens should be kept refrigerated but not frozen.
- The clinical laboratory will forward the specimens to the LPHL, which will then forward the specimens to MDL (**See III. B.**).

MDL Select Agents and Laboratory Response Procedures:

- MDL utilizes the mouse bioassay to detect BoNT in clinical specimens. The mouse bioassay is a functional assay that detects biologically active BoNT, a labor- and resource- intensive process that take approximately one week to complete.
- In some instances where the mouse bioassay result is indeterminate, or if the volume of the collected sera is insufficient to test, MDL will forward the specimen to the CDC for MALDI-TOF testing.
- If specimens were sent to MDL, the final test results will be sent to the submitting LPHL (submitting laboratory is the jurisdiction where the hospital is located), not necessarily the LPHL of the patient's residence. Please follow up with the submitting laboratory to verify final results.
- If suspected food items are identified, the MDL will test suspect items.

IV. CASE MANAGEMENT AND PUBLIC HEALTH CONTROL MEASURES

A. Management of Cases

All patients suspected to have botulism should be closely monitored in the hospital setting as descending paralysis may progress rapidly to respiratory failure and death. While BAT does not reverse paralysis, BAT can prevent progression of illness and shorten its duration if administered early in the course of illness. In addition to BAT, supportive care, including ventilator support if necessary, is the mainstay of botulism treatment. Additionally, neurology and infectious disease consultations may be very important in helping manage the patient's course.

B. Management of Contacts

- When a suspected food item is implicated in a foodborne botulism case, it is paramount to identify individuals who may have been exposed (e.g., consumed the

suspected food item). Obtain the name, address and telephone number of every person who might have consumed the suspected food item.

- If a cluster of botulism cases or suspected shared exposure is identified, obtain as much information as possible (e.g., the venue name, contact telephone number and attendance lists for every suspected gathering, public event, or other exposure).
- Persons who ate food items potentially contaminated with BoNT (this includes those who shared meals with the suspected botulism case, or those who ate a food item that has been recalled due to the risk of *C. botulinum* contamination) should be educated about the signs and symptoms of botulism and seek medical care immediately if symptoms develop. They should also be instructed to alert medical providers that they were potentially exposed to botulism. However, there is no role for administering BAT prophylactically in these situations, as BAT will only bind with circulating BoNT.
- Determine if any leftovers or suspicious food items are still available in the patient's household or other setting and alert contacts to not eat those items until cleared by the LHD. These items should be held at refrigerated temperature for evaluation by the LHD communicable disease and/or environmental staff for potential testing.
- Though most wound botulism cases are sporadic, individuals who have shared drugs, needles, or other equipment with a wound botulism patient may be at increased risk for developing botulism. Contacts can be instructed to self-monitor for signs of botulism and seek medical care immediately if symptoms develop. They should also be instructed to alert medical providers that they were potentially exposed to botulism.

C. Infection Control Measures

- Environmental inspection of the suspected botulism patient's home is indicated if foodborne botulism is suspected. Until environmental inspection performed, household contacts should be told not to eat any opened items/items that the patient may have consumed (see **IV. B.**). CDPH FDB RRT is available to consult on the environmental inspection.
- If a restaurant or commercial source is suspect, conduct an immediate inspection (24/7) in coordination with the CDPH FDB RRT. The Botulism SME will notify the CDC and alert the CDPH FDB RRT.
- Suspected food sources should be collected and tested for toxin. Please see Food Sampling and Collection Guidelines (**Appendix B**) for more information.
- If home canned/preserved/jarred foods are implicated, those responsible for preparing the canned/ preserved/ jarred foods person should be educated on food safety and proper preparation.
- For suspected wound botulism clusters potentially associated with contaminated drugs or drug paraphernalia: provide outreach to healthcare providers, drug

treatment centers, and users about risks of wound botulism with injection drug use as well as risk mitigation strategies.

D. Special Situations:

- Outbreaks and Clusters: If more than one patient with botulism is identified without an obvious source of exposure, consider the possibility of a contaminated commercial food product or intentional exposure. Call CDPH IDB (either directly during office hours or call the CDPH Duty officer or DCDC DOD) immediately for guidance on next steps.
- Bioterrorism: BoNT is classified as a potential CDC category A bioterrorism agent due to its extreme potency and lethality. The toxin may be deliberately disseminated via contaminated food or may be aerosolized leading to inhalational botulism. Inhalational botulism or iatrogenic botulism from a non-commercial source are considered potential acts of bioterrorism and should be immediately reported to CDPH.

