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Operational Antecedents Associated with *Clostridium perfringens* Outbreaks in Retail Food Establishments, United States, 2015–2018

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Abstract

Clostridium perfringens is a common foodborne pathogen, frequently associated with improper cooking, cooling or reheating of animal products. The US Food and Drug Administration Food Code outlines proper food preparation practices to prevent foodborne outbreaks; however, retail food establishments continue to have *C. perfringens* outbreaks. We qualitatively analyzed responses to two open-ended questions from the National Environmental Assessment Reporting System (NEARS) to understand patterns of unique circumstances in the retail food establishment that precede a *C. perfringens* outbreak. We identified three environmental antecedents, with three sub-categories, to create nine operational antecedents to help explain why a *C. perfringens* outbreak occurred. Those antecedents included factors related to (1) people (a lack of adherence to food safety procedures, a lack of food safety culture and no active managerial control), (2) processes (increased demand, a process change during food preparation and new operations) and (3) equipment (not enough equipment, malfunctioning cold-holding equipment and holding equipment not used as intended). We recommend that food establishments support food safety training and certification programs and adhere to a food safety management plan to reduce errors made by people and processes. Retail food establishments should conduct routine maintenance on equipment and use only properly working equipment for temperature control. They also should train workers on the purpose, use and functionality of the equipment.

Keywords

foodborne outbreak; *Clostridium perfringens* ; retail food; environmental health

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Disclosure Statement

The authors declare no conflict of interest.

Introduction

Clostridium perfringens (*C. perfringens*), the third most common foodborne pathogen, causes around 1 million foodborne illnesses each year in the U.S. (Scallan *et al.*, 2011). *C. perfringens* is a bacterium found on raw animal products and produces spores that form a coating to help it survive cooking. When food is kept at unsafe temperatures during cooking, cooling, and holding processes, *C. perfringens* can proliferate (Smith-Simpson and Schaffner, 2005). Proper reheating can kill *C. perfringens* that survived the original cooking process or multiplied during improper cooling (Taormina and Dorsa, 2004). Data obtained from investigations of *C. perfringens* outbreaks provide important insights into prevention of *C. perfringens* illness; these data can identify food preparation practices and circumstances that lead to illness. For example, the Centers for Disease Control and Prevention's (CDC) outbreak investigation data indicate that *C. perfringens* outbreaks are commonly associated with foods prepared in large quantities (CDC, 2018).

The US Food and Drug Administration (FDA) Food Code contains food safety guidelines intended to reduce foodborne illness risk from pathogens, such as *C. perfringens,* in retail food establishments. The Food Code lists specific time and temperature ranges for proper cooking, holding, cooling, and reheating (FDA, 2017). Despite these guidelines and our increased understanding of the foods and practices associated with *C. perfringens* outbreaks, illnesses and outbreaks continue to occur (Hedeen and Smith, 2020). Understanding environmental antecedents, the root causes, to *C. perfringens* outbreaks can help us prevent future outbreaks. Environmental antecedents are factors in the environment that ultimately lead to pathogen contamination, proliferation, or survival to cause an outbreak (CDC, 2015).

We examined data from the National Environmental Assessment Reporting System (NEARS), a voluntary reporting system that some state and local environmental health regulatory programs use to report data to the CDC from their investigations of retail food establishment outbreaks (CDC, 2019). NEARS data from *C. perfringens* outbreak investigations describe the environment in which the outbreaks occurred and can identify outbreak antecedents (Lipcsei *et al.*, 2019). This study analyzed these data to better understand environmental antecedents of *C. perfringens* outbreaks. These data were used to identify operational antecedents of outbreaks, or the actions or factors that occur during food operations that explain the survival or proliferation of pathogens in food.

Method

Ten state and local health departments reported 41 confirmed or suspected *C. perfringens* outbreaks that occurred from 2015 to 2018 to NEARS. We excluded seven outbreaks that were missing 75% or more NEARS data. The final dataset consisted of 34 single-setting retail food establishment outbreaks that occurred in Connecticut, Georgia, Iowa, Minnesota, New York, Rhode Island, South Carolina, Tennessee, Washington, and Wisconsin.

