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Risk Factors for Foodborne Illness Outbreaks in Retail Food Establishments

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Abstract

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MPH, University of New England, 2015

BS, Rhode Island College, 2012

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Despite policies and interventions over the last two decades, foodborne illness remains a significant public health concern. According to the CDC's Foodborne Disease Outbreak Surveillance System, 60% of reported foodborne illness outbreaks involved food that was prepared at a restaurant. Reducing foodborne illness outbreaks that occur at restaurants would have a significant impact on the overall number of foodborne illnesses that occur each year. The purpose of this study was to quantitatively analyze the differences in risk factors in food establishments that have had a foodborne illness outbreak compared to food establishments that have not. This study used Reckwitz's theory of practice as well the framework of the epidemiology triangle to better understand the differences in foodborne illness risk factors. The two research questions for this study were (a) what is the relationship between a food establishment's food inspection and complaint history and the occurrence of a foodborne illness outbreaks at a licensed food establishment, and (b) what is the relationship between a food establishment's characteristics and the occurrence of a foodborne illness outbreak in a food establishment? Secondary data were used to conduct a case-control study on licensed food establishments in Rhode Island. Seventy-four percent of establishments that had an outbreak were full-service restaurants, and 79% of the establishments used advanced preparation procedures. Binominal logistic regression determined that the number of routine inspections and the number of complaints were statistically associated with the occurrence of an outbreak. The results from this study can be used to implement hazard surveillance to prevent foodborne illness outbreaks in restaurants and create positive social change.

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Chapter 1: Introduction to the Study

The Centers for Disease Control and Prevention (CDC) estimates that 48 million individuals are impacted by foodborne illness each year, making it a significant public health concern (CDC, 2013). Although foodborne illness can result from poor food handling and preparation practices at home or at a restaurant, recent studies have found that the majority of foodborne illness occur from food consumed in a restaurant setting (Angelo et al., 2017). The U.S Food and Drug Administration (FDA) provides regulations in the Food Code, which state and local health departments often use as the standards to inspect food establishments. The frequency of inspections varies by jurisdiction but many states and/or local health departments conduct at least an annual routine inspection of full-service establishments, with the FDA suggesting it should be done quarterly (FDA Retail team, 2018). Despite these regulations being enforced since the early 1990s, limited progress has been made to reduce foodborne illness (CDC, 2016).

The amount of money Americans spend on food that is consumed outside of the home is increasing each year (Saksena et al., 2018). In fact, in 2010 the United States Department of Agriculture (USDA) reported that for the first time the amount of money that Americans spent on food consumed outside of the house was greater than what was spent on food consumed at home (Saksena et al., 2018). Dining out has become increasingly more popular in the last decade, meaning that now more than ever, it is imperative to ensure that food being prepared at a food establishment is safe for consumption. The majority of foodborne illness outbreaks occur in a restaurant setting, putting many Americans at risk. Conducting a study to prevent foodborne illness outbreaks from occurring in restaurants would have a significant impact on the reduction of foodborne illnesses in the United States.

Historically, data has been collected during foodborne illness outbreak investigations and entered into surveillance systems, such as the Foodborne Disease Outbreak Surveillance System (FDOSS) and the National Environmental Assessment Reporting System (NEARS), to help identify contributing factors that led to the outbreak (Angelo et al., 2017). According to a recent study, only 50% of contributing factors are identified during an investigation, suggesting that the cause of the outbreak is unknown in half of outbreaks (Lipscei, 2019). This data is often summarized to describe characteristics of food establishments that have had a foodborne outbreak but has yet to be compared to data collected from food establishments that have not had outbreaks. This study will use secondary data from inspection reports of routine inspections of licensed food establishments in Rhode Island. Data from establishments that have had a foodborne illness outbreak will be compared to establishments that have not had an outbreak.

Identifying differences in restaurant characteristics and inspection history could help identify high risk variables that put a food establishment at a higher risk for having a foodborne illness outbreak. The results of this study could be used as a predictive model to help state and local health departments identify early warning signs that an establishment may be at risk for an outbreak and should be inspected more frequently. The potential impact of this study is to better identify high-risk establishments that may need a routine inspection to prevent a foodborne illness outbreak from occurring.

Preventing foodborne illness outbreaks from occurring in restaurants would have a significant impact on reducing foodborne illness and thus, create positive social change and improve health outcomes in the population.

This chapter will review background information on foodborne illness outbreaks, the top risk factors associated with foodborne illness, and the importance of putting food safety policies and regulations into place. Furthermore, it will clearly identify the current problem surrounding foodborne illness outbreaks and the purpose of this study. Chapter 1 will introduce the research questions, as well as the nature of the study and the theoretical and conceptual foundation that was used to design this study. Common food safety terms that are used throughout this dissertation will be defined in this chapter. This chapter concludes with an emphasis on the significance of this study and its potential to provide evidence-based data to support policy and regulation changes. These changes could lead to a reduction in illness that would not only improve population health but creates positive social change.

Background

In 2013, CDC declared foodborne illness a winnable battle, meaning there are several known effective control strategies to mitigate the hazard, yet little progress has been made to reduce illness (Angelo et al., 2017; CDC, 2013; CDC, 2016). Roughly 60% of all foodborne illness outbreaks occur in a restaurant setting (Angelo et al., 2017). Several studies have been done that have identified restaurant characteristics such as restaurant type, restaurant size, and the complexity of the restaurant type to all be associated with foodborne illness (Angelo et al., 2017; Dewey-Mattia et al., 2018).

Inspection history of a restaurant and having a history of foodborne illness complaints have also been identified as possible indicators of foodborne illness (Brown et al., 2013; Cruz et al., 2001; FDA Retail Team, 2018; Irwin et al., 1989; Jemaneh et al., 2018; Jones et al., 2004).

In addition to restaurant characteristics, several food safety practices have also been identified as the cause of foodborne illness. The FDA published the food code in 1993 and updates it every 4 years (FDA, 2019). The FDA Food Code provides states and local jurisdictions with scientifically researched technical and legal guidelines for regulating the retail food industry (FDA, 2019). The inspection form, that corresponds to this food code, identifies several potential critical violations, which have been directly linked to the cause of foodborne illness (FDA Retail Team, 2018; Irwin et al., 1989). The FDA and CDC have narrowed these violations down even further, categorizing these critical violations into the five major risk factors associated with foodborne illness: holding foods at improper temperatures, cooking foods to the wrong temperature, using contaminated utensils and equipment, failing to follow personal hygiene rules, and purchasing food from unsafe suppliers or sources (FDA Retail Food Team, 2018; State Food Safety, 2020). To ensure that proper food safety practices are being followed, the FDA Food Code requires food establishments to have a Certified Kitchen Manager (FDA Retail Team, 2018). This manager is someone who has received training in food safety and completed and passed a national test. Several studies have found that having a Certified Manager on site reduces the chance of having a foodborne illness outbreak (FDA Retail Team, 2018).

Several descriptive studies have been done to identify restaurant characteristics and food safety practices associated with foodborne illness outbreaks using data collected from surveillance systems, such as FDOSS (Angelo et al., 2017; Dewey-Mattia et al., 2018). However, very few analytical studies have been done to compare these risk factors to food establishments that have not had a foodborne illness outbreak. Understanding the differences between restaurants that have had a foodborne illness outbreak and how they differ from restaurants that have not had a foodborne illness outbreak will help close the gap and identify more effective ways to reduce illness caused by foodborne illness outbreaks.

The results from this study can be used to implement policies and regulations that improve food safety, thus preventing foodborne illness outbreaks in restaurants. According to data collected from FDOSS, 60% of foodborne illness outbreaks were caused by food consumed from a restaurant (Angelo et al., 2017). Reducing foodborne illness outbreaks in restaurants could significantly reduce overall rates of foodborne illness and would create positive social change in the community.

Problem Statement

The CDC estimates that each year 48 million individuals will become ill from foodborne illness (CDC, 2016; Scallan et al., 2011). As a result of foodborne illness, 128,000 individuals end up hospitalized and 3,000 die each year (Scallan et al., 2011). In addition to the burden on health outcomes, the economic burden associated with the top 15 pathogens that cause foodborne illness is estimated to be over $15 billion annually (Hoffman, 2015). From 2009 to 2015, the CDC's FDOSS had almost 6,000 foodborne illness outbreaks reported, and it is estimated that roughly 60% of those involved food prepared in a restaurant (Angelo et al., 2017; Dewey-Mattia et al., 2018).

Foodborne illness outbreaks are often a result of poor practices within a food establishment and are a significant public health burden. An analysis of environmental health data collected at establishments that had a foodborne illness outbreak revealed that ill food workers and poor hand hygiene were risk factors for foodborne illness outbreaks (Lipisci et al., 2019). Additionally, improper temperature control and cross contamination have historically been identified as risk factors (FDA, 2000). It is estimated that Americans visit restaurants an average of five times per week (NRA, 2015). This suggests that many Americans may be at risk for foodborne illness. Recent studies have analyzed and evaluated what is being captured in surveillance systems for foodborne illness outbreaks, such as the NEARS and FDOSS, but there is limited recent literature on the comparison of risk factors and environmental findings found in outbreak establishments compared to non-outbreak establishments (Angelo et al.,2017; Dewey et al., 2018; Lipisci et al., 2019). The previous studies that examined routine inspections of outbreak establishments compared to non-outbreak establishments found mixed results and these studies used data that was collected over 20 years ago, prior to when the FDA streamlined their inspection process to a risk-based approach (Cruz et al., 2001; Irwin et al., 1989; Weschler, 2006). A more recent study that compared routine inspections of outbreak to non-outbreak establishments over a 1-year time period, found that some violations were more likely to be associated with a foodborne illness outbreak and suggested that further research should be conducted in this area (Petran et al., 2012). This study focused on Rhode Island because environmental findings from routine inspection reports from food establishments in Rhode Island that have had a foodborne illness outbreak have not been compared to routine inspection reports from non-outbreak food establishments. In addition, from 2009-2017, the average number of outbreaks per year in Rhode Island that was reported to NORS was 8.6, with a rate of 0.81 outbreaks per 100,000 people and a hospitalization rate of 3.19 persons hospitalized per 100,000 people (CDC, 2018). This is significantly higher than the national rate of the foodborne outbreaks that were reported to NORS, which was 0.26 outbreaks per 100,000 individuals and a hospitalization rate of 0.27 persons hospitalized per 100,000 people (CDC, 2018). Therefore, it is necessary to conduct a statewide comparison over a 10 year period of time to determine the differences between risk factors that are occurring in establishments that have had a foodborne illness outbreak to establishments that have not had a foodborne illness outbreak to clarify which risk factors are associated with an outbreak and identify early indicators that could be used by public health professionals to prevent similar foodborne illness outbreaks from occurring in other establishments.

Purpose

The purpose of this study was to quantitatively analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak. Secondary data from routine inspection reports were examined to identify differences in outbreak restaurants versus non-outbreak restaurants. For this study, the dependent variable was the status of having a foodborne illness outbreak or not. To determine the relationship between a food establishment's food inspection and complaint history and the occurrence of a foodborne illness outbreaks at a licensed food establishment, the independent variables were the number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received. The covariate variables are risk category and license type. To determine the relationship between a food establishment's characteristics and the occurrence of a foodborne illness outbreak in a food establishment, the independent variables are risk category, restaurant type, and restaurant size. This project is unique in that this is the first time that Rhode Island has compared data from outbreak establishments to non-outbreak establishments.

Research Questions and Hypothesis

Research Question 1(RQ1; Quantitative): What is the relationship between a food establishment's food inspection and complaint history (number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received) and the occurrence of a foodborne illness outbreaks at a licensed food establishment, controlling for risk category and restaurant size?

$H_0 1$: There is no relationship identified between a food establishment's food inspection history and the occurrence of a foodborne illness outbreak at a licensed food establishment.

H_a1: There is a relationship identified between a food establishment's food inspection history and the occurrence of a foodborne illness outbreak at a licensed food establishment.

Research Question 2 (RQ2; Quantitative): What is the relationship between a food establishment’s characteristics (risk category, restaurant type, and restaurant size) and the occurrence of a foodborne illness outbreak in a food establishment?

H_02: There is no relationship identified between a food establishment’s characteristics and the occurrence of a foodborne illness outbreak at a licensed food establishment.

H_a2: There is a relationship identified between a food establishment’s characteristics and the occurrence of a foodborne illness outbreak at a licensed food establishment.

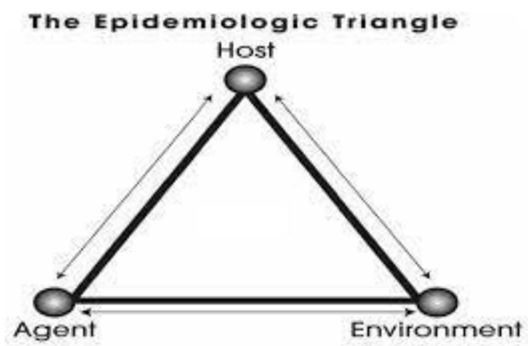
Theoretical and Conceptual Framework

The theoretical foundation includes the consumption and theory of practice from Reckwitz (2002). This theory suggests that analysis should focus on the social level as opposed to the individual level because an individual's behaviors are greatly influenced by their surroundings (Reckwitz, 2002; Warde, 2005). This implies that interventions that are implemented at the restaurant level will influence the behaviors of the food workers who work there (Jackson & Meah, 2017; Warde, 2005). This theory aligns with the idea that active managerial control in a restaurant and food safety plans are the gold standard in food safety (FDA National Retail Team, 2018; Warde, 2014). Similar to the consumption and theory of practice, the better procedures and practices that a restaurant sets as their standard, the more likely that food workers are to follow these procedures.

Epidemiology is an essential discipline of public health and as such, was included in the framework of this study (Friis, 2014). More specifically, it was used to understand how foodborne illness outbreaks occur (Merrill, 2017). This model suggests that to determine what the causative agent is in an outbreak, it is critical to understand the agent, host, and environment in which the outbreak occurred (Merrill, 2017).

Figure 1

Epidemiological Triangle



Note. Adapted from Understanding the Epidemiologic Triangle Through Infectious Disease, by CDC, n.d.

https://www.cdc.gov/healthyschools/bam/teachers/documents/epi_1_triangle.pdf

To help translate the findings of this study into public health policy, the 2005 National Institute for Health and Clinical Excellence's (NICE) emerging conceptual framework for public health was incorporated into the framework of this study. Applying this framework to this study suggests that population patterns of disease have a causal mechanism that can be used to examine contributing factors of foodborne illness outbreaks at restaurants (Kelley et al., 2009). Additionally, Kelly (2009) suggests that there is an emphasis on fundamental social causes and provides insight into which public health policy or interventions that are needed to eliminate social inequalities.

This study investigates the relative risks identified from food safety practices among two groups: establishments that have had outbreaks compared to establishments that have not had outbreaks. To compare the relative risks, routine inspections for both groups were analyzed to assess if outbreak establishments had poorer food safety practices prior to the outbreak when compared to non-outbreak establishments. This can help provide insight into interventions or policies that can be developed to eliminate these risks in establishments, thus preventing foodborne illness outbreaks.

Nature of Study

The nature of the study is a quantitative study. Specifically, a case-control study was conducted. Quantitative methods are used to examine the relationship between variables with the goal of showing the relationship of those variables through statistics (Creswell, 2015). The first research question analyzed the relationship between an establishment's food inspection and complaint history and if an establishment had a foodborne illness outbreak. The dependent variable is the status of having a foodborne illness outbreak or not. The independent variables are the number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received. The covariate variables are risk category and restaurant size. The second research question is to determine the relationship between a food establishment's characteristics and the occurrence of a foodborne illness outbreak in a food establishment. The dependent variable is the status of having a foodborne illness outbreak or not and independent variables are risk category, restaurant type, and restaurant size.

The study population is licensed food establishments in Rhode Island between 2010-2019. There were two groups: (a) licensed food establishments that have had a foodborne illness outbreak between 2010-2019 and (b) the control group that consists of randomly selected licensed food establishments that had no outbreaks reported between 2010-2019. There are three controls to match each establishment that had an outbreak. For this case-control study, secondary data was collected from inspection reports, outbreak records, and complaints from the Digital Health Department (DHD) inspection software at the Rhode Island Department of Health. Data was kept in excel spreadsheets and uploaded to SPSS for multiple logistic regression. Chi-square analysis was conducted to determine if there is an association between the dependent and categorical independent variables. Simple logistic regression was conducted to investigate the individual continuous variables and the dependent variables.