V. APPLICABLE STATE STATUTES AND REGULATIONS

A. California Code of Regulations, Title 17, Public Health, Section 2500, 2502, 2505

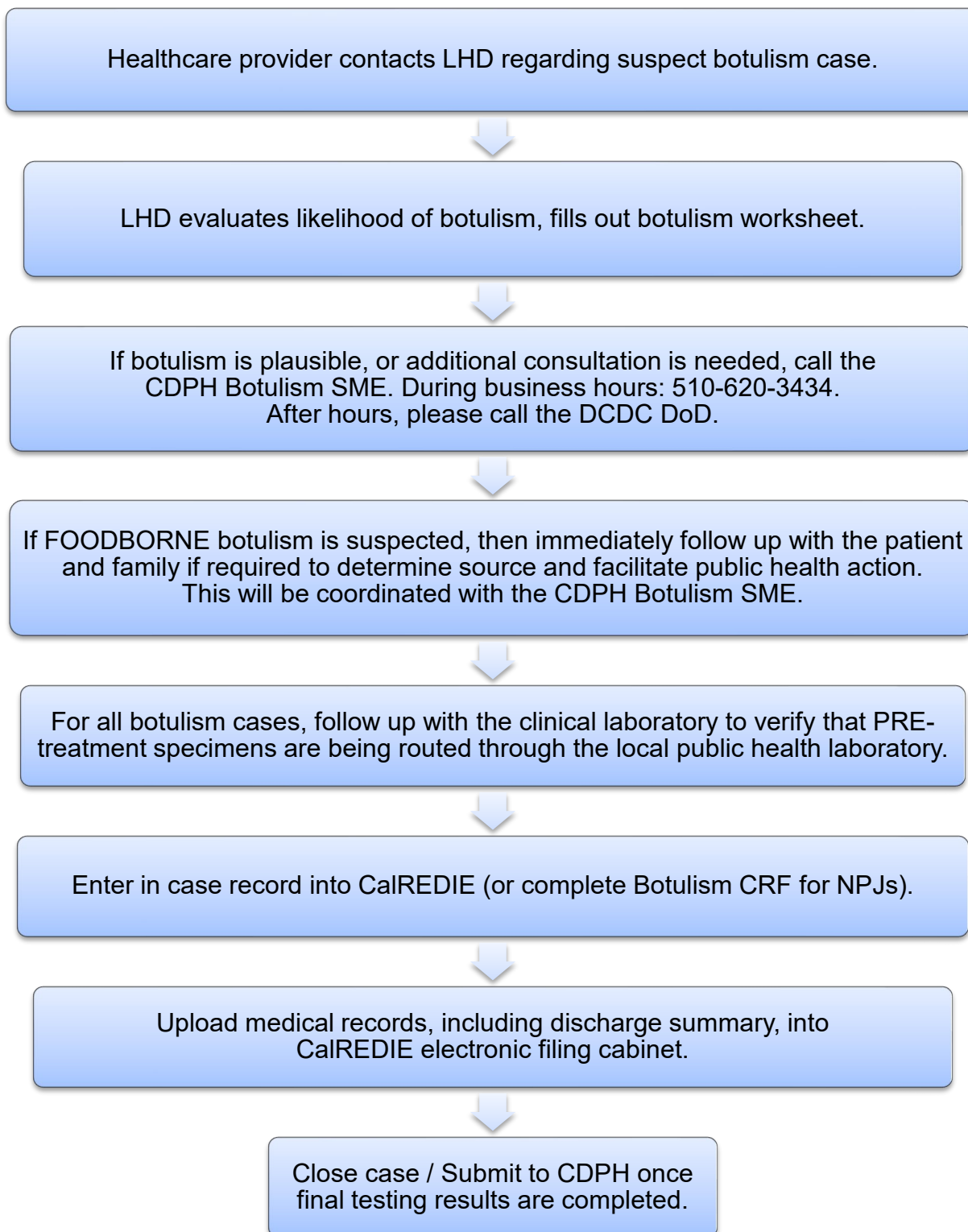
- All outbreaks and individual cases of botulism (Infant, Foodborne, Wound, Other) are immediately reportable in California by telephone.
- 2500: Health care providers are required to report suspected botulism cases immediately by telephone.
- 2502: The Local Health Officer is required to report suspected botulism cases immediately by telephone to CDPH.
- 2505: the laboratory is required to report to CDPH or to MDL immediately by telephone all requests for botulism testing.