During their investigations, environmental health staff interview outbreak establishment managers about establishment characteristics (e.g., food safety policies and practices that might have contributed to the outbreak). They also observe worker food preparation,

especially of items suspected to be associated with the outbreak. Afterward, investigators report selected information and observations from their investigations to CDC through the NEARS web-based reporting system (Brown *et al.*, 2017; Lipcsei and others, 2019).

Our analysis focused on qualitative data collected from two open-ended questions investigators answered about the outbreak establishments' food operations after they completed their establishment observations:

1. 'Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?'
2. 'During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?'

The first question was designed to identify differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. If the investigation implicated a food item associated with the outbreak, investigators also answered the second question. These questions were asked because research suggests that unusual circumstances frequently precede outbreaks (World Health Organization, 2008). Understanding these circumstances can enhance our understanding of outbreak antecedents.

Analysis

We first calculated descriptive statistics on several outbreak and establishment characteristics collected through manager interviews and establishment observations to describe our sample (Table 1). We then conducted a qualitative analysis of the data from the two open-ended questions about differences in establishment operations at the time of *C. perfringens* exposure. We used the grounded theory approach, in which we identified patterns and groupings in the qualitative data using inductive reasoning (i.e., from the 'ground up') (Corbin and Strauss, 1990). The food system environmental antecedent conceptual model was used to categorize the data; researchers have theorized that five main variables of environmental antecedents influence food safety in establishments (Selman and Guzewich, 2014):

1. People (characteristics and attitudes of people working in the establishments)
2. Processes (characteristics of the processes used to prepare food and food preparation complexity)
3. Economics (costs and profit margins)
4. Equipment (the physical layout and equipment of establishments)
5. Food (the inherent qualities of food prepared in establishments)

Two independent coders reviewed the raw text responses to the two open-ended questions with other NEARS variables to obtain a comprehensive view of the outbreak; they identified environmental antecedent themes based on above model. They then again reviewed the raw text responses and further grouped the environmental antecedents into sub-categories

for each theme, or operational antecedents, applying theoretical comparison coding. For each review of the data, the coders independently identified their antecedents and then compared them. If the coders differed in their groupings, they each reviewed the data again, repeating this process until they reached a consensus. The final framework consisted of three environmental antecedents and nine operational antecedents (Fig. 1).

Results

Outbreak and establishment characteristics.

In 41.2% of the outbreaks, the pathogen was confirmed in one or more clinical or environmental samples (Table 1). The primary outbreak contributing factor was pathogen proliferation (90.6%) and occurred while the food was at the establishment (i.e., during food preparation) (81.2%). Most of the outbreak establishments were restaurants (82.3%) and independently owned (84.0%). The majority served more than 100 meals per day on average (54.2%) and had a menu type classified as Latin cuisine (41.2%). Among the outbreak establishments, 44.1% had two or more critical violations (i.e., violations more likely to contribute to pathogen contamination, proliferation, or survival) on their last routine inspection. All establishments engaged in complex food processes (i.e., food preparation requiring a kill step and holding beyond same-day service or a kill step and some combination of holding, cooling, reheating, and freezing). These processes present a higher risk for bacterial contamination, proliferation, and survival.

For 13 outbreaks (38.2%), investigators answered the question about differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. For 32 outbreaks (94.1%), investigators answered the question about differences from ordinary operating procedures at the time customers were exposed, as described by managers or workers. A qualitative analysis of these responses (see Table 2 for text excerpts) yielded the identification of three categories of antecedents: people, processes, and equipment. Further analysis of these antecedents led to nine operational antecedents. Although the antecedents of food and economics were considered, analysis found they were not applicable to this dataset.

Antecedents related to people.

People antecedents were identified in 27 outbreaks (79.4%). All three operational antecedents in this category were related to workers' failure to follow food safety practices to prevent pathogen survival and proliferation.

1. In 15 outbreaks (55.6%), workers did not follow established food safety procedures designed to control bacterial survival and proliferation. In some of these outbreaks, investigators noted that the establishments had formal food safety procedures, but workers were not following them. For example, during one investigation, some pieces of meat required three attempts at reheating to achieve the proper internal temperature even though the establishment's process was to reheat only once.

