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Inadequate Refrigeration of Some Commercial Foods Is a Continued Cause of Foodborne Botulism in the United States, 1994–2021

Seth Edmunds[1,2,*], **Duc J. Vugia**[3], **Hilary E. Rosen**[3], **Karen K. Wong**[1], **Janet K. Dykes**[4], **Patricia M. Griffin**[1], **Kevin Chatham-Stephens**[1]

[1]Centers for Disease Control and Prevention, Enteric Diseases Epidemiology Branch, Atlanta, Georgia, USA.

[2]Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee, USA.

[3]California Department of Public Health, Richmond and Los Angeles, California, USA.

[4]Centers for Disease Control and Prevention, Enteric Diseases Laboratory Branch, Atlanta, Georgia, USA.

Abstract

Foodborne botulism is a rapidly progressive potentially fatal paralyzing illness caused by the consumption of botulinum neurotoxin, which is most commonly produced by *Clostridium botulinum.* Refrigeration is the primary barrier to botulinum neurotoxin production in many processed foods. *C. botulinum* toxin production has occurred and caused botulism in the United States when foods that were not processed to destroy spores of *C. botulinum* were stored in an anaerobic environment and not properly refrigerated. We identified 37 cases, including 4 deaths, that occurred during 1994–2021 in the United States from 13 events associated with inadequate refrigeration of commercially produced products. In 11 events, the patient stored the product unrefrigerated at home; in 2 events, a product was kept unrefrigerated at the store before the consumer purchased it. In three events, refrigeration instructions were inadequate or not easily accessible (one label printed on outer but not inner packaging, one label not clearly visible, and one label was not in English). The number of people affected per event ranged from 1 to 16. Using enhanced cost estimates for foodborne botulism cases from a published economic model, these events were estimated to cost >$79M. Potential solutions to this recurring problem include the addition of a secondary barrier, such as an acidifier, to prevent botulinum toxin production, and better labeling to convey risks of refrigerated foods that have not been processed to destroy spores of *C. botulinum* and to decrease the occurrence of improper storage and handling.

Address correspondence to: *Seth Edmunds, MPH, Department of Epidemiology and Biostatistics, Indiana University School of Public Health-Bloomington, 1025 7th street, C113, Bloomington, IN 47405, USA*, shedmund@iu.edu.

[*]*Current address:* Department of Epidemiology and Biostatistics, Indiana University School of Public Health-Bloomington, Bloomington, Indianapolis, USA.

Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Disclosure Statement

No competing financial interests exist.

Keywords

food safety; botulism; temperature abuse; low acid; *Clostridium botulinum*

Introduction

FOODBORNE BOTULISM IS a rapidly progressive potentially fatal paralyzing illness caused by the consumption of botulinum neurotoxin, which is most commonly produced by *Clostridium botulinum* and, rarely, by strains of closely related species (*Clostridium baratii* and *Clostridium butyricum*) (Rao, 2021). Symptoms and signs typically begin within 12–36 h after toxin ingestion. Foodborne botulism is a public health concern due to the severity of illness and the potential for large outbreaks, especially from commercially produced foods. Of the seven botulinum toxins, A through G, only types A, B, E, and, rarely, F cause human illness; toxin type A is the most common cause of foodborne botulism in the United States (Sobel *et al.*, 2004).

In 1994, health officials linked illnesses in three patients with foodborne botulism to commercially produced foods that consumers had kept at room temperature despite “keep refrigerated” labels—one illness linked to a black bean dip and two linked to clam chowder. In 1997, after reviewing these reports and considering recommendations from the U.S. Centers for Disease Control and Prevention (CDC), National Advisory Committee on Microbiological Criteria for Foods (NACMCF), Association of Food and Drug Officials (AFDO), and National Food Processors Association (NFPA), the U.S. Food and Drug Administration (FDA) issued guidance that created three new categories for labels related to refrigeration of foods: Group A—“Must be kept refrigerated to maintain safety,” Group B—“Must be kept refrigerated after opening to maintain safety,” and Group C—“Refrigerate for quality.”

Despite these recommendations, which were not used by the food industry, severe illnesses and deaths from botulism linked to temperature-abused commercially produced foods have continued to occur. We describe these events.