VI. ADDITIONAL RESOURCES

- [Centers for Disease Control and Prevention Botulism website](https://www.cdc.gov/botulism/)
<https://www.cdc.gov/botulism/>
- [California Department of Public Health Botulism website](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Botulism.aspx)
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Botulism.aspx>
- California Department of Public Health. [Epidemiologic Summary of Foodborne Botulism in California, 2013 – 2019](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/FoodborneBotulismEpiSummary2013-2019.pdf). Accessed September 12, 2022.
<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/FoodborneBotulismEpiSummary2013-2019.pdf>

- California Department of Public Health. [Microbial Diseases Laboratory - Adult Botulism Diagnostic Testing](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/TestOrderAdultBot.aspx). Updated July 22, 2022.
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/TestOrderAdultBot.aspx>
- California Department of Public Health. [Epidemiologic Summary of Wound Botulism in California, 2013 – 2019](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/WoundBotulismEpiSummary2013-2019.pdf). Accessed September 12, 2022.
<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/WoundBotulismEpiSummary2013-2019.pdf>
- Rao AK, Sobel J, Chatham-Stephens K, Luquez C. [Clinical Guidelines for Diagnosis and Treatment of Botulism, 2021](https://www.cdc.gov/mmwr/volumes/70/rr/rr7002a1.htm). MMWR. 2021;7(2);1-30. Available at:
<https://www.cdc.gov/mmwr/volumes/70/rr/rr7002a1.htm>
- Sobel J. Botulism. *Clinical Infectious Diseases*. 2005;41:1167-73.
- American Public Health Association. [Botulism]. In: Heymann, David L., ed. *Control of Communicable Diseases Manual*. 20th Ed. Washington, DC. American Public Health Association; 2015:71-7.

Figure 1. Suspected Botulism Step-by-Step Guide



Appendix A: LHD BOTULISM WORKSHEET
For non-infant (>16 months) botulism cases

Section 1: LHD/CALLER INFORMATION

1. LHD Point of Contact Information

Name: _____ Phone Number: (____) _____ - _____

Email Address: _____

Local Health Department: _____

2. Physician Name:

Name of Hospital: _____ Phone/pager: _____

Position: Hospitalist Neurologist ER MD Infectious Disease Specialist

Resident/trainee* _____ *obtain # for attending of record

Other: _____

3. Date (MM/DD/YYYY): _____ Time: _____

Section 2: PATIENT DATA

1. Patient Name:

2. Birthdate: _____

(if age <15 months, call Infant Botulism Program: **510-231-7600, 24/7/365**)

3. Sex: Male Female Unknown

4. County of Residence:

5. Medical Record Number:

6. Patient Location in Hospital: ER ICU Room #

Section 3: CLINICAL INFORMATION

1. Onset date of neurological symptoms: ___/___/_____ Onset Time: _____ Unknown

2. General description of clinical presentation, including type and progression of symptoms:

3. Does the patient have at least one cranial nerve abnormality, including:

Eye problems: double/blurry vision, ptosis; difficulty moving the eyes, pupils that don't react to light

Difficulty swallowing or speaking

Facial paralysis

(If none of these symptoms are present, it is unlikely to be botulism.)

