**Suspected Botulism Cluster Associated with Inconsistently Labeled Prepackaged Soup: Implications for Food Labeling Guidelines**

Christina A. Mikosz¹ ², David E. Dassey², Moon Kim², Patricia Bolivar³, Anton Mayr³, Salette Amador⁴, Emoke Csegeri⁴, Ziad Askar⁴, Agam Rao⁵, and Laurene Mascola²

¹Epidemic Intelligence Service, Centers for Disease Control and Prevention

²Acute Communicable Disease Control, Los Angeles County Department of Public Health

³Public Health Laboratory, Los Angeles County Department of Public Health

⁴Food and Milk Program, Los Angeles County Department of Public Health

⁵Enteric Diseases Epidemiology Branch, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

**Corresponding contributor:** Christina A. Mikosz, MD, MPH; 313 N. Figueroa St, Room 212; Los Angeles, CA 90012; CMikosz@cdc.gov. Phone: (213) 240-7941. Fax: (213) 482-4856.

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ABSTRACT

Objectives: Botulism, which may be foodborne in origin, causes a potentially fatal neurotoxin-mediated acute descending paralysis. In February 2012, the Los Angeles County Department of Public Health (LAC DPH) was notified of two suspected foodborne botulism cases. We investigated to confirm the diagnoses, identify the source, and prevent additional cases.

Methods: We reviewed medical records and interviewed physicians and both patients. Food samples were collected during a home inspection. Food, serum, stool, and gastric aspirate specimens underwent botulism testing by mouse bioassay, polymerase chain reaction, and enzyme-linked immunoassay at the LAC DPH Public Health Laboratory; CDC conducted matrix-assisted laser desorption/ionization time-of-flight testing.

Results: The patients, a male and female aged 23 years, experienced ptosis, blurry vision, dizziness, and dysphagia 4 days after sharing rancid-tasting soup left sealed and unrefrigerated for 11 days after purchase. Both patients were hospitalized; while laboratory botulism testing of patient specimens was negative, clinical findings were consistent with botulism. Patient interviews indicated that confusion over inconsistent refrigeration instructions on the soup container and packaging led to improper home storage of the soup. The Food and Drug Administration and the store of purchase, a national chain, were notified of the labeling inconsistency. The store chain immediately changed the instructions throughout similarly packaged food products to emphasize the need for refrigeration. No other cases were identified; both patients recovered.

Conclusions: Illness in both patients was highly suspicious for botulism, which likely occurred from prepackaged soup stored improperly because of inconsistent refrigeration instructions on
package labeling. Food storage instructions should be displayed clearly and consistently to avoid life-threatening foodborne illnesses.
INTRODUCTION

Botulism is caused by a neurotoxin typically produced by *Clostridium botulinum*, whose spores are ubiquitously found in soil. Botulinum toxin, which has been described as the most poisonous substance known (1), causes illness via irreversible blockade of acetylcholine release from presynaptic nerve endings, leading to acute cranial neuropathies and a descending flaccid paralysis that may lead to death, typically via respiratory failure, if not diagnosed in time.

Botulism spores may be present on certain ingredients in prepackaged foods, most commonly root vegetables, if these foods are not sterilized during production, either via adequate heating, pressure cooking (as required for commercially-produced canned foods), or addition of an acidifying agent or other microbial barrier. Under certain environmental conditions (anaerobic, low salt and sugar content, low acidity, and unrefrigerated), these spores can germinate, leading to bacterial growth and production of toxin (2).

In early February 2012, the Los Angeles County Department of Public Health (LAC DPH) was notified by a physician at a local hospital of two patients with suspected foodborne botulism, a male and female both aged 23 years who lived together. We investigated to confirm the diagnosis, identify the source of exposure, and to prevent further exposure and illness.

METHODS

*Case Investigation.* LAC DPH epidemiologists reviewed patient medical records and interviewed physicians, both patients, and one of two roommates of the patients who also provided information on a second roommate who was not accessible. Botulism cases were defined based on the standard National Notifiable Diseases Surveillance System case definition (3).
Environmental Inspection. LAC DPH conducted an inspection of the patients’ home to identify and collect for laboratory testing foods suspicious as a vehicle for botulism. Traceback investigation of the implicated soup product was conducted via the store of purchase, Store X.

Laboratory Testing. Patient specimens and food samples were tested for botulinum toxin by mouse bioassay and enzyme linked immunosorbent assay (ELISA) at the LACDPH Public Health Laboratory (PHL); the presence of botulinum toxin genes was tested by polymerase chain reaction (PCR) and by culture for *C. botulinum*. CDC conducted toxin testing via matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF).