Definitions

Certified Food Safety Manager: Food safety managers ensure that proper procedures are followed to prevent food-related illness in businesses that serve food but only trained, certified people may use the title or act as "Certified Food Safety Managers."

Critical violations: Critical violations are identified on the inspection report as violation numbers 1-29. Critical violations have directly been linked to illness and pose a greater threat than noncritical violations.

Environmental Health Food Specialists (EHFS): EHFS inspect, investigate, and evaluate for public health hazards, environmental conditions, and compliance with rules and regulations and federal standards at Rhode Island food service establishments (Rhode Island Department of State, 2018).

Food: a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum (FDA Food Code, 2017).

Food employee: an individual working with unpackaged food, food equipment, or utensils, or food-contact services (FDA Food Code, 2017).

Foodborne Illness: An illness caused by consuming contaminated food or drink.

Foodborne Illness Complaints: Foodborne Illness Complaints are complaints submitted by the consumer after they ate a licensed food establishment and believe they became ill as a result of consuming food at that restaurant.

Foodborne Illness outbreak: the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food (FDA Food Code, 2017).

Food service establishment: any fixed mobile restaurant, coffee shop, cafeteria, short-order café, luncheonette, grill, tea room, sandwich shop, soda fountain, tavern, bar, cocktail lounge, nightclub, roadside stand, industrial feeding establishment, cultural heritage education facility, private, public or nonprofit organization or institution routinely serving food, catering kitchen, commissary or similar place in which food or drink is prepared for sale or for service on the premise or elsewhere, and any other eating or drinking establishment or operation where food is served or provided for the public with or without charge (Rhode Island Department of State, 2018).

Frequency between inspections: The frequency between inspections is the time period that elapsed between the routine inspections.

Hazard: a biological, chemical, or physical property that may cause an unacceptable consumer health risk (FDA Food Code, 2017).

Manager certified in food safety: a person certified in Rhode Island in accordance with the requirements in R.I. Gen. Laws Chapter 21-27 and "Certification of Managers in Food Safety" (Rhode Island Department of State, 2018). This person must receive formal training and take an approved exam.

Priority item: a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard. This includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, and handwashing (FDA Food Code, 2017).

Priority foundation item: an item that requires the purposeful incorporation of specific actions, equipment, or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling (FDA Food Code, 2017).

Ready-to-eat food: A food that is in a form that is edible without additional preparation to achieve food safety (FDA Food Code, 2017).

Restaurant Size: Restaurant size will refer to the number of seats in a food establishment. Restaurant size will be determined by the License type given at the time of opening.

Restaurant Type: Restaurant type will refer to the type of food service operation that is indicated on the license application.

Risk Category: The risk category for an establishment is a categorical variable based upon the FDA categories of risk and are categorized into the following groups: prepackaged non potentially hazardous foods (NPHF) cook/serve, Advanced Prep, smoking/curing/reduced oxygen packaging, high risk population, and other (temp vendors, mobile vendors, vending machines). The risk category is determined by the inspector based upon the food preparation practices that the establishment is conducting.

Routine inspections: Routine inspections are unannounced to the restaurant. An inspector will conduct a complete inspection covering all items in the regulations for compliance.

Sanitization: The application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance (FDA Food Code, 2017).

Time/Temperature Control for Safety Food (formerly "potentially hazardous food" (PHF): a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation (FDA Food Code, 2017).

Assumptions

This study was designed on the assumption that several criteria were true. First, I assumed that the violations identified during a routine inspection represent the general practices of that food establishment. Although there may be an incident where a violation occurs as a result of a single occurrence, it is assumed that a food establishment with several violations is indicative of poor food safety practices. There is also an assumption that outbreaks at food establishments are often caused by poor food safety practices of the food workers, which are often influenced by their environment (e.g. establishment policies and procedures). If an establishment does not encourage proper food safety practices, or provide an environment in which proper food safety practices can be followed (e.g. requiring food workers to work while ill), then food workers are more likely to implement poor food safety practices that can lead to foodborne illness.

It is also assumed that certified food safety kitchen managers are implementing the knowledge they learn in their food safety training while they are working in an establishment. Certified food safety kitchen managers must complete a food safety course and examination to obtain that title. It is assumed that they take this knowledge back to the establishment that they work in to ensure that the food workers implement proper food safety practices. Additionally, it is assumed that the number of seats in a restaurant have a direct relationship with the number of meals served in a restaurant daily. More seats in a restaurant increase the capacity, and thus increase the number of meals prepared. An increase in the number of meals prepared presents more opportunity for food safety errors to occur. The last assumption is that the inspection data and records obtained from the Rhode Island Department of Health are accurate and complete. These assumptions are critical to the design of this study and provide a foundation in which this study is built upon.

Scope and Delineations

The scope and delineations for this study include licensed outbreak establishments and non-outbreak establishments in Rhode Island. These boundaries and scope are due to the available dataset in the Digital Health Department Database provided by the Rhode Island Department of Health. Additionally, because over 60% of foodborne outbreaks have occurred in a retail food establishment, this study will be limited to retail licensed food establishments (Dewey et al., 2016). A sample of 210 licensed establishments for non-outbreak establishments will be randomly selected from the total population of licensed food establishments in the Digital Health Department. A 10-year analysis was conducted due to the relatively low number of outbreaks per year in Rhode Island. This study uses a statistical generalization model and probability sampling to ensure that the results of the study can be used to make inferences on risk factors that may lead to a foodborne illness outbreak at a Rhode Island licensed establishment (Polit & Beck, 2010). A sample of 280 randomly selected licensed food establishments in Rhode Island would largely represent the entire population of licensed food establishments.

Limitations

One limitation for this study is that not all outbreaks are identified and investigated, this study only includes outbreaks identified and it is unknown to what extent this study represents all outbreaks. The foodborne outbreaks that are identified and investigated may not be representative of all foodborne outbreaks. In Rhode Island there is a standardization process that all inspectors must go through to ensure consistency. Despite the standardization process, some variability may still occur. Variations may occur due to mistakes or human error. Additionally, just because a foodborne risk factor might not be observed during the inspection does not necessarily mean it is not there. The time of day that the inspections are conducted may also present differences in the findings (e.g. if inspections are done at a busier time there might be more violations observed). Lastly, this study is based on outbreaks in Rhode Island so it may be generalizable to other populations; however, Rhode Island adopted the 2013 FDA Food Code and the regulations are consistent with what many other jurisdictions are using. Despite their limitations, inspections are a useful tool to determine the conditions in the restaurant and appropriate control measures.

Significance

A statewide comparison study analyzing the difference in risk factors between outbreak establishments and non-outbreak establishments helps provide additional insight into what causes foodborne illness outbreaks. This data creates a predictive model that could be used for hazard surveillance. Creating a predictive model allows health departments to identify establishments that have characteristics and risk factors that are more likely to result in foodborne illness outbreak. The health department could use this information for early detection of high-risk establishments to send inspectors to an establishment to ensure interventions are put in place and violations are corrected. Correcting violations in these establishments would reduce the risk factors that lead to foodborne illness outbreaks, likely leading to a reduction in illness. This would directly impact any individual who dines out at restaurants. Reducing illness not only improves population health but creates positive social change.

Summary

Despite foodborne illness being declared a winnable battle, little progress has been made to reduce illness (Angelo et al., 2017; CDC, 2013; CDC, 2016). Majority of foodborne illnesses have occurred after consuming food in a restaurant setting (Angelo et al., 2017). The FDA has provided guidance on food safety regulations since 1993 and updates these regulations every 4 years (FDA, 2019). Although several descriptive studies have suggested an association between certain key characteristics and foodborne illness, very few analytical studies have been conducted in the last 20 years to determine a definitive association (Angelo et al., 2017; Dewey-Mattia et al., 2018).

Each year, the CDC estimates that there are 48 million people who experience foodborne illness each year with an economic burden of $15 billion annually (CDC, 2013; Hoffman, 2015). Previous descriptive studies conducted using data collected from food establishments that have had a foodborne illness outbreak identified contributing factors such as ill workers, poor personal hygiene, inadequate temperature control, and cross-contamination (FDA, 2000; Lipisci et al., 2019). A study conducted by Petran et al.

in 2012 identified that some violations were more likely to be associated with a foodborne illness outbreak compared to other violations and that further research should be done in this area. The purpose of my study was to quantitatively analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak. I focused on Rhode Island because environmental findings from routine inspection reports from food establishments in Rhode Island that have had a foodborne illness outbreak have not been compared to routine inspection reports from non-outbreak food establishments.

The research questions of this study sought to assess a food establishment’s inspection history to determine if there is an association with a food establishments inspection history and if an establishment is more likely to have a foodborne illness. The inspection history included their history of complaints, the number of critical violations on their routine inspections, the status of having a certified manager, and frequency between inspections. Additionally, key characteristics, such as restaurant type, risk category, number of seats in the facility, and restaurant type were included in the analysis. The theoretical foundation for this study included the consumption and theory of practice from Reckwitz and the epidemiological triangle (Friis, 2014; Reckwitz, 2002). To help translate the findings of this study into public health policy, the 2005 NICE’s emerging conceptual framework of the epidemiological triangle for public health was incorporated into the framework of this study (Kelley et al., 2009).

Thiscase-control quantitative study included all licensed food establishments in Rhode Island from 2010-2019. The main assumptions of this study were that food safety practices within a restaurant are important in controlling foodborne illness and that food safety regulations can prevent it. One major limitation to this study was that not all foodborne illness outbreaks are identified, and thus, the ones that are may not fully represent all foodborne illness outbreaks. However, the significance of this study outweighed the limitations. The results of this study can be used to develop a predictive model for preventing foodborne illness outbreaks. Preventing foodborne illness outbreaks from occurring in a restaurant setting would have a significant impact on reducing overall foodborne illness rates, improving population health.

Chapter 2 will provide justification through a thorough literature review for examining a food establishment's inspection history and characteristics. It will highlight key studies and findings that support why each specific variable was chosen for this study. Moreover, Chapter 2 will further explore the theoretical and conceptual framework and the rationale for why these theories were used for this study design and research question.

Chapter 2: Literature Review

Introduction

Despite advancements in technology and multiple food safety interventions, foodborne illness remains a significant public health concern, causing an estimated 48 million illnesses each year. Licensed food establishments are a major source of these illnesses, causing roughly 60% of the reported foodborne illness outbreaks (Angelo et al., 2017; Dewey-Mattia et al., 2018). Several descriptive studies have been conducted to describe restaurant characteristics found at food establishments that have had a foodborne illness outbreak, yet few analytical studies have been done in recent years to compare these characteristics to non-outbreak food establishments. The purpose of this study is to analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak.

Poor food safety practices within a food establishment can contribute to a foodborne illness outbreak. Several risk factors have been identified, such as ill food workers and poor personal hygiene, as the cause of a foodborne illness outbreak (Lipisci et al., 2019). Surveillance systems that capture environmental health data collected during foodborne illness outbreak investigations have provided insight into why foodborne illness outbreaks continue to be a public health concern (Angelo et al.,2017; Dewey et al., 2018; Lipisci et al., 2019). This data can be used to identify characteristics that should be further explored using analytical studies to determine an association.

Recent studies have found that the majority of foodborne illness outbreaks occurred in full-service restaurants, where consumers dine at the restaurant (Angelo et al., 2017; Dewey-Mattia et al., 2018). Furthermore, evidence suggests that larger restaurants with a greater number of seats are more likely to have a foodborne illness outbreak. Additionally, these studies identified that foodborne illness outbreaks were largely occurring in restaurants that use advanced preparation practices (Angelo et al., 2016; Lipcsei et al., 2019). Analytical studies conducted in the late 1980s and 1990s suggest that a food establishment inspection history may identify risk factors that put the establishment at a higher risk for having a foodborne illness outbreak. Other variables that have often been associated with an increase in risk factors during inspections include not having a certified manager on site, a low frequency of inspections, and having a history of multiple foodborne illness complaints. This information should be further explored using binomial logistic regression to identify food establishments that are more likely to have a foodborne illness outbreak and putting primary prevention intervention strategies in place to ensure a foodborne illness outbreak does not occur.

This chapter will provide information on the literature search strategy, including search terms and databases used. It will also include a description of the theoretical foundation and conceptual framework used to design this study and identify variables that could be used to help predict foodborne illness outbreaks. Lastly, it will provide a review of key variables and concepts from previous studies that will be included in a predictive model for foodborne illness outbreaks.

Literature Search Strategy

The literature review search strategy used for this review was to explore both descriptive and analytical research studies conducted on food establishment characteristics or risk factors. This review included studies conducted between 1989-2019. The databases used to search for these studies included: Proquest Central, ProQuest Dissertation and Thesis Global, Proquest Science Journals, Science Direct, Proquest Health and Medical Collection, MEDLINE with full text, and ProQuest Nursing & Allied Health. Several different search terms were used to ensure sensitivity and specificity of the literature review. These search terms include: *foodborne illness risk factors, foodborne illness* and *food establishments, foodborne illness* and *restaurants, foodborne outbreaks* and *descriptive, foodborne outbreaks* and *analytical, National Environmental Assessment Reporting System, FDOSS, foodborne illness* and *inspection history, foodborne illness* and *Certified Manager, Certified food safety manager, foodborne illness complaint, food establishment* and *risk factors, foodborne illness* and *inspection frequency,* and *Environmental Health Specialist Network (EHS-Net).*

Seminal work reviewed included research studies conducted by the CDC's EHS-Net and the pioneer study conducted by Irwin et al. (1989). EHS-net is a collaborative group of individuals from different state and local health departments that research food safety risk factors to prevent foodborne illness. The study conducted by Irwin et al. (1989) was the first study that compared outbreak establishments to non-outbreak establishments and has paved the way for future research studies upon which to build. Several other research studies were reviewed, both descriptive and analytical. Outside of pioneer studies, most of the studies reviewed were peer-reviewed studies from the last 5 years. This demonstrates that the problem discussed is current and that a primary prevention intervention is needed.

One limitation with this literature search strategy was the lack of analytical studies found surrounding key variables, such as risk category and restaurant type. For these variables, more emphasis was placed on the synthesis of several recent descriptive studies. Furthermore, these descriptive studies indicated that further analytical analysis should be conducted, supporting the decision to include them in this review. Despite limited analytical studies, a thorough search was conducted to find all the available literature.

Theoretical Foundation

The theoretical foundation of this study is influenced by the works of Reckwitz (2002) and Warde (2005) that discuss consumption and the theory of practice. This theory stems from the beliefs that social practices or structures should be the focus of analysis as opposed to the individual (Jackson & Meah, 2017; Warde, 2005). The assumption is that the individuals are the carriers of practice and are greatly influenced by the social structures (Jackson & Meah, 2017; Warde, 2005). Thus, any interventions should be applied at the social practices or structure level and that the improvements of those practices will trickle down to the individual level.

This theory can be applied to the concept of food safety practices of restaurants and food workers. The restaurant, acting as the social structure, and the food worker representing the individual level. This theory aligns with the idea that active managerial control in a restaurant and food safety plans are the gold standard in food safety (FDA National Retail Team, 2018; Warde, 2014). Similar to the consumption and theory of practice, the better procedures and practices that a restaurant sets as their standard, the more likely that food workers are to follow these procedures. Food workers that are held accountable for their individual practices in a restaurant with active managerial control are more likely to follow the proper food safety practices (FDA National Retail Team, 2018; Warde, 2005; Warde, 2014).

Byrd-Bredbenner et. al. (2013) used this theory to examine the food safety practices of domestic kitchens, finding that the individuals in these households were greatly influenced by social factors as opposed to their individual behavior. This qualitative study found a common theme of individuals identifying that they do things because "it's just how things are done" suggesting that their cultural and social influences greatly determine their behavior (Byrd-Bredbenner et. al., 2013). Additionally, Jackson and Meah (2017) reviewed other studies that have used this theory, identifying that many individuals change their behavior based upon the advice from their social setting. These findings suggest that if a restaurant has a positive food safety culture and encourages their food workers to follow regulations, then food workers are more likely to follow those practices (Byrd-Bredbenner et. al., 2013; Jackson & Meah, 2017). Similarly, if an establishment has a poor food safety culture and is often found not in compliance with regulations, food workers are more likely to follow poor food safety practices. Therefore, identification of high-risk establishments with poor food safety history.is essential. Early identification of these high-risk establishments allows public health professionals to implement the control measures needed to prevent a foodborne illness outbreak.