Comments:

Section 4: RISK FACTORS

Does the patient have:

1. History of injection drug use? Yes No Unknown

If Yes, Describe: _____

Last used: _____

2. A history of eating home-canned or other high-risk foods? Yes No Unknown

a) If Yes, Describe: _____ Unknown

In the one month prior to illness onset, did the patient:

3. Sustain any wounds or injuries (e.g., fractures, falls, etc.)? Yes No Unknown

a) If Yes, Describe: _____ Unknown

4. Receive any pharmacologic botulinum toxin (such as Botox, Myobloc) for cosmetic or therapeutic reasons? Yes No Unknown

a) If Yes, Describe: _____ Unknown

b) Date of most recent use: _____ Unknown

Comments:

Section 5: DISPOSITION

1. Suspicion for Botulism: High Low Unknown

2. Referred to CDPH for consultation: Yes (*fill out a and b*) No

CDPH IDB: 510-620-3434; DCDC DOD pager (afterhours)

a) If Yes: Name of CDPH contact: _____

b) Email: _____ Phone: _____

3. BAT released: Yes Date: _____ No

4. Patient interviewed: Yes Date: _____ No

5. Patient specimens sent to MDL: Yes Date: _____ Results: _____ No

6. *For suspected foodborne botulism*: Home inspection completed Yes No

7. Medical Records Requested

8. Case Closed in CalREDIE: Yes No

a) CalREDIE ID: _____

b) Resolution Status: Confirmed Probable Suspect Not a case

Comments:

Appendix B: Suspect Foodborne or Unknown Etiology (Non-Wound) Botulism Case Interview Form for Hypothesis Generation

Patient interview is best. If the patient is paralyzed, but able to communicate, please obtain as much information directly from the patient as possible, with supplementation by family/friends. If the patient is unable to be interviewed, please obtain history from as many different sources as possible, including household contacts (e.g., spouse, parents, siblings, roommates) and friends. Ask to review social media contacts/threads (e.g., Facebook). It is critical to fill in every aspect of the days leading up to onset! Have a calendar handy and note any major holidays or events as reference. A contact tracing table is available in Section 3.

Section 1: INTERVIEW INFORMATION

(Questions 1-2 to be completed by interviewer prior to questionnaire administration)

1. State/Local/Other ID (CaREDIE, VCMR) #: _____
2. Interviewer Information
Name: _____
Contact phone number: (____) _____ - _____
Agency or Organization: _____
3. Respondent was: Self Parent Spouse Other: _____
If patient was interviewed, responses were:
 Verbal Written Hand squeeze Other: _____
4. Interview Date(s) (MM/DD/YYYY):
Int #1: ___/___/____ Int #2: ___/___/____ Int #3: ___/___/____
5. Interview Language: English Spanish Other: _____

Section 2: CLINICAL INFORMATION (For all dates below, use MM/DD/YYYY format)

1. Onset date of neurological symptoms: ___/___/____ Onset Time: _____
 Unknown Onset
2. Hospital name: _____
Date of admission: ___/___/____ Not hospitalized
3. Number of days in ICU: _____ No ICU stay
4. Number of days intubated: _____ No intubation
5. Date of discharge: _____ Not discharged as of ___/___/____
6. Disposition: Home Rehabilitation facility Deceased Unknown

Comments:

Section 3: CONTACT LIST

Are you aware of anyone who has a similar illness that has been in contact with you, or anyone that you have been in contact with in the 10 days before illness who may have shared a meal with you, purchased food for you, or would otherwise know about your food sources?

Name	Relationship	Same Household	Ill?	Phone #	Email/Other	Interviewed (Y/N)

Section 4: MEDICAL HISTORY, TRAUMA, AND PROCEDURES

Does the patient have:

1. Underlying medical problems? Yes No Unknown
 - a) *If Yes, Describe:* _____ Unknown
2. A history of surgery to the GI tract (e.g., bowel resection, gastric bypass)?

Yes No Unknown
 - a) *If Yes, Describe:* _____ Unknown

In the one month prior to illness onset, did the patient:

3. Sustain any wounds or injuries (e.g. fractures, falls, etc.)? Yes No Unknown
 - a) *If Yes, Describe:* _____ Unknown
4. Receive any pharmacologic botulism toxin (such as Botox, Myobloc) for cosmetic or therapeutic reasons? Yes No Unknown

If Yes,

 - a) Describe: _____ Unknown
 - b) Date of most recent use: _____ Unknown
 - c) Number of units: _____ Unknown

In the one month prior to illness onset, did the patient:

