

Application of Restaurant Inspection Data Analysis to Increase Assurance of
Food Safety

A DISSERTATION

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Dedication

This thesis is dedicated to my father, Jack Lindenthal, whose own PhD has been an inspiration to me nearly all my life. Back when I was growing up, I knew no one else who had a doctorate so I was constantly in awe of his accomplishment. And as I progressed through school, his achievements became more notable to me, but he rarely spoke about them nor publicized his credentials. The day I was able to track down a copy of his thesis in an online source was very exciting and helped set me on the path to having my thesis similarly located.

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Abstract

Foodborne illness affects 48 million Americans annually with the majority of reported foodborne outbreaks due to food prepared and served by restaurants. Food safety practices at restaurants are verified via periodic inspections by health department personnel. With millions of such inspections conducted every year, concentrating on the most frequently identified risk factors could focus interventions where they will have the most impact. This would be particularly beneficial for restaurant chains with establishments across the country. Compared in this study were recent health department inspections in Minnesota and Arizona that had been performed at restaurants known to have had confirmed outbreaks to matched control restaurants that did not have outbreaks during the same time period.

No overall relationship to foodborne illness risk factors was demonstrated. However, a set of violations more likely to be associated with outbreak restaurants was identified. These violations likely represented a lack of overall control of food safety processes in the outbreak restaurants. There were differences in the specific violations identified between the two states, most likely attributable to the high variability in inspection approaches among different health department jurisdictions. The results highlight the need for a more consistent, nationwide approach to restaurant inspections than exists currently and suggest several approaches to improve the use of inspection data to reduce foodborne illness rates.

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Introduction

Foodborne illness is estimated to afflict an estimated 48 million Americans annually (84, 85). Among these millions afflicted each year, it is further estimated that foodborne illness causes 128,000 hospitalizations and 3000 deaths.

However, close to 80% of the 48 million cases are caused by so-called “unspecified agents”, which represent a variety of types of pathogens. These include agents for which limited information is available to enable calculation of valid estimates; those known to be in food but with unproven pathogenicity; and agents not yet identified. Overall, this is a tremendous burden of illness with about one in six Americans affected annually at an estimated cost of \$1626 per case and an aggregated cost of \$77 billion. (86)

The Centers for Disease Control (CDC) accumulate data on foodborne illness reported in the United States (US) from local and state health departments. From these reports, summary information can be gleaned. Contributing Factors to foodborne illness outbreaks, which are broken down into three categories of contamination, proliferation and survival have been reported (67). It is also reported that the top location to which foodborne illness outbreaks are attributed is restaurants and delis (24).

There would be significant public health advantages to decreasing the annual rates of foodborne illness in the US. This is a daunting problem and focus is needed to ensure effective use of resources to develop interventions that will have significant impact. Restaurants follow many food-handling and other related

practices to decrease the risk of foodborne illness against guidance published by the Food and Drug Association (FDA) (33). Their performance against these criteria is evaluated in periodic inspections conducted by health department personnel. The objective of the present study was to systematically study restaurants that had had foodborne illness outbreaks to identify any differences revealed in inspections between these and similar types of restaurants that did not have outbreaks. Knowledge of these differences can help in suggesting interventions that are likely to have the most significant effect.

The objectives of this thesis are:

1. To analyze recent health department inspections performed as part of outbreak inspections and those performed routinely at restaurants known to have had confirmed outbreaks to detect differences and to relate this information to future food borne illness likelihood.
2. To analyze routine health department inspections done at outbreak restaurants and comparing these to routine inspections done at non-outbreak restaurants in Minnesota to highlight criteria more likely to be associated with outbreak restaurants.
3. To apply the methods for analysis used with the Minnesota data to data from Arizona to determine if similar conclusions can be drawn.
4. To identify improvement strategies for restaurant inspections.

Chapter 1 - Literature Review

1.1 Background

Of the total 48 million cases of foodborne illness estimated to occur annually, it is further estimated that 9.4 million of them are attributable to 31 known disease agents. Among these 31, norovirus, nontyphoidal *Salmonella*, *Campylobacter* and *Clostridium perfringens* account for 88% of illnesses, listed in the order from highest to lowest incidence. Norovirus alone causes 58% of these illnesses. However, *Salmonella* causes the most hospitalizations and deaths for known agents (85).

These numbers are lower than the 1999 estimates, but provide a more valid summary of the burden of foodborne disease. Reasons for the lower estimates are use of more accurate data, new methods for data analysis and the incorporation of outbreaks which were only associated with foods that were consumed in the US. Despite the lower estimates, these data show that there is still a significant burden of foodborne illness in the US with current estimates suggesting that one person out of six suffers annually. Since there remains the potential for serious consequences from foodborne illness, these data and their implications must continue to be a significant focus for those who can most effectively influence them. Identification of the most impactful interventions is important and it is essential to continue to learn more about foodborne illness.

It is also understood that the majority of these illnesses are sporadic; this generally means they are not associated with recognized multi-state outbreaks

(58). Available data on *Salmonella* illustrate this point. The United States Department of Agriculture (USDA) estimates that sporadic *Salmonella* cases outnumber outbreak-associated cases by at least 15 to 1 (25).. According to CDC scientist, Ian Williams, the majority of cases of all foodborne illness are sporadic and outbreaks only represent the tip of the iceberg of total outbreaks (52). CDC data from 2004-2009 reports that the percent of *Salmonella* infections that related to an outbreak consistently remained between 5-8% of all cases (17). Another study estimated that only 3% of *Salmonella* infections are confirmed and reported to surveillance systems (95). This information demonstrates that outbreaks do not contribute much to the overall incidence rate.

While this could be used to justify that the controls that have been implemented have been largely ineffective, it would more beneficial to try to identify and adopt proactive strategies that can be specifically applied across the farm to table continuum in order to affect illness rates regardless of whether they are part of outbreaks or sporadic. Because of this inherent and intermittent nature of foodborne illness, determining the cause of these episodes is difficult, but attempts must be made. As more information is gathered on the actual causes, proactive strategies to combat illnesses can be effectively developed and implemented. One needs to be aware of results from multiple sources of data in order to identify and target strategies effectively.

1.2 Disease Agents

The agents of disease are variable. Scallan et al. (85) reported that 31 different bacteria, parasites, and viruses are responsible for the estimated 9.4 million annual cases of foodborne illness in the US. Of the 31 known agents, top pathogens included norovirus, nontyphoidal *Salmonella* and *Clostridium perfringens*, which account for 79% of illnesses. Norovirus alone causes 58% of these illnesses, affecting an estimated 5.5 million people annually. These top pathogens have some similarities and all are able to opportunistically infect people, but there are differences in their ecologies including where they are typically found, how they grow, their transmission routes, and the types of illnesses they cause.

1.3 Norovirus

The primary reservoir for norovirus is humans and the virus can be spread rapidly among people since it is shed by infected people in feces and vomitus. It is commonly transmitted person to person, through unwashed hands (64). People begin to shed the virus before the signs of illness occur, and they continue to shed long after they recover. It is known that low levels of ingested viral particles (i.e., 10-100) can cause illness and estimates suggest that ill people may shed as many as 10^{12} norovirus particles per gram of feces (1). Researchers have studied fecal shedding as measured by RT-PCR in experimentally infected healthy people (1, 64). Shedding was observed three to 14 hours before symptoms appeared. Although this shedding time period is slightly shorter than that of one day reported by other researchers (83), it does

illustrate the high transmission potential of this virus, as people can unknowingly shed the virus when they are still feeling healthy.

Although the majority of shedding occurs in the first few days of illness, it can continue for a longer time enhancing the spread of norovirus. Rockx, et al. (83) showed that even at eight days post infection and well after recovery, about 25% of infected adults were still shedding. Children under twelve years old tended to shed longer with more than 25% still shedding after 22 days post infection. At 14 days post infection, patients still shed with levels exceeding one million viral copies per gram of feces. Some patients continued to shed norovirus particles in feces for as long as eight weeks after the initial infection (1). Glass, et al. (43) reported that as many as one third of intentionally infected human volunteers remained asymptomatic despite shedding large amounts of the virus in their feces. This very likely could set up conditions in which shedders potentially pass viral particles to others, and several researchers have hypothesized that healthy shedders have been associated with outbreaks (1, 43, 76, 83)

Another transmission route is via contaminated food or water or contact with contaminated surfaces (64). Norovirus is incredibly stable. Doultree et al. (31) studied the persistence of feline calicivirus, a commonly used and accepted surrogate for norovirus, on a variety of surfaces after initially inoculating with 100 million viral particles. They found that on a dry surface at ambient temperatures (20°C), the surrogate survived for as long as 28 days, and under refrigeration

(4°C), recovery lasted through the duration of the study, for up to 56 days.

Although persistence on wet surfaces was slightly shorter, up to 21 days at 20°C, a long-surviving reservoir of viral particles on a surface could prolong an outbreak or lead to persistent outbreaks.

Along with persistent survival, norovirus is able to be transferred easily. One route is from fingers to other surfaces. Finger pads contaminated with the norovirus surrogate feline calicivirus, were allowed to dry and then touched to various surfaces to evaluate the percent of transfer (3). Forty six, nineteen, and thirteen percent of particles were transferred from untreated fingers to ham, lettuce and stainless steel, respectively. Treating hands with water, soap and water, or alcohol significantly reduced the percentage transferred, but the overall levels transferred were still greater than 0.5%. Since actively suffering people may shed trillions of norovirus particles in their feces, even with some level of hand washing and bathroom disinfection being practiced, it is still very likely that transfer of norovirus particles will occur, with potential to cause illness since low levels of virus particles cause illness.

This transmissibility of norovirus from fingers to other surfaces has feasibly contributed to outbreaks. In 2007, three separate groups of people who dined at a Dutch restaurant suffered subsequent gastroenteritis. Public health authorities investigating the outbreak collected swabs from environmental surfaces in the kitchen and bathroom, including soap dispensers, cupboard door handles and a knife handle. They also swabbed food worker's hands. By

studying extracts of RNA detected in the swabs, researchers detected the same norovirus strain on many of the environmental surfaces. With detection of the same strain on the food worker's hand, they reported the first instance of detection of norovirus on the hands of a food worker directly associated with an outbreak (6).

There is further evidence that fomites contaminated with norovirus have lead to recurring outbreaks. In 2004, there were three sequential, five night duration houseboat trips that included a total 54 passengers over the three trips. The houseboat had on-board kitchen and bathroom facilities. One passenger on the first trip had gastroenteritis upon boarding; all other passengers were reportedly healthy upon embarking. Through the three trips, the gastroenteritis attack rates of passengers were 80, 60 and 70 percent respectively, and norovirus was confirmed in ill people. Follow-up investigation revealed widespread positive norovirus isolation from random surfaces in the kitchen and bathroom including 100% of doorknobs. The outbreak demonstrated the potential role of widespread surface contamination (60). Boxmann, et al. (5) evaluated a variety of high touch points (knife handles, salt and pepper shakers, refrigerator door handles, etc.) in kitchens of Dutch catering companies who had and had not had gastroenteritis outbreaks, for the presence of norovirus genetic material. They found about a 1% contamination rate in non outbreak kitchens, but in those that had had recent outbreaks, the isolation rate was about 30%.

In essence, previously ill people, who are typically recovered in about 3 days, can potentially serve as human reservoirs for secondary spread of norovirus for periods of time that can extend for many weeks through a wide variety of transmission pathways, many of which may be found in food service environments.

1.4 Non-Typhoidal *Salmonella*

Although norovirus is the agent responsible for the majority of foodborne illness outbreaks, *Salmonella* remains a significant threat as well. This review will address only non-typhoidal *Salmonella*, which is most commonly associated with human infection and can be transmitted by food. Scallan et al. (85) estimated that 11% of the estimated annual foodborne illness in the US is attributable to *Salmonella*, with about 1 million cases occurring each year. However, only about 3% of these cases are actually reported and tracked via public health surveillance. The number of laboratory confirmed cases is about 42,000 which equates to an under-diagnosis multiplier of 29.3. Despite the under-reporting, *Salmonella* illnesses are serious with estimated hospitalization and death rates of 27.2% and 0.5% respectively.

FoodNet data are collected annually via active population-based surveillance and represent a collaboration of CDC, ten states, USDA-Food Safety Inspection Service (FSIS) and the FDA. *Salmonella* is one of the agents that has been tracked through this system since 1996 when the program was initiated. The most recent available data from 2010 (12) indicate that *Salmonella*

was most commonly reported among the tracked pathogens, with an incidence rate of 17.6 cases per 100,000 persons. Since 1996, when data collection began, there has not been a significant decrease in overall *Salmonella* incidence and in the last several years, rates have actually increased. The estimated rates from FoodNet for hospitalization and death rates at 27.7 and 0.4% respectively match well with Scallan et al. (85) data.

Salmonella is a zoonotic disease since its primary reservoir is in the intestinal tracts of both wild and domestic animals and it can be transmitted via fecal contamination. Foods of animal origin such as raw meats, eggs and raw milk are commonly contaminated with *Salmonella*. The USDA reported *Salmonella* isolation rates in 2010 of up to 18% in poultry products, about 2% in beef and <1% in swine, in analysis of nearly 30,000 samples (94). A study of eggs from flocks previously tied to outbreaks of *Salmonella* Enteritidis showed contamination rates up to 0.9% (54). A review of raw milk safety revealed *Salmonella* contamination rates in this product up to 11% (74).

The agricultural environments in which these animals' products are raised can be easily contaminated with *Salmonella*. These environmental *Salmonella* can in turn contaminate agricultural commodities via fecally contaminated sewage or runoff water. The presence of *Salmonella* in the natural environment can lead to contamination of food production environments as well.

Outbreaks of *Salmonella* in humans have been linked to consumption of a wide variety of foods demonstrating that the contaminant can transcend many

environments. Salami coated with black and red pepper was linked to 272 cases of *Salmonella* Montevideo in 2010 (18) and the outbreak strain was isolated from samples of the spice. Produce can also become contaminated with *Salmonella*. Tomatoes have been found to be contaminated with *Salmonella* in several outbreaks including those that occurred 1989-90 (29), 1990 and 1993 (51), and were suspected in a 2008 outbreak, though the final vehicle was determined to be jalapeno peppers (13). Other agriculturally-derived products including peanut butter (22), chocolate (96) and cereal (23) have also been contaminated with *Salmonella* despite their undergoing typical processing that should destroy contaminants. In these outbreaks a persistent environmental niche may have lead to widespread contamination.

Outbreaks of salmonellosis have been reported in food service settings as well (50, 53, 58, 63). A study of 23 restaurant-associated outbreaks revealed a strong association of infected workers to persistently contaminated environments and prolonged outbreaks. The complexity of the infection pathway is emphasized in many of these outbreaks (69).

The persistence of *Salmonella* in food growing and manufacturing environments is becoming more commonly recognized. Uesugi (90) reported finding 53 isolates of the same strain of *Salmonella* on an almond farm for 5 years. The 2008 cereal outbreak due to *Salmonella* Agona was linked to an outbreak attributed to the same strain in the same facility ten years earlier (23), (14). It is known that *Salmonella* can survive for extended times in a variety of

dry products, including chocolate, gelatin, and spices (55). Since the levels of heat needed for inactivation of *Salmonella* cells in these types of products is higher than is typically required, an adaptability of the strain to low-moisture conditions both in foods and in production environments is suggested (44).

While *Salmonella* can persist in a dormant state for extended times in the environment, the organism can emerge from dormancy and grow very well when conditions become more favorable. It is reported (55) that the organism is able to grow over a pH range of 3.8-9.5, water activity 0.94 - >.99, and temperatures 41-115°F. These conditions exist in many food products, which, if contaminated either naturally or via cross-contamination from one of the animal primary sources, can and have served as sources of *Salmonella* illness. Because of this, transmission to humans via a variety of routes including food and food environments is widely reported, as stated above.

It is believed that the infective dose for *Salmonella* is low and levels as low as 10-15 cells have been reported in some outbreaks. The actual effects are dependent on host age and underlying medical conditions and there also are some differences among *Salmonella* strains. Acute symptoms of salmonellosis include gastro-intestinal distress plus fever and headache which typically occur within 6-48 hours after exposure to a contaminated food. There can also be longer lasting symptoms of arthritis that appear several weeks after the initial symptoms (36). Scallan (85) reports that the majority of serious outcomes attributed to *Salmonella* occurred in immune-compromised populations.

1.5 *Clostridium perfringens* and other toxin-mediated illnesses

C. perfringens is estimated to cause an estimated 1 million cases in the US annually (85). *C. perfringens* cells or spores are ubiquitous. They are commonly found in dust, vegetation, and intestinal tracts of animals, so are present in raw meats, flour or dough-based products, vegetables, etc. (35).

With proper cooking, vegetative cells will be inactivated, but the spores of *C. perfringens* may survive and can grow to large numbers if the cooked food is held between 40° and 140°F for an extended time period. The absence of competing bacteria in the cooked food will produce an environment favorable to the growth of the surviving *C. perfringens* spores. If levels of *C. perfringens* in a food increase to greater than 10⁵/g, this agent may cause foodborne illness, especially if the food is consumed without any further cooking. Ingesting large numbers of *C. perfringens* can lead to formation of a toxin in the human intestine; this characteristic is why *C. perfringens* is known as a toxico-infectant. Meat and poultry dishes, sauces and gravies are the foods most frequently involved. To control the growth of *C. perfringens*, hot foods should be served immediately or held above 140°F. Care must be taken to cool foods properly to limit the time that surviving spores might be in the range of 40-140°F where outgrowth can occur (15). Practically, this means that large volumes of gravies, meat dishes, etc., should be refrigerated promptly and divided into small portions so they will cool rapidly. And for safety, the food should be reheated to 165° F prior to serving (34).

Transmission of *C. perfringens* to people is via foods in which populations have increased to 100,000 per gram or greater. After ingestion of large numbers of cells, the toxin that is produced causes cramping and diarrhea occurring 8-22 hours after eating. The illness is self-limiting with recovery after 24 hours (35). Since this is a toxin-mediated illness, ill people are not infectious and the organism is not generally transmitted from person to person. However, isolating high levels of spores from fecal samples from ill people is part of confirming *C. perfringens* as the causative agent (48). Outbreaks may be suspected when groups of diners become ill and there is evidence of poor temperature control among the foods that were consumed.

There are other toxin-related types of foodborne illnesses; all are related to poor temperature control of the implicated food when contaminating cells are allowed to increase to harmful levels. *Bacillus cereus* produces one type of toxin in the human gut like *C. perfringens* after consumption of large numbers of cells. However, there is also a different kind of *B. cereus* toxin produced in the food when cells proliferate that can cause vomiting within a few hours of consumption. Similarly, *Staphylococcus aureus* also produces a pre-formed toxin in a food when contaminating cells grow to high levels that results in symptoms of vomiting and diarrhea after ingestion of the food. Lab testing of food or stool or vomitus samples can assist with specific diagnosis, but generally if an evaluation of food handling conditions reveals instances where temperature control of a food was suspected, toxin-related illnesses might be suspected. Recent data estimate that

foodborne *B. cereus* cause 63,623 and *S. aureus* cause 241,994 cases/year.

(85)

1.6 Types of illnesses transmitted via foods

The CDC (21) provides a list of infectious diseases that are transmitted through handling in the food supply. Two categories are identified: 1) those pathogens that are often transmitted by food when handled by an infected person and 2) those pathogens that are occasionally transmitted thorough handling by an infected worker but usually transmitted by contamination at the source or in food processing or by non-foodborne routes. Those “often” involving infected workers include pathogens that have a low infectious dose and those that are shed in high numbers when an active infection exists. Norovirus can fit both of these categories, though is typically in the first category; non-typhoidal *Salmonella* fits the second; *C. perfringens* is in neither.

Being armed with information on how agents are typically transmitted can assist with identification of the specific cause of the foodborne illness. There are other sources of data that can also help with this task.

1.7 Contributing Factors to Foodborne Illness

In foodborne illness investigations, the CDC requests that so-called “Contributing Factors” to the outbreak be identified if there is evidence that the factor was substantially related to the overall cause of the outbreak. This evidence is collected through a systematic process that gathers information about the environmental conditions that were in place when the outbreak was

suspected to have begun. Often, this is done by state-level environmental health personnel who are investigating the outbreak. This evidence might point to a direct cause of the outbreak or to a series of events and/or conditions that together may have led to the outbreak. Guidance from the CDC in the National Outbreak Reporting System (NORS) is used to help identify relevant contributing factors. There are 32 different types of these factors, broken down into three categories of contamination, proliferation and survival. Fifteen of these related to how the agent got into or contaminated the implicated food. Twelve of these relate to growth or proliferation of an agent in the food, and by definition are only assigned when a bacterial agent is suspected. The final five contributing factors relate to the failure to inactivate an agent in a food pointing to its survival and again are also designed to be assigned when a bacterial agent is suspected (20).

Lynch et al. (67) published foodborne illness contributing factors that were reported for outbreaks occurring from 1998-2002; this is the most recent time period for which these data are published. During this time period, there were 3072 outbreaks for which contributing factors were reported and 1238 of these had a confirmed etiology. Among those outbreaks with a confirmed etiology, the top identified contamination contributing factors were "infected worker", recorded in 28% of these outbreaks and "bare hand contact", in 19% of outbreaks. The top proliferation factor was "food at room temperature for several hours" in 24% of the outbreaks and the most commonly reported survival factor was "insufficient time and/or temperature during initial cooking/heat processing," in 16% of

outbreaks. Not surprising, in many outbreaks more than one contributing factor was reported. An example of this might be when an ill food handler contaminates a food that is then improperly cooked or held and the contaminant is allowed to grow to harmful levels. Identification and categorization of this information can assist in determination of patterns of factors and knowledge of these (20) can assist with development of appropriate control strategies.