Conceptual Framework

Modern day epidemiology and the investigation into infectious disease in a community dates back to the 19th Century with the John Snow investigation into the London Cholera outbreaks (Friis, 2014). Since this time, the field of epidemiology has evolved and is now known as an interdisciplinary field that incorporates several different fields of study including but not limited to microbiology, biostatistics, social and behavioral determinants of health (Friis, 2014). Epidemiology is an essential discipline of public health, and as such, this study will incorporate key elements from the framework of epidemiological and public health principles (Friis, 2014).

The basic epidemiological triangle discusses the relationship between the host, agent and the environment (Gulis & Fujino, 2015). This triangle is used to describe how an individual became ill (Gulis & Fujino, 2015). The epidemiological triangle can be used to understand the cause of foodborne illness outbreaks. (Friis, 2014; Gulis & Fujino, 2015). Harris (2015) used this conceptual framework in a study that examined risk factors in Restaurants in Georgia. This study aimed to identify risk factors to break the link in transmission from agent to host in a restaurant (Harris, 2015). Thus, disrupting the link of transmission can prevent foodborne illness outbreaks from occurring in restaurants (Harris, 2015).

Another study used the epidemiological triangle to reduce the risk of *Salmonella* in eggs (Wright et al., 2016). This study reviewed several *Salmonella* outbreaks with eggs as the source of the outbreak to determine the linkage between *Salmonella* and eggs (Wright et al., 2016). These studies demonstrate the importance of understanding more about the relationship between the host, agent, and environment to determine where interventions are needed to prevent further illness. This study will investigate the relationship between contaminated food and foodborne pathogens (agent), licensed food establishments (the environment) and how this relationship is causing illness among consumers (the hosts). The results from this study can influence intervention methods to prevent illness by breaking the chain of transmission and help identify high-risk establishments that should be inspected at a greater frequency.

In 2005, the National Institute for Health and Clinical Excellence (NICE) established a conceptual framework for public health guidance (Kelly et al., 2009). This framework is based upon the vectors of public health: the population vector, the environmental vector, the organizational vector, and the social vector (Kelly et al., 2009). Kelly et al., (2009) then describe how these vectors are influenced by human behavior. The NICE conceptual framework is based on the assumption that a group patterning of diseases has a common cause (Kelly et al., 2009). These vectors of public health help facilitate a causal approach (Kelly et al., 2009). Additionally, it is often used to determine if there is rationale to implement new regulations or policies (Kelly et al., 2009). For this study, the population and environmental vectors are of particular interest.

The population vector includes elements that impact an entire population and often include state and local government (Kelly et al., 2009). The environmental vector includes microbiological agents and the systems of clean food and water (Kelly et al., 2009). The environmental vector identifies that a causal pathway from agent to host is used as a basic tool for understanding the interaction of elements. For this study, the agent to host relationship is important but will also include how the environment impacts this relationship. Thus, concepts from the basic epidemiological triangle will also be incorporated (Gulis & Fujino, 2015). Claxton et al., (2002) used the NICE framework to determine if the research supported the rationale to implement new regulations. This framework can be applied to help provide rationale to make regulation or policy changes to improve food safety practices and prevent foodborne illness. Using this theoretical and conceptual framework, several variables will be analyzed to determine if there is an association between those variables and a food establishment having a foodborne illness outbreak.

Literature Review Related to Key Variables and Concepts

Restaurant Type, Size, and Menu Served

From 1998-2013, there were 9,788 restaurant-associated outbreaks reported to the Centers for Disease Control and Prevention's (CDC's) Foodborne Disease Outbreak Surveillance System (FDOSS; Angelo et al., 2017). A descriptive study conducted by Angelo et al. (2017) found that 79% of these establishments were establishments that had an area for customers to dine in the restaurant, otherwise known as sit-down dining establishments. Similarly, another study concluded that out of 5,022 outbreaks reported to FDOSS between 2009 and 2015, 61% were associated with a restaurant and 48% of those occurred in a sit-down dining establishment (Dewey-Mattia et al., 2018).

Although the recent literature on restaurant type associated with foodborne outbreaks is limited, the data suggest that compared to fast-food restaurants and caterers, a sit-down dining establishment has been associated with an increased risk in having a foodborne illness outbreak (Angelo et al., 2017; Dewey-Matia et al., 2018; Lipinksi et al., 2019). This is consistent with a case-control study conducted by the CDC Environmental Health Specialist Network (EHS-Net) that examined the differences between 22 investigations that took place at outbreak establishments and 347 investigations that took place at non-outbreak establishments among eight different EHS-Net sites across the country (Hedberg et al., 2006). Hedberg et al. (2006) compared characteristics between outbreak establishments and non-outbreak establishments using categorical univariate analyses along with calculations of odds ratios. This study found that sit-down dining restaurants were more likely to be associated with an outbreak compared to fast-food restaurants (*OR* 5.0,95% *CI*,1.4 to 21.6; Hedberg et al., 2006). Additionally, Dewey-Mattia et al. (2018) reported that between 2009-2015,48% of outbreaks that occurred in a restaurant setting occurred in a sit-down style restaurant, followed by 14% at catered events, 8% in fast-food restaurants, and 9% at buffets. However, analytical studies have been limited and more studies are needed to examine the relationship between sit-down dining establishments and foodborne illness outbreaks

Irwin et al. (1989) examined factors associated with foodborne outbreaks in restaurants and found that restaurants that had greater than 150 seats (*OR* 3.4, 95% *CI*, 1.1, 9.9) were more likely to have an outbreak compared to restaurants with less than 150 seats. Similarly, Jones et al. (2004) found that restaurants that had a seating capacity of greater than 50 seats were more likely to have an outbreak when compared to non-outbreak restaurants (*OR* 2.1, 95% *CI* 1.0, 5.0). Lipinski et al. (2019) reported that almost 75% of the outbreaks entered into the National Environmental Assessment Reporting System (NEARS) occurred at independent establishments and the most common restaurant type was American (55.9%, 232 of 415). These studies suggest that larger restaurants, restaurants that are independently owned, and specific restaurant types may be indicators of foodborne illness outbreaks and should be further examined (Irwin et al., 1989 Jones et al., 2004; Lipinkski et al., 2019).

Risk Category

Food inspection programs typically group restaurants into different risk categories. Although these vary from program to program, they typically are based upon the FDA categories (CFSAN, 2017). There are four categories that are grouped according to risk level. These risk levels are nonpotentially hazardous/pre-packaged items, require cook/serve only, or if they require advanced preparation or complex food preparation. The size of the establishment is also used as a criterion to determine these categories (CFSAN, 2017). Examples of establishments that serve pre-packaged foods would be a convenience store that only sells packaged foods, whereas a cook/serve risk type would be an establishment that might cook food, but the food is served immediately. Pre-packaged foods are foods where the establishment selling them does not do any food preparation or handling and the products are sold as is. Therefore, the temperature of these food items does not go through the danger zone of between 40 degrees F and 140 degrees F and are considered a lower risk (CFSAN, 2017; FSIS, 2019). Cook/serve risk category establishments prepare food items that only go through the danger zone once, increasing the risk of potential hazards in comparison to the establishments that serve pre-packaged foods. Complex preparation is the highest of the risk categories and the temperatures of the food items prepared at these establishments usually go through the danger zone multiple times (e.g. cooking, cooling, reheating), increasing the risk of error during the danger zone (CFSAN, 2017; FSIS, 2019). Limited analytical studies were available that examined the relationship between risk category and foodborne illness outbreaks, however descriptive studies suggest that complex food preparation restaurants are more likely to have a foodborne illness outbreak (Angelo et al., 2016; Lipcsei et al., 2019). The CDC found that 85% of the restaurant-associated outbreaks entered into NEARS served complex food items (Lipcsei et al., 2019). Similarity, Angelo et al., (2016) found that the majority of restaurants associated with outbreaks were at sit-down restaurants where food items served would be more likely to require complex preparations.

The National Food Service Management Institution (2009) defines complex food preparation as foods that require time and temperature control and are often cooled and reheated. Foods that require complex food preparation present an increased number of potential hazards that exists throughout the handling and processing of that item (e.g. cooking, cooling, reheating; Panisello et al., 2000). For these foods, monitoring and record keeping is especially important (NFSMI, 2009). Traditionally, independent full-service restaurants have had higher rates of foodborne illness outbreaks, compared to chain restaurants likely because they use more complex food preparations (Leinwand et al., 2017; Phillips et al. 2006). Chain restaurants generally have fewer violations per inspection compared to nonchain restaurants likely because their menu consists of cook/serve food items (CFSAN, 2017; Leinwand et al., 2017). Cook/serve food items require less complex processing and are considered to be lower risk food items (CFSAN, 2017; Leinwand et al., 2017).

Inspection History

Over the past several decades, there have been inconsistencies with the research conducted around the association of inspection scores with foodborne illness outbreaks. In the late 1980's Seattle-King County Department of Public Health conducted a case-control study that analyzed inspection scores of food establishments that have had a foodborne illness outbreak and compared them to active permit food establishments that did not have a foodborne illness outbreak (Irwin et al., 1989). Data was collected between January 1, 1986 and March 1987. During this time, there were 28 foodborne illness outbreaks that were cases and 56 controls were randomly selected and matched to each case on the health district and routine inspection date (Irwin et al., 1989). The study concluded that a food establishment that receives an inspection score of less than 86 had higher odds of having a foodborne illness outbreak (*OR* 5.4, 95% *CI* 1.5,24.2; Irwin et al., 1989). Additionally, they found that having violations during an inspection associated with improper food protection (*OR* 15.8,95% *CI* 2.0,124.1), improper storage and handling of equipment and utensils (*OR* 14.9, 95% *CI* 2.6,85.4), and potentially hazardous foods at unsafe temperatures (*OR* 10.1, 95% *CI* 2.2,45.7) made a restaurant more likely to have a foodborne illness outbreak (Irwin et al., 1989).

Despite these findings, two studies conducted using inspection data from the 1990s using similar methods to the study conducted by Irwin et al. (1989) found conflicting results, concluding that poor inspection scores alone were not an indicator of foodborne illness outbreaks (Buccholz et al., 2002; Cruz et al., 2001). Similar to Irwin et al. (1989) Cruz et al. (2001) conducted acase-control study using 39 cases and 50 controls, calculating odds ratios. Their results indicated that the overall inspection rating satisfactory was not associated with having a foodborne illness outbreak *(OR* 0.6. 95% *CI,* 0.2,1.7; Cruz et al., 2001). However, they did find that having a seating capacity of over 50 seats (*OR* 2.1, 95% *CI* 1.0,5.0) and having evidence of vermin on their inspection report (*OR* 3.3, 95% *CI* 1.1, 13.1) were more likely to be associated with having a foodborne illness outbreak.

Jones et al. (2004) also conducted a retrospectivecase-control study using inspection data from Tennessee from 1999 to 2002. During this time there were 49 restaurants that were identified as having a foodborne illness outbreak. A perfect score for a routine inspection is a score of 100 (Jones et al., 2004). Violations cited are debited from this score (Jones et al., 2004). For this study, the difference in mean scores was measured to determine the association of inspection scores and foodborne illness. The mean inspection scores for cases was 81.2 and for controls 82.2; this was not significant. Jones et al. (2004) did conclude that violations associated with proper storage of toxic items and proper handwashing and hygiene practices were more likely to have been cited during the routine inspection prior to the outbreak.

Although these studies found that inspection scores alone were not an indicator of a foodborne outbreak, they did suggest that inspection scores in conjunction with other factors such as establishment size, preparation type, or specific risk factors found during an inspection might be a better predictor of foodborne illness outbreaks (Cruz et al., 2001; Jones et al., 2004). Additionally, the conflicting results regarding overall inspection scores could be partially due to differences in inspection criteria and grading systems. Each jurisdiction has different rules and regulations, and therefore there may be differences in the criteria used to determine those inspection scores.

At the time the study was conducted, King County used a form with 42 types of violations that were considered either critical or noncritical (Irwin et al., 1989). Critical violations are thought to have a direct impact on causing foodborne illness and noncritical violations are thought to play a minor role in causing foodborne illness (Irwin et al., 1989). For each critical violation a debit of 4-5 points is subtracted from a perfect score of 100. Every noncritical violation would only subtract 1-2 points from the total score (Irwin et al., 1989). Cruz et al. (2001) described their inspection process as having 57 types of violations, with 12 of those being critical violations. Each inspection report resulted in one of four outcomes ranging from an order to correct violations to a warning that legal action may be taken; no numeric scoring existed at that time (Cruz et al., 2001). In addition, inspectors had to conduct a minimum of six routine inspections a day and therefore had shorter inspections than other jurisdictions (Cruz et al., 2001). In fact, Cruz et al. (2001) found that inspections that took longer than 36 minutes were more likely to have a foodborne illness outbreak (*OR* 5.6, 95% CI, 1.1,26.9) suggesting that the longer the inspection the greater the number of violations found. The study conducted by Jones et al. (2004) in Tennessee used data from inspections that were performed using a report with 44 scored items, of which 13 were critical items. Similar to King County, the highest possible score was a score of 100. Inspectors in Tennessee were standardized, which means they went through rigorous training and field audits to ensure that each inspector was consistent (Jones et al., 2004). Despite inconsistencies with results and their varying inspection protocols and scoring system, all three studies suggested that inspection results should be further examined (Irwin et al., 1989, Cruz et al., 2001, Jones et al., 2004).

Jones et al. (2004) and Cruz et al. (2001) hypothesized that inspection scores in conjunction with other factors would be a better indicator of foodborne illness outbreaks. More recently, studies have shown that specific inspection criteria or violations such as not having a certified food safety manager and having violations for bare hand contact, were more likely to be associated with outbreaks. (Arviera et al., 2018; Hedberg et al., 2006; Lee & Hedberg, 2018; Petran et al., 2012a; Petran et al., 2012b). Similar to previous studies conducted, these studies used inspection data to compare risk factors of outbreak-associated restaurants and non-outbreak associated restaurants using a two-proportion test and Fisher exact test. Additionally, Petran et al. (2012b) found that the violations cited on prior inspection reports were associated with CDC's contamination contributing factors. Contamination factors are the most commonly cited contributing factors during outbreaks, and this suggests that the violations cited during routine inspections could be used in addition to other variables to predict foodborne outbreaks.

Inspection Frequency

Limited studies have been conducted on the association between inspection frequency and foodborne illness outbreaks. The FDA recommends inspecting full-service restaurants three times a year. However, this is not a requirement and each jurisdiction may establish more lenient inspection frequencies. Leinwand et al. (2017) conducted a retrospective study to assess the impact that routine inspection frequency had on foodborne illness risk factors. Routine inspection data in Philadelphia, PA from 2013 and 2014 was used for this study. The study categorized the restaurants into restaurants that had been inspected once within the two-year study period, twice within the two-year study period, or three or more times within the two-year study period (Leinwand et al., 2017). Groups were compared using Pearsons χ^2 tests. The study concluded that an increase from one to two inspections during the 2-year study period was significantly associated with a 0.9 decrease in the mean number of violations per inspection ($p < 0.001$) and an increase from one ≥ three inspections was significantly associated with a 1.4 decrease in the mean number of violations per inspection ($p < 0.001$; Leinwand et al., 2017).

Despite these findings the impact that inspection frequency has on foodborne illness risk factors has been unclear. Another study conducted by Medu et al. (2016) found that an increased inspection frequency did not decrease foodborne illness risk factors. Medu et al. (2016) conducted a two-arm randomized controlled trial between November 2012 and October 2014. One arm included a twice-yearly routine inspection as the intervention (n=73) and the other arm had a standard once-yearly routine inspection (*n*=78). Independent sample t-tests were conducted between both groups to compare the average number of critical hazards per inspection and found no statistical difference between the two groups (Medu et al., 2016). With limited studies available on inspection frequency, and the results being unclear, further examination into the relationship between inspection frequency and foodborne illness outbreaks should be considered.

Foodborne Illness Complaint History

Many health departments receive foodborne illness complaints from restaurant patrons that often result in a follow up inspection with a food establishment. Health departments have standardized foodborne illness forms that review the patron's symptoms and food history to determine the likelihood that that establishment may have caused the illness (Smith et al., 2010; Yousaf et al., 2019). If two cases from different households' report becoming ill after sharing the same exposure (e.g. restaurant), the Council for Foodborne Illness Outbreak Response (CIFOR) recommends that an outbreak investigation be conducted (Smith et al., 2010; Yousaf et al., 2019).