RESULTS

Case Investigation

On January 10, 2012, the male and female purchased a prepackaged, ready-to-eat broccoli soup from Store X, a national chain. The package of soup they purchased was alone on an unrefrigerated shelf of the store, presumably left there inadvertently by another person. Upon returning home, the soup’s outer packaging, a cardboard sleeve, was removed and the soup was stored in a kitchen cabinet.

On January 21, the soup was microwaved to a lukewarm temperature and shared by both patients. The female tasted the soup, noticed a rancid taste, and spit it out; the male ate several spoonsful before discarding all remaining soup. Four days later, on January 25, both patients awoke with ptosis, blurry vision, dizziness, and dysphagia, without sensory deficits or mental status changes, prompting evaluation at several medical facilities.

The male visited two outpatient medical facilities, an urgent care clinic then an emergency room, on January 27 with the above symptoms, complaining primarily of throat
discomfort/difficulty swallowing and dizziness, without fever. He was evaluated for possible epiglottitis, but with negative neck imaging, this diagnosis was felt to be less likely and he was discharged home. Progressive dysphagia, now accompanied by dysphonia and anorexia, prompted him to visit a third facility on January 30, where epiglottitis was again considered and he was hospitalized for treatment of this diagnosis and dehydration. He developed progressive upper extremity weakness over the next few days in the hospital. Botulism was considered as a possible diagnosis on February 2, at which point LACDPH was notified. He developed respiratory failure requiring mechanical ventilation later that same night and received treatment with botulinum antitoxin on February 3. His hospital course was complicated by development of a pulmonary embolus. He was extubated on February 17, and on February 23, after 25 days of hospitalization, he was discharged home and ultimately recovered fully.

The female visited outpatient medical facilities on January 27 and January 30 complaining of persistent dizziness and was discharged home each time. She presented to a third outpatient medical facility on January 31 with continued dizziness and throat tightness, as well as several other nonspecific complaints, and mentioned at this visit that the male patient had also been ill and had just been hospitalized for presumed epiglottitis. However, this was felt to be a less likely diagnosis to explain her symptoms and she was discharged home. She was then electively hospitalized for observation on February 2 once botulism was suspected in the male patient. On her admission exam, mild upper extremity weakness, mild ptosis, and a weak gag reflex were noted, all findings consistent with possible botulism. Her symptoms did not progress, and she did not require antitoxin treatment; she was discharged home 2 days later.

Electromyography performed on both patients was reviewed by three independent neurologists but interpretations of these studies and their compatibility with a botulism diagnosis
varied. However, both cases met the National Notifiable Diseases Surveillance System case definition for a probable botulism case (3). The patients had two roommates, neither of which had shared the soup but had shared other recent meals with the patients. Both roommates were healthy and denied symptoms of botulism upon interview. No other cases were identified in Los Angeles County.

**Environmental Inspection**

Leftover homemade spaghetti, the last meal shared by the patients prior to symptom onset and prepared immediately after discarding the broccoli soup, was collected for laboratory testing. The broccoli soup was unavailable for testing. No other suspect foods were identified via inspection of the patients’ home or by interview.

**Laboratory Testing**

Serum (collected pre-antitoxin administration, in the male patient) and stool from both patients, as well as gastric aspirate from the male, were tested at the LACDPH PHL for botulinum toxin by mouse bioassay; serum was also tested by ELISA. Stool and gastric aspirate were tested by direct culture for *Clostridium botulinum*; the enrichment broths of the stool and gastric aspirate were screened for the presence of toxin genes by PCR and by culture for *C. botulinum*. The spaghetti was tested for toxin by mouse bioassay and ELISA, and the enrichment broth of the spaghetti was tested by PCR. CDC conducted toxin testing on all specimens by MALDI-TOF. All LACDPH PHL and CDC laboratory botulism testing of patient and food specimens was negative.
**Traceback Investigation**

Traceback of the implicated broccoli soup by LACDPh Environmental Health found that Store X properly stored the soup in the refrigerator case; holding temperature in the refrigerator case was in compliance with regulations. The soup was commercially packaged in two individual tubs encased in a cardboard sleeve. Refrigeration instructions printed throughout the tubs and the cardboard sleeve differed: the tubs and back of the sleeve were marked with instructions to “Promptly Refrigerate Remaining Soup” while the front and top of the sleeve stated, “Keep Refrigerated.” The soup’s manufacturer produced other ready-to-eat soup products packaged in various ways; however, the broccoli soup implicated in this outbreak was packaged as described only for Store X. Based on review of the soup’s ingredient list, the soup contained small amounts of onions and pureed garlic, but no other root vegetables or other ingredients likely to have been contaminated with soil at the time of processing.