1.8 In what setting does most foodborne illness occur?

Despite the fact that the majority of foodborne illness is sporadic, data are also recorded on where outbreaks have originated, when this information is available. The CDC has their on-line searchable database (NORS) that can be used to provide descriptive summaries of outbreak data (24). Within the database are several options for health department personnel to record data about outbreaks. Types of recorded data include epidemiological information such as mode of transmission, food vehicle, and setting of the exposure. CDC publishes guidance to assist the users of this database from across the country to record data in a consistent manner against standardized criteria (20).

Contained within NORS is information about food and waterborne outbreaks, as well as those transmitted person-to-person. When personnel from states input data about their outbreaks, this system is able to provide comprehensive national surveillance and information about disease burden and attribution to settings, transmission routes, and food vehicles. The types of outbreaks included are those reported to the CDC by state, local and tribal health

departments where the outbreak occurred, but it should be recognized that not all outbreaks may be reported to the CDC. In addition, the specifics of all reported outbreaks may not be completely represented. Despite these restrictions, this data set does provide a relatively comprehensive picture of recently reported foodborne illness in the US and is available in an easily accessible format that is broadly available. Studying these data can provide valuable insights on foodborne illness incidence, and even with the recognized limitations, this may assist with focusing control efforts in areas where they may have an impact.

There are several types of settings from which a health department official can select when inputting data. These include: camp, daycare, community-wide, hospital, hotel, nursing home, prison/detention facility, private setting (home), religious facility, restaurant, school, ship, and workplace. The guidance includes definitions of these types of settings. Published data from 2008 indicates that the majority of outbreaks caused by *C. perfringens*, *Salmonella*, or norovirus resulted from food consumed in restaurants (10). This is supported by an evaluation of the most recent data from 2009 extracted from NORS (24). Also, in a study of about 800 outbreaks in which infected workers were involved, the majority or nearly 40% were reported to have been attributed to restaurant meals (89). Outbreaks do occur in other settings. NORS data shows that other specific settings where exposure to these agents was identified are home, school, church, picnic, fair, prison, camp, nursing home, grocery, and hospital. However, the strong association of foodborne illnesses to restaurant-consumed meals

suggests that it is worthwhile to learn more about this setting to ascertain where controls may be most impactful.

The National Restaurant Association (NRA) (73) estimates that there are nearly one million restaurants in the US. There is great breadth in the types of these locations from full service sit down establishments to quick service restaurants defined as those at which a patron pays for food at a counter prior to being served. There are also more limited service establishments but the reality is that food preparation and service occurs in a variety of places. Eating out is a very common occurrence. The NRA estimates that nearly half of American's food dollars are spent at restaurants. On a typical day, 130 million Americans will be foodservice patrons and the average American eats 4.8 meals per week outside the home (82).

It is known that the majority of illnesses attributed to norovirus, *Salmonella*, and *C. perfringens* are linked with restaurant consumed meals. Coupling this with the fact that large numbers of consumers eat outside of the home means that there may be a large proportion of the public who could be at risk for foodborne illness if proper food-handling practices are not followed. Verification of these behaviors and the existence of proper systems are an important public health intervention.

1.9 How is food safety verified at restaurants?

The US FDA publishes guidance for restaurants in the Food Code (34). The Food Code is a considered a model designed to safeguard public health and

ensure that food is not adulterated. It sets forth advice from FDA for standards related to management and personnel; food; equipment, utensils and linens; water, plumbing and waste; physical facilities; poisonous or toxic materials; and compliance and enforcement. Information in the Food Code is supplemented by seven annexes which offer more detailed background justification for the Food Code provisions. The full document is re-issued every four years to incorporate new scientific information as it becomes available, with supplementary information issued periodically. The full Food Code was most recently issued in 2009 and continues to represent a uniform set of provisions that addresses the safety and protection of food offered at retail and in food service. A supplement to the Food Code was recently issued (33). States have the option to adopt the federal Food Code or may elect to adopt their own, often more-restrictive version.

Restaurant locations in the US are inspected against the Food Code guidance by local and state health department personnel. The inspections evaluate against criteria related to foodborne illness risk factors and good retail practices. Application of these criteria varies by jurisdiction with requirements and the frequency of inspections and scoring differing widely. While the primary purpose of inspections is to communicate to the restaurant management their compliance status with the particular relevant requirements, inspections also present an opportunity for educating food handlers and identifying and correcting risky practices when these are observed (34).

Restaurant patrons expect that the food they eat in restaurants is prepared safely. Unfortunately, this may not always be true. A survey of restaurant workers demonstrated that unsafe food handling practices were common (46). These practices included improper use of gloves, inadequate handwashing, not using a thermometer and working when ill. The FDA conducted evaluations at over 200 full and quick serve restaurants in 2008 and found consistent violations in areas including improper holding/time and temperature, poor personal hygiene, contaminated equipment/protection from contamination and inadequate cooking (37). These results were similar to those identified in earlier studies done in 2000 (39) and 2004 (38).

An important conclusion of these studies was that continued emphasis on active managerial control was needed. Active managerial control focuses on ensuring that preventive controls aimed at the CDC's most commonly identified contributing factors to foodborne illness are effectively implemented (34). These include safe sourcing, proper cooking, adequate temperature control, clean equipment and satisfactory personal hygiene. Active managerial control infers that a preventive system is established which includes continuous monitoring and verification. An important part of such a system is effective management oversight. Certified managers are required to carry out certain duties related to food safety. Examples include: identification of food safety hazards, policy development and implementation, employee training, daily inspections, and directing food preparation activities with effective corrective actions implemented

when indicated. (72). Two separate studies have found that the presence of a Certified Manager has a positive impact on restaurants since their presence was associated with better inspection results (8) and fewer outbreaks (49).

The existence of effective food safety programs is verified via periodic routine inspections (usually one to four times per year, depending on locale) conducted at food service establishments by health department environmental health specialists. These are done to assess a restaurant's adherence to Food Code criteria and guidance has been written to provide information to inspectors on how to most effectively conduct a risk-based inspection (34). The outcome of the inspection is an indication of how well the restaurant is complying to provide an assessment of the overall performance and to identify areas for improvement. Most inspections are scored and increasingly, information about the ranking of the establishment is publicly available, either through postings in the restaurant itself or online. Consumers have a strong desire for this information (40), but having this available so easily has led to several misconceptions. While most consumers are aware that routine inspections are done, they also believe that they should be conducted much more frequently than they really are done and that responses by public health officials to results should be much stronger (61). However, having this information available can be beneficial as it may suggest where training is needed (66).

There have been several studies that have attempted to relate foodborne illness likelihood to restaurant inspection results. Two studies have found a

relationship (56, 75), but in these studies, the agent involved was not identified and the outbreaks selected for the study do not appear to be confirmed. These were also small studies involving six or fewer locations that had had outbreaks (75) and very low numbers of cases (56). A different study which examined confirmed and larger outbreaks refutes this idea (59). Other studies determined that specific types of violations were more likely found in restaurants that had had or might have outbreaks (7, 28). Clearly the research presents a varied picture. In a review of confirmed outbreaks as well as sporadic illnesses, another study found a positive association of illnesses with meals consumed outside the home, mainly at restaurants. Further, they concluded that to help prevent illnesses, restaurants needed to remain diligent in their focus on food safety practices. (58).

1.10 Summary

This thesis will examine some of the challenges with the current system for evaluating the food safety practices that exist at restaurants today, show what can be gleaned from a review of health department inspections of restaurants and suggest ways that the current system can be improved. This will be done through a series of three papers, focused on data from Minnesota and Arizona restaurants some of which had recent foodborne illness outbreaks.

Paper one evaluates inspection data from MN restaurants that had confirmed foodborne illness outbreaks attributed to *C. perfringens* or other suspect toxin mediated agents, *Salmonella* and norovirus. By comparing the findings from inspections performed to investigate the outbreak with findings from

recent routine inspections done at these same restaurants, this paper will determine if a relation exists between overall conclusions. If such a whole scale relationship cannot be found, further analysis will be done to determine if there might be differences in specific types of criteria typically evaluated in outbreaks attributed to the three top occurring agents.

Paper two will draw from the conclusions of paper one. It will compare inspection findings from restaurants that had confirmed foodborne illness outbreaks attributable to *C. perfringens* or other suspect toxin mediated agents, *Salmonella* and norovirus with a set of restaurants from Minnesota that did not have outbreaks. The aim will be to determine if different patterns of violations are observed among the outbreak and non-outbreak locations. If this can be done, it may be possible to develop a profile of what an outbreak-prone restaurant could resemble. Using this scheme to evaluate inspection data could permit identification of locations at potentially higher risk of an incident and worthy of increased attention as well as targeting of appropriate interventions.

Paper 3 will examine another data set from the Maricopa County, Arizona jurisdiction to see if conclusions developed in paper two can be applied elsewhere. An additional set of outbreak and non-outbreak restaurants will be compared. Given the broad inconsistencies among different health departments and how they approach restaurant inspections, it is expected that some differences may be seen. Identified differences will be used as a basis for suggestions as to how the overall restaurant inspection process in the US may

be improved to better enable to consistent identification of and response to food safety issues at restaurants.

1.11 Human Subjects and Institutional Review Board (IRB) Approval

This study involved the collection and evaluation of restaurant health department inspection information and data that are publicly available and collected via routine public health surveillance. These generally involve a listing of the specific health-related violations that an inspector might have found upon visiting a restaurant. The University of Minnesota IRB was consulted on January 21, 2011 and confirmed that this study did not qualify as Human Subjects Research under the IRB's definition as the research is about "what" not "who" and was deemed "exempt" from needing IRB approval.

Chapter 2

Manuscript 1 - Analysis of Outbreak Restaurants and their Recent Health Department Inspections and Relation of this information to Foodborne Illness Likelihood

With US restaurants inspected at least annually against criteria in the FDA Model Food code, large amounts of data are generated and should be systematically reviewed. The purpose of the study is to determine what relationships between health department inspection data, CDC-identified contributing factors to foodborne illness, and the risks of outbreaks of norovirus, *Salmonella*, and *C. perfringens* may exist at a specific restaurant. To accomplish this analysis, a theoretical, predictive assessment tool was built that extracts data from inspection reports to establish a risk profile for a specific restaurant location to identify its likelihood of a norovirus, *Salmonella*, or *C. perfringens* outbreak. The tool was used to examine inspection reports from restaurants known to have had confirmed norovirus, *Salmonella*, and *C. perfringens* outbreaks. Despite the fact that evaluation of an extensive set of data revealed lack of an overall association between inspection scores of outbreak and routine inspections done at outbreak restaurant locations, certain specific violations were more likely to be recorded ($p \leq 0.05$). Significant differences in types of violations recorded in outbreak and routine inspections were determined. Where risks based on violation type are identified, targeted actions may be able to be prioritized and implemented to help decrease illnesses.

2.1 Introduction

An estimated 48 million Americans are afflicted by foodborne illness annually and norovirus, *Salmonella*, and *Clostridium perfringens* cause 79% of cases (85). The majority of these illnesses are sporadic, generally meaning they are not associated with recognized multi-state outbreaks. The USDA estimates that sporadic *Salmonella* cases outnumber outbreak-associated cases by at least 15 to 1 (25). The US CDC reports similar data; from 2004-2009, the percent of *Salmonella* infections that related to an outbreak consistently remained between 5-8% of all cases (17). This emphasizes that large outbreaks are having little effect on the overall incidence rate. While this could be used to justify that implemented controls have been ineffective, it would more beneficial to identify and adopt proactive strategies that can be specifically applied across the farm to table continuum to affect illness rates.

When studying foodborne illness, it is important to extract out data to be used for identifying such strategies. A review of current reported foodborne illness data reveals many useful pieces of information. CDC data summarizing outbreaks from 1998 – 2002 indicates that the majority of outbreaks are associated with foods consumed at restaurants and delis (67). More recent data from CDC reveals a similar pattern with restaurant and deli associated meals accounting for more than half of all outbreaks; in 2007, restaurants or delis accounted for 51% (16) and in 2008, for 52% of reported outbreaks (10).

Restaurant locations in the US are inspected against guidance published by the FDA in the Food Code (34), though the application of these criteria varies by jurisdiction. The Food Code was most recently updated in 2009 and represents a uniform set of provisions that address the safety and protection of food offered at retail and in food service and a supplement was recently issued (33). The Food Code is said to be a model to safeguard public health and ensure that food is not adulterated by evaluating inspected locations on foodborne illness risk factors and good retail practices.

Although the Food Code is a recognized guidance document, it is adopted by local and state health departments in a variety of ways with requirements and the frequency of inspections and scoring differing among jurisdictions. As an example, the State of Minnesota (MN) has its own state-specific version of the Food Code (72) which is based on the federal code. For MN licensed establishments, it is regulation and all locations are expected to meet its provisions. It consists of minimum design, installation, construction, operation and maintenance requirements for all food establishments in Minnesota and includes compliance standards for food handling, storing, preparation and service. The MN Food Code is presently undergoing revision to bring it more in line with the most current US Food Code.

In an appendix to the 2009 Food Code, there is a useful model form 3-A which includes a listing of 54 standardized criteria or questions (34); these are summarized in table 1 and shown in their entirety in Appendix 1. Questions 1

through 27 are identified by the FDA as “Foodborne Illness Risk Factors and Public Health Interventions” and questions 28-54, as “Good Retail Practices”.

Some jurisdictions including some in Minnesota use the exact criteria detailed in this form in their restaurant inspections while others have adopted different versions. Generally, the same criteria are evaluated, but since different tools are used to capture this information, comparison among different jurisdictions is hampered. As evidence of the differences that various states may adopt, since the current MN Food Code does not include reference to consumer advisories, use of pasteurized foods for highly susceptible populations, variances for specialized processing methods, and plant foods properly cooked for hot holding, no violations against criteria 23, 24, 30 and 32 would be recorded in current inspections performed in MN. Regardless of which specific form is used, observations are recorded and violations identified in a systematic way by health department personnel.

Additional data about reported foodborne illness is available from the CDC. In a detailed analysis of reported foodborne illness outbreaks for the period of 1998-2002, the CDC identified 32 factors contributing to foodborne illnesses (67) based on information provided in foodborne illness investigations. These separate factors, characterized as contamination (C), proliferation (P) and survival (S) factors are listed in Table 2.

Illnesses reported by the CDC between 1998 and 2001 (67) attributed to the 32 individual factors can be grouped into five categories (Fig. 1). “Inadequate

cooking” includes violations related to insufficient time and/or temperature during cooking, reheating, and thawing and insufficient thawing and cooking. “Improper holding” includes violations related to food at room temperature for several hours, inadequate cold temperatures in storage, slow cooling, insufficient times and temperatures in hot holding, food prepared more than a half day before serving, and prolonged cold storage (e.g., for weeks). “Contaminated equipment and the environment” includes violations related to toxic substances, polluted source, inadequate cleaning, raw ingredient contaminated by pathogens from animal or environment, cross-contamination by raw animal product, contaminated environment and other contamination factors. “Poor personal hygiene” violations include bare hand contact, infected worker and gloved hand contact. “ Other” includes violations in areas of insufficient acidification, inadequate acidification, inadequate fermentation, addition of excessive quantities of ingredients at toxic levels, insufficient low water activity, anaerobic or modified atmospheric packaging concerns, poisonous substance intentionally added, toxic container/pipes, ingestion of contaminated raw product, poisonous or physical substance accidentally added and other survival and other proliferation factors. Analysis of these data in this fashion shows that close to three quarters of illnesses can be linked to improper holding of foods, contaminated equipment and/or the environment and poor personal hygiene.

The present study sought to determine what relationship might exist between health department inspection data, targeted towards gathering data on

Food Code criteria on foodborne illness risk factors and good retail practices, and the CDC-identified contributing factors to actual reported and confirmed foodborne illness. Using these data sources, a model was constructed to relate risks of outbreaks of norovirus, *Salmonella*, and *C. perfringens* at a restaurant to what is known about how outbreaks of these agents may typically occur. After a preliminary analysis of data from restaurants involved in an egg-associated *Salmonella* outbreak, an evaluation of a larger set of restaurants associated with other foodborne illness outbreaks was done.

2.2 Methods

Preliminary Study

In the summer of 2010, increased incidence of illnesses attributed to a specific Pulse Field Gel Electrophoresis (PFGE) pattern of *Salmonella* Enteritidis was reported. By the end of the outbreak, it is estimated that more than 1,900 illnesses occurred. A linkage to consumption of shell eggs was reported commonly in epidemiological investigations of these illnesses, conducted by several states. In addition, among these illnesses, public health officials from 11 states identified 29 restaurant or event clusters where more than one person became sick. (9) Three of these occurred in Minnesota.

Through cooperation with the Minnesota Department of Health (MDH) and various local health departments in three cities in MN, these locations were identified and results of recent health department inspections were obtained. This included the investigational inspections associated with the reported illnesses

and up to four years of preceding routine inspections performed at these same locations as well as the routine inspection done immediately after the outbreak. This totaled three investigational inspections and 10 routine inspections. Violations from these inspections were recorded and compared to FDA Food Code Form 3-A criteria (See table 1) to determine to which criteria they linked. Once mapped to this standard form, comparison was better enabled against a common platform. Violations were examined to determine if patterns and repeats were observed.

Construction of a Model

As a first step in model construction, data from the CDC on contributing factors related to foodborne disease outbreaks in the US from 1998-2002 were reviewed (67). These data reported a total number of outbreaks for each of the three pathogens under consideration (norovirus, *Salmonella*, and *C. perfringens*) where contributing factors were reported. For each of the 32 contributing factors, a number was recorded representing how many of the outbreaks were attributed to that particular contributing factor. These numbers were each divided by the total number of outbreaks to get the initial weights that were used as part of the model and are shown in Table 3.

As a second step, a matrix was created using the 54 Food Code survey questions shown in Table 1 as row labels and the CDC contributing factors as column labels. The generally known causal pathways for each pathogen type were considered. Generally among foodborne outbreaks of these pathogens, *C.*

perfringens outbreaks are associated with temperature abuse; norovirus, with person to person contamination and transmission; and *Salmonella*, with a range of factors including personal, food and surface contamination, temperature abuse, and failure to inactivate the organism. Based on these known causal factors for these three pathogens and information from NORS guidance (20), contributing factors were related to Food Code standardized questions (Table 1) in a matrix by placing an “N”, “S”, and/or “C” in the intersecting cell For norovirus, *Salmonella*, and *C. perfringens*, respectively. This is in Table 4.

The probabilities identified in step one were placed into each of the corresponding cells where the an “N”, “S”, and/or “C” were named and summed to obtain a weighting for each of the 54 Food Code questions (described in Table 1) for each specific pathogen type and normalized against the total for all questions. These are shown in table 5. To obtain an overall “score” for a typical inspection report, the value from table 5 associated with each type of violation identified in a typical report are summed. The resulting summed value provides a total score for each individual inspection report based on the identified violations. These are expressed as values from 0.0 to 1.0. A relationship between health department inspection data and contributing factors to foodborne illness can be calculated to provide a comparative risk value for foodborne illness outbreaks for one or more pathogens at a restaurant or other food establishment based on the food establishment’s inspection data.

Data from a restaurant inspection and its identified specific violations were compared to each of these weightings specific to each pathogen type. Assuming the logic is sound, this would permit identification of the pathogen outbreak type more likely to be associated with a particular restaurant inspection result. To validate that this tool has the power to discriminate when an outbreak might occur, data from restaurants known to have had outbreaks was needed. What would be most preferable would be to see a clear separation of values for each kind of pathogen when comparing results from outbreak investigational inspections to routine inspections done at these same establishments.

Expanded Study

To test this model concept, further cooperation with the MDH and various local health departments in jurisdictions across the state identified 68 distinct confirmed restaurant-associated outbreaks that occurred from 2005-2009 about which both illness investigational and routine inspection information could be obtained. These were linked to 63 separate restaurant locations; one location experienced three outbreaks (one attributed to two agents) and two locations each had two outbreaks over this time period. 44 norovirus outbreaks, 13 *Salmonella*, and 11 *Clostridium perfringens* or toxin-mediated outbreaks were included in the sample set.

As was done in the preliminary study, information about recent inspections was obtained from the affected locations. This included the investigational inspections associated with the reported outbreaks and up to four years of

preceding routine inspections performed at these same locations as well as the routine inspection done immediately after the outbreak. This totaled 68 investigational inspections and 257 routine inspections done at these 63 individual locations. Violations from these inspections were recorded and compared to FDA Food Code Form 3-A criteria (table 1) to identify to which criteria they linked. Once mapped to this standard form, comparison was better enabled against a common platform. Violations were examined to determine what patterns and repeats were observed and Fisher's Exact Tests ((Excel 2007 and Minitab version 16.2.1) run, to determine where significant differences in recorded violations were observed. Using the model, risk weightings for each of the standard restaurant inspection criteria were constructed and normalized using CDC identified contributing factors for foodborne disease outbreaks.

2.3 Results

Preliminary Study

Violations observed at three MN restaurants at which cases consumed *Salmonella*-contaminated eggs in spring-summer 2010 were recorded and mapped to FDA Food Code Form 3-A. Details of the 26 total violations recorded at these locations and their frequency in the three outbreak investigational inspections as well as in ten routine inspections done at these locations before and after the outbreak are in table 6.