Materials and Methods

We obtained reports from the CDC botulism surveillance database of patients with confirmed and probable foodborne botulism in the United States associated with temperature-abused commercially produced foods from 1994 through 2021. CDC, the Alaska Division of Public Health, and the California Department of Public Health (CDPH) provide clinical consultations on suspected botulism cases and are the only U.S. sources of botulinum antitoxin. Consultants provide guidance to clinicians and collect epidemiologic and medical information (e.g., demographics, signs, and symptoms of botulism at the time of consultation, laboratory results) for all suspected botulism cases.

For suspected foodborne cases, health departments conduct investigations to identify possible food sources of botulinum neurotoxin. CDC and the local or state health department verify epidemiological, medical, and exposure data. For surveillance purposes, a confirmed

foodborne botulism case is a clinically compatible illness that is laboratory confirmed (i.e., by presence of toxin in serum, stool, or food, or by isolation of *C. botulinum* from stool) or that occurred in a person who ate the same food as a person with laboratory-confirmed foodborne botulism.

A probable foodborne botulism case is a clinically compatible illness in a person who consumed a suspect food (e.g., home-canned food) within the incubation period for botulism, without laboratory confirmation (CDC, 2011). We included two probable foodborne botulism cases because the clinical presentations were typical for botulism, and electromyography with nerve conduction studies was supportive of botulism.

Suspected foods in some events were not available for testing or tested negative for *C. botulinum* toxin. We considered a food to be the source of *C. botulinum* toxin in each event based on one or more of the following: reported improper food handling, the food was consumed by several patients, a manufacturing process may have created conditions conducive to *C. botulinum* toxin production. In events 3, 7/8, 9, and 12, the suspected foods were not stored properly in a refrigerator. In events 9, 11, and 12, more than one person consumed the suspected food and soon after developed symptoms of botulism. In event 11, the manufacturing conditions of the tea were conducive to *C. botulinum* toxin production. In no event was a food that is another known source of botulinum toxin, for example, home-canned food, among the suspect vehicles.

To estimate economic impact, we used state-specific cost estimates for botulism (Scharff, 2015). These 2013-valued (adjusted for 2021 inflation) economic cost model estimates include medical costs, illness-related mortality, and a productivity loss estimate. The model estimated enhanced cost per case as $1,522,887–$2,498,991. The cost per case in states with the most patients was $2,107,239 for California and $1,901,903 for Texas. We multiplied state-specific enhanced cost per case by the number of cases per event in that state to estimate the enhanced cost of each event.

Results

We identified 37 cases, including 4 deaths, from 13 botulism events associated with the temperature abuse of commercially produced products during 1994 through 2021. Three products were clam chowder. All laboratory-confirmed events were caused by proteolytic *C. botulinum*. Toxin type A was identified in a food or patient sample or both from 12 events, and toxin–producing proteolytic *C. botulinum* type Bf was isolated from a patient specimen in 1 event. These illnesses resulted in an estimated cost of over $79M. We describe each event hereunder and in Table 1. These represent 7.8% of the 473 foodborne botulism cases reported to CDC during this period (2020 and 2021 are preliminary data) (L. Edwards, pers. comm.).

1. In 1994, a woman in California developed botulism after consuming a commercially produced ready-to-eat bean dip packaged in a sealed plastic container. She stored it at room temperature for 3 weeks; the “perishable, keep refrigerated” instruction on the container was not clearly visible (Sobel *et al.*, 2004).

2. In 1994, a couple in California developed botulism after consuming a commercially produced clam chowder, a low-acid food packaged in a sealed plastic bag inside a paper carton. The product was purchased in a box labeled “Keep Refrigerated” from the refrigerated section of a supermarket. It was stored in a home pantry at room temperature for a month before being heated and served. Although it “tasted bad,” both patients consumed it (Sobel *et al.*, 2004).

3. In 1997, a man in Oregon developed botulism after consuming a commercially produced burrito purchased at a roadside store. He heated it in a microwave and then left it at room temperature for about 1 d. He took one bite, noticed a bad taste and odor, and discarded it. The burrito was not available for testing (Sobel *et al.*, 2004). The CDC laboratory isolated type B and type F toxin–producing *C. botulinum* type Bf from stool. (This is a correction from the original report by Sobel *et al.*, 2004.) (CDC, unpublished data).

4. In 2001, an outbreak involving 16 patients in Texas was traced to a frozen chili product in 5 pound (2.2 kg) plastic tubs that was intermittently left at room temperature in a salvage store. The airtight containers warmed to room temperature for several hours at a time. The chili was not a canned product, so it had not undergone retort cooking or any other process to destroy spores (Kalluri *et al.*, 2003).