2. A lack of food safety culture (i.e., the values, shared assumptions, and behaviors of workers) anteceded eight outbreaks (29.6%); examples included a documented pattern of poor inspections, longstanding critical violations, and a history of outbreaks. This antecedent is characterized by multiple, consistent poor food safety practices. For example, one investigator noted that the establishment was 'in the exact same (poor) condition as during a previous norovirus outbreak investigation.' Many establishments had multiple temperature issues; one investigator said, 'there is a history of repeated temperature violations, including reheating, cold holding, hot holding and room temperature storage noted on 3 consecutive visits in the last 8 months.'

3. A lack of managerial control, or food safety supervision, to ensure adherence to food safety policies or processes was mentioned for four outbreaks (14.8%). In one outbreak, the manager was on leave at the time of the outbreak and many workers did not show up to work, leaving the establishment short-staffed and vulnerable to food safety errors. In two outbreaks, untrained persons were responsible for food safety at a catered event; they did not ensure that food temperatures were monitored and controlled.

Antecedents related to processes.

At least one process antecedent was identified in 14 outbreaks; a total of 18 process antecedents (52.9%) were associated with these outbreaks. All three categories in this antecedent theme were characterized by insufficient processes to control foodborne pathogens.

1. In 11 of the outbreaks with process issues (61.1%), preparation of the implicated food item differed from the establishment's normal procedure. For example, in one establishment, time constraints caused by the late arrival of a food item led to suspension of standard preparation processes. Other observations included workers using ineffective cooling procedures (e.g., inappropriate food depth, cooling at room temperature), and failing to verify temperatures during cooling.

2. A new circumstance, such as a new establishment, food preparation process, or event type was mentioned for four outbreaks (22.2%). For example, an establishment prepared a large roast for a holiday buffet, but the staff were not familiar with the proper procedure of cooking and holding this item. One establishment (which did not have a permit to operate) stored food in 'a car from 6:00 a.m. to 6:00 p.m.,' and neglected to ensure that time or temperature parameters were met.

3. Increased capacity led to three outbreaks (16.7%). Because of increased demand, these establishments exceeded their typical operational volume and were unable to manage food safety risks. For example, one establishment experienced an extremely busy night, during which they prepared large quantities of food for a large number of people in a short time. Another establishment catered three events on the same night. The investigator noted that 'this is an unusually large amount of food for the establishment, a higher volume of food being prepared

in the establishment at one time.' These establishments were not equipped to handle the increased volume and had difficulty properly cooling the food.

Antecedents related to equipment.

Equipment antecedents were identified in 14 outbreaks (41.2%). Retail food equipment includes cold-holding (e.g., refrigerators, freezers) and hot-holding equipment (e.g., bain-maries or hot-holding cabinets), and food storage and insulated transportation containers. The three categories in this antecedent theme were related to failure of equipment intended to prevent bacterial growth in food.

1. In seven outbreaks (50.0%), the establishment did not have enough equipment or used inappropriate alternatives to approved equipment for food storage or holding. For example, in one outbreak, food was transported in cardboard boxes, which lacked appropriate temperature control, instead of in insulated or temperature-controlled units. Additionally, in five outbreaks, investigators reported that the cold- or hot-holding equipment used was not large enough for the establishment's operational demand.
2. Malfunctioning cold-holding equipment that did not keep food cold enough to minimize pathogen proliferation anteceded five outbreaks (35.7%). Several investigators reported that establishments were using inoperable or malfunctioning refrigerators for cooling and storing hot foods. One investigator stated that the establishment's 'walk-in was being repaired due to temperature issues on the meal date in question.'
3. Hot-holding equipment was not used as intended in two outbreaks (14.3%). Thus, foods were not held at temperatures hot enough to control pathogen proliferation. For example, one establishment held hot foods in an oven without power; another used containers designed for food transportation, rather than for maintaining appropriate temperatures, to hold hot foods.

Discussion

This qualitative analysis identified three environmental antecedents of *C. perfringens* outbreaks — people, processes, and equipment — which break down further into nine operational antecedents. These antecedents led to inadequate temperature control of food, which led to *C. perfringens* survival and proliferation in food and subsequent outbreaks among those who ate the food. Our findings suggest that establishments and regulators should consider focusing outbreak prevention efforts on workers, food preparation processes, and equipment used to prepare, store, and serve food.