The outbreak inspections of the three restaurants found 11 violations in the following general areas: Unclean food contact surfaces and utensils;

Improper wiping cloths storage; Handwashing; Bare hand contact with foods; Cross contamination; and Improper cooking. When routine inspections of these same three locations were examined, some of the same violations were revealed, but no outbreaks were believed to be associated with any of these earlier inspections. Generally the types of violations recorded in the routine inspections include: Unclean food contact surfaces and utensils; Improper wiping cloths storage; Facility concerns; Inadequate food temperature control; Unclean nonfood contact surfaces; and Ill employee exclusion. As shown, several of the violations observed in outbreak investigations overlapped with the 22 violations detected in routine inspections done at these same locations. With some similar violations observed prior to the outbreak, there was a desire to examine these types of data further to see if any relationship among violation type could be observed in a larger data set.

Construction of Model

When viewing the results from the preliminary study (table 6), the overlap in types of violations observed in routine inspections and the outbreak investigational inspections was observed. A tool that could relate observed violations to the CDC's contributing factors to foodborne illness (Table 2) to the criteria against which restaurants are inspected (Table 1) was developed. Risk weightings for each of the standard restaurant inspection criteria were constructed and normalized using CDC identified contributing factors for

foodborne disease outbreaks. These weightings were compared to routine and outbreak-related restaurant inspection reports in the expanded study.

Expanded Study

Results, from outbreak investigational inspections and routine inspections done at the 63 restaurants in MN, showed violations at 49 of the 54 questions. No violations were observed at Question 5 (No discharge from eyes, nose & mouth) and for the 4 criteria that MN does not evaluate (Questions 23, 24, 30 and 32). Table 7 shows the frequencies of the types of violations recorded in the outbreak investigational inspections and table 8, those recorded in routine inspections done at these same locations. Data on routine inspections from the location with the double-agent outbreaks was combined with the single agents others. This resulted in a total of 172 routine inspections done at restaurants that had norovirus outbreaks; 54, at routine inspections done at restaurants that had *Salmonella* outbreaks; and 49 routine inspections done at restaurants that had *C. perfringens* or toxin-mediated outbreaks.

When the violations identified in the outbreak and routine inspections were run in the model, no clear separation of overall results was observed. Figure 2 shows the raw values obtained for aggregated data for investigational outbreak (O) and routine (R) inspections done at the 63 establishments under study separated by the three pathogen types. There was also no real similarity in violation type related to how close in time the routine inspections were done either before or after the outbreak (data not shown).

However, while total results of a routine inspection do not appear to predict outbreaks, via the model structure presented here, it is worthwhile to look at individual violations. When this was done, there were certain violations recorded more frequently in outbreak inspections. Certain violations were more likely to be recorded in the outbreak investigational inspections done at locations that had had outbreaks (Table 9) than in the routine inspections done at the same locations.

2.4 Discussion

Although restaurant inspections are an important public health measure, relating the results of inspections to the risk of illness has been difficult. Jones et al. (59) found that total inspection scores between outbreak and non-outbreak restaurants were equivalent. Studying a multi-year data set which was not specific to one agent or contaminated vehicle, they found that the large variability in results over time made comparisons very difficult and subjective. Other researchers have seen some relationship between health department inspection results and the links to foodborne illness occurrence. Patel et al. (75) concluded that overall inspection scores might be able to be used to identify restaurants at high risk for outbreaks. They studied a small set of restaurants involved in a *Salmonella* Montevideo outbreak. Irwin et al. (56) found similar results in their study of case restaurants; they concluded that restaurants that had had outbreaks had lower mean inspection scores than those that did not. A larger study comparing restaurants that had previous foodborne illness outbreaks with

those that did not, identified several factors significantly associated with the occurrence of foodborne illness (7). One of these was a lower total inspection score, but they also found that specific factors including incorrect food storage, reuse of food and improper employee hand washing were cited more frequently at outbreak locations. While Cruz et al. (28) did not find that total scores were predictive of future outbreaks; they did find one critical violation (evidence of vermin) more likely to be recorded at restaurants that had had outbreaks.

Based on data from MN outbreak restaurants, there were no observable differences between summarized total findings from outbreak inspections and routine inspections done at the same locations, since the overall scores of the inspections related to outbreaks looked very similar to those for routine inspections when evaluated in the constructed tool. It was hoped that after calculating the total scores via the model for routine inspections and for outbreak-related inspections, that outbreak inspections would have clearly higher scores than the routine inspections. Thus, the results agree with Jones et al. (59) and Cruz et al. (28) that total results from routine inspection were not different than outbreak inspections and not predictive. The conclusions from the study by Irwin et al. (56) which suggested that routine inspections may be able to identify restaurants at higher risk of future outbreaks, have been refuted by other researchers (47). The criticism highlighted inherent inconsistencies that exist in typical restaurant inspections primarily due to the biases of different inspectors, and this was true in the present study as well. It needs to be recognized that

inspections offer a brief picture of facility at a specific point in time and therefore, present an indication of the compliance status of the establishment at that point. It can be difficult to evaluate behavior modification by operators during an inspection as well as the specific operation's policies, especially when the personnel interviewed have the correct responses to questions which are designed to gauge knowledge and behavior. Also, the reality is that it is difficult to observe all the CDC-identified contributing factors (Table 2) to foodborne illness during inspections given time limitations of a typical inspection.

There are many subjective factors inherent in the inspection process. One relates to the timing of inspections. In MN, routine inspections are typically done just once per year, though this frequency might increase if there are repeated issues or a need for follow-up inspections to verify that issues have been addressed. Outbreak inspections are done as soon as an epidemiological investigation of illness complaints indicates a common eating location among cases. Regardless, it could still theoretically be several months to nearly a year since the last routine inspection and when environmental health personnel might return to investigate a complaint or illness. In this ensuing time, issues identified in the previous routine inspection could have been fully addressed or new issues could have developed since that previous inspection was done. Evidence of this may be that in about 6% of inspections, there were "No violations" recorded and half of these were in outbreak investigations.

Another limitation in this study was that the number of available outbreaks associated with restaurants for which full data was available was restricted. The data that was needed included several years of previous routine inspections and the outbreak investigational inspection reports. In a state such as MN, some inspections are delegated to local health departments whereas some are done by state employees. Accumulating information on recent inspections required cooperation from the appropriate departments and their tracking down of information from several years back. In some instances, records were not retrievable or were hand written and difficult to interpret. The findings in inspection reports are inherently biased by the individual inspector and what they are capable of and actually during a visit at a restaurant. It is possible that an observed issue might not be documented if it is corrected during the inspector's visit and occasionally mistakes in recording information will be made.

While the tool promoted in the present study appears to not have value in evaluating total inspection reports and their summary results, studying individual results from inspection reports did show statistically significant differences. Other researchers have also seen that specific types of violations were more likely to be observed in outbreak inspections (7, 28). In the present study, several specific violations were found to more likely be recorded in outbreak inspections, indicating that failing to control foodborne illness risk factors might be associated with illness. For *C. perfringens* outbreaks, these fell directly along the typical causal pathway for this agent (35) where improper reheating and poor time and

temperature control were recorded. Violations recorded in norovirus outbreaks were more likely to be related how this virus may be typically spread in food handling settings, by improper illness exclusion and poor hand washing in agreement with CDC guidance (11). Violations more likely recorded in the *Salmonella* outbreaks highlight a wider variety of issues across the food handling continuum in a typical restaurant setting. The majority of these were related to the food itself and how it may be handled. It should be recognized that findings observed in outbreak inspections are influenced by direction from epidemiological investigations suggesting a specific agent. For example, if *C. perfringens* is strongly suspected based on illness onset time and duration, there would likely be less focus on evaluating food worker illness status, whereas if norovirus is suspected, attention on employee illness would be enhanced.

Violations more likely to be recorded in the present study in *Salmonella* outbreak inspections relate to typical foodborne illness risk factors including management of the food itself from receipt in good condition, to protection during storage, proper time and temperature control, disposal of unsafe food, and the use of HACCP for variances. Additionally, proper sourcing of ice and water and ensuring that water is of appropriate temperature were more likely to be recorded in outbreak settings. These types of findings relate to the need to have preventative controls in place across the entire food production system both within the restaurant and in the upstream food and water supply chain. It is incumbent to verify that such preventative controls are effectively implemented

and being followed appropriately. The present study did not find that a violation of having a knowledgeable person in charge was significantly more likely seen in outbreak inspections. This disagrees with Hedberg et al. (49) who found that a certified kitchen manager was more likely to be present in restaurants that did not have outbreaks. A more recent study also suggests that the presence of a certified manager was protective for most types of recorded violations (8). Despite a lack of statistical significance at $p \leq 0.05$ in the present study, violations related to the presence of a certified manager were detected 11% of the time in outbreak inspections and 24%, in non-outbreak inspections and are worthy of recognition based on the previous work.

While total results of inspections focusing on risk factors may not reliably predict the risk of transmitting foodborne disease, specific violations or groups of violations may be an indicator of overall process control. Restaurant inspections offer a wealth of data that could be used to provide feedback to the operator on verification that the establishment's process controls are effective. To enable use of these data, they need to be systematically evaluated against a common standard to help to smooth out the intrinsic inconsistencies that will always be part of restaurant inspections. It is suggested that Food Code form 3-A offers a standardized way to categorize observed violations which could allow for a more consistent evaluation of data and provide the ability to compare results of inspection among jurisdictions.

While there is no single answer to stemming the tide of foodborne illness, understanding the specific violations that most closely correlate with actual outbreaks may help restaurants to prioritize corrective actions in those areas. Based on the types of findings recorded in this study focus needs to remain on identifying and controlling sources of contamination with continued emphasis on basic cleanliness and hygiene, supported by management engagement and effective training. It is worthwhile to consider restaurant inspections as part of verification of existence of a preventative control system such as these in a restaurant setting.

2.5 Tables

Table 1. Questions from Model Form 3-A of US FDA Food Code

1–Person in charge	28–Pasteurized eggs Use
2–EE health awareness/policy	29–Water & ice source
3–Illness exclusion	30–Variance - specialized process
4–Proper eating, tasting, tobacco use	31–Proper cooling methods
5–No discharge - eyes, nose & mouth	32–Plant foods properly cooled
6–Hands washed	33–Approved thawing
7–Bare hand contact procedure	34–Thermometers - accurate
8–Hand washing facilities supplied	35–Food properly labeled
9–Approved source	36–Pest/animals not present
10–Receipt at proper temperature	37–X Contam prevented
11–Food in good condition	38–Personal cleanliness
12–Shellstock records	39–Wiping cloth use
13–Food separated/protectedd	40–Washing fruits & vegetables
14–Food contact surfaces, cleaned	41–In-use utensils, properly stored
15–Disposal of food	42–Utensils, equipment, linens
16–Proper cooking time/temp	43–Single use/service articles
17–Proper re-heating for hot holding	44–Gloves used properly
18–Proper cooling time/temp	45–Food/nonfood contact design
19–Proper hot holding temp	46–Warewashing, incl test strips
20–Proper cold holding temp	47–Non food contact surfaces
21–Proper date marking & dispo	48–Hot/cold water available
22–Time as public health control	49–Plumbing installed
23–Consumer advisory – raw foods	50–Sewage/waste water disposal
24–Highly susceptible population foods	51–Toilet facilities adequate
25–Food additives, properly stored	52–Garbage/refuse disposal
26–Toxic substances	53–Physical facilities
27–Compliance with variance & HACCP	54–Ventilation & lighting

Table 2. CDC-identified Contributing Factors to Foodborne Illness

Contamination Factors (C)	Proliferation Factors (P)	Survival Factors (S)
C01 Toxic substance part of tissue	P01 Room temp several hours	S01 Insufficient time/temperature during cooking
C02 Poisonous substance intentionally added	P02 Slow cooling	S02 Insufficient time/temperature during reheating
C03 Poisonous or physical substance accidentally added	P03 Inadequate cold temp	S03 Inadequate acidification
C04 Addition of excessive quantities of ingredient at toxic levels	P04 Prep >1/2 day before serving	S04 Insufficient thawing & cooking
C05 Toxic container/pipes	P05 Prolonged cold storage (weeks)	S05 Other
C06 Raw ingredient contaminated by pathogens from animal or environment	P06 Insufficient time/temperature during hot holding	
C07 Ingestion of contaminated raw product	P07 Insufficient acidification	
C08 Polluted source	P08 Insufficient low aw	
C09 Cross contamination by raw animal product	P09 Inadequate thawing	
C10 Bare hand contact	P10 Anaerobic or MAP	
C11 Gloved hand contact	P11 Inadequate fermentation	
C12 Infected worker	P12 Other	
C13 Inadequate cleaning		
C14 Contaminated environment		
C15 Other		

Table 3. Numbers of Norovirus, *Salmonella* and *C. perfringens* Outbreaks during 1998-2002 Attributed to each Contributing Factor (67)

Contributing Factor Designator	Contributing Factor Description	# confirmed Norovirus outbreaks related to factor	% of confirmed Norovirus outbreaks related to factor (n=319)	# of confirmed <i>Salmonella</i> outbreaks related to factor	% of confirmed <i>Salmonella</i> outbreaks related to factor (n=326)	# of confirmed <i>C. perfringens</i> outbreaks related to factor	% of confirmed <i>C. perfringens</i> outbreaks related to factor (n=102)
c01	Toxic substance part of tissue	0	0.0	1	0.00	0	0.0
c02	Poisonous substance intentionally added	0	0.0	0	0.00	0	0.0
c03	Poisonous or physical substance accidentally added	0	0.0	0	0.00	0	0.0
c04	Addition of excessive quantities of ingr at toxic levels	0	0.0	0	0.00	0	0.0
c05	Toxic	1	0.0	4	0.01	0	0.0

Contributing Factor Designator	Contributing Factor Description	# confirmed Norovirus outbreaks related to factor	% of confirmed Norovirus outbreaks related to factor (n=319)	# of confirmed <i>Salmonella</i> outbreaks related to factor	% of confirmed <i>Salmonella</i> outbreaks related to factor (n=326)	# of confirmed <i>C. perfringens</i> outbreaks related to factor	% of confirmed <i>C. perfringens</i> outbreaks related to factor (n=102)
	container/pipes						
c06	Raw ingr contaminated by pathogens from animal or environment	21	0.1	97	0.30	14	0.1
c07	Ingestion of contaminated raw product	18	0.1	42	0.13	1	0.0
c08	Polluted source	3	0.0	3	0.01	0	0.0
c09	Cross contamination by raw animal product	9	0.0	85	0.26	5	0.0
c10	Bare hand contact	129	0.4	37	0.11	8	0.1
c11	Gloved hand	30	0.1	4	0.01	2	0.0

Contributing Factor Designator	Contributing Factor Description	# confirmed Norovirus outbreaks related to factor	% of confirmed Norovirus outbreaks related to factor (n=319)	# of confirmed <i>Salmonella</i> outbreaks related to factor	% of confirmed <i>Salmonella</i> outbreaks related to factor (n=326)	# of confirmed <i>C. perfringens</i> outbreaks related to factor	% of confirmed <i>C. perfringens</i> outbreaks related to factor (n=102)
	contact						
c12	Infected worker	202	0.6	64	0.20	2	0.0
c13	Inadequate cleaning	40	0.1	82	0.25	12	0.1
c14	Contaminated environment	7	0.0	17	0.05	6	0.1
c15	Other Contamination	28	0.1	23	0.07	11	0.1
p01	Room temp several hours	17	0.1	110	0.34	53	0.5
p02	Slow cooling	4	0.0	26	0.08	50	0.5
p03	Inadequate cold temp	8	0.0	53	0.16	20	0.2
p04	Prep >1/2 day before serving	3	0.0	33	0.10	27	0.3
p05	Prolonged cold storage	0	0.0	3	0.01	0	0.0

Contributing Factor Designator	Contributing Factor Description	# confirmed Norovirus outbreaks related to factor	% of confirmed Norovirus outbreaks related to factor (n=319)	# of confirmed <i>Salmonella</i> outbreaks related to factor	% of confirmed <i>Salmonella</i> outbreaks related to factor (n=326)	# of confirmed <i>C. perfringens</i> outbreaks related to factor	% of confirmed <i>C. perfringens</i> outbreaks related to factor (n=102)
	(weeks)						
p06	Insufficient time/temperature during hot holding	6	0.0	28	0.09	39	0.4
p07	Insufficient acidification	1	0.0	0	0.00	0	0.0
p08	Insufficient low aw	0	0.0	1	0.00	0	0.0
p09	Inadequate thawing	0	0.0	4	0.01	4	0.0
p10	Anaerobic or MAP	0	0.0	0	0.00	0	0.0
p11	Inadequate fermentation	0	0.0	0	0.00	0	0.0
p12	Other Proliferation	1	0.0	25	0.08	5	0.0
s01	Insufficient time/temperature during	5	0.0	104	0.32	33	0.3

Contributing Factor Designator	Contributing Factor Description	# confirmed Norovirus outbreaks related to factor	% of confirmed Norovirus outbreaks related to factor (n=319)	# of confirmed <i>Salmonella</i> outbreaks related to factor	% of confirmed <i>Salmonella</i> outbreaks related to factor (n=326)	# of confirmed <i>C. perfringens</i> outbreaks related to factor	% of confirmed <i>C. perfringens</i> outbreaks related to factor (n=102)
	cooking						
s02	Insufficient time/temperature during reheating	4	0.0	23	0.07	41	0.4
s03	Inadequate acidification	0	0.0	1	0.00	0	0.0
s04	Insufficient thawing & cooking	0	0.0	5	0.02	5	0.0
s05	Other Survival	10	0.0	21	0.06	4	0.0

Table 4. Matrix showing the 54 Food Code survey questions by NORS contributing factors for each of the 3 agents (N = norovirus, S = *Salmonella*, and C= *C. perfringens*, X = all three agents) and the criteria listed in Food Code form 3-A.

		Contributing Factor																																															
		c	c	c	c	c	c	c	c	c	c	c	c	c	c	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	p	s	s	s	s	s									
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	1	2	3	4	5	6	7	8	9	0	1	2	1	2	3	4	5	1	2	3	4	5											
Que	stio																																																
n #																																																	
Q01		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X								
Q02																																																	
Q03																																																	
Q04																																																	
Q05																																																	
Q06																																																	
Q07																																																	
Q08																																																	
Q09																																																	
Q10																																																	
Q11																																																	

		Contributing Factor																																	
		c 1	c 2	c 3	c 4	c 5	c 6	c 7	c 8	c 9	c 10	c 11	c 12	c 13	c 14	c 15	p 1	p 2	p 3	p 4	p 5	p 6	p 7	p 8	p 9	p 10	p 11	p 12	s 1	s 2	s 3	s 4	s 5		
Q12									N S																										
Q13									N S	N S					N S																				
Q14						S								N S	N S																				
Q15															N S																				
Q16						S																										C S			
Q17																					C S												C S		
Q18																		C	C																
Q19																							C S												
Q20																			C																
Q21																					C S	C S													
Q22																					C S		C S												
Q23						N S	N S																									N S	S		
Q24																															S				
Q25																																			

		Contributing Factor																																		
		c 1	c 2	c 3	c 4	c 5	c 6	c 7	c 8	c 9	c 10	c 11	c 12	c 13	c 14	c 15	p 1	p 2	p 3	p 4	p 5	p 6	p 7	p 8	p 9	p 10	p 11	p 12	s 1	s 2	s 3	s 4	s 5			
	Q26																																			
	Q27															X													C S		X				X	
	Q28						S S			S																										
	Q29						N S		N																											
	Q30																																			
	Q31																	C	C																	
	Q32																													C S						
	Q33																									C S										
	Q34																		C											S	S					
	Q35																						C													
	Q36						S																													
	Q37									N S					N S	N S																				
	Q38										N S	N S	N S																							
	Q39														N S	N S																				
	Q40						N S	N S																												
	Q41														N	N																				

		Contributing Factor																																					
		c	c	c	c	c	c	c	c	c	c	c	c	c	c	p	p	p	p	p	p	p	p	p	p	p	p	p	p	s	s	s	s	s					
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	1	2	3	4	5	6	7	8	9	0	1	2	1	2	1	2	3	4	5				
														S	S																								
	Q42													N	S																								
	Q43														S																								
	Q44											N	S																										
	Q45													N	S																								
	Q46													N	S																								
	Q47													N	S																								
	Q48																																						
	Q49																																						
	Q50																																						
	Q51																																						
	Q52																																						
	Q53													N	S																								
	Q54																																						

Table 5. Probability Weights Associated with each type of Outbreak (N = norovirus, S = *Salmonella*, C = *C. perfringens*)

Question	Weights N	Weights S	Weights C
2-EE health awareness/policy	0.080	0.017	0.000
3-Illness exclusion	0.080	0.017	0.000
4-Proper eating, tasting, tobacco use	0.000	0.000	0.000
5-No discharge - eyes, nose & mouth	0.000	0.000	0.000
6-Hands washed	0.143	0.029	0.000
7-Bare hand contact procedure	0.143	0.029	0.000
8-Hand washing facilities supplied	0.143	0.029	0.000
9-Approved source	0.010	0.027	0.000
10-Receipt at proper temperature	0.000	0.030	0.088
11-Food in good condition	0.001	0.024	0.000
12-Shellstock records	0.001	0.001	0.000
13-Food separated/protected	0.008	0.029	0.000
14-Food contact surfaces, cleaned	0.019	0.053	0.000
15-Disposal of food	0.003	0.005	0.000
16-Proper cooking time/temp	0.000	0.055	0.055
17-Proper re-heating for hot holding	0.000	0.015	0.113
18-Proper cooling time/temp	0.000	0.000	0.116
19-Proper hot holding temp	0.000	0.008	0.065
20-Proper cold holding temp	0.000	0.000	0.033
21-Proper date marking & dispo	0.000	0.010	0.045
22-Time as public health control	0.000	0.017	0.109
23-Consumer advisory – raw foods	0.017	0.073	0.000
24-Highly susceptible population foods	0.000	0.028	0.000
25-Food additives, properly stored	0.000	0.000	0.000
26-Toxic substances	0.000	0.000	0.000
27-Compliance with variance & HACCP	0.017	0.025	0.101
28-Pasteurized eggs Use	0.000	0.061	0.000
29-Water & ice source	0.010	0.026	0.000
30-Variance - specialized process	0.000	0.000	0.000
31-Proper cooling methods	0.000	0.000	0.116
32-Plant foods properly cooled	0.000	0.028	0.055
33-Approved thawing	0.000	0.001	0.007

34-Thermometers - accurate	0.004	0.035	0.033
35-Food properly labeled	0.000	0.000	0.065
36-Pest/animals not present	0.000	0.026	0.000
37-X Contam prevented	0.022	0.050	0.000
38-Personal cleanliness	0.143	0.029	0.000
39-Wiping cloth use	0.019	0.027	0.000
40-Washing fruits & vegetables	0.015	0.038	0.000
41-In-use utensils, properly stored	0.019	0.027	0.000
42-Utensils, equipment, linens	0.019	0.027	0.000
43-Single use/service articles	0.003	0.005	0.000
44-Gloves used properly	0.012	0.001	0.000
45-Food/nonfood contact design	0.019	0.027	0.000
46-Warewashing, incl test strips	0.016	0.022	0.000
47-Non food contact surfaces	0.016	0.022	0.000
48-Hot/cold water available	0.000	0.000	0.000
49-Plumbing installed	0.000	0.000	0.000
50-Sewage/waste water disposal	0.000	0.000	0.000
51-Toilet facilities adequate	0.000	0.000	0.000
52-Garbage/refuse disposal	0.000	0.000	0.000
53-Physical facilities	0.019	0.027	0.000
54-Ventilation & lighting	0.000	0.000	0.000
28-Pasteurized eggs Use	0.000	0.000	0.000
29-Water & ice source	0.000	0.000	0.000

Table 6. Violations recorded at Restaurants with contaminated shell egg *Salmonella* Enteritidis-associated outbreaks in Minnesota in 2010.