Many people do not report foodborne illness and therefore, foodborne illnesses go undetected (Smith et al., 2010; Yousaf et al., 2019). In Rhode Island, if only a single foodborne illness complaint is received it would only trigger a routine inspection as opposed to an outbreak investigation. For every reported case of foodborne illness, studies show that it is estimated that there are an additional 38 cases that go unreported (Li et al., 2011; Mead et al., 1999). While not all complaints that are received are valid, many complaints received identify a restaurant with a suspect food that fits a pathogen incubation period that is appropriate for their reported symptoms (Li et al., 2011; Smith et al., 2019; Yousaf et al., 2019). Some studies have tried to create a predictive model to identify etiology from illness complaints received, which would help identify individual illness complaints that are likely valid and require an investigation (Li et al., 2011; Saupe et al., 2013). This would help investigators identify outbreaks with only a single illness complaint and also suggests that even a single illness complaint may be an indicator of an outbreak that has yet to be detected (Li et al., 2011; Saupe et al., 2013).

The detection of foodborne illness outbreaks using illness complaints has been used for quite some time (Smith et al., 2010). However, in recent years, health departments have gone to social media to actively search for illness complaints to detect foodborne outbreaks (Harris et al., 2014; Sadilek et al., 2017). Foodborne illness complaints are helpful in detecting outbreaks because oftentimes people are still ill when they call to report the illness, making it more likely to identify the exposure and place associated with the cause of the illness (Yousaf et al., 2019). Using social media to detect illness complaints would allow health officials to identify the illness in real time, making it even more likely to identify the source of illness (Sadilek et al., 2017; Yousaf et al., 2019). This innovative way to detect foodborne illness outbreaks suggests that even a single foodborne illness complaint may be an indicator of a foodborne outbreak. Additionally, when inspectors do follow up on individual illness complaints, evidence suggests that food safety risk factors have been found during follow-up inspections (Jermaneh et al., 2018).

Jemaneh et al. (2018) conducted a nonexperimental quantitative study for 120 complaints using correlation analysis to determine the association between patron foodborne illness complaints received by the health department and risk factors identified during the inspection. The study found that foodborne illness complaints were statistically associated with both improper holding temperatures (r= -.27, p <.05) and contamination of equipment (r=-.30, p= <.05), two high-risk factors for foodborne illness (Brown et al., 2013; FDA Retail Team, 2018; Jemaneh et al., 2018).

The researchers suggest that the majority of foodborne illnesses go undetected (Li et al., 2011; Mead et al., 1999; Smith et al., 2010; Yousaf et al., 2019). For this reason, health departments are trying to implement innovative ways to better detect outbreaks, such as using predictive models for foodborne illness complaint systems and social media screening for illness (Li et al., 2011; Sadilek et al., 2017; Saupe et al., 2013). Additionally, when following up at an establishment based on foodborne illness complaints, Jemenah et al. (2018) found an increased risk of finding common risk factors associated with foodborne illness outbreaks. This suggests that single foodborne illness complaints may lead investigators to an establishment that is more high-risk for a foodborne illness outbreak. Thus, reviewing the illness complaint history of a food establishment in conjunction with other variables may help identify a high-risk establishment that requires an inspection to prevent further illness.

Certified Kitchen Manager

The 2017 FDA added a provision into the Food Code that now requires the Person-In-Charge (PIC) to be a certified food safety manager and to demonstrate knowledge of required information by passing a test from an accredited program (Arviera et al., 2018; FDA, 2018a). This provision expands upon the previous provision in the 2013 Food Code that the establishment must employ at least one Certified Food Safety Manager (Arviera et al., 2018; FDA, 2018a). The rationale behind this new provision of ensuring that the PIC is the certified manager was supported by research conducted that demonstrate that restaurants with a certified manager have fewer critical violations on inspection reports and are less likely to have a foodborne illness outbreak (Arviera, 2018; Brown et al., 2013;.Brown et al., 2014). These studies are consistent with the findings from the 2013 FDA Risk Factor study that indicated that establishments with a certified manager present during data collection had significantly fewer out of compliance items marked (FDA National Retail Team, 2018).

The 2013 FDA Risk Factor study looked at the importance of a food safety management system (FSMS; FDA National Retail Team, 2018). A FSMS refers to a specific set of actions (e.g. procedures, training, monitoring) to help achieve active managerial control within the restaurant. The sample size for this prospective cohort study was determined by statisticians to ensure the validity of the results (FDA National Retail Team, 2018). Observations were collected by standardized data collectors at roughly 400 full-service restaurants and 400 chain restaurants (FDA National Retail Team, 2018). The risk factor study considered the establishments' FSMS to be well developed if they had a certified manager present that could demonstrate active managerial control (FDA National Retail Team, 2018). The determination that a well-developed FSMS must have a certified manager present that could demonstrate active managerial control was based on previous studies conducted (Brown et al., 2014; Cates et al., 2009; Hedberg et al., 2006). The FDA risk factor study stratified the data collected into three different FSMS categories: establishments where the PIC was the certified food safety manager, at establishments where they employed a certified food safety manager but they were not on-site and thus not the PIC, and an establishment where they did not have a certified food safety manager at all. Using correlation analysis, the study concluded that the presence of a well-developed FSMS was correlated with the presence of a certified food safety manager (0.2882) and fewer out of compliance items (-0.4549 Spearman's $\rho = 0.2509$ and -0.4102, respectively; $p < 0.01$ for each; FDA National Retail Team, 2018).

Brown et al. (2014) conducted face-to-face interviews with kitchen managers and food workers. Additionally, the kitchen manager also completed a self-administered multiple-choice food safety knowledge assessment (Brown et al., 2014). Bivariate and multivariable logistic regression models were done for managers to examine associations between explanatory variables and the outcome variable of passing the assessment (Brown et al., 2014). For explanatory variables using bivariate analysis, variables were considered significant at $p<0.30$ to allow for more inclusiveness (Brown et al., 2014). For the final multivariable model, variables were considered significant at $p<0.05$. The multivariable analysis determined that kitchen managers that are certified in food safety (*OR* 2.20, 95% CI 1.27,3.81, $p=0.01$) and have experience of greater than 2 years (*OR* 1.82, 95% CI 1.14,2.91, $p=0.01$) are more likely to pass the knowledge assessment compared to noncertified managers and managers with less than two years of experience

(Brown et al., 2014). This data suggests that food safety certification improves food safety knowledge and therefore could lead to fewer critical violations in restaurants.

Hedberg et al. (2006) compared the differences between outbreak establishments and non-outbreak establishments using an instrument they developed to assess establishment characteristics, environmental conditions, sanitation practices, and individual food flows of suspect food items. This instrument was used at outbreaks that occurred in any of the EHS-Net sites (California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee) from June 2002 and June 2003 (Hedberg et al., 2006). Each EHS-Net site also used this instrument to evaluate 50 non-outbreak establishments during this same time period. A total of 22 outbreaks were compared to 347 non-outbreak restaurants using univariate analysis with calculations of odds ratios, 95% confidence intervals, and chi-square and fisher's exact tests (Hedberg et al., 2006). The results indicated that only 32% of outbreak restaurants had a certified kitchen manager compared to 71% of the non-outbreak restaurants (*OR* 0.2, 95% CI 0.1,0.5), which suggests that having a certified kitchen manager has a protective effect for having a foodborne illness outbreak (Hedberg et al., 2006). Additionally, having a certified kitchen manager was associated with the absence of bare hand contact with ready-to-eat foods as a contributing factor and with fewer Norovirus and *C. perfingens* associated outbreaks (Hedberg et al., 2006).

In 2009, Cates et al., found that restaurants with a certified food safety manager are less likely to have critical violations on their food safety inspections compared to restaurants without a certified food safety manager (*OR* 0.82, $p = < 0.01$; Cates et al., 2009). This retrospective study examined Iowa Inspection data from 2005 and 2006 for 4,461 establishments using logistic regression analysis (Cates et al., 2009). Additionally, restaurants that had a certified kitchen manager on site were less likely to have a critical violation for personnel (*OR* 0.73, $p < 0.01$), food source and handling (*OR* 0.80, $p < 0.01$), ware-washing (*OR* 0.82, $p < 0.10$), facility and equipment requirements (*OR* 0.85, *p* (0.05) and other operations (*OR* 0.87, $p < 0.10$; Cates et al., 2009).

Similar to the FDA risk factor study, the studies described above suggest that the presence of a certified food safety manager would lead to a reduction in critical violations and thus should be further examined (Brown et al., 2014; Brown et al., 2013; Cates et al., 2009; Hedberg et al., 2006). More recently, Arviera et al. (2018) examined this relationship. Arviera et al. (2018) collected data from routine inspection reports to analyze the effectiveness of a certified food safety manager. This study looked at the differences between the percentage of out of compliance items cited in the presence of a certified manager vs. if the establishment employed a certified food safety manager but they were not the PIC at the time of the inspection. For establishments where the PIC at the time of inspection was the certified food safety manager, 3.8% of the observations were out of compliance compared to the 4.1% of the observations at establishments that only employed a certified food safety manager (Alviera et al., 2018). For establishments that did not employ a certified food safety manager, 5.4% of observations were out of compliance (Arviera et al., 2018). Although not significant, fewer violations were observed the stronger the FSMS was (Arviera et al., 2018). This study was consistent with the FDA Risk Factor study that concluded the presence of a certified food safety manager reduces critical violations (FDA Retail Team, 2018).

Although there have been a few studies that did not find a correlation between having a certified food safety manager and a reduction in violations, only one study actually contradicted these findings and found that having a certified manager was significantly associated with having more violations cited on routine inspections (Harris, 2017). The study conducted by Harris (2017) found that the certified food safety manager was not effective in reducing violations may be due to the fact that the certified food safety manager during that time did not have to be the PIC and may suggest that a certified food safety manager is only effective when on-site. This cross-sectional study analyzed routine inspection data for 1,547 establishments throughout the state of Georgia from 2013 (Harris, 2017). Despite this inconsistency with other studies, the data collected in 2013 would have been based upon the 2013 Food Code requirement of just having an employee on staff that is a certified food safety manager as opposed to the PIC being the certified food safety manager. The new provision in the 2017 Food Code was added because oftentimes the certified food safety manager was not the PIC and the food safety knowledge of this person was not passed on to the other food employees and therefore not always being implemented in the establishment (Arviera et al., 2018; FDA, 2018a; FDA National Retail Team, 2018). Consistent with other studies, Harris (2017) reported that an increase in knowledge and food safety training is critical to reducing foodborne illness risk factors. Therefore, these studies support the fact that in order to be effective, the certified food safety manager should be someone who is onsite and has direct oversight over food employees (Brown et al., 2014; FDA National Retail Team, 2018; Harris, 2017).

Although there have been some mixed results on the effectiveness of a certified food safety manager on reducing foodborne illness outbreaks, the researchers do suggest that certified food safety managers who passed an accredited test have an increased knowledge in food safety risk factors (Arviera et al., 2018; Brown et al., 2014). Researchers have shown that having an increased knowledge in food safety risk factors can result in fewer violations, thus decreasing the risk of having a foodborne illness outbreak (Avriera et al., 2018; Brown et al., 2014; Cates et al., 2009;.FDA National Retail Team, 2018). These studies are consistent with the changes made to the 2017 FDA Food Code (FDA, 2018a; FDA Retail Team, 2018). These studies suggest that a lack of a certified manager at a food establishment may be associated with an increase in critical violations, thus being more likely to have a foodborne illness outbreak. This study will further examine the relationship between the presence of a food safety manager and the occurrence of a foodborne illness outbreak.

The Rhode Island Food Code has required one full time certified food safety manager since 1993 and in 2017, this provision was expanded to require a certified food safety manager on-site during all hours of operations (RI Food Code, 2017). Given the recent food code change in Rhode Island, this study will further examine the gap in literature on the relationship between the presence of a safety manager and the occurrence of foodborne illness outbreaks. The results from this study could then be used to encourage policy changes in other states that have not adopted the 2019 FDA Food Code provisions regarding a certified food safety manager.

Summary and Conclusions

A thorough search of descriptive and analytical studies related to foodborne illness characteristics and causes were reviewed to identify variables that can be used to help predict foodborne illness outbreaks. This search included studies that were published between 1989-2019. Despite the 20-year time frame, few analytical studies were found in previous literature. Constructs from the NICE emerging framework and the epidemiological triangle were used to develop this study. The NICE framework describes how the environment and population vectors have an impact on health and often includes state and local government (Kelly et al., 2009). The epidemiological triangle was used to describe the relationship between foodborne pathogens, contaminated food, and a food establishment (Gulis & Fujino, 2015). Reckwitzs' (2002) work with consumption and the theory of practice was used as a theoretical foundation.

The theory of practice suggests that any analysis should focus on the social structure level as opposed to the individual level because if control measures are implemented at the social structure level they will trickle down to the individual level (Reckwitz, 2002). When implementing this theory to assess foodborne illness, it suggests that efforts should focus on the restaurants as opposed to the food worker. Thus, this study will analyze risk factors observed at outbreak restaurants compared to non-outbreak restaurants to help identify high-risk establishments. The literature review in this chapter identified several variables that have been associated previously with foodborne outbreaks.

Seminal research, such as the EHS-Net findings and the study conducted by Irwin et al (1989) suggest that several risk factors, such as risk category, having a certified manager, inspection history, and restaurant type can help identify high-risk establishments that may be at risk for a foodborne illness outbreak (Lipinsci et al., 2019; Brown et al., 2014). Several studies identified that restaurants that serve complex food items are at a higher risk for foodborne illness, as well as restaurants that do not have a certified manager on site (Brown et al., 2014; Brown et al., 2013; Hedberg et al., 2006; Lipinski et al., 2019). Additionally, reviewing a food establishment's inspection and illness complaint history is thought to provide insight into an establishment's food safety practices (Cruz et al., 2001; Irwin et al., 1989; Jones et al., 2004; Li et al., 2011; Saupe et al., 2013).

Identifying high-risk establishments can help put intervention measures in place more quickly, thus preventing foodborne illness. Each year, it is estimated that there are 48 million foodborne illnesses, a significant public health concern (CDC, 2011). Dewey et al. (2013) reported that 60% of foodborne illness outbreaks occur at licensed food establishments, supporting the need for public health interventions at food establishments to reduce foodborne illness. In current literature, few analytical studies examine the differences between outbreak establishments and non-outbreak establishments. Furthermore, in Rhode Island this data has not yet been analyzed.

This study attempts to close the gap in determining the differences between outbreak establishments and non-outbreak establishments in Rhode Island. Logistic regression was used to determine how each variable independently and collectively can impact the relative risk of a food establishment having a foodborne illness outbreak. Chapter 3 will discuss methods in greater detail.

Chapter 3: Research Method

Introduction

From 2009 to 2015, the CDC's FDOSS had almost 6,000 foodborne illness outbreaks reported, and it is estimated that roughly 60% of those involved food prepared in a restaurant (Angelo et al., 2017; Dewey-Mattia et al., 2018). Foodborne illness outbreaks are often a result of poor practices within a food establishment and are a significant public health burden. Analytical studies conducted in the late 1980s and 1990s suggest that a food establishment inspection history may identify risk factors that put the establishment at a higher risk for having a foodborne illness outbreak. Since the 1990s information regarding the use of inspection reports has been debated, however there seems to be a general consensus that looking at certain risk factors cited in the report can provide insight into an establishment's food safety practices and the causes of an outbreak.(Cruz et al., 2001; Irwin et al., 1989; Jones et al., 2004; Li et al., 2011; Saupe et al., 2013;). The purpose of this study was to analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak.

This chapter will provide detailed information on the research design and rationale and the methodology for the relationship between the risk factors identified and the occurrence of a foodborne illness outbreak. Furthermore, this chapter will discuss the population of interest, sample size, data collection instrument, and a plan for data analysis. The ethical procedures and concerns will also be discussed. Lastly, any threats to internal and external validity will be addressed in this chapter.