The patients had discarded the cardboard sleeve upon returning home from Store X without noticing the “Keep Refrigerated” instructions. They only saw the “Promptly Refrigerate Remaining Soup” refrigeration instructions on the tubs, which they interpreted to mean that because the soup was not yet opened, it did not require refrigeration. The Food and Drug Administration (FDA) and Store X were notified of the conflicting instructions, and in response, clearer instructions were immediately affixed by Store X to all similarly-packaged soups, with plans for permanent labeling changes with the next production cycle by the soup’s manufacturer.

**DISCUSSION**

This outbreak emphasizes the importance of clear, consistent food storage instructions on commercially packaged, ready-to-eat food products to prevent illness including foodborne
botulism. The patients in this outbreak did closely inspect the soup packaging for refrigeration instructions, but inconsistent labeling that included instructions not emphasizing the need for refrigeration at all times, compounded by the product being found in a non-refrigerated area at Store X, led them to store this product at room temperature. Other recently reported foodborne botulism cases have been linked to improper storage of prepared soups requiring refrigeration (4,5), demonstrating that ready-to-eat soups and possibly other prepared foods requiring refrigeration may be a source of botulism. Consumer research shows an increasing consumption of prepackaged, chilled convenience foods (6), emphasizing further the need to minimize food safety risks for such products.

Several strategies may be implemented to reduce the risk of foodborne botulism in prepackaged foods. Inclusion of messaging on food packaging specifically describing the role for refrigeration in reducing the risks of illness has been previously discussed in FDA guidance as a possible strategy to improve food safety (7), although this would not have prevented illness in this outbreak. An alternative consideration is the addition of an acidifying agent or other antimicrobial compound to prepackaged food products that do not otherwise contain a natural barrier to C. botulinum growth. A series of foodborne botulism outbreaks in the 1980s linked to garlic-in-oil products prompted FDA to require the addition of an acidifying agent such as citric or phosphoric acid (8); no botulism outbreaks linked to garlic-in-oil products have been reported in the literature since. Similarly, an international botulism outbreak associated with commercially produced carrot juice—which is naturally low in acid, salt, and sugar—led to modified FDA guidance recommending acidification or thermal treatment for refrigerated, low-acid juices (9). Such strategies may also be broadly indicated for prepackaged, ready-to-eat foods including soups, particularly since the soup implicated in this outbreak did not contain large
amounts of root vegetables or other ingredients classically linked to foodborne botulism, implying that any ready-to-eat food product may be at risk.

This investigation also serves as a reminder of the importance of clinician knowledge about botulism symptoms. Textbook electromyography results and laboratory confirmation of botulism in suspected cases do not always occur (10). Furthermore, even if laboratory testing confirms a diagnosis of botulism, results may take several days to return, meaning that diagnosis, prompt management, and public health investigation of suspected botulism initially relies only on clinical suspicion.

However, the clinical syndrome of botulism is likely underrecognized, with one study finding that only approximately 50% of surveyed physicians correctly diagnosed botulism when presented with a fictional clinical case (11). In this outbreak, botulism was not included in the differential diagnosis for either patient despite symptoms suggesting descending paralysis and, during at least one visit, discussion of the other patient’s symptoms, an epidemiologic link that could have provided diagnostic clues (12), particularly in light of the female patient’s subtle, less severe presentation that was attributed to other disease processes. While these two patients had a slower progression of illness following exposure than the classic rapid presentation often associated with botulism, botulism outbreaks characterized by prolonged symptom duration have been reported (13). Additionally, symptoms not classically associated with botulism, such as paresthesias and normal pupils, were frequently noted in a review of botulism cases reported to the Centers for Disease Control and Prevention (14), highlighting that atypical features should not automatically eliminate botulism from consideration if other diagnostic clues are present. Importantly, the clinical syndrome of an acute, descending paralysis with cranial nerve involvement and the epidemiologic linkage to another patient with similar symptoms are
collectively highly suggestive of botulism even in the absence of laboratory confirmation (12). Despite their varying presentations, both patients met the standard case definition of a probable botulism case (3). Because of its lethality, botulism is always considered a medical emergency requiring rapid notification of public health officials to rule out widespread exposure to a contaminated item or product, but prompt reporting relies on high clinical suspicion and consideration of a botulism diagnosis. Clinicians are reminded to consider botulism in the differential diagnosis of descending paralysis involving cranial nerves and to immediately alert health officials to investigate.

**CONCLUSIONS**

In summary, we describe an outbreak of suspected foodborne botulism likely caused by consumption of a prepackaged soup stored improperly due to confusing, inconsistent package refrigeration instructions. Food product labeling addressing storage requirements should be clearly and consistently worded throughout product packaging. Clinicians should consider the possibility of botulism for any patient with acute onset of descending paralysis involving cranial nerves and notify public health officials immediately if suspected.

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