5. Have any dental procedures, such as a root canal? Yes No Unknown
a) *If Yes*, Describe: _____ Unknown
6. Have any surgical procedures, either elective or emergent, such as a c-section, gallbladder removal, etc.? Yes No Unknown
a) *If Yes*, Describe: _____ Unknown
7. Get tattoos or piercings? Yes No Unknown
a) *If Yes*, Describe: _____ Unknown
8. Does the patient have any food allergies or dietary restrictions? Yes No Unknown
a) *If Yes*, Describe: _____

Comments:

Section 5: DRUG AND MEDICATION USE

In the one week prior to illness onset, did the patient:

1. Take any prescription medications? Yes Maybe No Unknown
If Yes or Maybe,
a) Name of medication(s): _____ Unknown
b) Route (oral, injection, etc.) _____ Unknown
2. Take any illicit medications, drugs? Yes Maybe No Unknown
If Yes or Maybe,
a) Name of medication(s): _____ Unknown
b) Route (oral, injection, etc.) _____ Unknown

Comments:

Section 6: EVENTS, PLACES, TRAVEL

Next, I would like to ask you a few questions about any events, gatherings, or travel (*patient name*) may have participated in the 10 days before the illness.

Did (*patient name*):

1. Travel outside your city of residence for work or pleasure?

Yes Maybe No Unknown

If Yes or Maybe,

a) List Place(s): _____ Unknown

b) Dates of travel: _____ Unknown

2. Attend any other events such as school events, church events, track meets, sporting events, fairs, festivals, wedding receptions, parties picnics, etc.?

Yes Maybe No Unknown

If Yes or Maybe,

a) Types of events: _____ Unknown

b) Locations (cross-streets, city): _____ Unknown

c) Dates: _____ Unknown

d) Other ill attendees (describe who, how many): _____ Unknown

e) Foods eaten: _____ Unknown

3. Additional events, if any? Yes Maybe No Unknown

If Yes or Maybe,

a) Types of events: _____ Unknown

b) Locations (cross-streets, city): _____ Unknown

c) Dates: _____ Unknown

d) Other ill attendees (describe who, how many): _____ Unknown

e) Foods eaten: _____ Unknown

4. Attend school/work? Yes Maybe No Unknown

If Yes or Maybe,

a) Name of school/place of employment: _____ Unknown

b) Grade in school/Occupation: _____ Unknown

c) Locations (cross-streets, city): _____ Unknown

d) Other ill persons (describe who, how many): _____ Unknown

Comments:

Section 7: SOURCES OF FOOD AT HOME

Now I have a few questions about where the food came from that (*patient name*) ate **at home** in the 7 days before your illness began. This isn't necessarily where you shopped during that week, but where the food (*patient name*) ate came from. I'm going to list several types of stores, for each type please tell me the names of each store (*patient name*) would have eaten food from during the 7 days before you (your family member/friend/child) were sick.

1. Did you (your child) eat foods from:

Please check all that apply and list all sources in the table below.

- Grocery stores or supermarkets
- Health food stores or co-ops
- Warehouse stores (Costco, Sam's Club, etc.)
- Farmer's markets, roadside stands, open-air markets, or food purchased directly from a farm
- Small markets or mini markets (convenience stores, gas stations, etc.)
- Fish or meat specialty shops (butcher's shop, etc.)
- Ethnic specialty markets (Mexican, Asian, Indian, etc.)
- Other

Store/Retail Name	City	Cross-streets/Address

Comments:

Section 8: SOURCES OF FOOD OUTSIDE THE HOME

Now I have a few questions about where the food came from that you (*patient name*) ate **outside your home**, such as restaurants or fast food chains. I'm going to list several types of restaurants, for each type please tell me the names of each place you (your child) would have eaten food from during the 7 days before you (your child) were sick.

1. Did you (your family member/child/friend) eat at any:

Please check all that apply and list all places in the table below.

- Food trucks, food stands/stalls
- Salad bar at a grocery store or restaurant
- Any take-out food from restaurant
- An event where food was served, such as a catered event, food festival, church or community meal, etc.
- School or other institutional setting
- Other

Restaurant/Eatery Name	Location	Foods Eaten	Date

Comments:

Section 9: FOOD HISTORY

Now I have a few questions about other food items that you (*patient name*) ate in the 7 days before the illness.