People.

Overall, most outbreaks had a people operational antecedent characterized by workers' lack of adherence to food safety procedures. In some outbreaks, workers did not follow established food safety procedures. This oversight could be attributed to several factors, including a lack of food safety culture, a lack of knowledge about proper procedures, and feelings of 'burn-out' (Powell *et al.*, 2011; Sahin, 2012).

Some research indicates that establishments with higher frequencies of regulatory inspections are less likely to be associated with a foodborne outbreaks (Kufel *et al.*, 2011). Regulatory programs might consider providing additional support to establishments with a pattern of poor inspections, longstanding critical violations, or a history of outbreaks. FDA data indicate that cooling violations are among the most common problems noted by inspectors in restaurants that engage in complex food preparation practices (FDA National Retail Food Team, 2018). Regulatory programs might consider developing a better understanding of complex food preparation to identify risks and target worker training.

Establishment workers with food safety training or certification have greater food safety knowledge than those without (Brown *et al.*, 2016; Brown *et al.*, 2014; Hedberg *et al.*, 2006; Hoover *et al.*, 2020; Sumner *et al.*, 2011). Inspectors could educate managers about the public health reasoning behind food safety errors to empower managers to train other workers. By providing a train-the-trainer approach, establishments might be more likely to follow sustainable food safety practices to prevent risk factors and avoid errors.

Certification and training alone are likely not sufficient to control all foodborne risks. Active managerial control and a strong food safety management system, such as a hazard analysis critical control point (HACCP) plan, are strategic approaches to reduce food safety errors (FDA, 2017). Corrective actions, including monitoring and recording of food temperatures, or the critical limits of critical control points, and the verification of the HACCP plan, are essential steps to ensure safe food. Regulatory programs and the restaurant industry should consider supporting food safety training and certification programs and active managerial control, cultivation of a food safety culture, and the use and verification of a robust food safety management system.

Process.

Standard food preparation processes were not followed at many outbreak establishments; instead, a different process that contributed to food temperature abuse and pathogen proliferation was used. Often, these differences resulted from unusual circumstances, like preparation of larger food amounts than usual and increased customer volume. Ensuring that workers follow their establishment's procedures, rather than revising processes (e.g., taking shortcuts) regardless of unusual circumstances, is key to outbreak prevention.

Studies show that proper cooling is critical to avoiding *C. perfringens* proliferation and that cooling errors are a common cause of *C. perfringens* outbreaks (Hedeen and Smith, 2020; Kalinowski *et al.*, 2003; Smith-Simpson and Schaffner, 2005). Research suggests that many establishments do not follow proper cooling procedures (e.g., no recording or verification of cooling processes) (Brown *et al.*, 2012; Hedeen and Smith, 2020). Establishments can help prevent *C. perfringens* proliferation by monitoring temperatures during cooling and taking corrective actions when temperatures are not met. The use of a HACCP principles to develop a risk control plan can help establishments identify process failures to avoid pathogen proliferation (FDA, 2017). If process parameters (i.e., time and temperature) are too difficult to use, managers could consider using physical parameters, such as cooling pan depth, to ensure proper cooling. For example, one jurisdiction assesses whether foods are cooled using procedures likely to ensure rapid cooling (uncovered in shallow [≤2 inches]

containers), rather than assessing time and temperature. This alternative method can help ensure proper cooling and increase verification efficiency for inspectors and operators (Oravetz, 2019).

Equipment.

Equipment operational antecedents included a lack of or improper equipment for food storage and holding. Ensuring an establishment has proper equipment for these processes requires an understanding of the establishment's operational capacity, which is based on the volume of complex preparation food items and the capacity and functionality of existing equipment. Other equipment issues included malfunctioning cold-holding equipment and improper use of hot-holding equipment. Hedeen and Smith (2020) recently found that improper cooling procedures and inadequate equipment are prevalent in the retail food industry. Research has also found that equipment problems are the most common barrier to holding food properly in restaurants (Green and Selman, 2005), restaurants with sufficient refrigeration capacity were more likely to have properly cold-held food (Liggans et al., 2019), and restaurants with multiple refrigerators had a lower likelihood of bacterial outbreaks (Kramer, 2019).