Research Design and Rationale

I conducted a quantitative case-control study using secondary data from the Digital Health Department inspection database. This research design was chosen because there are two groups of interest for this study: one with a particular outcome of interest and a comparison group without that outcome of interest (see Friis & Seller, 2018). Furthermore, a case-control study was chosen due to the small number of outbreaks that occur each year in Rhode Island (Song & Chung, 2010). Case-control studies are often used for rare occurrences and to determine risk factors associated with outbreak investigations (Lewallen & Courtright, 1998; Song & Chung, 2010). In addition, reviewing a 3-year history for each food establishment is a tedious task, thus a case-control was selected for feasibility.

The outcome of interest for this case-control study was if a restaurant has had a foodborne illness outbreak and therefore, the two groups were defined as restaurants who have had a foodborne illness outbreak (cases) and restaurants that have not had a foodborne illness outbreak (controls). Furthermore, this study design allowed me to seek possible causes of a foodborne illness outbreak by determining how the two groups differ with respect to the suspect risk factors (Friis & Seller, 2018). Foodborne illness outbreaks do not occur at random and thus, the case group must have been exposed to one or more risk factors (Friis & Sellers, 2018). A comparison of the frequency of exposure among the cases may provide insight into the difference of disease status, or in this case, whether a foodborne illness outbreak has occurred (Friis & Sellers, 2018). Lastly, case-control studies have been proven to be efficient for outbreak investigations (Devleesschauwer et al., 2019; Friis & Sellers, 2018).

The research questions identified for this study are:

RQ1: What is the relationship between a food establishment's food inspection and complaint history (number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received) and the occurrence of a foodborne illness outbreaks at a licensed food establishment, controlling for risk category and restaurant size?.

RQ2: What is the relationship between a food establishment’s characteristics (risk category, restaurant type, and restaurant size) and the occurrence of a foodborne illness outbreak in a food establishment?

For both research questions, the dependent variable is the status of having a foodborne illness outbreak in a restaurant. For RQ1, the independent variables are the food establishments food inspection and complaint history. The food inspection and complaint history was defined as number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received. For RQ2, the independent variables are the food establishments characteristics. For this study, a food establishment's characteristics were defined as their risk category, restaurant type, and license type. The results from this study could help identify a predictive model for the cause of foodborne illness outbreaks, alerting health professionals to implement early intervention strategies to prevent an outbreak from occurring.

As previously mentioned, secondary data from the Digital Health Department inspection database was used for this study. Inspection data for all Rhode Island licensed food establishments (for both groups) are located in this database. Inspection data is collected by a Rhode Island Environmental Health Food Specialists (EHFS) who undergo a rigorous training and standardization process. Therefore, the data provided on these inspection reports is both reliable and valid. Using inspection data to conduct research on foodborne illness risk factors is a widely accepted practice and has been used in many studies (Cruz et al., 2001; Irwin et al., 1989; Weschler, 2006). Furthermore, it allowed me to identify potential risk factors of foodborne illness outbreaks, which could further advance the knowledge in food safety and likely reduce illness.

Methodology

Population

The population for this study is licensed food establishments in Rhode Island between 2010-2019. For this case-control study, there are two groups: (a) licensed food establishments that have had a foodborne illness outbreak and (b) licensed food establishments that have not had a foodborne illness outbreak. Establishments that had a foodborne illness outbreak will be known as the cases. The controls for this study were licensed food establishments that have not had a foodborne illness outbreak and three controls were randomly selected for each case.

All licensed food establishments that prepare and sell food at the retail level, or otherwise, directly to the consumer, were included in this study. Licensed manufacturing firms were excluded from this study, as the scope of this study will solely focus on retail establishments.

Sampling and Sampling Procedures

OpenEpi was used to determine the sample size needed to provide the statistical power needed to draw conclusions. Using the Sample Size for Unmatched Case-Control Study calculator, it was determined that setting the parameters at a 95% two sided confidence level (1-alpha) with a power of 80%, 88 cases and 264 controls are needed to detect a Odds Ratio of 2.0 (Fahim, 2019; OpenEpi, 2020). These parameters are based upon methods used in observational epidemiology (Kelsey et al., 1996). The effect size was based on a dichotomous dependent variable—whether a food establishment had a foodborne illness outbreak. Effect size was estimated using the odds ratios of variables associated with foodborne illness outbreaks from previous studies. For example, a study conducted by Jones et al. (2004) found that restaurants that had a seating capacity of greater than 50 seats were more likely to have an outbreak when compared to non-outbreak restaurants (*OR* 2.1, 95% CI 1.0, 5.0). Furthermore, a study concluded by Irwin et al. (1989) found that a food establishment that receives an inspection score of less than 86 had higher odds of having a foodborne illness outbreak (*OR* 5.4, 95% CI 1.5,24.2).

The cases were identified according to archival outbreak records from the Rhode Island Department of Health. Upon review of the data, there were only 68 establishments that had a foodborne illness outbreak between 2010-2019. The time frame could not be expanded due to electronic reports not being available. Thus, the sample size for this study will limit the statistical power. A total of 210 controls were randomly selected so that there was a 3:1 ratio of controls to cases. Inspection reports were obtained from the Digital Health Department (DHD). Controls were randomly selected using stratified sampling. The inspection data was first separated into different stratum's based upon the year the inspection occurred. The data was further stratified by risk category to ensure that licensed establishments were sampled proportionately. The stratified sample was collected by independently selecting 21 controls from each year at random. Stratified sampling was used to ensure high statistical precision and that licensed food establishments from each year are equally represented (Seita, 2016). This help to reduce any bias of inspections being conducted by different staff and to account for any bias due to new regulations that were implemented during this time.

The data was extracted by searching in DHD for routine inspection data for each year and then exported to Microsoft Excel. For the risk category, the percentage of establishments in each risk category out of the total licensed establishment population was used to determine how many establishments per risk category should be randomly selected for the study. The data for each year was then filtered to each risk category to select the appropriate number of controls from that category. A number generator was used to select all 21 controls at random. This was repeated for all years from 2010-2019. The random samples from each stratum were then added together for a total sample size of 210 controls.

Archival Data

Once the cases and controls were identified and randomly selected, data collection was done by extracting data from the DHD inspection database for each food establishment. The following variables were collected from the DHD inspection database: number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, number of complaints received, risk category, restaurant type, and license type. These variables were collected for both cases and controls and managed using Microsoft Excel.

Secondary data was used for this study and thus recruitment into the study is based upon licensed food establishments in Rhode Island. The data that was used for this study was routine inspections of licensed food establishments. Per Rhode Island regulations, in order for a business to sell food in the State of Rhode Island they must have a license with the Rhode Island Department of Health. By obtaining a permit with the Rhode Island Department of Health, the licensee agrees to allow EHFS on the premises to conduct routine inspections and investigate any complaints that are filed.

Routine inspections are unannounced visits where an EHFS reviews 58 different risk factors. These risk factors on the report are split up into two groups: foodborne illness risk factors and public health interventions (violations 1-29) and good retail practices (30-58). The foodborne illness risk factors are considered the most serious violations that have been directly associated with causing illness and include items such as: food from unsafe sources, inadequate cooking, improper holding temperatures, contaminated equipment, and poor personal hygiene. The good retail practices refer to preventative measures that should be taken to control hazards. Each item is marked “IN”, “OUT”, “N/A”, N/O”. “IN” refers to in compliance and “OUT” refers to out of compliance. “N/A” is marked when a violation is not applicable to that establishment and

"N/O" is marked when that food safety practice could not be observed during the inspection. These risk factor categories were adopted from the FDA inspection report.

The severity of the violation can be determined based upon what type it is. There are three types of violations: priority, priority foundation, and core. Priority violations are the most severe and require immediate corrective action. These violations have directly been associated with causing illness. Priority foundation items are items that help keep priority items in compliance and are less severe than priority violations. Core items are typically noncritical violations related to general sanitation or facility maintenance and the least severe. At the conclusion of a routine inspection, an EHFS completes an inspection report and reviews all violations and control measures with the person in charge. These inspection reports are housed in DHD. DHD is the inspection database used by the Rhode Island Department of Health and will thus require permission to gain access to the data set.

These historical records are reputable and the best sources of data for this study because the Rhode Island Department of Health is the regulatory agency responsible for conducting inspections and investigating foodborne illness outbreaks. These government records fall under the Freedom of Information Act (FOIA). Additionally, the Rhode Island Department of Health has a strong commitment to working with Scholars through their Academic Institute and encourages researchers to use Rhode Island Data (RIDOH, 2020). A request and IRB application were submitted to the Chair of the Rhode Island Department of Health, which determined that the research would be exempt from IRB review.

EHFS undergo standardized training to conduct these inspections. Every EHFS is required to be standardized according to FDA standards. This training includes FDA courses, field inspections, and several inspections that are audited by an FDA standardization officer (FDA, 2020). These standards ensure that every EHFS has the proper knowledge and skills related to the Food Code provisions. In addition, it ensures that they use a uniform system of measurement that provides valuable insight into the risk factors associated with food establishments (FDA, 2020). Additionally, it is assumed that this information is up-to-date and accurate as it is used daily to capture inspections and to identify trends for program planning.

Data Collection Instrument

The variables that were chosen for this study were selected based on a thorough literature review. The variables are broken into two categories:.(a) Food establishment characteristics (risk category, restaurant type, and restaurant size) and (b) Food establishment's food inspection and complaint history (number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received). These variables have all been identified in previous studies as risk factors that have been associated with foodborne illness outbreaks.

Secondary data is often used to determine information about the food environment (Fleischhacker et al., 2018). In fact, Fleishchacker et al. (2012) found a high sensitivity for health department data representing data that was listed on business sites such as ReferenceUSA. Additionally, the DHD database has been used since 2007 and is used daily to capture data collected during inspections. The Rhode Island Department of Health uses an inspection form that is based upon the FDA inspection form and each inspector undergoes a year-long training and standardization process that includes training on how to complete inspection forms. Additionally, the food establishment characterization variables are completed by the owner of the business when they complete the application for a license. This data is regularly used to analyze risk factors associated with foodborne illness to identify trends and implement control measures to reduce illness, as needed.

The variables selected to answer the research questions were selected based upon a thorough literature search of previous studies conducted to identify risk factors associated with a food establishment having a foodborne illness outbreak. Risk category, restaurant type, and license type have all been independently associated as risk factors in a foodborne illness outbreak (Angelo et al., 2017; Dewey-Matia et al., 2018; FDA National Retail Team, 2018; Lipinksi et al., 2019). Therefore, looking at the relationship between these variables together may provide further insight into the cause of a foodborne illness outbreak. Furthermore, the variables used to explore the relationship between a food establishment's inspection and complaint history and the occurrence of a foodborne illness outbreak have also been selected based upon a review of previous studies. Number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received have all been used to potentially identify poor practices within a food establishment (Avriera et al., 2018; Brown et al., 2014; Cates et al., 2009; FDA National Retail Team, 2018).

Operational Definition of Variables

The variables for this study are grouped into two categories: Food establishment characteristics (see Table 1) and a food establishment's food inspection and complaint history (see Table 2). The variables for this study can be defined as follows:

Food establishment characteristics

Risk Category. The risk category for an establishment is a categorical variable based upon the FDA categories of risk and are cook/serve, advanced prep, high risk population, smoking/curing/reduced oxygen packaging, and other (temp vendors, mobile vendors, vending machines). For this study, the smoking/curing/reduced oxygen packaging and the other category were excluded. For those that were high risk population, they were categorized into the cook/serve and advanced prep categories based upon the complexity of the foods served. The risk category is determined by the inspector based upon the food preparation practices that the establishment is conducting. The variable “Risk Type” on the inspection report will be used to identify the risk category.

Restaurant Type. Restaurant type will refer to the type of food service operation that is indicated on the license application. Restaurant type is a categorical variable and will be identified using the “Secondary License Description” in DHD which is categorized into the following categories: “Bakery”, “Cafeteria, Buffet Service”, “Markets”, “Full Service Restaurant”, and “Institutions”. “Markets” includes all restaurant types including markets and convenience stores. “Fast Food Service” includes all restaurant types including fast food service, take out only, food trucks, and temporary events. “Full-service Restaurants” includes restaurant types full-service restaurants and bar, lounge, tavern.

License Type. License type will refer to the type of license an establishment has. Restaurant size is determined by the License type given at the time of opening. This categorical variable will use the variable “License Type” in DHD to determine if the establishment is “Registers/Non Sit-Down Dining”, “Seats-Less than 50”, “Seats-50 or more”, “Food Service” or “Caterer or Commissary”. “Seats-Less than 50” indicates that an establishment has less than 50 seats. “Registers/Non Sit-Down Dining” consists of all license types that have cash registers or license types that do not have a sit down dining area such as, Bakeries, and Mobile Food Trucks. “Seats-50 or more” indicates the establishment has more than 50 seats in the restaurant. “Food Service” includes schools and health care facilities. “Caterer or Commissary” indicates that an establishment can prepare foods for large events outside of their establishment.

Food establishment's food inspection and complaint history

Number of critical violations. Critical violations are identified on the inspection report as violation numbers 1-29. The number of critical violations will be added up for each inspection to identify the “number of critical violations.” This will be a continuous variable.

Number of routine inspections. The number of routine inspections will be determined by the number of inspections in the system for each licensed food establishment during a three-year time span. For cases, it will be the three years prior to having an outbreak. For controls, it will be the three years prior to the routine inspection selected in the initial sampling. This will be a continuous variable.

Average frequency between inspections. The average frequency between inspections will be calculated as the average time between the routine inspections identified in "number of routine inspections". This variable will be reported in months and will be a continuous variable.

History of having a certified manager. The inspection history for each case and control will be reviewed. History of having a certified manager will have two categories: Unsatisfactory and Satisfactory. Establishment's with an unsatisfactory certified manager history will be identified as an establishment that had a violation for not having a certified manager on-site during an inspection in the three-year span of interest. Establishments with a satisfactory certified manager history will be identified as an establishment that had no certified manager violations on their inspection reports during the three-year time span of interest.

Number of complaints received. The number of complaints received will be calculated using DHD and will be a count of complaints received during the three-year time span preceding the routine inspection. This will be a continuous variable.

Table 1

Food Establishment Characteristic Variable Descriptions

Variables	Variable Type	Data Source	Operationalized
Risk Category	Categorical	Inspection Report: Risk Type	Cook/serve Advanced Prep Pre-packaged NPHF
Restaurant Type	Categorical	Inspection Report: Secondary License Type	Bakery Cafeteria, Buffet Service Markets Fast Food Service Full-Service Restaurant Institutions
Restaurant Size	Categorical	Inspection Report: License Type	Registers/Non Sit-Down Dining Seats-Less than 50 Seats-50 or more Food Service Caterer or Commissary

Table 2

Food Establishment Inspection and Complaint History Variable Descriptions

Variables	Variable Type	Data Source	Operationalized
Number of critical violations	Continuous	Inspection Reports	Count of violations 1-29 on inspection form.
Number of routine inspections	Continuous	Inspection Reports	Count of routine inspection in three-year span.
Frequency between inspections	Continuous	Inspection Reports	Average time (in days) between routine inspections identified in "Number of routine inspections".
Certified Manager	Categorial	Inspection Reports	Unsatisfactory Satisfactory Unknown
Number of complaints received	Continuous	Complaints	Count of complaints received in three-year time span prior to routine inspection.
Risk Category	Categorical	Inspection Report: Risk Type	Cook/serve Advanced Prep Pre-packaged NPHF
Restaurant Type	Categorical	Inspection Report: Secondary License Type	Bakery Cafeteria, Buffet Service Markets Fast Food Service Full-Service Restaurant Institutions
Restaurant Size	Categorical	Inspection Report: License Type	Registers/Non Sit-Down Dining Seats-Less than 50 Seats-50 or more Food Service Caterer or Commissary

Data Analysis Plan

Data was managed using a Microsoft Excel spreadsheet and analyzed using SPSS V.27. To ensure accuracy, data cleaning was done in Microsoft Excel. Categorical variables were coded to numerical values prior to being uploaded into SPSS. All variables for RQ1 and RQ2 were uploaded into SPSS for multiple logistic regression. Chi-square analysis was used to determine if there is an association between the dependent variable and the categorical independent variables. Simple logistic regression was conducted to investigate the individual continuous variables and the dependent variables.

Prior to running the logistic regression model, tests to check linearity between the predictor variables and the logit of the dependent variable and collinearity were conducted. Testing these assumptions ensured that the predictor variables in the regression have a straight-line relationship with the outcome variable and that the logistic regression model accurately associates variance in the outcome variable with the correct predictor variable.