***Note to interviewer: If patient has any leftovers of suspect food items, please have them save for potential testing. Conditions that are conducive to toxin production include high water, high pH, low salt, low sugar; prolonged incubation at room temperature, not heated to 65°C before eating, anaerobic environment.*

Food Item	Yes	No	Unk	If Yes: Details (type of food, how store, refrigerated, etc.)	Type of packaging, Labeling, if any	Where obtained
Any home-canned or jarred product (made at home or by friend/ family), such as preserved vegetables, Canned meat, spreads, jellies, etc.)						
Any fermented or otherwise preserved product (e.g., bean paste, tofu, pickles, fish, etc.)						
Dried or fermented meat not packaged at the store						
Garlic or herbs marinated in oil (e.g., including pesto)						
Unpasteurized juices (either fruit or vegetable, including carrot juice)						
Vacuum packed foods (e.g., smoked fish, meat)						
Olives or other vegetables kept in jars						
Dips and spreads, especially home prepared or from a farmer's market						
Any prepackaged grain product (e.g., rice), including commercially prepared foods stored at inappropriate temperature prior to eating (e.g., foods that are meant to be						

Food Item	Yes	No	Unk	If Yes: Details (type of food, how store, refrigerated, etc.)	Type of packaging, Labeling, if any	Where obtained
refrigerated stored at room temperature)						
Any soup or other ready-to-eat product packaged in plastic container (e.g., that are meant to be refrigerated stored at room temperature)						
Dried salted fish (especially un-eviscerated)						
Pre-prepared herbal teas (liquid form. Ready-to-drink)						
Herbs or supplements						
Any specialty or ethnic foods or snacks						
Specialty prepared nutritional food or drink						
Home brewed alcohol, such as pruno						
Baked potato or other foods stored in foil and not promptly refrigerated						
Foods cooked at home and not refrigerated or frozen promptly as per the recipe/instructions						
Other food items of interest						

Comments:

Section 10: OPEN-ENDED DAILY HISTORY

I am now going to ask you about the activities, (*patient name*) participated in the 3 days before illness onset, including all the food eaten and places (*patient name*) visited in the 3 days before (*patient name*) got sick. (add days if move to the end)

Note to interviewer: Go through the entire day, from the moment the patient woke up to the time he/she went to bed- there should be an account of every waking moment.

Seven days are optimal, but the three days prior to illness would be most crucial. Use additional sheets of paper if recall is good for all seven days.

Days before illness onset: 0 (only ask about activities before onset): Date:	Food eaten/ Activity	At Home	Outside Home (location)	Describe activity (i.e., attended school, attended birthday party or other event, went to work, etc.) and all things consumed, including food, drink, supplements, drugs
Morning (wake up time- noon): ask about breakfast				
Afternoon (noon- 5PM): ask about lunch, snacks				
Evening (5PM- 9PM): ask about dinner				
Night (9PM- bedtime); any snacks				

Days before illness onset: 1 (only ask about activities before onset): Date:	Food eaten/ Activity	At Home	Outside Home (location)	Describe activity (i.e., attended school, attended birthday party or other event, went to work, etc.) and all things consumed, including food, drink, supplements, drugs
Morning (wake up time- noon): ask about breakfast				

Days before illness onset: 1 (only ask about activities before onset): Date:	Food eaten/ Activity	At Home	Outside Home (location)	Describe activity (i.e., attended school, attended birthday party or other event, went to work, etc.) and all things consumed, including food, drink, supplements, drugs
Afternoon (noon-5PM): ask about lunch, snacks				
Evening (5PM-9PM): ask about dinner				
Night (9PM-bedtime); any snacks				

Days before illness onset: 2 (only ask about activities before onset): Date:	Food eaten/ Activity	At Home	Outside Home (location)	Describe activity (i.e., attended school, attended birthday party or other event, went to work, etc.) and all things consumed, including food, drink, supplements, drugs
Morning (wake up time- noon): ask about breakfast				
Afternoon (noon-5PM): ask about lunch, snacks				
Evening (5PM-9PM): ask about dinner				
Night (9PM-bedtime); any snacks				

Days before illness onset: 3 (only ask about activities before onset): Date:	Food eaten/ Activity	At Home	Outside Home (location)	Describe activity (i.e., attended school, attended birthday party or other event, went to work, etc.) and all things consumed, including food, drink, supplements, drugs
Morning (wake up time- noon): ask about breakfast				
Afternoon (noon- 5PM): ask about lunch, snacks				
Evening (5PM- 9PM): ask about dinner				
Night (9PM- bedtime); any snacks				

Comments:

Section 11: OTHER EXPOSURES

We have covered a wide variety of foods and activities. After answering all these questions are there any other exposures (food, drinks, animals, activities, ill persons) that occurred in the 7 days before your (the patient's) illness onset?