Food Code Form Specific Violation	% of time recorded in outbreak inspection (n=3)	% of time recorded in routine inspection (n=10)
2-EE health awareness/policy		3.9
3-Illness exclusion		3.9
4-Proper eating, tasting, tobacco use		3.9
6-Hands washed	9.1	1.9
7-Bare hand contact procedure	9.1	
8-Hand washing facilities supplied	9.1	5.8
9-Approved source		3.9
12-Shellstock records		1.9
13-Food separated/protected	9.1	3.9
14-Food contact surfaces, cleaned	9.1	9.6
18-Proper cooling time/temp		3.9
20-Proper cold holding temp		5.8
21-Proper date marking & dispo	9.1	
31-Proper cooling methods		5.8
34-Thermometers - accurate		1.9
37-X Contam prevented	9.1	1.9
39-Wiping cloth use		9.6
41-In-use utensils, properly stored		1.9
42-Utensils, equipment, linens	9.1	3.9
45-Food/nonfood contact design	9.1	7.7
47-Non food contact surfaces	9.1	3.9
48-Hot/cold water available	9.1	
51-Toilet facilities adequate		1.9
53-Physical facilities		9.6
54-Ventilation & lighting		1.9

Table 7. Percentages of Violations Recorded in Outbreak Investigational Inspections (N = Norovirus, C = *C. perfringens* or toxin suspected, S = *Salmonella*)

Food Code Form Specific Violation	C (n=11)	N (n=44)	S (n=13)
1–Person in charge	9.09%	15.91%	0.00%
2–EE health awareness/policy	0.00%	2.27%	7.69%
3–Illness exclusion	9.09%	65.91%	0.00%
4–Proper eating, tasting, tobacco use	0.00%	9.09%	7.69%
5–No discharge - eyes, nose & mouth	0.00%	0.00%	7.69%
6–Hands washed	9.09%	11.36%	0.00%
7–Bare hand contact procedure	9.09%	31.82%	7.69%
8–Hand washing facilities supplied	9.09%	34.09%	0.00%
9–Approved source	0.00%	0.00%	7.69%
10–Receipt at proper temperature	0.00%	0.00%	7.69%
11–Food in good condition	0.00%	2.27%	15.38%
12–Shellstock records	0.00%	2.27%	23.08%
13–Food separated/protected	18.18%	9.09%	53.85%
14–Food contact surfaces, cleaned	18.18%	31.82%	15.38%
15–Disposal of food	0.00%	2.27%	23.08%
16–Proper cooking time/temp	18.18%	0.00%	0.00%
17–Proper re-heating for hot holding	36.36%	2.27%	15.38%
18–Proper cooling time/temp	36.36%	4.55%	38.46%
19–Proper hot holding temp	45.45%	4.55%	0.00%
20–Proper cold holding temp	45.45%	18.18%	0.00%
21–Proper date marking & dispo	9.09%	11.36%	30.77%
22–Time as public health control	18.18%	2.27%	23.08%
23–Consumer advisory – raw foods	0.00%	0.00%	0.00%
24–Highly susceptible population foods	0.00%	0.00%	0.00%
25–Food additives, properly stored	0.00%	0.00%	15.38%
26–Toxic substances	0.00%	6.82%	0.00%
27–Compliance with variance & HACCP	0.00%	2.27%	15.38%
28–Pasteurized eggs Use	0.00%	0.00%	0.00%
29–Water & ice source	0.00%	0.00%	15.38%
30–Variance - specialized process	0.00%	0.00%	0.00%
31–Proper cooling methods	9.09%	6.82%	7.69%
32–Plant foods properly cooled	0.00%	0.00%	0.00%
33–Approved thawing	0.00%	2.27%	7.69%
34–Thermometers - accurate	0.00%	9.09%	7.69%
35–Food properly labeled	0.00%	6.82%	15.38%
36–Pest/animals not present	9.09%	2.27%	23.08%
37–X Contam prevented	18.18%	25.00%	53.85%

Food Code Form Specific Violation	C (n=11)	N (n=44)	S (n=13)
38-Personal cleanliness	0.00%	4.55%	15.38%
39-Wiping cloth use	9.09%	6.82%	23.08%
40-Washing fruits & vegetables	0.00%	0.00%	0.00%
41-In-use utensils, properly stored	18.18%	9.09%	15.38%
42-Utensils, equipment, linens	0.00%	6.82%	38.46%
43-Single use/service articles	0.00%	11.36%	0.00%
44-Gloves used properly	0.00%	0.00%	0.00%
45-Food/nonfood contact design	9.09%	22.73%	30.77%
46-Warewashing, incl test strips	0.00%	25.00%	23.08%
47-Non food contact surfaces	0.00%	6.82%	15.38%
48-Hot/cold water available	0.00%	2.27%	7.69%
49-Plumbing installed	0.00%	6.82%	15.38%
50-Sewage/waste water disposal	0.00%	0.00%	0.00%
51-Toilet facilities adequate	9.09%	0.00%	15.38%
52-Garbage/refuse disposal	0.00%	0.00%	0.00%
53-Physical facilities	9.09%	9.09%	15.38%
54-Ventilation & lighting	9.09%	13.64%	23.08%

Table 8. Percentages of Violations Recorded in Routine Investigational Inspections Done at Restaurants that had Outbreaks (N = Norovirus, C = *C. perfringens* or toxin suspected, S = *Salmonella*)

Food Code Form Specific Violation	C (n=49)	N (n=172)	S (n=54)
1–Person in charge	32.65%	19.30%	31.48%
2–EE health awareness/policy	2.04%	1.75%	3.70%
3-Illness exclusion	4.08%	1.17%	9.26%
4-Proper eating, tasting, tobacco use	12.24%	14.62%	12.96%
5-No discharge - eyes, nose & mouth	0.00%	0.00%	0.00%
6-Hands washed	18.37%	9.94%	14.81%
7–Bare hand contact procedure	32.65%	15.20%	14.81%
8-Hand washing facilities supplied	32.65%	47.95%	37.04%
9-Approved source	2.04%	0.00%	3.70%
10–Receipt at proper temperature	0.00%	1.17%	1.85%
11–Food in good condition	0.00%	4.68%	3.70%
12-Shellstock records	0.00%	5.85%	1.85%
13-Food separated/protected	30.61%	16.37%	9.26%
14-Food contact surfaces, cleaned	40.82%	38.60%	44.44%
15–Disposal of food	0.00%	1.75%	0.00%
16-Proper cooking time/temp	2.04%	0.58%	0.00%
17–Proper re-heating for hot holding	2.04%	2.34%	0.00%
18-Proper cooling time/temp	26.53%	7.02%	16.67%
19–Proper hot holding temp	10.20%	10.53%	16.67%
20-Proper cold holding temp	22.45%	35.09%	33.33%
21-Proper date marking & dispo	24.49%	20.47%	12.96%
22–Time as public health control	0.00%	4.09%	3.70%
23-Consumer advisory – raw foods	0.00%	0.00%	0.00%
24-Highly susceptible population foods	0.00%	0.00%	0.00%
25-Food additives, properly stored	0.00%	0.58%	0.00%
26-Toxic substances	6.12%	16.37%	9.26%
27-Compliance with variance & HACCP	2.04%	3.51%	1.85%
28–Pasteurized eggs Use	0.00%	0.58%	0.00%
29-Water & ice source	0.00%	0.00%	0.00%
30-Variance - specialized process	0.00%	0.00%	0.00%
31–Proper cooling methods	20.41%	12.87%	12.96%
32-Plant foods properly cooled	0.00%	0.00%	0.00%
33-Approved thawing	4.08%	2.34%	9.26%

Food Code Form Specific Violation	C (n=49)	N (n=172)	S (n=54)
34-Thermometers - accurate	10.20%	18.71%	7.41%
35-Food properly labeled	12.24%	14.04%	12.96%
36-Pest/animals not present	8.16%	12.28%	11.11%
37-X Contam prevented	20.41%	39.18%	27.78%
38-Personal cleanliness	2.04%	4.09%	11.11%
39-Wiping cloth use	12.24%	18.13%	35.19%
40-Washing fruits & vegetables	2.04%	1.17%	0.00%
41-In-use utensils, properly stored	16.33%	16.37%	22.22%
42-Utensils, equipment, linens	24.49%	18.71%	22.22%
43-Single use/service articles	14.29%	14.62%	12.96%
44-Gloves used properly	0.00%	0.58%	0.00%
45-Food/nonfood contact design	53.06%	52.63%	50.00%
46-Warewashing, incl test strips	20.41%	21.64%	12.96%
47-Non food contact surfaces	16.33%	34.50%	22.22%
48-Hot/cold water available	4.08%	1.17%	0.00%
49-Plumbing installed	22.45%	23.39%	18.52%
50-Sewage/waste water disposal	0.00%	0.58%	0.00%
51-Toilet facilities adequate	10.20%	5.85%	7.41%
52-Garbage/refuse disposal	12.24%	3.51%	3.70%
53-Physical facilities	59.18%	61.99%	37.04%
54-Ventilation & lighting	44.90%	30.99%	25.93%

Table 9. Violations significantly more likely to be recorded in Outbreak inspections ($\alpha \leq 0.05$) when comparing foodborne illness investigational inspections to routine inspections.

Question # from Form 3-A & Violation	<i>C. perfringens</i> /toxin	<i>Salmonella</i>	Norovirus
3 - Proper use of illness exclusion			X
5-No discharge - eyes, nose & mouth		X	
7 - No bare hand contact with food			X
12 - Required records for shellstock		X	
13 - Food separated & protected		X	
15 - Proper disposal of returned, previously served, reconditioned & unsafe food		X	
16-Proper cooking time/temp	X		
17 - Proper re-heating for hot holding	X	X	
19 - Proper hot holding temp	X		
22 - Time as public health control	X	X	
25 - Food additives, properly stored		X	
27-Compliance with variance & HACCP		X	
29 - Water & Ice from approved source		X	
48-Hot/cold water available		X	

2.6 Figures

Figure 1 CDC Risk-Factors for Foodborne Illness, 1998-2002

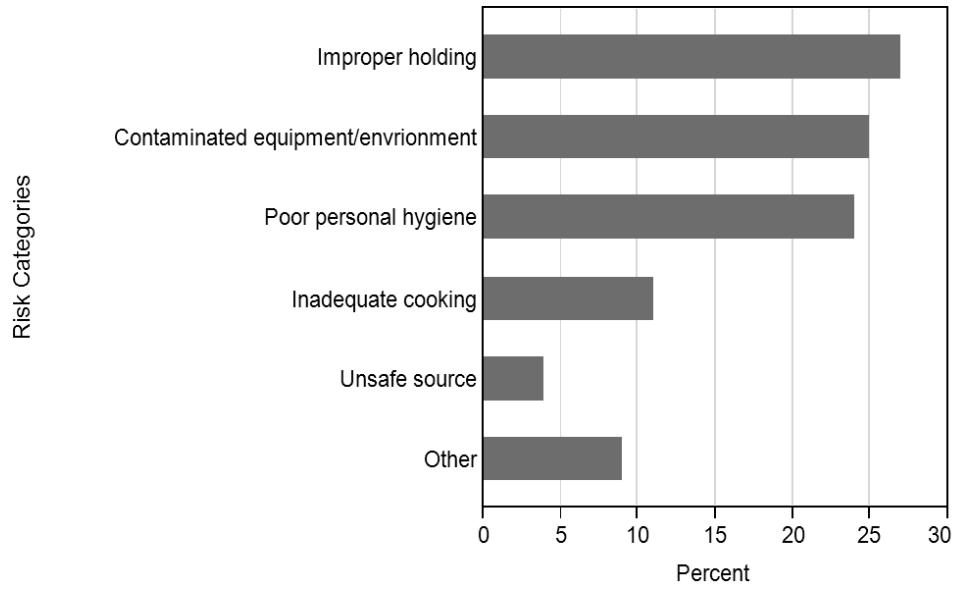
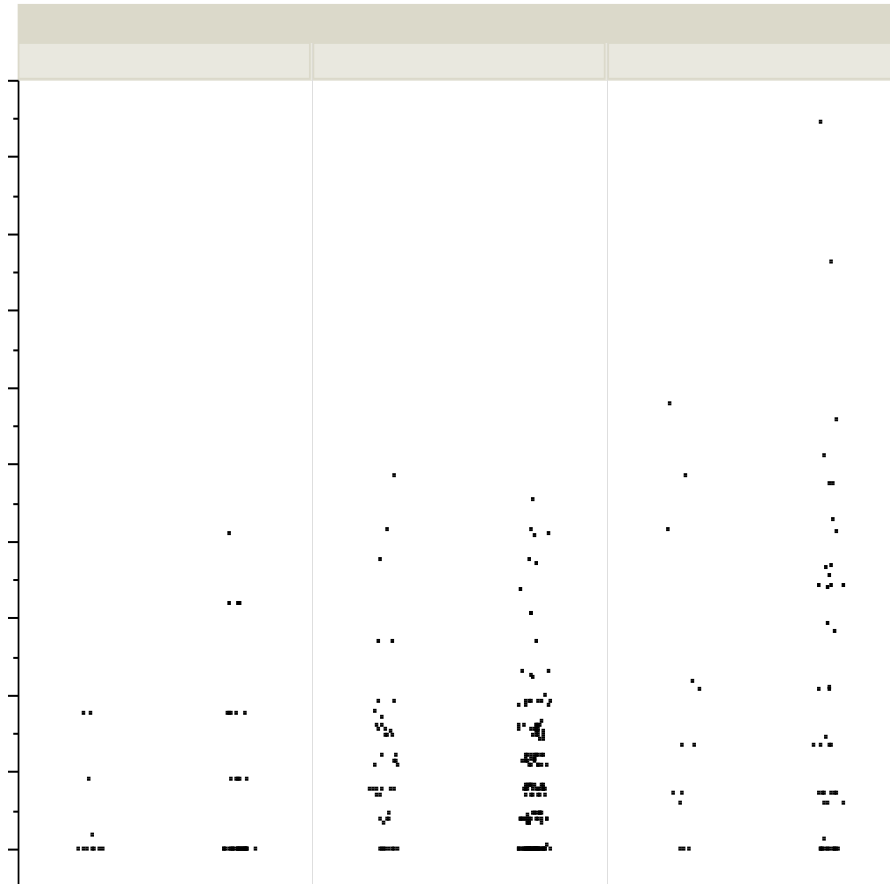


Figure 2. Output of Model by Pathogen Type Comparing Weighted Risk Calculations Obtained by Examining Identified Violations from Outbreak and Routine Inspections Performed at Restaurants that had Outbreaks Attributed to *C. perfringens*, norovirus, and *Salmonella*.



Chapter 3

Manuscript 2 - Analysis of routine health department inspections done at outbreak and non-outbreak restaurants in Minnesota to highlight criteria more likely to be associated with outbreak restaurants.

Routine inspection data from outbreak restaurants in Minnesota were compared with those done at non-outbreak restaurants in Minnesota to determine if and where differences in recorded violations were seen. Significantly more violations were recorded at restaurants that had outbreaks. The majority of these violations related to contamination in the facility and environment and to food handling procedures. In addition, relative risks were calculated for violations significantly more likely to occur at locations that had had norovirus, *C. perfringens*/toxin-type, and *Salmonella* outbreaks. Meta analysis of composited data among the three agents identified 11 violations significantly more likely ($\alpha \leq 0.05$) to be identified in routine inspections done at outbreak restaurants v. non-outbreak restaurants. Application of this information permits assessment of health department inspection data in a consistent fashion and can assist with identifying criteria more likely associated with outbreak locations and allow focus on the interventions that will have the most significant impact.

3.1 Introduction

Restaurant locations in the US are inspected against guidance published by the FDA in the Food Code (34), though the application of these criteria varies by jurisdiction. The Food Code was most recently issued in 2009 and represents a uniform set of provisions that addresses the safety and protection of food offered at retail and in food service. A supplement to the Food Code was recently issued (33). The Food Code is considered a model which is designed to safeguard public health and ensure that food is not adulterated by evaluating inspected locations on foodborne illness risk factors and good retail practices. Although it is a recognized guidance document, it is adopted by local and state health departments in a variety of ways with requirements and the frequency of inspections and scoring differing among jurisdictions. As an example, the State of Minnesota has its own state-specific version of the Food Code (72) which is based on the federal code, but for MN licensed establishments, it is not guidance, but rather is a regulation and all locations are expected to meet its provisions. It consists of minimum design, installation, construction, operation and maintenance requirements for all food establishments in Minnesota and includes compliance standards for food handling, storing, preparation and service.

In an appendix to the 2009 Food Code, there is a useful model form 3-A which includes a listing of 54 standardized criteria or questions (34); these are summarized in table 1 and shown in their entirety in Appendix A. This form was

not changed in the Supplement to the 2009 Food Code issued in 2011.

Questions 1 through 27 are identified as “Foodborne Illness Risk Factors and Public Health Interventions” and questions 28-54 as “Good Retail Practices”.

Some jurisdictions including some in Minnesota use the exact criteria detailed in this form in their restaurant inspections while others have adopted different versions. Generally, the similar criteria are evaluated in inspections, but since different tools are used to capture this information, comparison among different jurisdictions is hampered. As evidence of the differences that various states may adopt, since the current MN Food Code does not include reference to consumer advisories, use of pasteurized foods for highly susceptible populations, variances for specialized processing methods, and plant foods properly cooked for hot holding, no violations against criteria or questions 23, 24, 30 and 32 would be recorded in current inspections in MN.

In Minnesota, although there are varying types of restaurant inspections performed, these are similar to what is done in other US states. In addition, it varies by jurisdiction and the specific situation as to whether inspections are announced or not. A “Plan Review” type of inspection occurs before construction and serves to evaluate building, other construction and any remodeling plans to ensure code requirements will be met. After construction is completed, the restaurant undergoes a “Pre-Operational” inspection and as long as required criteria are met, the establishment is given a license to operate and may open for business. Based on the determined public health risk of the restaurant and its

food types, the location will be inspected periodically to ensure continued compliance to the MN Food Code. Per MN Statute (88), such inspections are known as “routine inspections” or “full inspections” and are performed at least annually at so-called “High Risk” establishments that serve potentially hazardous foods requiring extensive processing (e.g., manual handling, cooking, cooling, etc.) on the premises. “Follow-up” inspections may be done to ensure that previously identified serious violations have been corrected. These will be done within several days to a few weeks after the routine inspection that identified the serious issues occurred. Another type of inspection is done in response to patron complaints or potential foodborne illness outbreaks, generally conducted within a few days after notice of a potential concern are recorded (88).

The National Restaurant Association (73) tracks data related to restaurant meals. Close to half of consumers’ food dollars are spent at restaurants with the most dollars spent at full-serve restaurants (48% of total), followed by quick serve establishments (41% of total), then at bars, cafeterias, and caterers. These locations number close to one million establishments across the US and it is estimated that they serve about 250 meals annually to each US resident; this equates to more than 77 billion meals annually (82). Along with these facts, the CDC reports that the majority of foodborne illnesses are attributed to restaurant or deli meals (10), with 52% of the total reported illnesses occurring at restaurants. Jones and Angulo (58) stressed that although reported outbreaks account for less than three percent of all foodborne illnesses, restaurants are an

important source of infection transmission. Gaining a better understanding of restaurants as causal pathways may help decrease overall incidence. To assist with that, if consumers believe that their illness may have occurred during one of these eating occasions, they can report it to their local health department and an investigation is initiated.