Research Questions and Hypothesis

Research Question 1(RQ1; Quantitative): What is the relationship between a food establishment's food inspection and complaint history (number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received) and the occurrence of a foodborne illness outbreaks at a licensed food establishment, controlling for risk category and restaurant size?

$H_0$1: There is no relationship identified between a food establishment's food inspection history and the occurrence of a foodborne illness outbreak at a licensed food establishment.

H_a1: There is a relationship identified between a food establishment's food inspection history and the occurrence of a foodborne illness outbreak at a licensed food establishment.

Research Question 2 (RQ2; Quantitative): What is the relationship between a food establishment’s characteristics (risk category, restaurant type, and restaurant size) and the occurrence of a foodborne illness outbreak in a food establishment?

$H_0$2: There is no relationship identified between a food establishment’s characteristics and the occurrence of a foodborne illness outbreak at a licensed food establishment.

H_a2: There is a relationship identified between a food establishment’s characteristics and the occurrence of a foodborne illness outbreak at a licensed food establishment.

Logistic regression is often used for quantitative studies and thus will be used for both RQ1 and RQ2 of this study (Palmer & O’Connell, 2009). Logistic regression will be used for this study because the relationship being examined consists of a single dichotomous dependent variable and multiple predictor variables (independent variables; Palmer & O’Connell, 2009). The analysis will provide a predicted value for the criterion from the combination of predictor variables (Palmer & O'Connell, 2009). The control group will serve as the “exploratory group”, while the cases will serve as the “validatory” group (Palmer & O’Connell, 2009).

Binomial logistic regression was utilized for this study because the dependent variable of this study, which is “the occurrence of a foodborne illness in a food establishment” is a dichotomous variable that will be either yes or no. Furthermore, this study includes multiple independent variables, which can be either continuous or categorical. For RQ1 the following independent variables were used: number of critical violations, average number of routine inspections, frequency between inspections, history of having a certified manager, and number of complaints received. For RQ2 the independent variables are restaurant type, restaurant size, and risk category. To explain the variation in the dependent variable, the Nagelkerke R2 was used. To determine the contribution of each independent variable to the model and its statistical significance, the Wald test was used. For this study, odds ratios are reported using a 95% confidence interval and a p-value of 0.05 to determine statistical significance.

Threats to Validity

External Validity

This study reviewed inspection reports for all licensed facilities in Rhode Island. Despite conducting a statewide study, the results of this study may not be generalizable to the food establishments of the entire U.S population. However, this study would be generalizable to populations with food establishments that have similar characteristics as Rhode Island food establishments. Furthermore, this study provides valuable insight into risk factors that may be associated with foodborne illness outbreaks in retail establishments.

Another threat of external validity would be representativeness of sample. However, given the stratified sample procedures by year and risk category the results of this study should not be subject to this threat. Lastly, researchers should be cautious about generalizing results from one time period to another. However, the regulations and knowledge around food safety has not changed significantly since 2010. Thus, the information learned over the last decade will be beneficial and appropriate.in future years to come.

Internal Validity

Instrumentation can be identified as an internal threat to validity. This study uses secondary data to measure risk factors identified with retail food establishments during routine inspection to determine if they are associated with having a foodborne illness outbreak. Although the data collection instrument being used (i.e. health inspection reports) was not created for the sole purpose of this research, the standardization of environmental health food specialist and training that is required to conduct inspections, ensures that the data is being collected consistently and accurately measures risk factors identified during routine inspections. Thus, for this study instrumentation will not be a threat. In addition, the Rhode Island inspection form was adopted from the FDA and was created based upon the FDA Food Code. There are no perceived threats with statistical conclusion validity for this research study. Appropriate statistical tests have been reviewed prior to beginning the research.

A sample size calculator was used to determine the statistical power to detect an odds ratio of 2.0. This calculation determined that 88 cases and 264 controls would be needed. However, only 68 cases were available to include in this study. To maintain the 1:3 cases to controls ratio, 210 controls were also included instead of 264 controls. This decrease in sample size does result in a loss of power and is stated as a limitation of the study. Due to the smaller than anticipated sample size, a new calculation was performed to determine the statistical power that the new sample size would provide. According to the statistical calculator, it was determined that setting the parameters at 95% two-sided confidence level (1-alpha) with a power of 80%, 63 cases and 188 controls would detect an odds ratio of 9.76 (OpenEpi, 2020).

Ethical Procedures

Permission was requested to obtain the health inspection report data from the DHD. An IRB application was submitted to the Rhode Island Department of Health (RIDOH) and was considered exempt from IRB review because this study does not include any data on human subjects and only utilizes data on food establishments. An IRB application was also submitted to Walden University and prior approval was obtained. The Walden University IRB approval number is 02-24-21-0786498. In addition, the name of each food establishment will not be recorded for the purposes of the study and each food establishment will be given a coded number. Any summarizing results that are published or disseminated will not include the name of any food establishments. Although this information is public information, ensuring there is no harm done to business during this research study is essential.

To protect the identities of restaurants, each restaurant was coded, and the name of the food establishment was not kept on file with the information identified through their reports. The list of coded restaurants will be kept in a password protected excel file. The research that is being conducted in this study is in the researcher's work environment. However, the research study that was conducted was done in addition to work related projects and responsibilities. Furthermore, this research study was conducted outside of working hours and as such, the researcher was not compensated for time spent on this study.

Summary

The purpose of Chapter 3 was to discuss research design and rationale, the methodology, and any threats to validity. This quantitative study used a case-control design due to the small sample size of foodborne illness outbreaks in RI and feasibility to manually review a significant number of inspection reports for each establishment in the study. The population for this study included all food establishments that are licensed in Rhode Island between 2010-2019. The cases were identified as any restaurant that has had an outbreak. The controls were licensed food establishments that have not had an outbreak and were identified through stratified sampling. Secondary data from DHD was used for this study and included information from routine health inspection reports and complaints received. The variables used for the data collection instrument are information that can be identified using DHD. Binomial logistic regression was used for analysis and odds ratios were reported using a 95% confidence interval and a *p*-value of 0.05 to determine statistical significance.

The validity and ethical procedures for this study are of the utmost importance to the researcher. Although the results of this study may not be generalizable to the entire U.S population of food establishments, the results of this study can provide further insight into risk factors associated with outbreaks that occur at retail food establishments. All appropriate ethical procedures were followed to ensure no businesses are harmed because of this study and IRB approval was obtained. Lastly, this study was conducted outside the scope of the researchers work responsibilities. The results of this study will be detailed in Chapter 4.

Chapter 4: Results

Introduction

The purpose of this study is to quantitatively analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak. This study has two research questions: (a) What is the relationship between a food establishment's food inspection and complaint history and the occurrence of a foodborne illness outbreaks at a licensed food establishment? and (b) What is the relationship between a food establishment's characteristics and the occurrence of a foodborne illness outbreak in a food establishment? For both research questions it was hypothesized that these factors were associated with the occurrence of a foodborne illness outbreak. The hypotheses were explored using simple and binary logistic regression.

Chapter 4 will discuss the data collection for this study including the time frame for data collection, any discrepancies in data collection, descriptive and demographic characteristics, and how representative the sample is of the population of interest. Univariate and multivariate logistic regression results will be reported for both research questions. This chapter will conclude with a summary of the results.

Data Collection

IRB approval was obtained for this study in February 2021. Data collection occurred between February 2021 and April 2021 and data was obtained from the Digital Health Department. The only discrepancy with the data collection that was proposed in Chapter 3 was with sample size. Using the Sample Size for Unnmatched Case-Control

Study calculator, I determined that setting the parameters at a 95% two sided confidence level (1-alpha) with a power of 80%, 88 cases and 264 controls are needed to detect a Odds Ratio of 2.0 (OpenEpi, 2020; Fahim, 2019). However, upon review of the data between 2010-2019 only 68 cases met the inclusion criteria for this study. All options were exhausted to include more cases, such as expanding the time frame for the study. However, electronic inspection reports would not have been available to review if the data prior to 2010 was included in this study. Thus, only 68 cases were available for this study. As described in Chapter 3, three controls were selected for each case. A total of 210 controls were included in this study so that an even number of controls could be collected from 2010-2019 for stratified sampling. Due to the smaller than anticipated sample size, a new calculation was performed to determine the statistical power that the new sample size would provide. According to the statistical calculator, it was determined that setting the parameters at 95% two-sided confidence level (1-alpha) with a power of 80%, 63 cases and 188 controls would detect an odds ratio of 9.76 (OpenEpi, 2020). However, because some of the groups for the categorical variables had fewer than 5 events, assumptions were violated. Despite these events per variable being low, there are instances when a total of less than 10 events per variable could demonstrate statistical significance within a logistic regression analysis (see Vittinghoff & McCulloch, 2006). Based on this theoretical justification, I initially conducted my logistic regressions using standard modeling. The initial modeling had very wide confidence intervals that made it difficult to interpret, likely due to the assumptions being violated. To mitigate this assumption violation, I opted to compute each regression model using 1,000 bootstrap samples. Bootstrapping is a nonparametric technique developed in the 1970s by Bradley Efron for assessing standard errors (Efron, 1987). This method has greatly evolved over the last 4 decades and is commonly used to create bias-corrected confidence intervals, particularly for data with small sample sizes that failed to meet the assumptions (Efron, 1987; LaFontaine, 2021). Furthermore, LaFontaine (2021) states that bootstrapping has allowed researchers to work with smaller sample size and has expanded the scope of research. The method allows studies to make inferences on the data that would not be possible with traditional modeling (Champlin, 2010; Lafontaine, 2021).

Descriptive and Demographic Characteristics for RQ1 and RQ2

Stratified sampling was used to ensure the sample was representative of the population. The data was stratified by year and risk category. The population for this study was Rhode Island licensed retail establishments. The percentage for each risk category for the total population of Rhode Island food establishments was as follows: 6% prepackaged, 33% cook/serve, and 61% advanced prep. The percentage for each risk category for the sample was 6% prepackaged, 32% cook/serve, and 62% advanced prep which demonstrates that this sample well represents the Rhode Island Food Establishment Population. Table 3 shows the frequencies and percentages for the categorical variables. The characteristics of the establishments that had outbreaks in Rhode Island are consistent with other studies (Angelo et al., 2017; Dewey-Matia et al., 2018; Lipinski et al., 2019;).

For restaurant type, 74% of the establishments that had an outbreak were full-service restaurants compared to 26% of the establishments that did not have an outbreak.

For restaurants with seating, 53% occurred in restaurants with 50 seats or more compared to 19% of the establishments that had seating and did not have an outbreak (Table 3). For risk category, 79% of the establishments that had an outbreak were considered advanced prep compared to 56% of the establishments that did not have an outbreak. The results indicate that 13% of establishments that had an outbreak did not have a certified manager compared to 17% of establishments that did not have an outbreak (Table 3).

Table 3

Demographic Information for Categorical Variables

Categorical Variable		Cases	%	Controls	%	Total
Risk Category						
	Pre-packaged Foods	1	1%	15	7%	16
	Cook/Serve	13	19%	77	37%	90
	Advanced Prep	54	79%	118	56%	172
		68		**210**		**278**
Restaurant Type	Bakery	5	7%	9	4%	14
	Cafeteria, Buffet Service	4	6%	6	3%	10
	Markets	1	1%	20	10%	21
	Fast Food Service	7	10%	74	35%	81
	Full-Service Restaurant	50	74%	55	26%	105
	Institutions	1	1%	46	22%	47
		68		**210**	100%	**278**
License Type	Cash Registers	3	4%	50	24%	53
	Seats - Less than 50	23	34%	70	33%	93
	Seats - 50 or More	36	53%	40	19%	76
	Food Service (Non-Profit)	0	0%	40	19%	40
	Caterer or Commissary	6	9%	10	5%	16
		68		**210**		**278**
Certified Manager	Unknown	6	9%	1	0%	7
	Satisfactory	53	78%	174	83%	227
	Unsatisfactory	9	13%	35	17%	44
		68		**210**		**278**

The common measures of central tendency and dispersion that were used to describe the continuous variables include mean and standard deviation. The average number of critical violations that were written on inspection reports during the 3-year span of time for the cases (M = 4.19, SD=4.39) was higher than the controls (M= *3.35*, *SD*= *4.43*: Table 4). However, it was not statistically significant. The average number of days between routine inspections was similar in both cases (*M*= 543, *SD*= 366) and controls (*M*=552, *SD*= 357; Table 4). The average number of days between each routine inspection was calculated for controls to determine this frequency. The average number of days between each routine inspection was also calculated for cases. However, the date of the outbreak investigation was used as the starting point to calculate this frequency for cases. The mean number of routine inspections conducted during the 3-year period was lower for cases (*M*= 1.56, *SD*=1.01) compared to controls (Table 4). The mean number of routine inspections conducted during the 3-year period for controls was 2.44 (*SD*= 1). Cases received a mean of 0.85 complaints (*SD*= 1.39) during a 3-year time period. Controls received a mean of 0.07 (*SD*= 0.31) complaints during a 3-year time period (Table 4).

Table 4

Descriptive Statistics for Continuous Variables

Variables	Cases		Controls	
	M	*SD*	*M*	*SD*
Number of critical violations (Average)	4.19	4.39	3.35	4.43
Frequency between inspections (Days)	543	366	552	357
Number of Routine Inspections (Average)	1.56	1.01	2.44	1
Number of complaints received (Count)	0.85	1.396	0.07	0.309

Chi Square Test of Independence for Categorical Variables

The chi-square test of independence was used to determine an association between each categorical independent variable and the dependent variable. The results of the chi-square analysis revealed a significant association between restaurant type and having a foodborne illness outbreak (X^2 (5) =60.810, $p < .001$) , risk category and having a foodborne illness outbreak (X^2 (2)= 12.235, $p < .005$), license type and having a foodborne illness outbreak (X^2 (4) = 46.151, $p < .001$) , and certified manager and having a foodborne illness outbreak(X^2 (2) = 19.094, $p < .001$:Table 5-Table 8). Thus, there is a statistical association between restaurant type and having a foodborne illness outbreak, risk category and having a foodborne illness outbreak, license type and having a foodborne illness outbreak, and certified manager and having a foodborne illness outbreak.

Table 5

Crosstabulation of Foodborne Illness Outbreaks and Risk Category

Foodborne Illness Outbreak	Risk Category				
	Pre-packaged	Cook/Serve	Advanced Prep	X^2	*p*
Yes	1	13	54	12.235**	0.02
No	15	77	118		

Note. One cell (10%) has expected counts less than 5. The minimum expected count is 3.91.

Table 6

Crosstabulation of Foodborne Illness Outbreaks and Restaurant Type

Foodborne Illness Outbreak	Restaurant Type							
	Baker y	Cafeteri a	Market s	Fast Food	Full-service Restaurant	Institutions	X^2	*p*
Yes	5	4	1	7	50	1	60.81**	< 0.00
No	9	6	20	74	55	46		

Note. Two cells (16.7%) have expected counts less than 5. The minimum expected count is 2.45.

Table 7

Crosstabulation of Foodborne Illness Outbreaks and Certified Manager

Foodborne Illness Outbreak	Certified Manager				
	Unknown	Satisfactory	Unsatisfactory	X^2	*p*
Yes	6	53	9	19.094**	< 0.00
No	0	175	35		

Note. Two cells (33.3) have expected counts less than 5. The minimum expected count is 1.47.

Table 8

Crosstabulation of Foodborne Illness Outbreaks and License Type

Foodborne Illness Outbreak	License Type					
	Non-Sit Down Dining	Seats: Less than 50	Seats: More than 50	Food Service	Caterer	X^2
Yes	3	23	36	0.00	6.00	46.151**
No	50	70	40	40.00	10.00	

Note. One cell (16.7%) have expected counts less than 5. The minimum expected count is 3.91.