5. In 2003, a woman in California developed botulism after eating commercially produced clam chowder. The packaging was labeled “Keep Refrigerated” but the product was reportedly kept in a cupboard at room temperature before being heated by microwave (CDC, 2003).

6. In 2006, an outbreak involving four patients in the United States (three in Georgia and one in Florida) and two in Canada was associated with commercial pasteurized carrot juice (Sheth *et al.*, 2008). All juice bottles were labeled “keep chilled” and bottle caps were labeled “keep refrigerated.” The juice had no barriers to growth of *C. botulinum* other than refrigeration. Investigators thought the bottles of carrot juice were probably at room temperature for extended periods between production and consumption. One bottle was recovered from a hotel room with no refrigerator (CDC, 2006; Sheth *et al.*, 2008). The Florida patient died.

7/8. In 2011, two unrelated events each involving a single patient were associated with different commercially produced potato soups in Ohio and Georgia. In both, the soup was labeled “Keep Refrigerated,” purchased refrigerated, then left at room temperature for several weeks. Both people reported only tasting the soup before noticing an “off” or “sour” flavor, which prompted them to discard the product. The Georgia woman reportedly heated the soup before tasting. In both events, no leftover soup was available (CDC, 2011).

9. In 2012, a couple in southern California developed signs of botulism after eating commercially produced broccoli soup. The Los Angeles County Department of Public Health conducted a traceback and found that the store had properly stored the soup in the refrigerator case. The soup was commercially packaged in two tubs in a cardboard sleeve. Internal and external packaging refrigeration instructions differed:

Both contained instructions to “Promptly Refrigerate Remaining Soup,” but only the external packaging (front and top) stated “Keep Refrigerated.” The couple purchased the package from the store and kept it unrefrigerated in their home for more than a week. They then microwaved the soup and reported it “tasted rancid.” No leftover soup was available (CDC, unpublished data).

10. In 2016, a woman in southern California developed botulism after consuming a packaged “fully cooked” grain and vegetable product sold through a chain store in California. It was kept refrigerated at the store. The plastic package was one of four in a box with “keep refrigerated” on the box label but not on the individual internal packages. The patient stored the product in the pantry at home at room temperature for >2 weeks before microwaving then consuming it (CDC, 2016).

11. In 2017, two elderly Asian patients were hospitalized in California with botulism: one died. The patients were from different households but knew each other. A locally produced Korean herbal tea was their only common exposure. The liquid tea product was made with local and imported ingredients, including dry herbs, roots, and deer antler. The instructions on each plastic tea pouch to refrigerate the product were not in English. Both patients reported keeping the pouches refrigerated.

Botulinum toxin was not detected in contents of pouches obtained from the production facility and culture of them did not yield *C. botulinum*. However, inspection of the facility found conditions conducive to contamination and botulinum toxin production, including unsterilized equipment or parts, multiple exposures of tea product to the processing room environment, and uncontrolled cooling process of sealed pouches (Kim *et al.*, 2019).

12. In 2019, four adults were hospitalized in Colorado with symptoms of botulism. One died. Three were from the same household; the fourth was a family friend who had dinner with the family. The source was a commercial prepackaged two-pack potato product that was stored unrefrigerated on a counter-top for 15 d. Although the package sleeve was marked “Keep Refrigerated,” one patient thought the product did not require refrigeration due to finding it in an unrefrigerated section in the grocery store. The individual potato packages did not have refrigeration instructions. Botulinum toxin type A was detected in all patients; no potatoes from the meal were available (CDC, unpublished data).

13. In 2021, an elderly person was hospitalized in Kentucky with symptoms of botulism after eating a commercially produced New England clam chowder. The soup was sold in a two-pack with both individual package and external labeling that said “Keep Refrigerated.” The patient stored an open container in the pantry and consumed the chowder over 2 weeks. The patient died (CDC, unpublished data).

Discussion

These data indicate that inadvertent temperature abuse of some commercially produced foods, particularly keeping products that require refrigeration at room temperature, at various points between production and consumption, has been causing foodborne botulism

for decades. We detected 37 cases of foodborne botulism with 4 deaths due to such events, with estimated costs exceeding $79 million.

This article includes the first report of *C. botulinum* type Bf associated with foodborne botulism in the United States. *C. botulinum* type Bf, a rarely identified bivalent organism that produces both types B and F toxins (the capital letter denotes the predominant toxin type), is typically associated with infant botulism (Smith *et al.*, 1989; Barash and Arnon, 2004).