Consumer complaints can signal that potential issues may exist and this may prompt an outbreak investigational inspection by health inspectors. With the information from complaints, the inspector is armed with knowledge of what agent could be responsible. This may result in a focus by inspectors on types of criteria generally associated with the typical causal pathways of certain agents. Generally, *C. perfringens* or suspect toxin-type outbreaks are associated with temperature abuse; norovirus, with person to person contamination; and *Salmonella*, with a range of factors including personal, food and surface contamination, temperature abuse, and failure to inactivate the organism (35, 36).

Previous research demonstrated that while overall evaluation of restaurant health department routine inspections was not predictive of foodborne illness likelihood (77). However, this study did reveal that certain criteria were more likely identified in outbreak inspections. Many of these lined up well against the typical causal pathways for these agents. The violations more likely recorded in *C. perfringens* or norovirus outbreak investigational inspections related to temperature related and personnel issues, respectively. Violations more likely

recorded in *Salmonella* outbreak investigational inspections highlight a wider variety of issues; the majority of these were related to the food itself and how it may be handled.

It is worthwhile to determine whether these specific violations more likely identified in outbreak investigational inspections are also recorded more frequently in routine inspections done at restaurants that had outbreaks. This may help to determine whether violations observed in routine inspections might be indicative of future concerns at an establishment. Further, comparing routine inspections done at outbreak locations to non-outbreak locations could reveal certain types of violations more likely to be associated with establishments that had outbreaks. Knowledge of this information could assist with identifying locations potentially more pre-disposed to having an outbreak and in directing proactive preventative resources in a direction where they have greater benefit.

The purpose of this study is to compare routine inspections done at outbreak and non-outbreak restaurants and to identify a set of common violations to enable development of a profile of a typical outbreak location. This can in turn assist in identifying major, modifiable risks and prioritizing actions to be taken so that efforts can be focused appropriately.

3.2 Methods

Outbreak Restaurants

Cooperation with the Minnesota Department of Health (MDH) and various local health departments in jurisdictions across the state identified 68 distinct

restaurant-associated outbreaks that occurred from 2005-2010 about which complete inspection information could be obtained. These were linked to 63 separate restaurant locations; one location experienced three outbreaks (one attributed to two agents) and two locations each had two outbreaks over this time period. 44 norovirus outbreaks, thirteen *Salmonella*, and eleven *Clostridium perfringens* or toxin-mediated outbreaks were included in the total sample set.

Information about recent inspections was obtained from the affected locations. This included the investigational inspections associated with the reported outbreaks and up to four years of preceding routine inspections performed at these same locations as well as the routine inspection done immediately after the outbreak. This totaled 68 investigational inspections and 257 routine inspections done at individual locations.

These 63 individual locations were further characterized into chains and non chains. For this study, a chain was defined as a restaurant that had more than ten separate locations. Nearly two thirds of the outbreaks occurred at non-chain locations. All of the locations that had more than one outbreak were non-chains. Among the chains, this resulted in a subset of 22 restaurants, who had 22 outbreak investigational inspections and 75 routine inspections done at these locations over the time period of 2005-2010. Among these 22 affected locations that had outbreaks attributed to norovirus, *Salmonella* and *C. perfringens*/suspect toxin, Table 2 describes the total numbers of affected establishments and the numbers of routine inspections collected from them.

Non-Outbreak Restaurants

Data from routine inspections done at restaurants in MN that did not have outbreaks from 2008-2011 were also gathered. These data were collected from 91 different chain restaurant establishments. These were also defined as restaurants having more than 10 individual separate locations. From these 91 different locations, 172 individual routine inspection reports were collected.

Mapping of Violations

Violations, from these routine inspections at outbreak and non-outbreak locations, were recorded and compared to FDA Food Code Form 3-A criteria (table 1) (33) to determine to which criteria they linked. Once mapped to this standard form, comparison between outbreak and non-outbreak locations was better enabled against a common platform.

Data Analysis

Initially, comparison was done between all routine inspections done at outbreak and non-outbreak locations. In this analysis, the outbreak locations included chain and non-chain locations compared against non-outbreak chain locations. Recorded occurrences of violations from FDA Food Code Form 3-A were compared in 2-proportion tests and 95% significances were determined.

Since the only types of non-outbreak locations from which data were collected represented chain locations, a comparison was also done using the subset of outbreak chain locations compared against non-outbreak chain locations. As this was considered to be a more valid comparison, more extensive

analysis was done. This included a comparison of violations between these two types of locations to determine what patterns and repeats were observed.

Fisher's Exact Test (Excel 2007 and Minitab version 16.2.1) was used for the analysis (since some proportions were small) to determine where significant differences in recorded violations were observed. Where significant differences were observed, relative risks were calculated. Additionally, recorded violations were compared between routine inspections done at each separate restaurant, split by outbreak type (norovirus, *C. perfringens* toxin-type, and *Salmonella*), against the total set of non-outbreak locations.

Breaking down the data by types of outbreak resulted in data sets that were very small since relatively few outbreaks occurred. Therefore, a final analysis combined the individually calculated relative risks for outbreaks attributed to all three agents back together to develop an overall profile of the likelihood of any of these types of outbreaks via Meta-analysis relative risk calculations using StatsDirect (StatsDirect Ltd., Cheshire, UK Software Version 2.7.8). In order to check the validity of these identified core violations, sensitivity analysis was done by systematically changing the occurrence of violations to determine the effects of such changes on p-values. The only violations that remained in the set were those whose p-values remained at ≤ 0.05 under 5 different scenarios – the actual data; outbreak restaurant violation occurrence plus and minus one; and non-outbreak restaurant violation occurrence plus and minus one.

3.3 Results

The initial analysis looked at all the routine inspection data, combining chain and non-chain locations which had had outbreaks compared with chains that did not have outbreaks. There were no violations more likely to be recorded in routine inspections done at non-outbreak locations when compared with the outbreak locations. Reported in Table 3 are the 14 violation types significantly more likely to be recorded ($\alpha \leq 0.05$) in routine inspections done at outbreak chain and non-chain locations than in chain non-outbreak locations.

Although this presents an interesting picture of the types of violations more likely to be recorded at outbreak locations, the reality is that many of non-chain locations were individually-owned single locations. Comparison of these types of restaurants against national chains does not seem to be a fair comparison since the types of programs in place across multiple locations are likely to be different than those in place at a single-owned establishment. Reported in Table 4 are the 13 violation types significantly more likely to be recorded ($\alpha \leq 0.05$) in routine inspections done outbreak chain locations ($n=75$) than in non-outbreak chain locations ($n=172$).

When violation types from routine inspections were compared from the aggregated data set of chain and non-chain outbreak locations to the chain non-outbreak locations, there were some differences in the types of violations observed, with an overall net of one more violation observed in the group consisting of chains and non-chain outbreak locations. Among the mixed chain

and non chain outbreak locations, violation 13 (Food separated & protected), 26 (Toxic substances properly identified, stored, used) and 33 (Approved thawing methods used) were observed, whereas among the chain outbreak locations, violations 17 (Proper re-heating for hot holding) and 35 (Food Properly labeled; original container) were significantly more likely to occur.

The observed violations more likely to occur at outbreak restaurants than at non-outbreak restaurants can be categorized. Generally, among the total violations two of these (Food Code Questions 4 and 7– see Table 1) or about 15% are related to personnel issues; eight (Food Code Questions 13, 17, 18, 20, 21, 31, 33 and 37 – see Table 1) or about 50%, to food handling concerns; and six (Food Code Questions 26, 35, 42, 43, 47, and 54 – see Table 1) or 37%, related to the facility itself and the environment within which the food is prepared (Figure 1). Lining up these same violation findings against contributing factors to foodborne illness as defined by the CDC (67), about two thirds of those observed more commonly in outbreak locations fall into the “Contamination” category, e.g., of hands, surfaces, food. The remaining violations are associated with “Proliferation” or growth since they relate to temperature related concerns that can occur in preparation or storage (Figure 2).

To evaluate data from chain locations further, additional calculations were done. Relative risks of the likelihood of a violation occurring at an outbreak chain location versus. a non-outbreak chain location were calculated. Generally, it's believed that a Relative Risk >1 indicates that an association exists and >5

means a relatively strong to strong association exists. Table 5 presents these data for the *Salmonella*, norovirus, and *C. perfringens*/toxin-type outbreaks.

Meta-analysis resulted in a subset of these data and development of an overall listing of violation types more likely to be associated with outbreak restaurants in general. Focus was on those violations which were more likely to be observed in outbreak restaurants whose confidence intervals in the overall analysis were greater than one and less than infinity. This resulted in identification of 11 violation types shown in table 6 that when observed provide a “profile” of an outbreak restaurant, not specific to any of the three individual agents. Sensitivity analysis resulted in dropping of violation 17 (Proper re-heating for hot holding) and 21 (proper date marking and disposition) since p-values were not maintained at ≤ 0.05 .

3.4 Discussion

There were no violations more likely to be observed at non-outbreak locations and when data from routine inspections done at outbreak non-chain locations were removed from the comparison, different types of foodborne illness-related violations were observed. The net difference when comparing these data sets shows that just one violation type was more likely to be recorded in the data which included chain and non-chain aggregated data. From this, one might infer that chains might be slightly better at managing these potential contributing factors to foodborne illness.

Among the outbreak locations studied and detailed in Table 2, it is interesting to note that only three *Salmonella* and *C. perfringens* outbreaks occurred at chain locations compared to 22 that occurred at non-chain locations. In contrast to this, the number of norovirus outbreaks is more consistent between the chain and non-chain locations. While this could suggest that chain restaurants may be better at managing risk factors related to *Salmonella* and *C. perfringens*, it also may be that there are fewer menu items that have preparation requirements (e.g., cooling) that could lead to these types of hazards if mistakes are made. The data on norovirus may indicate that this agent presents challenges which may be inconsistently managed regardless of ownership. This is further complicated by the fact that prevention of norovirus comes down to individual food handler's behaviors. Since norovirus remains a top cause of foodborne illness, continued focus on its specific risk factors is encouraged.

Jin and Leslie (57) reported that chain restaurants generally develop reputations for good quality hygiene practices which may provide ongoing motivation to maintain these standards. However, even though the total number of violations recorded in routine inspection were greater in the data set of chain and non-chain locations together, these differences are probably not practically significant. Bottom-line, there are significantly more violations recorded in routine inspections done at outbreak locations than at non-outbreak locations.

Jones and Angulo (58) reported that with cross-contamination and lapses in hygiene and sanitation practices identified as factors leading to illness,

improvements are needed. They caution that focus should be on areas where risks are modifiable and that adopted controls need to be re-evaluated periodically and with diligence to ensure that their appropriate focus. The observed violations more likely to be seen in outbreak locations demonstrate a wide range of issues, with half related to the Food Code-defined “Foodborne Illness Risk Factors and Public Health Interventions” (Food Code Form 3-A questions 1-27) and the other half in “Good Retail Practices” (Food Code Form 3-A questions 28-54) (33). The breadth of observations emphasizes the need for attention to the entire food production system, and not just foodborne illness risk factors. To better ensure restaurant food safety, consideration should be directed to a systems-based approach with active managerial control implemented.

To look at these data further, relative risks were calculated for the types of violations more significantly likely to be observed at outbreak versus non-outbreak chain locations. The calculated values help characterize the likelihood of a violation occurring at an outbreak location versus a non-outbreak location. Under consideration was the incidence of specific violations in inspections at outbreak versus non-outbreak restaurants. Several violation types occurred in more than one type of outbreak restaurant demonstrating a broad spectrum of potential issues. Violations related to bare hand contact and utensil and single-use article management were recorded in *Salmonella* and norovirus routine inspections and improper cooling methods occurred in norovirus and *C. perfringens*/toxin-type routine inspections. Violation 35, relating to improper

labeling of food was recorded more commonly in routine inspections done at all three types of outbreak locations. Except for the violations related to bare hand contact of food, these general violation types, are all in the “good retail practices” section of the Food Code form which may be more indicative of lapses in implementation of basic preventative controls which support food safety programs. Similar observations are seen in examination of specific violations related singly to each agent.

The types of violations more likely to be observed in routine inspections done at restaurant locations that had norovirus outbreaks also reveal a wide range of concerns. Violations related to question number seven, “No bare hand contact with food or use of approved alternate procedure” was found to occur more commonly among norovirus outbreak-prone restaurants. Norovirus survives on hands for extended times and the fecal-oral route is well established as a significant transmission path for this pathogen (11) . Surviving norovirus particles present a significant risk. Bidawid, et al. (4) demonstrated transfer of feline calicivirus, which remains the EPA-recognized surrogate for norovirus (92), from inoculated fingertips to ham, lettuce and stainless steel. In addition CDC data (67) demonstrated that bare hand contact was a contributing factor to about 54% of reported norovirus outbreaks from 1998-2002. The present study indicates that outbreak restaurants continue to experience issues with handwashing even during times when an outbreak is not occurring and are detectable in routine inspections. Focus on improving ongoing handwash compliance is stressed.

Five of the violations recorded during routine inspections of restaurants that had had norovirus outbreaks related to contamination of the food, utensils, equipment, single-use articles, non-food contact surfaces and physical facilities. It is well known that norovirus can survive for extended times on surfaces. Studies with feline calicivirus (31) demonstrated survival for up to 28 days at 20°C on dry surfaces. Proper cleaning and sanitization of surfaces and proper handling of other articles that could serve as vehicles for norovirus transfer are crucial to remove surviving virus particles. Two other violations related to employees eating or tobacco inappropriately and food improperly separated and protected; food can also be a vehicle for norovirus (32) and care must be taken to handle it sanitarily. The other violations more likely to be observed in routine inspections done at restaurants that had norovirus outbreaks relate to cold holding, date marking, and labeling of food and adequate ventilation and lighting. While these violations are not related to the typical transmission pathways for norovirus, they may be more indicative of basic systematic failures in overall management of food safety related issues.

One violation not observed more likely to occur in routine inspections at restaurants that had norovirus outbreaks was proper use of illness reporting, restriction and exclusion. This violation was found to be associated with norovirus outbreaks in a previous study when a comparison was done of outbreak investigational inspections and routine inspections done at restaurants that had had outbreaks (77). The fact that this was not seen to significantly occur in

routine inspections at norovirus outbreak restaurants indicates that attention to this basic norovirus control measure does seem to be practiced most of the time, but that occasional lapses may significantly contribute to outbreaks. However, it may also be a fact that concerns related to proper exclusion of ill workers may not be a focus during routine inspections and is probably difficult to reliably assess, but rather, is more commonly assessed in foodborne illness outbreak investigations.

Wide ranging concerns are also revealed in an examination of violations more commonly observed in routine inspections of restaurants that had had *Salmonella* and *C. perfringens*/toxin-type outbreaks. The types of violations more likely to be observed at routine inspections done at restaurants that had *Salmonella* outbreaks reveal issues related to personnel illness and handwashing concerns as well as problems related to food cooling and labeling and management of utensils, linens and single-use articles. FDA (36) reports that *Salmonella* contamination and outbreaks can be related to a variety of factors including personnel, food and surface contamination, temperature abuse, and failure to inactivate the organism. The violation types observed in the present study reflect this breadth of concerns. Similarly, the violation of “Proper cooling methods used; adequate equipment for temperature control” which was more likely to be observed in *C. perfringens*/toxin-type outbreaks lines up well against the expected causal path for this illness. The others related to proper labeling and garbage disposal may represent more broad potential sources of

contamination, but may also indicate more basic failures in overall management of food safety related issues.

The numbers of inspection reports associated with *Salmonella* and *C. perfringens*/toxin type outbreaks at chain locations were very low at 10 and 4 reports respectively. In order to manage this limitation, Meta analysis was done focusing on the premise that each violation type was considered to be an independent study and with combining the evidence from all three agents together, the data set is much more robust.

Meta analysis revealed a subset of core violations against which outbreak restaurants are more likely to line up. Eleven specific violations of the total possible 54 were identified that that when observed, provide a “profile” of an outbreak restaurant. Since it is not known before an outbreak which agent may cause it, knowledge of the overall risk of the top three types of outbreaks (norovirus, *Salmonella* and *C. perfringens*/toxin-type) could permit identification of appropriately targeted interventions to prevent such an outbreak. Further since the CDC reported that these three agents caused approximately three quarters of confirmed and suspected foodborne illness outbreaks in 2008 (10), knowledge of factors that may affect outbreaks attributed to these agents could have a significant impact on overall illness incidence. This listing could be used to assess whether a particular establishment may more closely resemble an outbreak location by determining which of these eleven violation types might be observed in their routine inspections.

Using this evidence-combined approach, the identified factors in the present study agree with those reported elsewhere. Gormley et al. (45) found repeated concerns related to cross-contamination over an 18 year study. Patel, et al. (75) also found cross-contamination to be an apparent factor in a *Salmonella* outbreak at multiple locations of a restaurant chain. Doménech (30) reported issues with structural design conditions and sanitation as key weaknesses in food establishments in implementation of food safety programs. Several researchers have attempted to relate inspection scores to foodborne illness likelihood and although findings are mixed, several types of violations more likely to be observed in outbreak locations were identified. Buchholz et al. (7) found that incorrect food storage and employee hand washing issues were predictors among other factors for an establishment becoming a case restaurant. Hedberg (49) reported that infected food handlers and bare hand contact of foods were the most commonly identified contributing factors to foodborne illness in a study of outbreak and non-outbreak restaurants. Although a Florida study (28) did not find inspections to be predictive of future outbreaks, they did report a larger seating capacity was more likely associated with outbreaks. An Iowa study also found that larger and full-service establishments were more likely to be cited for critical violations (8).

Despite this agreement, this study is subject to several limitations. Inherent in the inspections process are various subjective factors ranging from differences in inspection focus based on jurisdictional differences, to the fact that

these are done by personnel with varying levels of experience and tenure. How violations are characterized from one locale to another may vary and bias among inspectors likely does exist. Some inspectors may choose to not record a so-called non-critical violation in order to emphasize the importance of follow-up against what they deem to be more critical issues or against those that may need immediate and on-going correction. Also, assessing behaviors is challenging. Behaviors may be modified by operators and others being inspected only to change once the inspector departs. In addition, it can difficult to gauge operators' policies, especially when personnel are able to provide the correct responses to questions designed to gauge knowledge and behavior. Not all foodborne illness risk factors can be observed during inspections.

The timing of inspections can vary, occurring at different times of the day or year when certain concerns may be more or less problematic. An inspection done over a busy meal time may reveal issues more related to the hectic pace of work at that moment, rather than true systematic failures. Specifically in Minnesota, some inspections are announced but it is not the norm. There generally is a mix of both announced and unannounced inspections, depending on the particular situation. For instance, if an establishment with limited hours is inspected, it might be more reasonable to schedule an appointment to be sure that the restaurant will actually be open when the inspector arrives. If an establishment has a history of cooling violations, it would be worthwhile to schedule a visit to coincide with when the problematic process is typically

performed. If an inspection is planned for a busy meal time, scheduling the visit may help to ensure that the manager or person in charge will have the needed time to spend with the inspector. Also, inspections done after an outbreak might result in improvements.

This study focused on MN outbreaks, so may be subject to the limitations that are inherent in this state. Violations against raw food consumer advisories, use of pasteurized foods for highly susceptible populations, variances for specialized processing methods, and plant foods properly cooked for hot holding would not be recorded in this state, but they may be part of inspections conducted in other states. Regardless, these results are believed to be applicable to other states since it emphasizes that overall attention to food safety practices is in order, but suggests that adoption of a more universally consistent approach would be worthwhile to consider. It would however, be worthwhile to examine data from other states to see what differences might be detected.

This study suggests that attention to specific types of violations may permit identification of a restaurant profile at higher risk for foodborne illness. This may not always be the same as the location with the highest total number of violations, but rather suggests that a closer examination of the specific types of violations against the identified eleven criteria might be more prudent. Restaurant inspections are a valuable tool, but their limitation needs to be recognized and ultimately, they should be used to provide feedback to the operator on the

effectiveness of the establishment's process controls to enable focus on interventions and programs where they can have the greatest impact.

3.5 Tables

Table 1. Questions from Model Form 3-A of US FDA Food Code.

1–Person in charge	28–Pasteurized eggs Use
2–EE health awareness/policy	29–Water & ice source
3–Illness exclusion	30–Variance - specialized process
4–Proper eating, tasting, tobacco use	31–Proper cooling methods
5–No discharge - eyes, nose & mouth	32–Plant foods properly cooled
6–Hands washed	33–Approved thawing
7–Bare hand contact procedure	34–Thermometers - accurate
8–Hand washing facilities supplied	35–Food properly labeled
9–Approved source	36–Pest/animals not present
10–Receipt at proper temperature	37–X Contam prevented
11–Food in good condition	38–Personal cleanliness
12–Shellstock records	39–Wiping cloth use
13–Food separated/protectedd	40–Washing fruits & vegetables
14–Food contact surfaces, cleaned	41–In-use utensils, properly stored
15–Disposal of food	42–Utensils, equipment, linens
16–Proper cooking time/temp	43–Single use/service articles
17–Proper re-heating for hot holding	44–Gloves used properly
18–Proper cooling time/temp	45–Food/nonfood contact design
19–Proper hot holding temp	46–Warewashing, incl test strips
20–Proper cold holding temp	47–Non food contact surfaces
21–Proper date marking & dispo	48–Hot/cold water available
22–Time as public health control	49–Plumbing installed
23–Consumer advisory – raw foods	50–Sewage/waste water disposal
24–Highly susceptible population foods	51–Toilet facilities adequate
25–Food additives, properly stored	52–Garbage/refuse disposal
26–Toxic substances	53–Physical facilities
27–Compliance with variance & HACCP	54–Ventilation & lighting

Table 2. Description of Outbreak Locations Studied.