Simple Logistic Regression for Continuous Variables

Simple logistic regression was conducted for each continuous independent variable and the dependent variable. A logistic regression analysis to investigate if there is a relationship between the number of complaints and if the establishment had a foodborne illness outbreak was conducted. The predictor variable, number of complaints received, was tested a priori to verify there was no violation of the assumption of the linearity of the logit. The predictor variable, number of complaints received, in the logistic regression analysis was found to contribute to the model (Table 9). The unstandardized Beta weight for the Constant; *B* = (-1.543), *SE*=.167, Wald = 85.398, p < .001. The unstandardized Beta weight for the predictor variable: *B* = (1.49), *SE*=0.29, Wald = 26.74, *p* < .001. The estimated odds ratio favored an increase of 330% ([*OR* = 4.30, 95% CI (2.462, 7.512) for having a foodborne illness outbreak with an increase in number of complaints received (Table 9). A logistic regression analysis to investigate if there is a relationship between the number of routine inspections and if the establishment had a foodborne illness outbreak was conducted. The predictor variable, number of routine inspections, was tested a priori to verify there was no violation of the assumption of the linearity of the logit. The predictor variable, number of routine inspections, in the logistic regression analysis was found to contribute to the model. The unstandardized Beta weight for the Constant; *B*= (.081), *SE*=.272, Wald = .089, p < .765. The unstandardized Beta weight for the predictor variable: *B* = (-.541), *SE* =.135, Wald =15.976, p < .001. The estimated odds ratio favored a decrease of 42% ([*OR* = .582, 95% CI (.446, .759) for having a foodborne illness outbreak with an increase in the average number of routine inspections (Table 9).

Table 9

Bivariate Analysis for Food Inspection and Complaint History

Variables	*B*	*SE*	Wald X^2	*OR*	95% CI	*p*
# of complaints received	1.49	0.29	26.74	4.30	[2.462-7.512]	**0.00**
# of critical violations	0.40	0.03	1.87	1.04	[.983-1.103]	0.17
# of routine inspections	-0.54	0.14	15.98	0.58	[.446-.759]	**0.00**
Frequency between inspections	0.00	0.00	0.06	1.00	[.999-1.001]	0.81

Research Question 1 Multivariate Logistic Regression

Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell (1962) procedure. A Bonferroni correction was applied in the model resulting in statistical significance being accepted when $p < .00027$ (Tabachnick & Fidell, 2014). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable, as none of the continuous variables were found to be statistically significant. The variables were also checked for multicollinearity. The variance inflation factor (VIF) was used to determine if there was multicollinearity among factors. No multicollinearity was detected among the predictor variables. There were two standardized residuals with a value of 3.707 and 2.569 standard deviations, which was kept in the analysis.

A binomial logistic regression was conducted to investigate if risk category, restaurant type, restaurant size, certified manager, number of critical violations, number of routine inspections, frequency between inspections, and number of complaints received are factors that predict the likelihood that restaurants have a foodborne illness outbreak. The outcome of interest was if a restaurant had a foodborne illness outbreak. The possible predictor variables were risk category, restaurant type, restaurant size, certified manager, number of critical violations, number of routine inspections, frequency between inspections, and number of complaints received. The omnibus tests of model coefficient determined that the model was statistically significant, $\chi^2(17) = 142.105$, $p < .001$. Additionally, the log likelihood = 167.214 and the Nagelkerke R squared = .596. A Nagelkerke of .596 indicates that the variables in the model accounts for 59.6% of the observed outcome. The sensitivity for the regression model was 58.8% and the specificity of the model was 94.8%. Sensitivity refers to the rate of true positives or the actual number of positives correctly identified, while the specificity refers to the rate of true negatives or the actual number of negatives that are correctly identified. Thus, the regression model correctly identified 58.5% of the establishments that had a foodborne illness outbreak and correctly identified 94.8% of establishments that did not have an outbreak.

The model resulted in the independent variables risk category, restaurant size, certified manager, number of critical violations, and frequency between inspections as not significant ($p > 0.05$), however, the independent variables, number of routine inspections ([*OR* = (.486), 95% CI (.293,.805)]) and number of complaints received

([*OR*= (4.574), 95% *CI* (2.181, 9.590)]), were found to be significant (Table 10). For the restaurant type categorical variable, the group "Bakery" was significant when compared to the reference group "institutions" with an unstandardized *B*= [3.355], *SE*= 1.617, Wald= 4.304, $p < 0.05$. The estimated odds ratio favored an increase of nearly 2765%, [*OR*= (28.650), 95% CI (1.204-681.808)] (Table 10). Within the variable license type, the group "More than 50 Seats" was significant in contributing to the model when compared to the reference group "Registers/Non Sit-Down Dining" with an unstandardized *B*= [3.136], *SE*= [1.569], Wald=3.993, $p < 0.05$. The estimated odds ratio favored an increase of nearly 2200%, [*OR*= (23.00), 95% CI (1.062-498.494)] (Table 10). Controlling for risk category and restaurant type, the predictor variable, number of routine inspections, in the logistic regression analysis was found to contribute to the model. The unstandardized *B*= [-7.222], *SE*=.258, Wald = 7.847, $p < .05$. The estimated odds ratio favored a decrease of nearly 51%, [*OR* = (.486), 95% CI (.293,.805)] for every routine inspection conducted (Table 10). Controlling for risk category and restaurant type, the predictor variable, number of complaints received, in the logistic regression analysis was found to contribute to the model. The unstandardized *B*= (1.520), *SE*=.378, Wald = 16.194, $p < .001$. The estimated odds ratio favored an increase of nearly 357% [*OR*= (4.574), 95% CI (2.181, 9.590)] for every complaint received (Table 10).

Bivariate analysis was conducted for each independent variable to determine their significance and justify their inclusion in the multiple logistic regression model. Number of complaints received, and number of routine inspections were both statistically significant in the bivariate analysis and multivariate analysis (Table 11). Despite not being statistically significant in the bivariate analysis, frequency between inspections and number of critical violations were kept in the multiple logistic regression in the event that the interaction with the other variables made them statistically significant. However, both variables were also not significant in the multiple logistic regression model (Table 11).

Table 10

Multivariate Analysis for Food Inspection and Complaint History

Variables	B	SE	Wald X	df	p	*OR*	95% CI
Number of complaints received	1.520	0.378	16.194	1.000	**0.000**	4.574	[2.181-9.590]
Number of critical violations	0.035	0.046	0.587	1.000	0.444	1.036	[.947-1.132]
Number of routine inspections	-7.222	0.258	7.847	1.000	**0.005**	0.486	[.293-.805]
Frequency between inspections	-0.001	0.001	2.358	1.000	0.125	0.999	[.998-1.132]
Risk Category			2.177	2.000	0.337		
Cook/Serve	-2.196	3.898	0.317	1.000	0.573	0.111	[0.000- 231.306]
Advanced Prep	-1.481	3.911	0.143	1.000	0.705	0.227	[0.000-484.777]
Restaurant Type			14.662	5.000	0.012		
Bakery	3.355	1.617	4.304	1.000	**0.038**	28.650	[1.204-681.808]
Cafeteria, Buffet Service	1.822	1.468	1.541	1.000	0.215	6.184	[.348-109.847]
Markets	-0.197	3.862	0.003	1.000	0.959	0.822	[0.000-1590.847]
Fast Food Service	0.069	1.229	0.003	1.000	0.955	1.072	[0.96-11.923]
Full-Service Restaurant	20.036	1.120	3.307	1.000	0.069	7.661	[.854-68.764]
License Type			4.517	4.000	0.340		
Less than 50 seats	2.894	1.504	3.700	1.000	0.054	18.066	[0.947-344.701]
More than 50 seats	3.136	1.569	3.993	1.000	**0.046**	23.000	[1.062-498.494]
Food Service	-15.293	5621.662	0.000	1.000	0.998	0.000	[0.000-0.000]
Caterer	2.575	1.672	2.371	1.000	0.124	13.129	[.495-348.006]
Certified Manager			0.149	2.000	0.928		
Satisfactory	0.228	0.590	0.149	1.000	0.700	1.256	[.395-3.994]
Constant	-2.495	3.968	.395	1	.530	.083	

Note. Reference group for Risk Category is pre-packaged foods. Reference group for Restaurant type is Institutions. Reference group for License Type is Cash Registers/Non-Sit-Down Dining. Reference group for Certified Manager is Unsatisfactory.

Table 11

Bivariate vs. Multivariate Logistic Regression for Predictors of Foodborne Illness Outbreaks

	Unadjusted		Adjusted OR	
Variable	*OR*	95% CI	*OR*	95% CI
Number of complaints received	**4.301**	[2.462-7.512]	**4.574**	[2.181-9.590]
Number of critical violations	1.041	[.983-1.103]	1.036	[.947-1.132]
Number of routine inspections	**0.582**	[.446-.759]	**0.486**	[.293-.805]
Frequency between routine inspection	1.000	[.999-1.001]	0.999	[.998-1.132]

Note. For adjusted OR, risk category, license type, restaurant type, and certified manager were controlled for.

Bootstrapping for RQ1

The bootstrapping method was utilized to estimate the confidence intervals. Bootstrapping is a resampling method that uses the sample mean and standard deviation as parameter estimates for a hypothesized normal distribution (Lafontaine, 2021). Random samples are then generated from this hypothesized distribution to adjust the endpoints of the percentile confidence intervals (LaFontaine, 2021). Bootstrapping provides the ability to resample as many times as necessary and reduces bias through randomization (Lafontaine, 2021). When bootstrapping was applied to the model, the group "more than 50 seats" was no longer statistically significant in the License Type variable, as well as the group "Bakery" within the restaurant type variable (Table 12).

Controlling for risk category and restaurant type, the predictor variable, number of routine inspections, in the logistic regression analysis with bootstrapping applied was found to contribute to the model. The unstandardized *B*= [-.7222], *SE*=.258, Wald =

7.847, $p < .05$. The estimated odds ratio favored a decrease of nearly 51%, [*OR* = (.486), 95% *CI* (-1.612, -.158)] for every routine inspection conducted (Table 12). Controlling for risk category and restaurant type, the predictor variable, number of complaints received, in the logistic regression analysis with bootstrapping applied was found to contribute to the model. The unstandardized *B*= (1.520), *SE*=.378, Wald = 16.194, $p < .001$. The estimated odds ratio favored an increase of nearly 357% [*OR*= (4.574), 95% CI (1.015, 2.743)] for every complaint received (Table 12).

Table 12

Bootstrapping for RQ1

Variables	*B*	Bias	Std Error	Sig (2-tailed	95% CI
Number of complaints received	1.52	.170[b]	.428[b]	**.001[b]**	(1.015[b]-2.743[b])
Number of critical violations	0.03	.002[b]	.062[b]	.522[b]	(-.088[b]-.154[b])
Number of routine inspections	-0.72	-.064[b]	.367[b]	**.016[b]**	(-1.612[b]--.158[b])
Frequency between inspections	-0.00	.000[b]	.001[b]	.158[b]	(-.003[b]-.000[b])
Risk Category					
Cook/Serve	-2.19	-6.111[b]	17.279[b]	.072[b]	(-39.455[b]-15.431[b])
Advanced Prep	-1.48	-6.064[b]	17.366[b]	.129[b]	(-39.251b-16.257[b])
Restaurant Type					
Bakery	3.35	12.237[b]	12.412[b]	.026[b]	(-.149[b]-38.533[b])
Cafeteria, Buffet	1.82	6.389[b]	9.752[b]	.028[b]	(-4.119[b]-21.330[b])
Markets	-0.19	2.815[b]	14.285[b]	.249[b]	(-17.538[b]-35.943[b])
Fast Food Service	0.06	5.824[b]	8.645[b]	.580[b]	(-2.759[b]-18.15[b])
Full-Service Restaurants	2.03	6.280[b]	8.371[b]	.011[b]	(.656[b]-19.925[b])
License Type					
Seats: Less than 50	2.89	12.282[b]	17.220[b]	.125[b]	(-.659[b]-38.807[b])
Seats: More than 50	3.13	12.290[b]	17.303[b]	.108[b]	(-.529[b]-39.430[b])
Food Service	-15.23	11.837[b]	17.684[b]	.375[b]	(-30.193[b]-21.566[b])
Caterer	2.57	12.224[b]	17.277[b]	.137[b]	(-1.303[b]-39.249[b])
Certified Manager					
Satisfactory	0.22	.012[b]	.961[b]	.721[b]	(-1.147[b]-1.811[b])
Constant	-2.49	.12.42[b]	14.505[b]	0.036[b]	(-39.999[b]-14.279[b])

Note. a. Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples;

b. Based on 998 samples.

Research Question 2 Multivariate Logistic Regression

The variables were checked for multicollinearity prior to running the model. The Variance Inflation Factor (VIF) was to determine if there was multicollinearity among factors. No multicollinearity was detected among the predictor variables. There were five standardized residuals with a value of 3.11, 3.85, 7.81, 7.81, and 3.91 standard deviations, which were kept in the analysis.

A binomial logistic regression was conducted to investigate if risk category, restaurant type, and restaurant size are factors that predict the likelihood that restaurants have a foodborne illness outbreak. The outcome of interest was if a restaurant had a foodborne illness outbreak. The possible predictor variables were risk category, restaurant type, and restaurant size. The omnibus tests of model Coefficient determined that the model was statistically significant, $\chi^2(11) = 84.839$, $p < .001$. Additionally, the log likelihood = 224.480 and the Nagelkerke R squared = .392. The sensitivity for this model was 51.5% and the specificity was 88.1%.

The model resulted in the restaurant type categorical variable group "Bakery", "Cafeteria, Buffet Service", and Full-service Restaurant were significant when compared to the reference variable "Institutions." The group "Bakery" had an unstandardized B= [3.596], *SE*= 1.379, Wald= 6.796, $p < 0.05$. The estimated odds ratio favored an increase of nearly 3545%, [*OR*= (36.45), 95% CI (2.441-544.358)]. The group "Cafeteria, Buffet Service" had an unstandardized B= [2.674], SE= 1.379, Wald= 4.22, $p < 0.05$. The estimated odds ratio favored an increase of nearly 1349%, [*OR*= (14.494), 95% *CI* (1.131-185.694)]. The group "Full-service restaurant" had an unstandardized B= [2.482], *SE*= 1.066, Wald= 5.422, $p < 0.05$. The estimated odds ratio favored an increase of nearly 1096%, [*OR*= (11.964), 95% CI (1.481-96.637)]. Within the variable license type, the groups "Less than 50 seats" and "More than 50 Seats" was significant in contributing to the model. The group "Less than 50 seats" had an unstandardized *B*= [2.270], *SE*= 1.042, Wald=4.745, $p < 0.05$. The estimated odds ratio favored an increase of nearly 868%, [*OR*= (9.684), 95% *CI* (1.255-74.695)]. The group "More than 50 seats" had an unstandardized *B*= [2.709], *SE*= 1.109, Wald= 5.968, $p < 0.05$. The estimated odds ratio favored an increase of nearly 1401%, [*OR*= (15.012), 95% CI (1.708-131.917)] (Table 10).

Table 13

Multivariate Analysis for Restaurant Characteristics

Variables	*B*	*SE*	Wald X	*df*	*p*	*OR*	95% CI
Risk Category			1.766	2	0.413		
Cook/Serve	-1.979	2.172	0.830	1	0.362	0.138	[.002-9.756]
Advanced Prep	-1.551	2.173	0.509	1	0.476	0.212	[.003-15.010]
Restaurant Type			20.036	5	0.001		
Bakery	3.596	1.379	6.796	1	**0.009**	36.453	[2.441-544.358]
Cafeteria, Buffet Service	2.674	1.301	4.222	1	**0.040**	14.494	[1.131-185.694]
Markets	0.688	2.304	0.089	1	0.765	1.989	[.022-181-981]
Fast Food Service	0.857	1.149	0.556	1	0.456	2.355	[1.481-96.637]
Full-Service Restaurant	2.482	1.066	5.422	1	**0.020**	11.964	[1.481-96.637]
License Type			6.617	4	0.158		
Less than 50 seats	2.270	1.042	4.745	1	**0.029**	9.684	[1.255-74.695]
More than 50 seats	2.709	1.109	5.968	1	**0.015**	15.012	[1.708-131.917]
Food Service	-16.833	5976.546	0.000	1	0.998	0.000	[0.000-0.000]
Caterer	2.121	1.209	3.079	1	0.079	8.338	[0.780-89.102]

Note. Indicator variable for Risk Category is pre-packaged foods. Indicator Variable for Restaurant type is Institutions. Indicator variable for License Type is Cash Registers/Non Sit-Down Dining.

Bootstrapping for RQ2

The bootstrapping method was utilized to estimate the confidence intervals for RQ2. When bootstrapping was applied to the model only one of the variables had a group that remained significant when compared to the reference group. For the variable "Restaurant Type", the group "Bakery" had an unstandardized *B*= [3.596], *SE*= 1.379, Wald= 6.796, $p < 0.05$. The estimated odds ratio favored an increase of nearly 3545%, [*OR*= (36.45), 95% CI (1.118-39.224)]. "Cafeteria, Buffet Service" was no longer significant because the confidence interval crossed one. For the "License Type" category, "Less than 50 seats" and "More than 50 Seats" were both no longer significant because the confidence intervals crossed one.