Please describe:

Patient ID: _____

Appendix C: Home Inspection Guide for Suspected Foodborne Botulism

All patients with suspect foodborne botulism should have their home inspected for a potential source within 24 hours of identification, especially if a commercial product is suspected.

Botulism-associated food testing is a vital, but resource intensive, activity. Adequate forward planning is important to increase the chances that the potential source of foodborne botulism is identified and ensure that laboratory testing resources are used judiciously. Consider consulting with the California Food and Drug Branch, Microbial Diseases Laboratory (MDL), and Botulism subject matter expert (SME) prior to conducting a home inspection. MDL should be consulted prior to sending food specimens for testing.

Before the visit, ask patient's family to not discard any consumable product (food, drink, herbal supplements) until the inspection is conducted by public health. Persons living with the patient should not consume any products in the home until the inspection is completed.

I. Prior to going to residence:

Coordinate with epi staff regarding any information already collected from patient.

Name of patient: _____ Date of illness onset: ___/___/_____

Point of contact: _____ Phone: _____

Address of residence: _____

Persons living with patient or providing food for patient:

Name	Age	Relationship	Shared meals with patient (describe)	Symptomatic?

Patient ID: _____

II. Overview

- A. General description of home (level of organization, likelihood of mishandled food, etc.):
- B. Does the patient live alone? Yes No Unknown
- C. If a household member is available during the home visit, inquire:
1. What are the patient's usual food habits (prepares own meals, all take out, etc.)?
 2. Who does the patient usually eat with?
 3. Is there any food item that he/she eats that no one else in the household consumes?
 4. Where is food usually stored? This includes any area where food is kept, not just the kitchen and pantry, but also places like garage, bedroom, den, etc.

Let them know that you will be focusing your inspection on the kitchen and pantry and will be taking some pictures.

III. Detailed Inspection

Look for high risk foods. *C. botulinum* grows in an anaerobic (oxygen-free) environment. Conditions that are conducive to toxin production include high water content, high pH (>4.6), low salt, low sugar, inadequate heating of food before eating (botulinum toxin is heat labile and can be inactivated by heating to 176°F [80°C]), or prolonged storage of food at room temperature. You may want to look for food containers with tight fitting lids that sat outside of refrigerated temperatures. A localized anaerobic environment can sometimes be created during food preparation, for example when herbs are marinated in oil, or in the inner portion of a food item that has been heated (e.g., a case of botulism linked to chicken pot pie).

Potential high-risk items include:

- Any home-canned/jarred, fermented, or otherwise home-preserved product
- Products marinated in oil (e.g., garlic or herb infused oils)
- Any product, including commercially prepared foods stored at inappropriate temperature prior to eating (e.g., foods that are meant to be refrigerated but are stored at room temperature)
- Prepared herbal tea (liquid tea pouch, not dried tea)/ other liquid supplements
- Foods from prior foodborne botulism patients have included
 - Commercial soups or mixed grain product from refrigerator aisle kept in pantry
 - Commercial soup sold in pouches at room temperature that required refrigeration after opening
 - Commercial jarred black fungus
 - Commercial nacho cheese in a pump dispenser
 - Cooked spaghetti stored in plastic bag
 - Homemade pesto
 - Garlic in oil; herbs in oil

Patient ID: _____

- Home-canned potatoes used in potato salad
- Baked potato wrapped in foil, and potato salad made from foil wrapped potato
- Homemade chicken pot pie
- Dried salted and unsalted fish (especially uneviscerated)
- Home-fermented tofu
- Oriental herbal tea liquid pouches (herbal supplements, herbal remedies)
- Prison-brewed alcohol (“Pruno”)