Type of Outbreak	Number of Non-Chain Locations that had outbreaks 2005-2009	Number of routine inspections collected from identified Non-Chain locations *	Number of Chain Locations that had outbreaks 2005-2009	Number of routine inspections collected from identified chain locations
Norovirus	25	111	19	61
<i>Salmonella</i>	11	44	2	10
<i>C.perfringens</i> /toxin-type	10	45	1	4
Total	46	200	22	75

*Inspection data from locations that had more than one outbreak were counted in both outbreak types.

Table 3. Two-Proportion tests of violations significantly more likely to be recorded in routine inspections at chain and non-chain outbreak locations (n=275) compared to inspections at chain non-outbreak locations (n=172).

Violation Number from Form 3-A	Violation type	p-value
4	Proper eating, tasting, tobacco use	0.000074
7	Bare hand contact procedure	0.000442
13	Food separated/protected	0.000056
18	Proper cooling time/temp	0.000020
20	Proper cold holding temp	0.008675
21	Proper date marking & dispo	0.000002
26	Toxic substances	0.032055
31	Proper cooling methods	0.000214
33	Approved thawing	0.007911
37	X Contam prevented	0.000026
42	Utensils, equipment & linens	0.026917
43	43-Single use/service articles	0.000035
47	Non food contact surfaces	0.000015
54	Ventilation & lighting	0.001445

Table 4. Two-Proportion tests of violations significantly more likely to be recorded in routine inspections at chain outbreak locations (n=75) compared to inspections at chain non-outbreak locations (n=172).

Violation Number from Form 3-A	Violation type	p-value
4	Proper eating, tasting, tobacco use	0.015831
7	Bare hand contact procedure	0.012444
17	Proper re-heating for hot holding	0.031526
18	Proper cooling time & temp	0.004283
20	Proper cold holding temp	0.010912
21	Proper date marking & dispo	0.024866
31	Proper cooling methods	0.001742
35	Food properly labeled	0.000131
37	X Contam prevented	0.008542
42	Utensils, equipment & linens	0.001963
43	43-Single use/service articles	1.36E-06
47	Non food contact surfaces	1.3E-06
54	Ventilation & lighting	0.020778

Table 5. Relative Risks of violations in routine inspections at chain restaurants who had Salmonella (n=10), Norovirus (n=61) and *C. perfringens*/toxin-type (n=4) outbreaks v. non-outbreak restaurants (n=172). Bold Font signifies those violations types significant by agent at 95%.

Violation # and type	<i>Salmonella</i>		Norovirus		<i>C. perfringens</i> /toxin type	
	RR (95% CI)	Occurrence in <i>Salmonella</i> outbreak restaurant/non outbreak restaurant	RR (95% CI)	Occurrence in Norovirus outbreak restaurant/non outbreak restaurant	RR (95% CI)	Occurrence in <i>C. perfringens</i> /toxin-type outbreak restaurant/non outbreak restaurant
3-Illness exclusion	8.6 (2.51-29.4)	0.3/0.03	0.47 (0.08-20.03)	0.02/0.03	0	0/0.03
4 - Proper eating, tasting, tobacco use	0	0/0.02	5.64 (1.46-21.86)	0.09/0.01	0	0/0.02
7–Bare hand contact procedure	7.64 (2.84-20.6)	0.4/0.05	5.64 (1.46-21.86)	0.11/0.05	0	0/0.52
13-Food separated/protected	0	0/0.04	2.82 (1.03-7.71)	0.11/0.04	0	0/0.04
18 - Proper cooling time & temp	51.6 (5.88-452.63)	0.3/0.006	5.64 (0.52-61.1)	0.03/0.01	0	0/0.01
20 - Proper cold holding temp	1.15 (0.32-4.56)	0.2/0.17	2.07 (1.3-3.3)	0.36/0.17	0	0/0.2
21 - Proper date marking & dispo	2.87 (0.39-39.23)	0.1/0.03	3.29 (1.15-9.41)	0.11/0.03	0	0/0.02

Violation # and type	Salmonella		Norovirus		C. perfringens/toxin type	
	RR (95% CI)	Occurrence in Salmonella outbreak restaurant/non outbreak restaurant	RR (95% CI)	Occurrence in Norovirus outbreak restaurant/non outbreak restaurant	RR (95% CI)	Occurrence in C. perfringens/toxin-type outbreak restaurant/non outbreak restaurant
31 – 31–Proper cooling methods	4.3 (0.24-15.77)	0.1/0.02	4.93 (1.50-16.27)	0.11/0.02	10.75 (1.52-75.88)	0.25/0.023
35 - Food properly labeled	5.29 (2.11-13.3)	0.4/0.08	3.04 (1.52-6.09)	0.22/0.08	6.62 (2.18-20.09)	0.5/0.08
37 - X Contam prevented	0.72 (0.1-4.8)	0.1/0.1	2.23 (1.32-3.78)	0.31/0.14	1.79 (0.40-15.04)	0.3/0.2
42 - Utensils, equipment & linens	5.43 (2.81-10.52)	0.6/0.11	1.93 (1.02-3.67)	0.21/0.11	2.26 (0.58-26.01)	0.3/0.1
43 - Single use/service articles	28.67 (7.95-103.26)	0.5/0.02	8.46 (2.37-30.23)	0.15/0.02	0	0/0.02
47 - Non food contact surfaces	2.72 (0.92-9.26)	0.3/0.1	3.71 (2.37-30.23)	0.15/0.02	0	0/0.1
52-Garbage/refuse disposal	0	0/0.08	0.85 (0.25-2.89)	0.07/0.08	6.62 (2.18-20.09)	0.5/0.08
53-Physical facilities	0.67 (0.25-1.75)	0.3/0.4	1.39 (1.08-1.80)	0.62/0.45	0	0/0.4

Table 6. Overall Relative Risks of Specific Violations More likely to be observed in Routine Inspections at an Outbreak Restaurant

Violation Number from Form 3-A	Violation type	RR	95% CI	Violation occurrence in inspections at Outbreak restaurants (n=75)	Violation occurrence in inspections at Non Outbreak restaurants (n=172)
4	Proper eating, tasting, tobacco use	4.59	1.28-16.36	0.08	0.01
7	Bare hand contact procedure	2.8	1.23-6.32	0.15	0.05
18	Proper cooling time & temp	11.47	1.81-73.27	0.06	0.006
20	Proper cold holding temp	1.83	1.15-2.89	0.32	0.17
31	Proper cooling methods	5.16	1.73-15.37	0.12	0.02
35	Food properly labeled	3.53	1.87-6.64	0.18	0.14
37	X Contam prevented	2.01	1.19-3.34	0.28	0.14
42	Utensils, equipment & linens	2.41	1.37-4.21	0.27	0.11
43	Single use/service articles	10.7	3.40-33.98	0.19	0.02
47	Non food contact surfaces	3.38	2.03-5.63	0.37	0.11
54	Ventilation & lighting	1.72	1.09-2.68	0.32	0.19

3.6 Figures

Figure 1. Categorization of violations against three general categories more likely to be observed in routine inspections done at outbreak locations v. non outbreak locations

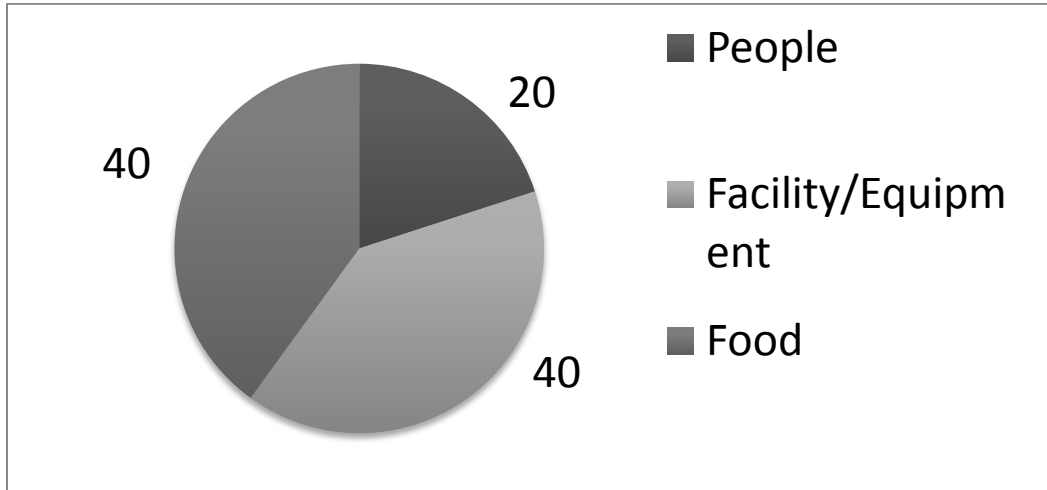
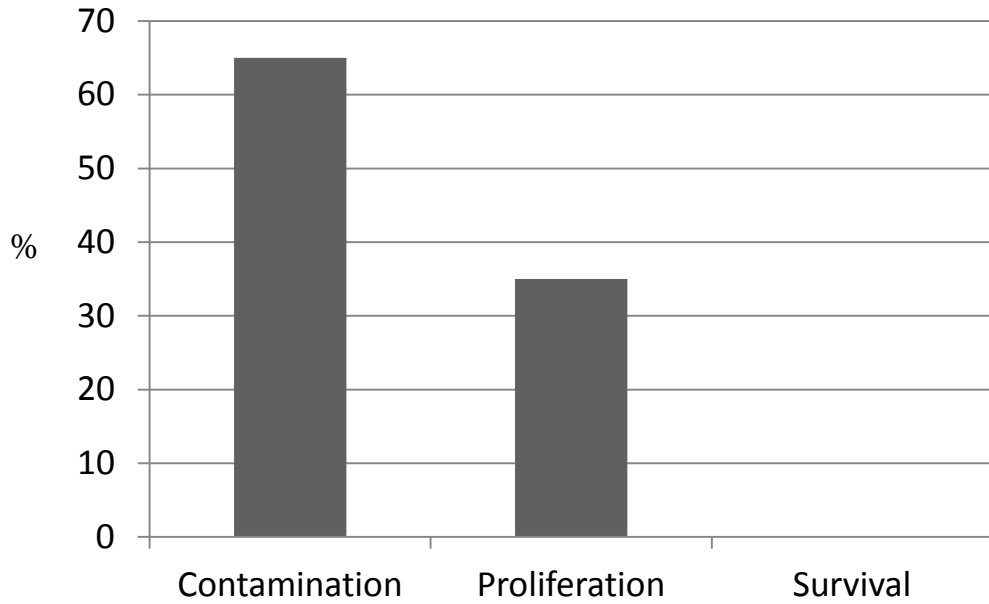


Figure 2. Categorization of violations as related to CDC Contributing Factors to Foodborne Illness (67), more likely to be observed in routine inspections done at outbreak locations v. non outbreak locations



Chapter 4

Manuscript 3. Application of restaurant inspection data analysis to help increase the assurance of food safety, especially at chain restaurants

A recurring theme of this thesis has been that there is an abundance of information continually generated from routine as well as investigative inspections conducted at food service establishments. While these data are becomingly increasingly available to researchers and the public through on-line sources, the reality is that since they are generated in such a wide variety of schemes, drawing truly actionable conclusions is challenging. Additional data gleaned from the Maricopa County (AZ) on-line restaurant inspection system were examined and compared to that previously generated from the Minnesota inspection system. In the AZ data sets examining data from chain restaurants, some types of violations were more likely to be associated with outbreak situations, but these varied somewhat from those identified from MN. With a more unified national approach to restaurant inspections, consistent identification of the top issues from establishments across the US would be enabled. For a typical chain restaurant with locations across multiple jurisdictions, this would allow for application of the most effective preventative controls and with focused attention, an eventual decrease in foodborne illness events associated with these types of restaurants.

4.1 Introduction

There continues to be abundant information continually generated from routine and investigative inspections conducted at food service establishments. While these data are becoming increasingly available to researchers and the public through on-line sources, they are generated in such a wide variety of schemes, that drawing truly actionable conclusions is challenging. Previous examination focused on data from Minnesota (77, 78). These studies demonstrated that certain types of violations were more likely to be observed during outbreak investigational inspections, even though the overall inspection summary scores were not determined to be different from the routine inspections conducted before and after the outbreaks at restaurants that had outbreaks (77). While studying investigational, outbreak-associated inspections can be helpful, the reality is that these do not occur frequently, perhaps representing 1-2% of all inspections (65).

By far, the majority of inspections are conducted on a routine basis by health department personnel in their standard assessments. If each of the estimated one million restaurant locations in the US (73) are inspected annually, there is a large body of data generated, and this is a conservative estimate. Another study (78) drew from these data and compared the types of violations recorded during routine inspections done at restaurants that had previously had outbreaks and at similar types of restaurants that did not have outbreaks. Analyses resulted in determination of a set of specific violations more likely to be

identified in restaurants that had previously had outbreaks. It was concluded that by examining other routine inspection reports and comparing the identified violations to this statistically valid outbreak associated listing of violations, one might be able to highlight specific restaurant locations at potentially higher risk of an outbreak and in need of extra attention.

These conclusions were based on data from Minnesota (MN) and its many jurisdictions. In the state of MN, the Minnesota Department of Health (MDH) or a local health agency licenses food establishments. This means that inspections are conducted either by MDH or local health agency personnel. About 42% of the inspections are either fully or partially delegated to local health agencies; MDH personnel conduct the remainder (71).

It is worthwhile to determine if different conclusions would be reached when examining data from a different region of the country. For the purpose of this analysis, additional data gleaned from the Maricopa County, Arizona (AZ) on-line restaurant inspection system were examined and compared to those previously generated from the Minnesota inspection system to determine what patterns of violations would be seen when comparing outbreak and non-outbreak restaurant locations. The aim of this study was to compare these two different areas of the country and from this, develop a series of recommendations for an ideal, effective restaurant inspection process to ensure generation of actionable data that generates actionable data.

4.2 Methods

Two sets of restaurant inspection data from AZ were examined. These include inspections done in AZ at a chain restaurant that had a confirmed *Salmonella* outbreak in 2008 and a select set of outbreak and non-outbreak restaurants from 2010-2011. Maricopa County, AZ is about 9200 square miles and includes the Phoenix metropolitan area and a population of close to four million people. It is among the largest counties in the US (91). The on-line Yellow Pages lists more than 21,000 restaurants in Maricopa County (97).

Maricopa County posts their results of restaurant inspections in an on-line source that is searchable (68) and reports are kept on-line for a period of three years. There are ten different categories of inspections noted in this database, including routine, complaint response and foodborne illness investigation. As in MN, routine inspections are scheduled, but unannounced. Foodborne illness investigations are done in response to an alleged food borne illness and concentrate on the suspect foods implicated in the food borne illness complaint. Likewise, complaint inspections focus on the specific area of concern. It appears that most inspections are done against the specific criteria spelled out in model form 3-A in the US FDA Food Code (34). This form includes 54 different types of violations, divided into “Foodborne Illness Risk Factors and Public Health Interventions” and “Good Retail Practices”. A copy of this form is in Appendix 1. Inspections done at a Chain Restaurant that had confirmed *Salmonella* Outbreak

Patel et al. (75) reported that an outbreak of salmonellosis occurred at restaurant chain A in Maricopa County in August 2008. Via searching in the on-

line database for foodborne illness investigations conducted in the summer of 2008, the specific identity of the chain was ascertained by considering the foodborne illness outbreak inspection dates reported in the paper and the types of findings reported. In 2008 per the on-line database, this chain had 19 different locations in Maricopa County. Via matching the dates of the foodborne illness inspections from the research paper (75) to those conducted by environmental health professionals from the on-line site, it was possible to narrow down the identity of the three locations where the majority of alleged cases consumed food. Once these three locations (specified as A, B, and C in the paper) were identified, the specific violation identifiers from Food Code form 3A were recorded using the method described previously (77, 78). See Table 1 for a listing of the standard criteria to which violations were mapped.

From the three locations where the majority of illnesses occurred, those violations identified in the inspections done to investigate the foodborne illness were recorded and compared to routine inspections conducted before and after the investigation. In addition, violations were recorded from routine inspections done at the other non-implicated locations of this chain restaurant during this same time period. The types of violations recorded in routine inspections at outbreak and non-outbreak locations were compared to determine if differences in types of violations were detectable via Fisher's Exact tests and calculation of relative risks and their confidence intervals (Excel 2007 and Minitab version 16.2.1).

Inspections of additional outbreak and non-outbreak restaurants in AZ

Since there were just three identified outbreak locations from the first analysis, additional searching of the on-line Maricopa database (68) was done to identify a larger data set of restaurant locations that appeared to have had recent outbreaks. Search criteria included: Category = "Food", Complaint type = "Food Poisoning" and Date range = "January 1, 2010 – December 31, 2011". This resulted in 1149 total identified locations, but 1057 of these were not usable in this study since the location names were withheld for a variety of reasons. Knowledge of the identification of the affected location was necessary to enable collection of other inspection information about the specific property. After removing the 1057 unidentified locations, this left a usable population of 92 locations whose names were identified. Since the previous study (78) focused on chain restaurants defined as having more than ten locations, this population of 92 locations had to be subdivided further. Of these, there were 17 chain locations about which inspection information was available. The specific inspection information of interest was that relating to the foodborne illness outbreak investigation as well as the routine inspections done before and after the alleged outbreak. This resulted in a data set of 17 outbreak inspections and 32 routine inspections. In two instances, routine inspections done after the outbreak were not available. This group of restaurants has been designated the "Outbreak locations."

Non Outbreak restaurants from the same general locale were identified as a control group. The desire was to match each identified outbreak restaurant to a chain restaurant from the same geographic area that had not had a foodborne illness investigation around the same time as was conducted at the outbreak restaurants or at any time during the study period of 2010-2011. A standardized process was used to find these controls in the online searchable database. First, searching by the street address and zip code of the outbreak location brought up other nearby locations. The first location on the resulting list that was a chain restaurant and had not had a foodborne illness inspection per the listed inspections was selected as a match to each outbreak location. From the identified non-outbreak location, two routine inspections done before and after the time when the outbreak inspections occurred, were selected. This process resulted in the identification of 17 non outbreak locations and a total of 34 routine inspection reports. This group was called the “Non-outbreak locations”.

From the identified outbreak and non-outbreak locations, the specific violation identifiers from Food Code form 3A were recorded using the method described previously (77, 78). Violations identified at the outbreak locations in the inspections done to investigate the foodborne illness were recorded and compared to routine inspections conducted before and after the investigation. In addition, the routine inspections done at the outbreak locations were compared with those done at the non-outbreak locations. Analysis was done to determine if there were differences in types of recorded violations via Fisher’s Exact tests and

calculation of relative risks and their confidence intervals (Excel 2007 and Minitab version 16.2.1).

In addition, analysis was done comparing the violation data from the identified locations of the chain to which the confirmed outbreak was attributed with the other identified outbreak and non-outbreak locations. This enlarges the data set and can help to identify more valid patterns in the information.

4.3 Results

Types of specific violations as mapped against the Food Code Form 3-A were compared among several sets of restaurants for this analysis. The frequency of violation occurrence in inspections done to investigate outbreaks was compared with the frequency of these same violations conducted during routine inspections at the same restaurant locations. Given the overall low numbers of recorded violations, Fisher's Exact Tests were used to provide a more valid analysis (41).

Evaluation of Inspections done at a Chain Restaurant that had *Salmonella* Outbreak

Outbreak inspections done at the three locations designated A, B, and C on 8/5/08, 8/13/08 and 8/13/08 were compared with routine inspections done at these three locations before and after the outbreak investigation, that were available in the on-line system (68). For location A, these routines were done on 5/19/08 and 12/16/08. Since the inspections of locations B and C occurred on the same day, it was not possible to definitively identify which location was which.

Once of these locations had a routine inspection on 12/28/08 after the outbreak, but no earlier routine inspection available. The other of these locations had routine inspections on 8/4/08, 4/15/08, and 10/14/08.

The frequencies of the twelve violations recorded in the three outbreak inspections and the routine inspections were compared. There were no significant differences ($p \leq 0.05$) in the types of violations recorded in the inspections done as part of the foodborne illness investigations at these three locations that had outbreaks versus routine inspections at these same three locations (Table 2). Overall, there were very low numbers of violations recorded since the group of inspections was so small.

Following the model of Petran, et al. (78), further analyses were done to expand the set of routine inspections by collecting information from routine inspections done in 2008 from the 16 non-implicated locations of restaurant chain A from the Maricopa database (68). This resulted in a data set of 63 routine inspections. The violations recorded in this expanded set were compared to those recorded in the outbreak inspections done at the three implicated locations. In this analysis, significant differences at $p \leq 0.05$ via Fisher's Exact tests were detected at violations 44 (gloves used properly), 45 (food and nonfood surfaces cleanable, properly designed, constructed & used) and 47 (non food contact surfaces clean) with these violations more likely to be recorded in inspections performed at locations A, B and C that had outbreaks. See Table 3.

Additional analysis compared the six routine inspections done at the implicated locations with the 57 routine inspections done at the non-implicated locations of chain A. Via Fisher's Exact tests, significant differences ($p \leq 0.05$) were detected at questions 36 (Insects, Rodents, and animals not present) and 47 (non food contact surfaces clean). Relative risk calculations show that these two violations had a strong and significant association ($RR > 5.0$) with the inspections done at the outbreak locations. Further, violations related to utensils, equipment, and linens; food and nonfood contact design; garbage disposal; and physical facilities had fairly strong associations ($1 \leq RR \leq 5$) with the inspections done at the outbreak locations. See Table 4.