Table 14

Bootstrapping for RQ2

Variables	*B*	Bias	Std Error	Sig (2-tailed	95% CI
Risk Category					
Cook/Serve	-1.98	0.39	14.26	0.04	(-38.709-16.342)
Advanced Prep	-1.55	0.42	14.30	0.10	(-38.264-16.886)
Restaurant Type					
Bakery	3.60	8.11	10.70	**0.01**	(1.118-39.224)
Cafeteria, Buffet Service	2.67	6.58	10.18	0.02	(-0.31-23.251)
Markets	0.69	-0.31	12.67	0.17	(-17.864-19.846)
Fast Food Service	0.86	6.09	8.55	0.23	(-1.24-18.768)
Full-Service Restaurant	2.48	6.22	8.50	0.01	(0.966-20.182)
License Type					
Less than 50 seats	2.27	4.01	11.63	0.08	(0.08-39.664)
More than 50 seats	2.71	4.03	11.66	0.04	(0.431-39.664)
Food Service	-16.83	3.51	12.13	0.11	(-33.1-20.517)
Caterer	2.12	3.97	11.71	0.11	(-0.408-39.191)
Constant	-3.42	-10.66	13.76	0.01	(-38.127-14.595)

Note. a. Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples.

Summary

The Pearson's chi-square analysis determined that categorical variables restaurant type, risk category, license type, and certified manager were all statistically associated with having a foodborne illness outbreak. Simple logistic regression determined that two continuous variables, the number of complaints received and the number of routine inspections, were statistically associated with having a foodborne illness outbreak. For Research Question 1, the null hypothesis is rejected as the multivariate analysis determined that the predictor variables in the model to determine if inspection and complaint history can predict the occurrence of a foodborne illness outbreak was statistically significant. Three variables within that model, restaurant type, the number of complaints received and the number of routine inspections, were statistically significant. For the variable restaurant type, "Bakery" was statistically significant when compared to the reference group "Institutions." For the variable License Type, "More than 50 Seats" was significant when compared to the reference group "Registers/Non Sit-Down Dining." However, once bootstrapping was applied, "More than 50 seats" was no longer significant.

For Research Question 2, the null hypothesis is rejected as the multivariate analysis determined that the predictor variables in the model to determine if the restaurant characteristics can predict the occurrence of a foodborne illness outbreak were statistically significant. Restaurant type was statistically significant. For restaurant type, "Bakery", "Cafeteria, Buffet Service", and Full-service restaurant" were all statistically significant when compared to the reference category "Institutions." Within the variable License Type, "Less than 50 Seats" and "More than 50 seats" were statistically significant when compared to the reference group "Registers/Non Sit-Down Dining." However, when bootstrapping was applied both variables were no longer significant. In Chapter 5, I will provide an interpretation of the results of the study, limitations, recommendations for future research, and implications for social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this study was to quantitatively analyze the differences in risk factors that are present in food establishments that have had a foodborne illness outbreak compared to food establishments that have not had a foodborne illness outbreak. This study is unique in that this is the first time that Rhode Island data has been used for an analytical study to compare data from outbreak establishments and non-outbreak establishments. The findings from this study can be used to identify high-risk establishments that may require a routine inspection to prevent an outbreak from occurring. Furthermore, these findings could be used to schedule inspections based upon risk. The results indicate that a restaurant that has fewer routine inspections is more likely to have a foodborne illness outbreak. Additionally, an establishment that has more complaints on file in a 3-year time period is also more likely to have a foodborne illness outbreak. Specific characteristics such as bakeries, buffets, and full-service restaurants are more likely to have an outbreak, as well as full-service restaurants with greater than 50 seats.

Interpretation of the Findings

The peer-reviewed literature from Chapter 2 supported the burden of foodborne illness outbreaks that are occurring in restaurants each year (Angelo et al., 2017; Dewey-Matia et al., 2018; Lipinski et al., 2019). However, very few analytical studies had been conducted and there is a gap in understanding the risk factors related to the restaurant characteristics and inspection history that cause a foodborne illness outbreak from occurring. The findings from this study support many of the findings from previous literature and expand insight on variables that may be associated with foodborne illness outbreaks. In this study, I sought to increase the knowledge surrounding variables that were more likely to cause a foodborne illness outbreak. Early identification of these high-risk establishments can prevent a future outbreak by sending an inspector to conduct a routine inspection to intervene.

Similar to the findings of Angelo et al. (2017), Dewey-Matia et al. (2018), and Lipinski et al. (2019), full-service restaurants accounted for majority (74%) of the foodborne illness outbreaks. This study also found that the majority of outbreaks that occurred were in full-service restaurants, with greater than 50 seats. This is also consistent with previous studies (Irwin et al., 1989; Jones et al., 2004). Similar to the Dewey-Matia et al. (2018) and FDA risk factor study, 79% of establishments that had a foodborne illness outbreak were considered advanced prep.

There were two categorical variables that had groups that significantly contributed to the original model: “More than 50 seats” from the license type variable and “Bakeries” from the restaurant type variable. “More than 50 seats” is a license type used for full-service restaurants and is a measure to capture the volume of business (e.g. more seats, more meals served). Several previous studies have cited that restaurants that serve more meals per day are at a greater risk for having a foodborne illness outbreak (Irwin et al., 1989; Jones et al., 2004; Lipinkski et al., 2019). Thus, these results are consistent with previous studies. Despite these findings in the original model, once bootstrapping was applied, these results were no longer statistically significant due to the confidence interval crossing one. However, this may be due to small sample size which is noted as a limitation for this study.

The group "Bakeries" from the restaurant type variable was statistically significant in the original model and once bootstrapping was applied. These results contradict previous literature, which found that a bakery is typically considered to be a low-risk establishment (Angelo et al., 2016; CFSAN, 2017; Lipcsei et al., 2019). Despite being low risk, bakeries do have several ready-to-eat foods that if contaminated could cause foodborne illness. A study conducted in Brazil did find that 21% of the outbreaks occurred in a bakery setting (Gustavo, 2016). Furthermore, the study indicated that the pathogen that was most frequently isolated from foods sampled during the outbreak investigation was *Staphylococcus aureus*.

Staphylococcus aureus is commonly associated with employee health and hygiene violations and suggest that violations such as bare hand contact may be associated with these types of outbreaks. Future analysis should be done to see if bakeries are associated with foodborne outbreaks caused by pathogens that are usually associated with employee health and hygiene violations, such as *Staphylococcus aureus* and Norovirus. Employee health and hygiene education could be provided to bakeries to help reduce foodborne illness. Additionally, ensuring bakeries have ill food worker policies (i.e. to prevent food workers from working while ill) and glove use policies (i.e. to prevent bare hand contact) can also help prevent foodborne illness.

Although the number of critical violations was higher in establishments that had a foodborne illness outbreak, it was not statistically significant. This is similar to the study conducted by Jones et al. (2004) where the overall inspection score was not statistically different between establishments that had an outbreak and those that did not. This may suggest that future analysis should focus on the specific risk factors themselves as opposed to overall score. Furthermore, looking at specific risk factors may provide insight into the poor food safety practices that are more likely to result in a foodborne illness outbreak.

Limited research has been conducted on the association between inspection frequency and the occurrence of a foodborne illness outbreak. The results of this study contradict Medu et al. (2017) who found that an increase in the number of inspections per year did not find any difference in risk factors among the two groups. Medu et al. (2017) conducted a two-year controlled trial study where one group had two routine inspections a year and the other group only had one routine inspection a year. The results indicated that there were no differences in risk factors among both groups, which does not support the need for an increased frequency of routine inspections. However, in the Medu et al. (2017) study they were not looking at restaurants that had a foodborne illness outbreak and instead were looking to see if there was a decrease in risk factors among restaurants that were inspected more frequently. This study compared the number of routine inspections conducted between establishments that had a foodborne illness outbreak and establishments that did not.

The findings from this study support the findings of Leinwand et al. (2017) who found that increasing inspections from once to twice a year significantly reduced the number of risk factors found. The results from this study found that an increase in the number of routine inspections had a protective effect for the occurrence of a foodborne illness outbreak (*OR*=-0.54, 95% *CI* .446-.759, $p < 0.001$), suggesting that more frequent routine inspections could prevent an outbreak from occurring at an establishment. The average number of routine inspections conducted during the 3-year period of time for restaurants that had a foodborne illness outbreak was 1.56 routine inspections compared to 2.44 routine inspections for restaurants that did not have a foodborne illness outbreak. This is still below FDA's recommendation of three times per year for high-risk establishments and suggests that following those guidelines could help prevent foodborne illness outbreaks (FDA Retail team, 2018).

Although the findings were not significant, restaurants that did not have a foodborne illness outbreak had a higher percentage of establishments that did not meet the certified manager requirements during the 3-year history of inspection reports reviewed. This contradicts the hypothesis for this study but supports the findings of Harris et al. (2017) who found that having a certified manager was statistically associated with an increase number of critical violations. Prior to 2018, an establishment only needed to have one certified manager who worked at the establishment full-time, but this certified manager was not required to be on-site during all hours of operation. This changed in late 2017 and the regulation now requires a manager to be on-site during all hours of operation and during food prep. Prior research did suggest that having a certified manager on-site during all hours of operation was more effective than only having one certified manager who was not required to be on-site during all hours of operation (FDA Retail Team, 2018). Given the fact that the data from this study was

2010-2019, majority of the establishments met the requirement for having a certified manager as long as they had one manager who worked there full-time. Further research should be conducted to determine if having a certified manager on site at all times is associated with preventing a foodborne illness outbreak.

The results of this study indicate that there is an association between the number of complaints received and a restaurant having a foodborne illness outbreak. These findings expand upon the knowledge of the study conducted by Jemeneh et al., (2018) who found that restaurants that had an illness complaint filed were associated with an increase number of critical violations. Together, these findings suggest that complaints may be an indicator that an establishment has an increased number of critical violations, and thus may be more likely to have a foodborne illness outbreak. This provides evidence for the importance of local and/or state health departments having a foodborne illness complaint system to monitor illness complaints. Furthermore, restaurants that have multiple complaints filed should be inspected more frequently to ensure they are following the food code.

To understand how foodborne illness outbreaks, occur, the framework from the epidemiological triangle model was used (Merrill, 2017). This model suggests that to determine what the causative agent is in an outbreak one must understand the agent, host, and environment in which the outbreak occurred. This study investigated how the characteristics and history of the licensed food establishments (the environment) contributed to the cause of the foodborne illness outbreak.

The theoretical foundation of this study was influenced by the works of Alan Warde (2005), who discusses the consumption and the theory of practice. The consumption and the theory of practice incorporates concepts from the work of Kyrk and Reckwitz. This theory stems from the beliefs that social practices or structures should be the focus of analysis as opposed to the individual (Jackson & Meah, 2017; Warde, 2005). Thus, ensuring interventions are put in place at the establishment level (e.g. implementing policies, inspections of restaurants, etc.) may prevent an outbreak from occurring. Inspecting restaurants more frequently to ensure that they are implementing appropriate policies and procedures may also prevent an outbreak from occurring. More frequent inspections may improve the overall food safety in the establishment and reduce the risk of an establishment having a foodborne illness outbreak.

The models that were run for both RQ1and RQ2 were statistically significant and could be used as predictive models to prevent foodborne illness outbreaks. The significant variables in the model can be used to create an inspection schedule for licensed facilities in Rhode Island based upon risk. More frequent routine inspections should occur at high-risk establishments. Compared to establishments that have either cash registers and/or no sit-down dining area, full-service restaurants with less than 50 seats and more than 50 seats should be inspected more frequently. Food inspection programs that regulate bakeries or buffet services should also consider inspecting these establishments more frequently. Inspecting restaurants based upon risk may prevent future foodborne illness outbreaks from occurring.

Limitations of the Study

One limitation to this study is the sample size. Upon review of the data, only 68 cases met the inclusion criteria for this study. The years of interest could be not be expanded due to inspection reports only being entered into the database in 2007. Thus, in order to review a three time-period for all cases, 2010-2019 was used. The small sample size generated large confidence intervals, making the results difficult to interpret. Bootstrapping was applied to better estimate the confidence intervals. However, many of the confidence intervals crossed one and thus there were no groups that were significant when compared to the reference group. None the less, this study can serve as an exploratory study in Rhode Island and the results still provide valuable insight into high-risk food establishments more likely to have an outbreak. Further research could be conducted in future years to increase the sample size to provide more confidence in the results.

Another limitation for this study is that not all outbreaks are identified and investigated. This study only includes identified foodborne outbreaks and it is unknown to what extent this study represents all foodborne outbreaks. The foodborne outbreaks that are identified and investigated may not be representative of all foodborne outbreaks. In Rhode Island there is a standardization process that all inspectors must go through to ensure consistency. Despite the standardization process, some variability may still occur. Variations may occur due to mistakes or human error. Additionally, just because a foodborne risk factor might not be observed during the inspection does not necessarily mean it is not there. The time of day that the inspections are conducted may also present differences in the findings (e.g. if inspections are done at a busier time there might be more violations observed). Despite their limitations, inspections are a useful tool to determine the conditions in the restaurant and appropriate control measures. Lastly, this study is based on outbreaks in Rhode Island so it may be generalizable to other populations with caution.

Recommendations

Based on the findings from this study, inspection frequency should be based upon risk. Although establishments that did have a foodborne illness outbreak had a higher number of critical violations, it was not significant. Further research should be conducted to determine if specific critical violations, as opposed to the total number of critical violations, are associated with the occurrence of a foodborne illness outbreak. Furthermore, the mixed results of previous research surrounding the impact of a certified manager and the results of this study suggest that more research is needed in this area. Specifically, the effect of having a certified food manager on duty at all times, as recently required, should be further investigated. The findings from this study should be used to create an inspection schedule for licensed food establishments. This schedule should establish frequencies for establishments, ensuring that high-risk establishments are inspected more frequently than lower risk establishments.

Implications

Foodborne illness is a significant public health burden, and the majority of foodborne illness outbreaks happen in a restaurant setting. This data creates a predictive model that could be used for hazard surveillance. Creating a predictive model allows health departments to identify establishments that have characteristics and risk factors that are more likely to result in a foodborne illness outbreak. The health department could use this information for early detection of high-risk establishments to send inspectors to an establishment to ensure interventions are put in place and violations are corrected. Correcting violations in these establishments would reduce the risk factors that lead to foodborne illness outbreaks, likely leading to a reduction in illness. It is estimated that Americans consume food purchased from a retail establishment an average of five times per week (NRA, 2015). This suggests that many Americans may be at risk for foodborne illness and using a predictive model for hazard surveillance can reduce this risk and create positive social change at the individual level.

Conclusion

In 2013, CDC declared foodborne illness a winnable battle, meaning there are several known effective control strategies to mitigate the hazard, yet little progress has been made to reduce illness (Angelo et al., 2017; CDC, 2013; CDC, 2016). Roughly 60% of all foodborne illness outbreaks occur in a restaurant setting (Angelo et al., 2017). The amount of money Americans spend on food that is consumed outside of the home is increasing each year (Saksena et al., 2018). In fact, in 2010 the USDA reported that for the first time the amount of money that Americans spent on food consumed outside of the house was greater than what was spent on food consumed at home (Saksena et al., 2018). This suggests that many Americans may be at risk for a foodborne illness.

The regulatory agency responsible for routine inspections often uses an electronic database to store the inspection data. This data can be used for hazard surveillance to identify the restaurants that are more likely to have a foodborne illness outbreak. The data from this study provides further evidence that full-service restaurants that used advanced preparation methods are more likely to have a foodborne illness outbreak. Furthermore, inspections that were conducted more frequently had a protective effect in preventing a foodborne illness outbreak. This suggests that routine inspections are an effective intervention in preventing foodborne illness outbreaks. Lastly, restaurants that had an increased number of complaints in their history were more likely to have a foodborne illness outbreak. Using data to identify the most high-risk establishments that need an inspection is an effective tool to ensure that resources are being used efficiently, especially when resources are limited. Interventions that encourage and promote social level (i.e., restaurant level) positive change should be implemented. Improving hazard surveillance can likely lead to a reduction in illness, thus creating social positive change.

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