A. Investigate food storage areas, especially the kitchen:

- Refrigerator, freezer, kitchen cabinets, pantry
- In addition to kitchen and pantry, make sure to inquire about/inspect other potential food storage areas:
 - Garage
 - Storage shed
 - Bedrooms
 - Living room/dining room
 - Car
- Investigation should include trash
 - Kitchen garbage (last emptied: ___/___/___)
 - Outside garbage (last trash pickup ___/___/___)
 - Other trash:

B. Take pictures:

- Inside of refrigerator
- Inside of freezer
- Inside pantry/ food storage areas
- Any food samples collected (including all sides of labeling, top and bottom of container)

C. Collect food samples:

Caution: Spoiled food can potentially contain high levels of botulinum toxin. Do not open containers with bulging lids or smell food to determine spoilage.

- Any homemade items that are suspicious (e.g., home canned or preserved meat, fish or vegetables/home prepared vegetable or meat pies)
- Food containers with obvious bulging lids (e.g., glass jar with metal screw cap lid where the top is dome shaped or does not easily depress when pushed indicates gas produced by bacteria) – **send entire container**
- Food containers where gas bubbles are evident in the food. Gas can be stationary in gas pockets (in viscous foods) or actively bubbling (e.g., glass jar of liquid food where gas can be seen actively bubbling from bottom – **send entire container**)
- Food that smells putrid (as noted by interviewee)

Patient ID: _____

- Any food item that was consumed only by the patient, if living with other people
 - Any commercial food items that were improperly stored (e.g., opened jars and containers that should have been refrigerated but were stored at room temperature, etc.). Include detailed photos that include product information and lot code.
 - Empty containers with food residue can still be submitted for testing
 - Note where/how the food was stored
 - Always collect and send food in the container in which it was found; either commercial or personal
 - Send high risk foods through local PHL to CDPH, Microbial Diseases Laboratory (MDL), Botulism Laboratory Unit
- Note:** Collected food samples should be stored and transported at the same temperature in which they were found (i.e., if the food sample was collected at room temperature, it should be stored and transported at room temperature).
- Call CDPH IDB Botulism SME with any questions

IV. Suspect Botulism Food Sampling and Collection Guidelines

Contact your public health laboratory and communicable disease counterparts before the investigation to determine what kinds of food to collect. Consider consulting with other environmental health programs such as the California Food and Drug Branch for guidance on sampling selection. Please see **Appendix C – III** to determine what types of food items to collect. For diagnostic testing guidance, see the [MDL Adult Botulism Diagnostic Testing webpage](#).

A. Equipment

- Gloves
- Sterile Containers
- Coolers
- Sharpies
- Labels

B. Collection

- Wash hands thoroughly and dry with paper towel
- Use properly fitting gloves and do not touch any portion of the food.
- Be mindful not to cross-contaminate samples
- Use the sterile collection tools to retrieve the sample
- Collect sample in sterile containers or bags from the kit.
- If product is still in its retail packaging:
 - Leave product in its original container

Patient ID: _____

- Collect an intact, unopened container of the same batch/lot for comparison if possible
- For foods with high moisture content or liquids:
 - Use containers that can be sealed securely
 - Store separately from other samples in case of leakage
- For large food items
 - Collect the entire food item
 - Leave product in the container it is found in and wrap product in foil and plastic to prevent spills and cross contamination
- Assign and label each sample with an identifying number
- Seal sample with tamper evident tape
- Place sample in proper storage container using the following guidelines
 - For foods that do not need refrigeration, use insulated coolers or clean containers/bags
 - For foods that do need refrigeration, use insulated coolers with ice packs
 - For foods that are frozen, keep frozen. Use insulated coolers with ice packs, then place in freezer as soon as possible
 - Note if food item is not frozen, do not freeze the specimen
- Fill out Chain of Custody and lab submission forms for each sample
- Create a log of all specimens collected
- Transport samples to the laboratory as quickly as possible.
 - If immediate delivery to lab is not possible, store specimens in a secured area
 - Check if types of samples collected have a time/temperature restriction upon collection and delivery to laboratory
- Make copies of all forms (chain of custody and laboratory submission forms) for your records