Many opportunities for temperature abuse occur during production, shipping, retail, and storage. The recurring problem of botulism linked to temperature-abused commercial foods shows that the current “keep refrigerated” labels alone are inadequate to prevent some customers from storing at room temperature some low-acid products that might contain spores of *C. botulinum*, putting them at risk for botulism. At least 11 of the food items implicated in these events were labeled as “keep refrigerated.” Any change in font size, wording, or placement on the packaging of “keep refrigerated” labels might still not adequately convey the potential consequences of inadequate refrigeration, specifically the risk of botulism.

When exposed to a specific combination of conditions, at minimum including an anaerobic environment; nonfreezing temperature >3°C (37.4°F); low acid (pH >4.6); and high water activity (>0.93), *C. botulinum* spores, if present, can germinate and produce neurotoxin, sometimes with no indication of food spoilage (Peck, 2006). For many commercially processed foods that do not incorporate treatment with heat (which would destroy the spores of *C. botulinum*), acid, or another additive that inhibits botulinum spore germination, refrigeration serves as the sole barrier to botulinum neurotoxin production.

The necessary combination of conditions for botulinum spore germination might be met for these products during manufacturing, transportation to or storage in a retail facility, or transportation to or storage in the home. Certain commercially produced foods, if packaged in a way that creates an anaerobic environment, can be conducive to botulinum neurotoxin production when not maintained at a safe temperature (i.e., inadvertent temperature abuse). *C. botulinum* type A and proteolytic types B and F can grow and produce toxin at temperatures as low as 50°F (10°C). Botulinum toxin can be destroyed by heating to 185°F (85°C) for 5 min, and spores are inactivated by heating to 250°F (121°C) at 15–20 PSI (103.4–137.9 kPa) for 3 min (Pflug *et al.*, 1985).

Although refrigeration is the sole barrier to toxin production in some foods, refrigerators are not always maintained at <40°F (<4.4°C), as recommended. The FDA and Audits International surveyed home refrigerators and retail backroom refrigerators and display cases in 1999. Temperatures exceeded 50°F (10°C) in 2% of 939 home refrigerators and 1% of 515 retail backroom refrigerators. Temperatures exceeded 50°F (10°C) in 3% of 979 retail food products in display cases (FDA, 1999). A similar survey in 2007 reported that the temperature of 0.8% of consumers’ refrigerators were >51°F (10.5°C) (Audits International *et al.*, 2007).

The findings in this report are subject to limitations. Botulism is a nationally notifiable condition; however, some cases, including those in persons with mild symptoms, may not be diagnosed and, therefore, not reported. Public health officials may be unable to determine the foods consumed during the incubation period, especially when botulism is suspected late in the illness or when the patient is unable to communicate. Suspected food is not always available for testing. Confidence intervals for cost estimates were not available.

FDA has previously amended policy guidance to prevent botulism. In 1985, an outbreak of botulism with 36 ill persons in Vancouver, Canada, was linked to a commercial garlic-in-oil product that had not been refrigerated in a restaurant (St. Louis *et al.*, 1988). In 1988, three people in New York developed botulism after consuming garlic bread prepared with a commercial garlic-in-oil product that was labeled “keep refrigerated” but was kept at room temperature in a home for ~3 months (Morse *et al.*, 1990). In response to these outbreaks, in 1989, FDA informed companies that, because of the risk of botulism, such products must contain specific levels of microbial inhibitors or acidifying agents and not rely on refrigeration alone (FDA, 1989; Morse *et al.*, 1990).

No botulism cases linked to commercially produced garlic-in-oil products have been reported in the United States since 1988. This success suggests that similar amendments for other Group A (must be kept refrigerated to maintain safety) foods could also prevent botulism (FDA, 1997). Similarly, in June 2007, in response to an outbreak, FDA issued nonbinding guidance to processors of refrigerated carrot juice and other low-acid juices (CDC, 2006; FDA, 2007; Sheth *et al.*, 2008).

Several strategies could be implemented to prevent botulism associated with temperature abuse of commercially produced foods.

1. Encourage or require the addition of intrinsic barriers if refrigeration is the sole barrier to toxin production. Many ready-to-eat refrigerated foods that have not been processed to destroy spores of *C. botulinum* may resemble products that do not require refrigeration and may be subject to temperature abuse despite “Keep refrigerated” labeling. A second barrier to botulinum toxin production besides refrigeration would add another layer of protection against temperature abuse that could occur during product packaging, shipping, retail display, or storage. Secondary barriers include acids or other compounds that can inhibit microbial growth (Graham *et al.*, 1997; Golden *et al.*, 2017a, b).