Equipment issues also could be related to the antecedent theme of economics. Financial challenges might limit establishments' ability to buy new equipment or maintain existing equipment. The role that economics plays in outbreaks is difficult for outbreak investigators to evaluate. They might not understand establishments' financial situations and are likely unable to collect economic data (e.g., profit margins). Further research is needed to understand and identify economic antecedents to outbreaks.

To help prevent equipment antecedents to *C. perfringens* outbreaks, establishments can conduct routine maintenance of equipment used for temperature control and worker training on proper equipment use and maintenance. Regulators can also assess equipment during routine inspections to ensure it meets the establishment's capacity and operational requirements and to verify that workers know how to properly use and maintain the equipment.

Limitations

The generalizability of this study's findings is limited because the sample is only a subset of all *C. perfringens* outbreaks—outbreaks investigated by state and local agencies that report to NEARS. The qualitative data we analyzed consisted of observations and perspectives of the investigator, which might be influenced by their unique experiences. Therefore, the investigative approach and outbreak explanation might vary between investigators and reporting sites. The results are qualitative and should not be generalized to a larger population in any statistical sense. However, these results can be useful for guiding future work in food safety.

Conclusion

Data on outbreak operational antecedents can inform food safety interventions to prevent future foodborne outbreaks. We recommend that retail food establishments and regulators

educate workers about why food safety tasks are performed. This will help instill a culture of food safety and support use of sustainable and robust food safety management systems. We also recommend incorporating principles of HACCP, a prevention tool used to prevent foodborne outbreaks and correct process failures, to verify food safety processes at establishments. Finally, regulators and establishments can train workers to use equipment properly and to determine when corrective actions are required to avoid equipment failures that contribute to pathogen proliferation and survival. More research will help to further understand the underlying antecedents of *C. perfringens* outbreaks and prevent them.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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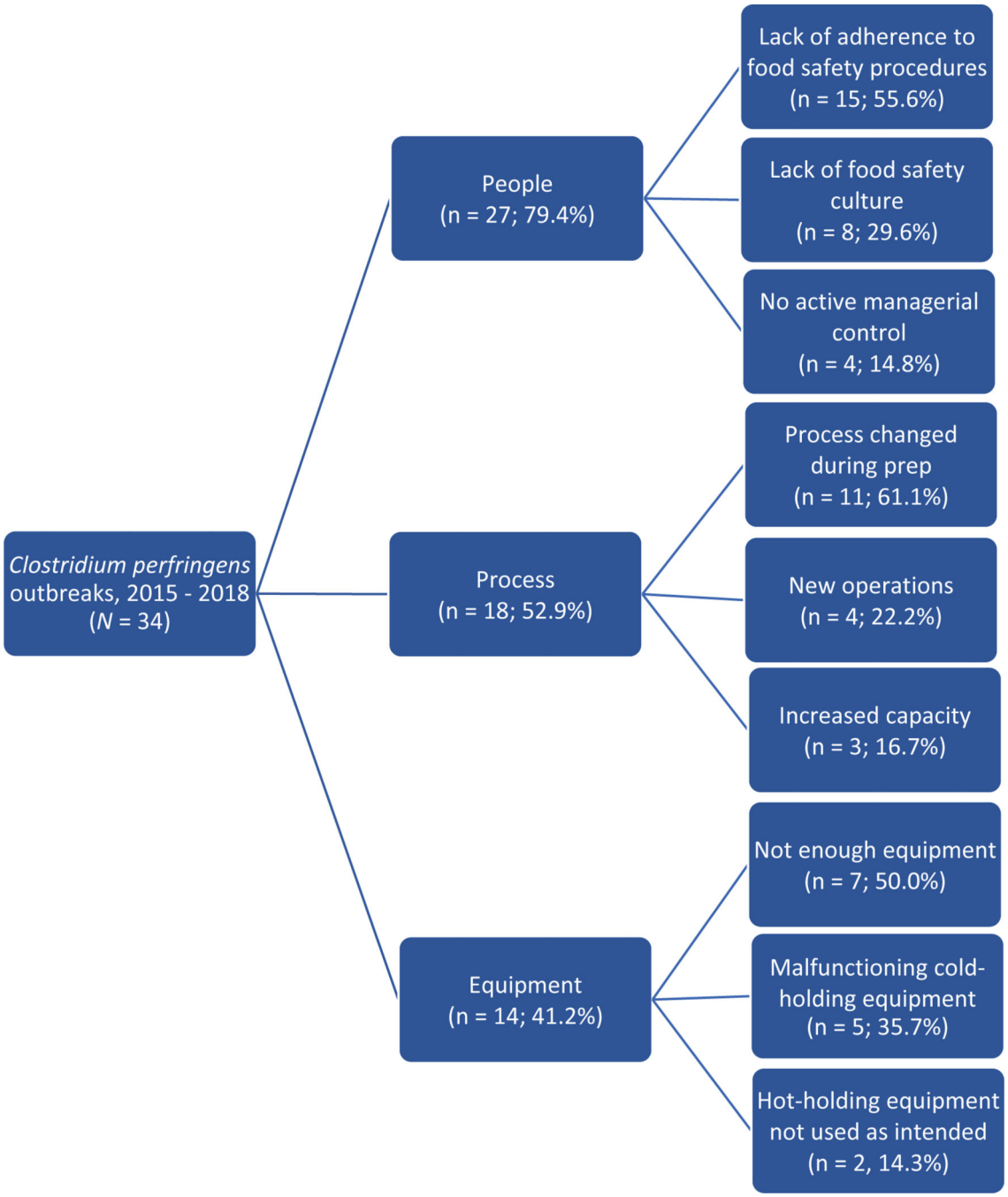