Inspections of additional outbreak and non-outbreak restaurants in AZ

One big limitation of the analysis of restaurant locations implicated in the *Salmonella* outbreak was that there were only three confirmed locations where significant illnesses were alleged to have originated. A larger number of outbreak locations would provide greater validity, and would be more in line with previous research (78) better enabling comparison of data sets. Additional searching of the Maricopa county on-line database (68) was done to further this objective. 17 chain locations that had foodborne illness investigations that were matched to 17 locations in the same locales that did not have foodborne illness investigations during 2010 and 2011.

The first analysis compared differences in types of violation among the set of restaurants that had foodborne illness investigations done. There was just one

type of violation that was significantly more likely to be recorded ($p < 0.05$) in the outbreak investigational versus routine inspections done at restaurants that had outbreaks (Table 5). This was in question 2 – Management awareness; policy present, related to employee illness awareness. Relative risk calculations revealed fairly strong associations ($1 \leq RR \leq 5$) of eight violations with the inspections done at the outbreak locations. See table 6. When violations recorded at routine inspections at the outbreak versus the non-outbreak locations were compared, violations at questions 49 (plumbing installed; proper backflow devices) and 53 (physical facilities installed, maintained and clean) were significantly more likely to be observed at the outbreak locations at $p \leq 0.05$ and violation at question 37 (contamination prevented during food preparation, storage and display) at $p < 0.1$ (Table 7). Relative risk calculations revealed fairly strong associations ($1 \leq RR \leq 5$) of 13 violations with the inspections done at the outbreak locations. See table 8.

The final analysis combined the information from routine inspections performed at the three implicated outbreak Chain A restaurants reported by Patel (75) with that collected from the Maricopa database (68). Although there were no significant differences in types of violations recorded at $p \leq 0.05$, violations at questions 13, 34, 37, 42, 53 were significantly more likely to be recorded in outbreak locations than at non-outbreak locations at $0.05 < p < 0.10$. Relative risk calculations revealed strong associations ($RR \geq 5$) of five violations with outbreak

locations and fairly strong associations ($1 \leq RR \leq 5$) of 15 violations with outbreak locations. Summary data are reported in table 9.

Table 10 summarizes these data from Arizona and compares the present results to Petran et al. (78). Listed are those criteria whose Relative risk confidence intervals did not include 1.0 indicating significant associations.

4.4 Discussion

The analysis done in the present work comparing specific violations identified in routine inspections done immediately prior to those recorded in foodborne illness investigational reports at restaurants associated with confirmed illnesses, did not show significant differences in the types of violations recorded. Previous analyses of these locations suggested that the three affected locations were more likely to have lower total scores on routine inspections done before the outbreak occurred but that this analysis was hampered by low sample numbers (75). These researchers suggested that focus on lower-graded locations needs to be done. This may be a prudent recommendation, but could be enhanced if more specific details were available on where and on which violation types to focus, especially for a typical chain restaurant with hundreds of locations across the country with potentially limited resources.

Among the three identified locations and within their chain's outbreak and routine inspections, the most frequently recorded violation at all of the implicated locations was at question 45, "food and nonfood surfaces cleanable, properly designed, constructed and used". The actual verbiage in the inspection reports

points to a scratched cutting board, recorded repeatedly dating back to April 2008 (68); no earlier inspections were available since this county only displays information for three years. The outbreak summary described that 88% of the cases occurred between May and October 2008 (75). Although the outbreak was attributed to contaminated chicken, the duration of illnesses over this six month period could suggest ongoing amplification of the outbreak *Salmonella* strain on the cutting board surfaces. Evidence of this could be related to an illness complaint lodged against one of these locations in early July 2008. The comments associated with this complaint suggest that this may have been linked to salsa preparation in the restaurant. One wonders if this complaint was related to the ongoing outbreak linked to chicken, potentially due to cross-contamination from the scratched uncleanable cutting board. In the past, outbreaks have been attributed to surfaces deemed uncleanable (59, 60). It was also acknowledged that ill food workers may have played a role in the ongoing transmission of the outbreak, even though stool testing proved negative, but that this did not definitely prove that they had been negative through the outbreak duration (75).

Nevertheless, the low numbers of overall violations recorded in this particular outbreak limited comparison and prevented statistical significance, in the analysis among criteria recorded at the identified outbreak locations. However, when comparing these three identified outbreak inspections to a larger set of routine inspections from the affected locations and others in the area from among the same chain restaurant company, there were some differences

detected in specific types of violations. These occurred in what are defined by the FDA as “good retail practices” per the Food Code Form 3-A (34) and include pest concerns; proper use of gloves; and sanitary design and cleanliness of food and nonfood contact surfaces. These may be suggestive of an overall lack of attention to the restaurant facility and program design and implementation, which could translate to insanitary food handling. The detailed review of the inspections over several time periods done at the three implicated restaurants suggested a significant recurrent concern with cutting boards that were difficult to clean (68, 75). While it is recognized that this was a very small sample set of outbreak locations, the detection of a violation, related to cleanliness of non-food contact surfaces, is in line with what reported previously (78) as a key difference between outbreak and non outbreak locations. Even with the numbers of non-outbreak locations increased in this analysis, the data set of outbreak locations is still very small and data are not as complete as would be preferred, but is reflective of the variability of inspections and the challenges encountered in their study. However, despite these findings and potential indicators of serious issues at these restaurants, there were relatively few critical violations, which is surprising given that 90% of the cases ate at these locations (75).

Consistent categorization of the types of violations recorded in restaurant inspections across the country could permit focus on the locations that could be most at risk for foodborne illness events and identify where increased focus might be needed. The on-line inspection database for Maricopa (AZ) County is a

good vehicle for collection of this information. Analysis of a portion of these data was done in this study to identify a larger set of potential outbreak locations, but even with this, there is a limitation that needs to be recognized. These locations are identified in the database as having inspections done under the category of “Foodborne illness”, but it is unknown how many of these are confirmed outbreaks. For purposes of this analysis, they were all treated equally.

This broader comparison of outbreak investigations to routine inspections revealed that a violation related to proper employee illness management was more likely to be reported in the outbreak investigations. Finding a difference at this criterion agrees with Petran (77), which found that this violation was significantly more likely to be recorded in norovirus outbreak inspections, although it cannot be definitively confirmed that these were norovirus outbreaks in the present analysis. However, based on data from the CDC, norovirus caused the majority of confirmed outbreaks in restaurants in AZ from 1998-2009 (19), and issues related to improper management of employee illness is in-line with typical transmission path for this agent when food handlers are suspected to be involved (11). In outbreak inspections in AZ and likely elsewhere, inspectors will concentrate on the suspect foods and behaviors potentially implicated in the food borne illness complaint (68). This can lead to bias in the types of criteria reported. For example, when the identity of the agent is suspected to be norovirus, part of the investigation focus will be on personnel behaviors and illness status of employees (2, 62, 87). But even for norovirus, judging the

presence of an illness policy is relatively easy to do in an inspection, but observing actively ill employees who may be shedding the organism is very difficult. While this information obtained can be very valuable, other possible sources of potential contaminants may be inadvertently ignored.

Overall, these results continue to support the previous conclusions of being aware of specific types of violations and considering what they may mean, but it is important to recognize that there may be limitations. Petran et al. (77) showed that certain types of violations were more likely to be recorded in outbreak inspections when compared with those recorded in routine inspections conducted at restaurants that had had recent outbreaks. For *C. perfringens* and norovirus, these were seen as typical of the causal paths for these agents, related to food temperature and personnel issues, respectively. The violations more likely to be recorded in *Salmonella* outbreaks showed a more varied picture, demonstrating that issues throughout the food handling system in a restaurant were identified in outbreak inspections. Although some violations may point towards one agent, inspections against the Food Code are not designed to provide a review consistent with all possible foodborne illness transmission pathways and some violations that may be very important in these paths cannot be effectively observed. A classic example of this relates to the direct observation of employee illness which is important in norovirus (11) and *Salmonella* (69) outbreaks.

Comparison of the confirmed and complaint investigational inspections to routine inspections showed some of two of the same differences as previously reported (78). These were at violations 37 (Contamination prevented during food prep, storage, & display) and 42 (Utensils, equipment & linens properly stored, dried, handled). The significance of this is that there are patterns of violations observed, but that these may vary by jurisdiction. Further studies (78) showed that specific types of inspection criteria were more likely associated with restaurants that had outbreaks based on a review of Minnesota data. The present study of Arizona data demonstrated that a different set of criteria emerged that were associated with restaurants that had had outbreaks. Other studies have found that other violation criteria were more likely identified at outbreak locations (7, 28, 49).

Although the specific criteria varied somewhat in Petran's two studies (77, 78) and from that of others, similar overall conclusions can be drawn. This is that focus on certain criteria is necessary to promote and maintain food safety. The reality is that since one cannot reasonably focus equally on everything, considering how to prioritize food safety resources and efforts is worthwhile. For an individual restaurant or small group of restaurants within one locale, this may be facilitated by examining the most recent health department report and reacting appropriately to the identified concerns.

However for a chain restaurant with locations in multiple health department jurisdictions across many states, this is more difficult due to the

differences that inherently exist in the inspection systems across the US. These include the use of different criteria against which restaurants are scored; how certain violations are characterized, rated or scored; what level of detail is included in the violations; and even the more basic issue of how the inspection reports are obtained. What is considered a violation does vary in different states. For example, in Minnesota, since the current MN Food Code (72) does not include reference to consumer advisories, use of pasteurized foods for highly susceptible populations, variances for specialized processing methods, and plant foods properly cooked for hot holding, no violations against these criteria would be recorded in current inspections performed in MN.

How specific types of violations are scored also varies widely (40) and some jurisdictions are known for being very tough in their scoring. Some violations may not consistently be recorded if they are corrected on site. However, in other jurisdictions, the violation may be specifically noted in the report to emphasize the need to correct it immediately and on an ongoing basis, and to draw the operator's attention to it. Behavior violations are often the most difficult to correct (26) and to ensure that emphasis is correctly placed, an inspector may choose to cite only this type of violation so that operators cannot ignore them in favor of what might be more 'simple' physical facility violations (42). However, a review of recent summaries of top recorded violations showed that facility-related violations were more detected more commonly (59, 70, 79, 81).

It sounds like a simple task to get a copy of an inspection report, but this can be variable as well. Some reports are left at the establishment at the conclusion of the inspection, while others may take days to weeks to be formalized. Increasingly reports are available on line, but how much detail is made public differs greatly and they are not available in all locales. Consumers expect a lot more out of inspections than they may be able to provide, believing that establishment should be expected several times a year and that more aggressive actions should be taken in response to violations (61). It is important to present a realistic picture of what inspection reports can offer as well as their limitations.

There are others besides consumers who rely on reports about conditions in restaurants. To a headquarters-based food safety leader charged with managing violations at their restaurant chain of dozens to hundreds of locations, the challenges of the current inspection systems can present barriers to verification of a consistent food safety practices that are applied across the chain. Avoidance of a foodborne illness outbreak is a key management goal, and information from inspections can provide an additional data source. However, the reality is that with the many demands on these personnel and the challenges of the present inspection system, there are inherent changes needed to the current system that would better facilitate this preventative control approach. The changes should center on consistency, including the use of the same set of criteria from the Food Code, the use of standard criteria to score and describe

violations, and making the data readily available to stakeholders to permit appropriate targeting of resources and trending over time to verify progress as well as redirection of resources where indicated.

4.6 Tables

Table 1. Questions from Model Form 3-A of US FDA Food Code.

1–Person in charge	28–Pasteurized eggs Use
2–EE health awareness/policy	29–Water & ice source
3–Illness exclusion	30–Variance - specialized process
4–Proper eating, tasting, tobacco use	31–Proper cooling methods
5–No discharge - eyes, nose & mouth	32–Plant foods properly cooled
6–Hands washed	33–Approved thawing
7–Bare hand contact procedure	34–Thermometers - accurate
8–Hand washing facilities supplied	35–Food properly labeled
9–Approved source	36–Pest/animals not present
10–Receipt at proper temperature	37–X Contam prevented
11–Food in good condition	38–Personal cleanliness
12–Shellstock records	39–Wiping cloth use
13–Food separated/protectedd	40–Washing fruits & vegetables
14–Food contact surfaces, cleaned	41–In-use utensils, properly stored
15–Disposal of food	42–Utensils, equipment, linens
16–Proper cooking time/temp	43–Single use/service articles
17–Proper re-heating for hot holding	44–Gloves used properly
18–Proper cooling time/temp	45–Food/nonfood contact design
19–Proper hot holding temp	46–Warewashing, incl test strips
20–Proper cold holding temp	47–Non food contact surfaces
21–Proper date marking & dispo	48–Hot/cold water available
22–Time as public health control	49–Plumbing installed
23–Consumer advisory – raw foods	50–Sewage/waste water disposal
24–Highly susceptible population foods	51–Toilet facilities adequate
25–Food additives, properly stored	52–Garbage/refuse disposal
26–Toxic substances	53–Physical facilities
27–Compliance with variance & HACCP	54–Ventilation & lighting

Table 2. Frequency of Violations Recorded in Outbreak and Routine inspections at Implicated Locations of Restaurant Chain A. (Only included are criteria against which violations were recorded)

Violation	% of time recorded in Outbreak inspection (n=3)	% of time recorded in routine inspection (n=6)	p-value (Fisher's)
Q06-Hands washed	0.00	0.17	1.0
Q14-Food contact surfaces, clean	0.33	0.00	0.33
Q31-Proper cooling methods	0.00	0.17	1.0
Q36-Pest/animals not present	0.33	0.17	1.0
Q39-Wiping cloth use	0.00	0.17	1.0
Q42-Utensils, equipment, linens	0.33	0.00	0.33
Q44-Gloves used properly	0.33	0.00	0.33
Q45-Food/non-food contact design	1.00	0.50	0.46
Q47-Non food contact surfaces	0.67	0.17	0.27
Q49-Plumbing installed	0.33	0.00	0.33
Q52-Garbage/refuse disposal	0.00	0.17	1.0
Q53-Physical facilities	0.33	0.00	0.33

Table 3. Frequency of Violations Recorded in Outbreak and Routine inspections at Chain A locations. (Only included are criteria against which violations were recorded)

Violation	% of time recorded in Outbreak inspection (n=3)	% of time recorded in routine inspection (n=63)	p-value (Fisher's)
1-Person in charge	0.00	0.17	1.000
3-Illness exclusion	0.00	0.02	1.000
6-Hands washed	0.00	0.06	1.000
8-Hand washing facilities supplied	0.00	0.17	1.000
13-Food separate/protect	0.00	0.03	1.000
14-Food contact surfaces, cleaned	0.33	0.16	0.427
16-Proper cooking time/ temp	0.00	0.03	1.000
18-Proper cooling time/temp	0.00	0.02	1.000
19-Proper hot holding temp	0.00	0.02	1.000
20-Proper cold holding temp	0.00	0.03	1.000
21-Proper date marking & dispo	0.00	0.02	1.000
26-Toxic substances	0.00	0.05	1.000
31-Proper cooling methods	0.00	0.02	1.000
35-Food Properly labeled	0.00	0.03	1.000
36-Pest/animals not present	0.33	0.03	0.132
37-X Contam prevented	0.00	0.02	1.000

39-Wiping cloth use	0.00	0.02	1.000
42-Utensils, equipment, linens	0.33	0.03	0.132
43-Single use/service articles	0.00	0.03	1.000
44-Gloves used properly	0.33	0.00	0.045
45-Food/nonfood contact design	1.00	0.21	0.012
46-Warewashing, incl test strips	0.00	0.03	1.000
47-Non food contact surfaces	0.67	0.06	0.020
48-Hot/cold water available	0.00	0.02	1.000
49-Plumbing installed	0.33	0.02	0.090
51-Toilet facilities adequacy	0.00	0.02	1.000
52-Garbage/refuse disposal	0.00	0.05	1.000
53-Physical facilities	0.33	0.05	0.174
54-Ventilation & lighting	0.00	0.05	1.000

Table 4. Frequency of Violations More Likely to be Observed during Routine Inspections at Implicated and Non-implicated Chain A Locations.

Violation	% of violations recorded in Outbreak inspection (n=6)	% of violations recorded in routine inspection (n=57)	RR	CI
14-Food contact surfaces, cleaned	16.67%	18.52%	0.9	0.15-6.20
36-Pest/animals not present	33.33%	3.70%	9	1.62-55.79
42-Utensils, equipment, linens	16.67%	3.70%	4.5	0.51-44.99
45-Food/nonfood contact design	50.00%	18.52%	2.7	1.07-7.58
47-Non food contact surfaces	50.00%	5.56%	9	2.43-37.07
49-Plumbing installed	16.67%	1.85%	9	0.67-133.28
52-Garbage/refuse disposal	16.67%	3.70%	4.5	0.50-44.98
53-Physical facilities	16.67%	5.56%	3	0.39-25.89

Table 5. Comparing Outbreak inspections at other AZ locations that had outbreak inspections with their routine inspections

	% of time recorded in Outbreak inspection (n=17)	% of time recorded in routine inspection (n=32)	p-value (Fisher's Exact Tests)
1–Person in charge	0.118	0.156	1.000
2–EE health awareness/policy	0.353	0.000	0.001
3–Illness exclusion	0.118	0.000	0.116
4–Proper eating, tasting, tobacco use	0.059	0.000	0.347
5–No discharge - eyes, nose & mouth	0.000	0.000	1.000
6–Hands washed	0.412	0.219	0.193
7–Bare hand contact procedure	0.059	0.031	1.000
8–Hand washing facilities supplied	0.118	0.125	1.000
9–Approved source	0.000	0.000	1.000
10–Receipt at proper temperature	0.000	0.000	1.000
11–Food in good condition	0.059	0.000	0.347
12–Shellstock records	0.000	0.000	1.000
13–Food separate/protectedd	0.118	0.125	1.000
14–Food contact surfaces, cleaned	0.353	0.250	0.516
15–Disposal of food	0.000	0.000	1.000
16–Proper cooking time/temp	0.000	0.000	1.000

	% of time recorded in Outbreak inspection (n=17)	% of time recorded in routine inspection (n=32)	p-value (Fisher's Exact Tests)
17-Proper re-heating for hot holding	0.000	0.000	1.000
18-Proper cooling time/temp	0.000	0.063	0.537
19-Proper hot holding temp	0.000	0.000	1.000
20-Proper cold holding temp	0.235	0.094	0.217
21-Proper date marking & dispo	0.118	0.063	0.602
22-Time as public health control	0.059	0.063	1.000
23-Consumer advisory – raw foods	0.000	0.031	1.000
24-Highly susceptible population foods	0.000	0.000	1.000
25-Food additives, properly stored	0.000	0.000	1.000
26-Toxic substances	0.176	0.094	0.405
27-Compliance with variance & HACCP	0.000	0.000	1.000
28-Pasteurized eggs Use	0.000	0.000	1.000
29-Water & ice source	0.000	0.000	1.000
30-Variance - specialized process	0.000	0.000	1.000
31-Proper cooling methods	0.000	0.031	1.000
32-Plant foods properly cooled	0.000	0.000	1.000
33-Approved thawing	0.000	0.031	1.000

	% of time recorded in Outbreak inspection (n=17)	% of time recorded in routine inspection (n=32)	p-value (Fisher's Exact Tests)
34-Thermometers - accurate	0.000	0.063	0.537
35-Food Properly labeled	0.059	0.000	0.347
36-Pest/animals not present	0.000	0.031	1.000
37-X Contam prevented	0.059	0.094	1.000
38-Personal cleanliness	0.059	0.031	1.000
39-Wiping cloth use	0.059	0.063	1.000
40-Washing fruits & vegetables	0.059	0.000	0.347
41-In-use utensils, properly stored	0.000	0.063	0.537
42-Utensils, equipment, linens	0.059	0.188	0.397
43-Single use/service articles	0.000	0.000	1.000
44-Gloves used properly	0.000	0.031	1.000
45-Food/nonfood contact design	0.059	0.188	0.397
46-Warewashing, incl test strips	0.118	0.063	0.602
47-Non food contact surfaces	0.000	0.000	1.000
48-Hot/cold water available	0.000	0.000	1.000
49-Plumbing installed	0.059	0.063	1.000
50-Sewage/waste water disposal	0.059	0.000	0.347
51-Toilet facilities adequacy	0.000	0.000	1.000
52-Garbage/refuse disposal	0.000	0.063	0.537
53-Physical facilities	0.000	0.000	1.000

	% of time recorded in Outbreak inspection (n=17)	% of time recorded in routine inspection (n=32)	p-value (Fisher's Exact Tests)
54-Ventilation & lighting	0.000	0.063	0.537

Table 6. Comparison of Violations Observed During Outbreak inspections and Routine Inspections at other AZ locations that had outbreaks

Violation	% of violations recorded in Outbreak inspection (n=17)	% of violations recorded in routine inspection (n=32)	RR	CI
1–Person in charge	11.76%	15.63%	0.75	0.17-3.48
2–EE health awareness/policy	35.29%	0.00%	Undefined	
6–Hands washed	41.18%	21.88%	1.88	0.80-4.48
7–Bare hand contact procedure	5.88%	3.13%	1.88	0.13-28.25
8–Hand washing facilities supplied	11.76%	12.50%	0.94	0.19-4.63
13–Food separate/protecte	11.76%	12.50%	0.94	0.19-4.63
14–Food contact surfaces, cleaned	35.29%	25.00%	1.41	0.59-3.40
20–Proper cold holding temp	23.53%	9.38%	2.51	0.63-9.94
21–Proper date marking & dispo	11.76%	6.25%	1.88	0.29-12.21
22–Time as public health control	5.88%	6.25%	0.94	0.09-9.65
26–Toxic substances	17.65%	9.38%	1.88	0.42-8.34
37–X Contam prevented	5.88%	9.38%	0.63	0.07-5.58
38–Personal cleanliness	5.88%	3.13%	1.88	0.13-28.25