2. Strengthen food labeling practices for certain refrigerated items to include messaging such as “IMPORTANT Must Be Kept Refrigerated To Maintain Safety” as recommended by FDA (FDA, 1989). This might include informing consumers that unsafe food may look and smell normal. Many refrigerated foods have external and internal packaging, and some have multiple internal packets; all should be labeled to ensure proper refrigeration from production to consumer usage. Consumers may benefit from internal package “Keep refrigerated” labeling that is easy to see and understand, in prominently placed large font, and that conveys the importance and potential consequences of nonrefrigeration.

3. Enhance messages to industry and consumers to regularly check and maintain safe refrigerator temperatures, and to discard “Keep refrigerated” foods that had been mistakenly kept at room temperature.

Conclusions

Botulism due to commercially produced foods that have been inadequately refrigerated has been occurring for >20 years after FDA published labeling recommendations for such foods. The economic impact of recognized cases alone is high. Many investigations have demonstrated that patients with both severe and mild botulism are commonly diagnosed as having other illnesses, such as Guillain–Barre syndrome and myasthenia gravis (Sobel and Rao, 2017). Therefore, the true morbidity, mortality, and cost of botulism are likely much higher than indicated by confirmed cases.

Policy changes and guidance related to commercial garlic-in-oil and carrot juice that had caused botulism have prevented botulism from those products. Illnesses and deaths from botulism due to occasional failure to refrigerate commercially produced foods for which refrigeration is the sole barrier to botulinum toxin production will likely continue until additional prevention strategies are implemented to improve the safety of these foods.

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TABLE 1.

FOODBORNE BOTULISM CASES, OUTBREAKS, AND ESTIMATED COST FROM TEMPERATURE-ABUSED COMMERCIALLY PRODUCED FOODS, UNITED STATES, 1994–2021

Event	*Year*	*State*	*Patients (no.)*	*Food vehicle*	*Laboratory confirmation of botulism* [a]	*Toxin type*	*Mean age (years)*	*Sex*	*Patients treated with antitoxin (no.)*	*Deaths (no.)*	*Estimated cost ($1M)* [b]
1	1994	California	1	Bean dip	Toxin in food	A	45	1 F	1	0	2.4
2	1994	California	2	Clam chowder	Toxin in food	A	36	1 M, 1 F	Unknown	0	4.9
3	1997	Oregon	1	Burrito	*Clostridium botulinum* in stool	Bf	63	1 M	0	0	2.1
4	2001	Texas	16	Frozen chili	Toxin in stool of 9 patients Toxin in food	A	40	12 M, 4 F	9	0	35.4
5	2003	California	1	Clam chowder	Toxin in food	A	60	1F	0	0	2.4
6	2006	Georgia, Florida	4[c]	Carrot juice	Toxin in serum and stool (3 patients) and in serum (1 patient) Toxin in food	A	57	1 M, 3 F	4	1	11.9
7/8	2011	Ohio	1	Potato soup	Toxin in stool	A	29	1 M	1	0	2.0
7/8	2011	Georgia	1	Potato soup	Toxin in stool	A	41	1 F	1	0	2.0
9	2012	California	2	Broccoli soup	None	—	23	1 M, 1 F	1	0	4.9
10	2016	California	1	Grain and vegetable product	Toxin in serum, stool, and food	A	55	1 F	1	0	2.4
11	2017	California	2	Herbal deer antler tea	Toxin in serum (2 patients)	A	65	1 M, 1 F	2	1	4.9
12	2019	Colorado	4	Potato product	Toxin in stool (3 patients) and serum (4 patients)	A	63	1 M, 3 F	3	1	2.3
13	2021	Kentucky	1	Clam chowder	Toxin in serum and food	A	73	1 M	1	1	1.8
Total			37				50	21 M, 16 F	24	4	79.4

[a] Most state public health laboratories use the mouse bioassay to detect toxin; not all laboratories reported their method. Centers for Disease Control and Prevention confirmed botulinum toxin detection by mouse bioassay in events 3, 6, and the Georgia case in 7/8 and mouse bioassay (stool) and by Endopep-MS (serum) in event 12.

[b] 2013 valuations adjusted for annual inflation to 2021 values.

[c] Two additional cases associated with this outbreak occurred in Canada.

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