Fig. 1.

Operational antecedents in *Clostridium perfringens* outbreaks, National Environmental Assessment Reporting System, 2015–2018 (*N* = 34).[a]

[a]Percentages might sum to more than 100% because some outbreaks had more than one identified environmental antecedent.

Table 1.

Outbreak and establishment characteristics of *Clostridium perfringens* outbreaks, United States, 2015–2018 (*N* = 34)

Characteristic	No. (%)
Agent (*N* = 34)[a]	
Suspected	20 (58.8)
Confirmed	14 (41.2)
Primary contributing factor[b,c] (*n* = 32)	
Contamination	2 (6.2)
Proliferation	29 (90.6)
Survival	1 (3.2)
When the primary contributing factor occurred[b,c] (*n* = 32)	
Before food vehicle entering establishment	1 (3.2)
While food vehicle was at the establishment	26 (81.2)
After food vehicle left the establishment	5 (15.6)
Establishment type[d] (*N* = 34)	
Complex	34 (100.0)
Cook–Serve	0 (0.0)
Prep–Serve	0 (0.0)
Facility type[c] (*N* = 34)	
Caterer	4 (11.8)
Mobile food unit	2 (5.9)
Restaurant	28 (82.3)
Ownership type[d] (*N* = 25)	
Independent	21 (84.0)
Chain	4 (16.0)
Meals per day[d] (*N* = 24)	
≤100	11 (45.8)
>100	13 (54.2)
Menu type[c] (*N* = 34)	
American	11 (32.3)
Latin	14 (41.2)
Other	9 (26.5)
Critical violations on last inspection[e] (*N* = 34)	
0–1	19 (55.9)
2–9	15 (44.1)

[a]Obtained from investigators' epidemiology and laboratory counterparts.

[b]Contributing factors are food preparation practices that lead to pathogens contaminating, proliferating and surviving in food.

[c]Environmental health investigator determination.

[d] Data obtained from the investigator's interview with the establishment manager.

[e] Critical violations are those more likely to contribute to the contamination of food or the proliferation or survival of the pathogens if not corrected. These are determined on a routine inspection and unrelated to the foodborne outbreak.

Table 2.