Violation	% of violations recorded in Outbreak inspection (n=17)	% of violations recorded in routine inspection (n=32)	RR	CI
39-Wiping cloth use	5.88%	6.25%	0.94	0.09-9.65
42-Utensils, equipment, linens	5.88%	18.75%	0.31	0.04-2.40
45-Food/nonfood contact design	5.88%	18.75%	0.31	0.04-2.40
46-Warewashing, incl test strips	11.76%	6.25%	1.88	0.29-12.21
49-Plumbing installed	5.88%	6.25%	0.94	0.09-9.65

Table 7. Comparing routine inspections at other AZ locations that had outbreak inspections with routine inspections at other AZ restaurants that did not have outbreaks

	% of time recorded in routine inspections done at other AZ outbreak locations (n=32)	% of time recorded in routine inspections done at other AZ non-outbreak locations (n=34)	p-value (Fisher's Exact Tests)
1–Person in charge	0.156	0.176	1.000
2–EE health awareness/policy	0.000	0.000	1.000
3–Illness exclusion	0.000	0.000	1.000
4–Proper eating, tasting, tobacco use	0.000	0.029	1.000
5–No discharge - eyes, nose & mouth	0.000	0.000	1.000
6–Hands washed	0.219	0.235	1.000
7–Bare hand contact procedure	0.031	0.059	1.000
8–Hand washing facilities supplied	0.125	0.088	0.705
9–Approved source	0.000	0.000	1.000
10–Receipt at proper temperature	0.000	0.000	1.000
11–Food in good condition	0.000	0.000	1.000
12–Shellstock records	0.000	0.000	1.000
13–Food separated/protected	0.125	0.029	0.190
14–Food contact surfaces, cleaned	0.250	0.176	0.554

	% of time recorded in routine inspections done at other AZ outbreak locations (n=32)	% of time recorded in routine inspections done at other AZ non-outbreak locations (n=34)	p-value (Fisher's Exact Tests)
15-Disposal of food	0.000	0.000	1.000
16-Proper cooking time/temp	0.000	0.029	1.000
17-Proper re-heating for hot holding	0.000	0.000	1.000
18-Proper cooling time/temp	0.063	0.000	0.231
19-Proper hot holding temp	0.000	0.088	0.239
20-Proper cold holding temp	0.094	0.118	1.000
21-Proper date marking & dispo	0.063	0.029	0.608
22-Time as public health control	0.063	0.029	0.608
23-Consumer advisory – raw foods	0.031	0.000	0.485
24-Highly susceptible population foods	0.000	0.000	1.000
25-Food additives, properly stored	0.000	0.000	1.000
26-Toxic substances	0.094	0.118	1.000
27-Compliance with variance & HACCP	0.000	0.000	1.000
28-Pasteurized eggs Use	0.000	0.000	1.000
29-Water & ice source	0.000	0.000	1.000
30-Variance - specialized process	0.000	0.000	1.000

	% of time recorded in routine inspections done at other AZ outbreak locations (n=32)	% of time recorded in routine inspections done at other AZ non-outbreak locations (n=34)	p-value (Fisher's Exact Tests)
31-Proper cooling methods	0.031	0.029	1.000
32-Plant foods properly cooled	0.000	0.000	1.000
33-Approved thawing	0.031	0.029	1.000
34-Thermometers - accurate	0.063	0.000	0.231
35-Food Properly labeled	0.000	0.000	1.000
36-Pest/animals not present	0.031	0.000	0.485
37-X Contam prevented	0.094	0.000	0.108
38-Personal cleanliness	0.031	0.059	1.000
39-Wiping cloth use	0.063	0.088	1.000
40-Washing fruits & vegetables	0.000	0.029	1.000
41-In-use utensils, properly stored	0.063	0.059	1.000
42-Utensils, equipment, linens	0.188	0.088	0.297
43-Single use/service articles	0.000	0.000	1.000
44-Gloves used properly	0.031	0.000	0.485
45-Food/nonfood contact design	0.188	0.176	1.000
46-Warewashing, incl test strips	0.063	0.029	0.608
47-Non food contact surfaces	0.000	0.088	0.239
48-Hot/cold water available	0.000	0.059	0.493
49-Plumbing installed	0.294	0.063	0.023
50-Sewage/waste water disposal	0.000	0.000	1.000
51-Toilet facilities adequacy	0.000	0.000	1.000

	% of time recorded in routine inspections done at other AZ outbreak locations (n=32)	% of time recorded in routine inspections done at other AZ non-outbreak locations (n=34)	p-value (Fisher's Exact Tests)
52-Garbage/refuse disposal	0.063	0.000	0.231
53-Physical facilities	0.176	0.000	0.025
54-Ventilation & lighting	0.063	0.029	0.608

Table 8. Comparison of Violations Observed During Routine Inspections at other AZ locations that had outbreaks and other AZ locations that did not have outbreaks

Violation	% of time recorded in routine inspections done at other AZ outbreak locations (n=32)	% of time recorded in routine inspections done at other AZ non-outbreak locations (n=34)	RR	CI
1–Person in charge	15.63%	17.65%	0.89	0.30-2.62
6-Hands washed	21.88%	23.53%	0.93	0.38-2.27
7–Bare hand contact procedure	3.13%	5.88%	0.53	0.05-5.58
8-Hand washing facilities supplied	12.50%	8.82%	1.42	0.34-5.84
13-Food separate/protected	12.50%	2.94%	4.25	0.50-36.03
14-Food contact surfaces, cleaned	25.00%	17.65%	1.42	0.55-3.63
20-Proper cold holding temp	9.38%	11.76%	0.80	0.18-3.09
21-Proper date marking & dispo	6.25%	2.94%	2.13	0.20-22.31
22–Time as public health control	6.25%	2.94%	2.13	0.20-22.31
26-Toxic substances	9.38%	11.76%	0.80	0.19-3.29
31–Proper cooling methods	3.13%	2.94%	1.06	0.07-16.28
33-Approved thawing	3.13%	2.94%	1.06	0.07-16.28
38-Personal cleanliness	3.13%	5.88%	0.53	0.05-5.58
39-Wiping cloth use	6.25%	8.82%	0.71	0.13-3.97
41-In-use utensils, properly stored	6.25%	5.88%	1.06	0.16-7.10
42-Utensils, equipment, linens	18.75%	8.82%	2.13	0.57-7.79
45–Food/nonfood contact design	18.75%	17.65%	1.06	0.38-2.96

46–Warewashing, incl test strips	6.25%	2.94%	2.13	0.20-2.42
49–Plumbing installed	29.40%	6.30%	4.67	1.12-20.47
53-Physical facilities	17.60%	0.00%	Undefined	
54-Ventilation & lighting	6.25%	2.94%	2.13	0.20-2/31

Table 9. Comparison of Violations Observed During Routine Inspections at Outbreak locations with Non-Outbreak locations. (Includes 3 locations named by Patel, et. al. 2010 and locations from Maricopa database.)

*Only included routine inspections done at identified outbreak locations done before the outbreak

Violation	% of violations recorded in routine inspections at Outbreak locations (n=35) *	% of violations recorded in routine inspection at non-outbreak s (n=91)	RR	CI
1–Person in charge	14.29%	19.32%	0.74	0.29-1.80
6-Hands washed	20.00%	12.50%	1.60	0.65-3.53
7–Bare hand contact procedure	2.86%	2.27%	1.26	0.12-13.88
8-Hand washing facilities supplied	11.43%	15.91%	0.72	0.27-2.11
13-Food separate/protected	11.43%	3.41%	3.35	0.82-14.71
14-Food contact surfaces, cleaned	22.86%	18.18%	1.26	0.58-2.58
18-Proper cooling time/temp	5.71%	1.14%	5.03	0.49-55.55
20-Proper cold holding temp	8.57%	6.82%	1.26	0.34-4.92
21-Proper date marking & dispo	5.71%	2.27%	2.51	0.38-17.75
22–Time as public health control	5.71%	1.14%	5.03	0.49-55.55
26-Toxic substances	8.57%	7.95%	1.08	0.31-4.07
31–Proper cooling methods	5.71%	1.14%	5.03	0.49-55.55
33-Approved thawing	2.86%	1.14%	2.51	0.17-40.44

Violation	% of violations recorded in routine inspections at Outbreak locations (n=35) *	% of violations recorded in routine inspection at non-outbreak s (n=91)	RR	CI
34-Thermometers - accurate	5.71%	0.00%	Undefined	
36-Pest/animals not present	5.71%	1.14%	5.03	0.49-55.55
37-X Contam prevented	8.57%	1.14%	7.54	0.84-72.49
38-Personal cleanliness	2.86%	2.27%	1.26	0.13-13.89
39-Wiping cloth use	8.57%	3.41%	2.51	0.55-12.28
41-In-use utensils, properly stored	5.71%	2.27%	2.51	0.38-17.75
42-Utensils, equipment, linens	17.14%	5.68%	3.02	1.02-9.57
45-Food/nonfood contact design	17.14%	18.18%	0.94	0.39-2.14
46-Warewashing, incl test strips	5.71%	3.41%	1.68	0.30-9.94
47-Non food contact surfaces	2.86%	6.82%	0.42	0.05-3.47
49-Plumbing installed	5.71%	12.50%	0.46	0.11-2.03
52-Garbage/refuse disposal	8.57%	2.27%	3.77	0.68-22.36
53-Physical facilities	0.00%	10.23%	0.00	0-∞
54-Ventilation & lighting	5.71%	4.55%	1.26	0.24-6.78

Table 10. Comparison of Identified Specific Violations More likely to be Observed in Routine Inspections at Outbreak Chain Restaurants in MN and AZ.

Violation Number from Form 3-A	Violation type	MN Study	AZ Study
4	Proper eating, tasting, tobacco use	X	
7	No bare hand contact with food or use of approved alternate procedure	X	
18	Proper cooling time & temperature	X	
20	Proper cold holding temperatures	X	
31	Proper cooling methods used; adequate equipment for temp control	X	
35	Food Properly labeled; original container	X	
37	Contamination prevented during food prep, storage, & display	X	
42	Utensils, equipment & linens properly stored, dried, handled	X	X
43	Single use/Single service articles; properly stored & used	X	
47	Non food contact surfaces clean	X	
54	Adequate ventilation & lighting	X	

Chapter 5 - Conclusion

A recurring theme of this thesis has been that there is an abundance of information continually generated from routine as well as investigative inspections conducted at food service establishments. However, these data are collected, evaluated, and reported in wide range of approaches that may serve the needs of the locale but can make identification of where to focus resources most effectively, problematic for a typical chain restaurant company that has locations across many jurisdictions. These data are becoming increasingly available to researchers and the public through on-line sources. Since they are generated in such a wide variety of schemes, drawing truly actionable conclusions is challenging. Improvements are needed to enable identification of interventions that will have the most beneficial effect on foodborne illnesses.

What's needed to better enable use of inspection data?

Within the current framework, there are limitations when relying on these inspections. The FDA has issued the federal Food Code as a model document and works through the Conference for Food Protection process seeking input from experts and stakeholders to ensure its ongoing scientific validity by issuing updates and supplementary information every two years (34). However, the Food Code is adopted differently across the US by the 3,000 state, local and tribal agencies that have primary responsibility to regulate the retail food and foodservice industries (93) with some states referring to documents that are close to 20 years old. Adoption of the same version of the food code across all

the jurisdictions in the country would put all inspected establishments on a level playing field. This would mean that the same food safety standards would be required and enforced similarly regardless of locale. Additionally, there is variability in how violations are described in reports and how this particular verbiage is interpreted (27). Going one step beyond adoption of the same Food Code is the use of consistent language when describing a violation and the level of its severity.

In order for this consistently applied Food Code to be more closely related to foodborne illness, its criteria must be more closely related to different types of agent transmission paths, and consistent attention should be directed towards these criteria. With this proposed approach, pathogen dependence among the different criteria should be recognized. As a start, if applying this to the top three reported agents (10) of norovirus, *Clostridium perfringens*, and *Salmonella*, certain types of violations relate differently. For example, norovirus is a human-derived agent and outbreaks are ultimately tied back to a human fecal or vomitus source, even though there may be several intermediate vehicles to which norovirus particles are transferred prior to their making another person sick. Outbreaks attributed to sporeformers like *Clostridium perfringens* or *Bacillus cereus* require conditions in which the spores become activated and are able to grow either producing toxin or growing to high enough levels to subsequently produce toxin in the human gut after ingestion.

Starting with these agents, if one were to “think like the agent”, focus would be enabled against the most likely transmission path, where this is possible. For example, the types of food code criteria related to human waste handling (e.g., hand washing, illness exclusion) or those related to transfer (e.g., utensil or surface cleanliness) apply to for those agents with a fecal-oral transmission route, like norovirus. Formation of toxin or of circumstances whereby toxin could be formed requires conditions allowing for growth, related to proper temperature control in cooking, cooling, holding, etc. of foods. Since an agent like *Salmonella* can come from a variety of sources including humans, animals, and the environment, broader criteria relate to its control.

The 2009 Food Code suggested terms to prioritize the type of criteria along this suggested scheme (34) based on a qualitative purposeful risk assessment approach. As a result, each provision of the food code received a descriptive designator. “Priority” items are provisions whose application contributes directly to the elimination, prevention or reduction to an acceptable level, of the hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard. “Priority foundation” denotes those whose application supports, facilitates or enables one or more priority items. A core criterion includes general sanitation, operational controls, sanitation standard operating procedures, facilities/structures, equipment design, or general maintenance. Consistent recognition of the types of criteria in each of these areas and ensuring that scoring is commensurate with them would further

support adoption of the risk assessment approach. Going one step further and relating each criterion to a specific type of foodborne illness agent could help to hone in on the true foodborne illness risks.

Recent studies have identified that the most commonly recorded violations in inspections have included direct food related concerns such as temperature control and storage and physical facility observations (70, 79, 81), but these may not always be deemed critical items, per the jurisdictions' categorization (59). While some of these, such as issues with temperature control, are more easily correlated with the typical transmission pathways of toxin-mediated foodborne illnesses, the reality is that this is an easy to observe violation. When critically evaluating the focus of inspections and their relation to risk factors as was done in this study, it was determined that routine inspections are generally targeted towards the types of violations recorded most commonly, which are time and temperature concerns. Focused inspections done to investigate an illness or complaint are understandably biased towards the agent suspected to be causing the issue. A better strategy would be to focus routine inspections on the real causes of illness attributable to the top reported agents.

Clearly, it is important to be aware of the types of observed violations and consider these within the context they are recorded. Announced inspections were found to be correlated to reduced violations related to cross-contamination (81), but during typically busier breakfast and lunch serving times, the observation of indirect cross contamination violations increased (26) presumably due to

employees feeling rushed and taking shortcuts. Standardization of inspections at a location to alternate between meal rushes and less busy times might provide a more complete picture of the overall food safety status of an establishment. The Food Code has suggested frequencies of inspection for various categories of restaurants based on the types of risks they may present; as an example, it is suggested that full serve restaurants be inspected three times per year (34).

Once the type of collected data is standardized, generating actionable reports will be enabled. However, there must also be consistency in collecting and assessing the data in a rapid and efficient manner. The use of a national database into which inspection reports from all jurisdictions are inputted could serve this function well. This would allow for comparison of data from different parts of the country, permit verification of standardization and lead to the development of properly aimed preventive controls by owner/operators. It could also be used by risk assessors and regulators to ensure that resources and regulatory efforts are focused in areas where public health will be impacted the most.

Inspections are just a part of the comprehensive food safety program of hazard identification and implementation of effective preventive controls. The recorded data may serve to verify the existence of such programs and can be used as an overall indicator of conditions in an establishment which may directly relate to the potential for foodborne illness or may affect when an illness is more likely to occur. They can help identify areas of focus for overall food safety

improvement (80) as long as they are used as a tool to get at the root cause of the issue and provide a coaching opportunity. However, since inspections are done just periodically, the most important activities to improving food safety rely on identification of the hazards most likely to occur and thorough implementation of the appropriate validated preventive controls targeted against these hazards.

In conclusion, the following are overall recommendations for improving the current restaurant inspection process in the United States to become more efficient and public health focused:

1. Adopt unified set of foodborne illness agent-based criteria against which all establishments would be monitored.
2. Use consistent inspection techniques & standard language to score and describe violations.
3. Ensure that inspections are done at a frequency consistent with the risks presented so that a more comprehensive review can be done
4. Make data readily available to stakeholders via a national database.
5. Use data from inspections to support implementation of active managerial control at restaurants.
6. Track progress over time to verify progress and ensure that food safety programs are maintained, re-assessing where indicated.
7. Ensure that valid preventive controls identified against the hazards of concern are fully implemented keeping in mind that these may extend outside of the restaurant environment.

In conclusion, highlighted here is the need for a more consistent, nationwide approach to restaurant inspections than exists currently and the suggestion of several approaches to improve the use of inspection data to reduce foodborne illness rates.

References

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Appendices

Appendix 1: Form 3-A from the US Food Code

Food Establishment Inspection Report							Page ____ of ____
As Governed by State Code Section XXX.XXX			No. of Risk Factor/Intervention Violations		Date		
Do Good County			No. of Repeat Risk Factor/Intervention Violations		Time In		
12344 Any Street, Our Town, State 11111			Score (optional)		Time Out		
Establishment		Address	City/State		Zip Code	Telephone	
License/Permit #		Permit Holder	Purpose of Inspection		Est. Type	Risk Category	
FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS							
Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item Mark "X" in appropriate box for COS and/or R							
IN=in compliance OUT=not in compliance N/O=not observed N/A=not applicable			COS=corrected on-site during inspection R=repeat violation				
Compliance Status			Compliance Status				
Supervision			Potentially Hazardous Food/Time/Temperature				
1	IN OUT	Person in charge present, demonstrates knowledge, and performs duties	16	IN OUT N/A N/O	Proper cooking time & temperatures		
Employee Health			17	IN OUT N/A N/O	Proper reheating procedures for hot holding		
2	IN OUT	Management, food employee and conditional employee; knowledge, responsibilities and reporting	18	IN OUT N/A N/O	Proper cooling time & temperatures		
3	IN OUT	Proper use of restriction and exclusion	19	IN OUT N/A N/O	Proper hot holding temperatures		
Good Hygienic Practices			20	IN OUT N/A	Proper cold holding temperatures		
4	IN OUT	N/O Proper eating, tasting, drinking, or tobacco use	21	IN OUT N/A N/O	Proper date marking & disposition		
5	IN OUT	N/O No discharge from eyes, nose, and mouth	22	IN OUT N/A N/O	Time as a public health control: procedures & record		
Preventing Contamination by Hands			Consumer Advisory				
6	IN OUT	N/O Hands clean & properly washed	23	IN OUT N/A	Consumer advisory provided for raw or undercooked foods		
7	IN OUT N/A N/O	No bare hand contact with RTE food or a pre-approved alternative procedure properly allowed	Highly Susceptible Populations				
8	IN OUT	Adequate handwashing sinks properly supplied and accessible	24	IN OUT N/A	Pasteurized foods used; prohibited foods not offered		
Approved Source			Chemical				
9	IN OUT	Food obtained from approved source	25	IN OUT N/A	Food additives: approved & properly used		
10	IN OUT N/A N/O	Food received at proper temperature	26	IN OUT	Toxic substances properly identified, stored, & used		
11	IN OUT	Food in good condition, safe, & unadulterated	Conformance with Approved Procedures				
12	IN OUT N/A N/O	Required records available: shellstock tags, parasite destruction	27	IN OUT N/A	Compliance with variance, specialized process, & HACCP plan		
Protection from Contamination			Risk factors are improper practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public Health Interventions are control measures to prevent foodborne illness or injury.				
13	IN OUT N/A	Food separated & protected					
14	IN OUT N/A	Food-contact surfaces: cleaned & sanitized					
15	IN OUT	Proper disposition of returned, previously served, reconditioned, & unsafe food					
GOOD RETAIL PRACTICES							
Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.							
Mark "X" in box if numbered item is not in compliance			Mark "X" in appropriate box for COS and/or R COS=corrected on-site during inspection R=repeat violation				
Safe Food and Water			Proper Use of Utensils				
28		Pasteurized eggs used where required	41		In-use utensils: properly stored		
29		Water & ice from approved source	42		Utensils, equipment & linens: properly stored, dried, & handled		
30		Variance obtained for specialized processing methods	43		Single-use/single-service articles: properly stored & used		
Food Temperature Control			44		Gloves used properly		
31		Proper cooling methods used; adequate equipment for temperature control	Utensils, Equipment and Vending				
32		Plant food properly cooked for hot holding	45		Food & non-food contact surfaces cleanable, properly designed, constructed, & used		
33		Approved thawing methods used	46		Warewashing facilities: installed, maintained, & used; test strips		
34		Thermometers provided & accurate	47		Non-food contact surfaces clean		
Food Identification			Physical Facilities				
35		Food properly labeled; original container	48		Hot & cold water available; adequate pressure		
Prevention of Food Contamination			49		Plumbing installed; proper backflow devices		
36		Insects, rodents, & animals not present	50		Sewage & waste water properly disposed		
37		Contamination prevented during food preparation, storage & display	51		Toilet facilities: properly constructed, supplied, & cleaned		
38		Personal cleanliness	52		Garbage & refuse properly disposed; facilities maintained		
39		Wiping cloths: properly used & stored	53		Physical facilities installed, maintained, & clean		
40		Washing fruits & vegetables	54		Adequate ventilation & lighting; designated areas used		
Person in Charge (Signature)			Date:				
Inspector (Signature)			Follow-up: YES NO (Circle one) Follow-up Date:				