Text Excerpts from Two Open-Ended Questions [a,b]

Theme	Operational Antecedent	Selected Text Excerpts
People	Lack of adherence to food safety procedures	While cold and hot holding temperatures are monitored and recorded, cooling, cooking and reheating temperatures are not being monitored or recorded. During the environmental assessment, it was observed that some larger pieces of the carnitas required three attempts at reheating in the fryer to reach an internal temperature of 165F. The normal establishment process is to only to fry once, then place in team table, without verifying internal temperature of pork before hot holding.
		Chicken was partially cooked then stored at room temperatures, then improperly cooled, stored at room temperature again, stir-fried to order.
	Lack of food safety culture	Improper cooling and hot holding of beans. Hot holding has been an ongoing problem at this facility. Cold holding problems regularly observed.
		Here is a history of repeated temperature violations – including reheating, cold holding, hot holding, and room temperature storage noted on 3 consecutive visits within the last 8 months.
		Establishment is in the exact same poor condition as during a previous noro outbreak investigation.
		Non-continuous cooking done improperly, RTS of foods, improper cooling of foods, unclean equipment and utensils used. Many foods found improperly cooled, undercooked, cross-contaminated.
	No active managerial control	Kitchen manager was on vacation, many workers did not show up for shift. Operating without hot water, cold hold units not maintaining proper temperature.
		The caterer had no other reports of issues from food served to other customers from the same pork that day. Also, the food was for a graduation party and most likely left out for an extended period of time.
Process	Process changed during prep	Managers said they were cooling with ice, but multiple large containers of food found out of temp. In walk-in cooler-hadn't cooled properly and were covered. Items discarded.
		Unusually large batch of pork was cooled improperly in large containers, in a walk-in cooler that was undersized, slow reheat. No temps recorded at any point in process.
	New operations	This is the first time that the facility prepared the large steamship round roast for the easter buffet.
		Warm food stored in a car from 6:00am to 6:00pm. Cooking/cooling in an unpermitted kitchen.-caterer
		The firm does not normally cater events. The cooking process for this event did not involve a cool step for food prepared for the event. Cook serve only.
	Increased capacity	Caterer had 3 large events to provide food for on the same evening, this is unusually large amount of food for him- higher volume of food being prepared in the establishment at one time- unusually large batch of pork was cooled improperly in large containers, in a walk in cooler that was undersized, slow reheat. No temps recorded at any point in process.
		Very large quantities of food prepared for large number of people over a short time
Equipment	Not enough equipment	Food was placed in cardboard boxes and transported without appropriate temperature control.
		Hot holding units were not functioning properly or adequately for food capacity.
		The food establishment has insufficient cold storage space for the amount of food preparation they do for events. Most foods are prepared the day before and many hot foods are kept in a small reach in cooler.
	Malfunctioning cold-holding equipment	Walk-in was being repaired due to temperature issues on the meal date in question which may have contributed to time/temperature abuse of food items.
		Deep pan cooling, covered cooling, cooling in broken refrigerator. a) rice improperly cooled in deep pans stored in a broken refrigerator at 65°f. b) goat was cooled in deep pan and broken refrigerator then cold held in 65°f refrigerator. reheated for service.
		Slow cooling at room temperature and in a broken refrigerator of both rice and chicken. a) after thawing, chicken is partially cooked, then cooled in malfunctioning refrigerator - reheated to order. no temperatures taken. b) rice held in steamer overnight - unattended and improperly cooled in bags in a malfunctioning refrigerator then microwaved to order.
	Hot-holding equipment not used as intended	Phfs stored in turned off oven, sometimes overnight. Continued history of hot holding, cold holding, and reheating of phfs. A) beans stored in the turned off oven. Room temperature storage

Theme	Operational Antecedent	Selected Text Excerpts
		followed by inadequate reheating. B) cooked carne asada held on the grill inadequate hot holding. C) ground beef held in the oven (turned off) at unsafe temperatures. Room temperature storage followed by inadequate reheating. D) rice hot held at 118°f. Extra rice held in the turned off oven followed by inadequate reheating.
		Roasts were stored in non-mechanical holding units for transport. Followed by inadequate reheating and hot holding of roasts at food service location.
		The establishment did not properly hot hold the hamburgers. Hamburgers were held in cambros that did not plug in and were meant for transport only.

[a]'Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?'

[b]'During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?'