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A Quantitative Study of the Effectiveness of Regulatory Policy in the Maryland Food Industry

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College of Social and Behavioral Sciences

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Alphonsus Korie

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Walden University
2016

Abstract

The Effectiveness of Regulatory Policy in the Maryland Food Industry

by

Alphonsus Korie

MA, Sojourner–Douglass College, 2010

BS, Alabama State University, 1986

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Policy and Administration Health Services

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February 2016

Abstract

Foodborne illness is a persistent problem in the food service industry. Restaurant inspections reveal that only 60-70% of restaurants are in compliance with health code requirements, which vary from state to state and county to county. In Maryland, 5 of the state's 24 counties have a requirement that restaurants classified as medium- or high-priority food establishments must employ certified food managers (CFMs). It is unknown how this requirement has influenced the operation of the affected restaurants and the extent to which the requirement has resulted in improved food handling safety. The purpose of this quantitative study was to determine the effectiveness of CFMs in reducing the incidence of foodborne illness in Maryland counties. The study was based on the theory of planned behavior. The study was also based on the relationship between foodborne illness outbreaks and the presence of CFMs and the role such managers can play in reducing those outbreaks. Data were collected from the Maryland Department of Health and Mental Hygiene reports regarding foodborne illness outbreaks from 2004 to 2013. A total of 288 establishments were selected for analysis. Data analysis involved comparing results for the 5 counties that require CFMs with the 19 counties that lack this requirement. Results showed a significance difference of 0.008 (95% CI, 0.005), $z = 4.71$, $p = 0.000$ in the proportion of foodborne illness outbreaks between county restaurants that require CFMs and those without such a requirement. Social change implications include the potential to reduce the incidence of foodborne illness, thereby contributing to improved public health. The patrons who live in Maryland counties without onsite CFMs risk exposure to foodborne illness more than those living in counties with CFMs.

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Chapter 1: Introduction to the Study

Introduction

Despite efforts by local, state, and federal health departments, food code violations in restaurants still occur (Koechlin, 2009). In the absence of federal standards for food safety, national trends are difficult to identify. The last effort by the U.S. Food and Drug Administration (FDA) to assess food safety compliance on a national scale was in 2008. That investigation revealed violations of food temperature management (55% of full-service restaurants), personal hygiene (41%), and food contact surfaces (35%).

Food safety regulations are typically formulated by state, county, and municipal governments. In Maryland, no statewide regulations exist. However, five of the state's 24 counties have addressed food safety by instituting a requirement that medium- and high-priority restaurants employ a certified food manager (CFM). The remaining 19 counties do not have such a requirement. One of the CFM's jobs is to ensure that the establishment is in compliance with county and local health code requirements.

Although Maryland's partial CFM requirement has been in place since 2004, no studies were found regarding its effectiveness. Consequently, it is unknown how restaurants in the five counties requiring a manager compare to the 19 counties lacking the requirement. To address this lack of knowledge, I compared the incidence of foodborne illness outbreaks between Maryland counties with and without the CFM requirement. Results of this study will help inform the efforts of restaurant owners to improve food-handling safety and reduce the number of foodborne illness outbreaks caused by eating restaurant food.

In the remainder of this chapter, the background of the study will be described, and the study's purpose will be further detailed. The study's theoretical basis will be explained, and its methods will be briefly presented. Research questions and hypotheses will be listed, key terms will be defined, and assumptions and limitations will be described. Chapter 2 consists of a review of the relevant literature on the theory of planned behavior, foodborne illness, food handling safety, food industry regulations, and public policy related to foodborne illness. In Chapter 3, I will describe the study's design, data collection and analysis procedures, and ethical protections. In Chapter 4 I will summarize the study's results, and in Chapter 5 I will present conclusions and recommendations.

Background of the Study

The safety of the U.S. food supply is affected by imports, domestic distribution and supply networks, dietary choices, and bacterial adaptations (Lee, 2013). A concern with food safety led the federal government in 1999 to create the National Food Safety System (NFSS), which established a task force to promote food safety at all levels, including food producers, retailers such as restaurants, and government entities that provide food through schools and relief agencies. In 2000, the U.S. Food and Drug Administration (FDA) directed each state to require food safety training for all food service managers. Because the FDA did not specify what such training should include, requirements vary from state to state. Some states have instituted their own training and certification programs. Others rely on organizations such as the National Restaurant Association (NRA) or private companies to provide that service. States also differ in the employment level at which external training is required (NAS, 1999; & Roberts, 2008).

According to the NRA (2012), food contamination is affected by acidity, oxygen and moisture content, and storage temperatures. Bacteria growth accelerates between 41° F and 135° F. Some bacteria (aerobic) grow in an oxygen environment, whereas others (anaerobic) flourish in hypoxic environments. Foodborne illness can result when people consume foods contaminated by bacteria (Jones & Agulo, 2006), and such illnesses affect about 48 million people annually in the United States, resulting in approximately 128,000 hospitalizations and 3,000 deaths (Centers for Disease Control [CDC], 2014).

To minimize the likelihood of foodborne illness, a variety of requirements have been instituted in foodservice establishments. These requirements cover food-handling techniques, maintaining proper food temperatures, avoiding cross-contamination of food contact surfaces, and personal hygiene (NRA, 2012). A lack of compliance with these requirements can result in illness to restaurant patrons because of contaminated food. The CDC (2011) defined a foodborne illness outbreak as "the occurrence of two or more similar cases resulting from the eating of a common food" (p. 1). Although it is unknown how many illnesses and deaths result from eating contaminated food at restaurants, experts have implicated the food service industry as a major contributor to foodborne illness, with some estimating that restaurants account for up to half of such illnesses (Jones & Angulo, 2006; Roberts et al., 2008). According to a report by United Press International (2011), adults in the United States eat an average of 4.8 meals per week in restaurants.

Estimates on the number of Americans who come down with acute gastroenteritis annually are as high as 50 million. Cases are most prevalent among children, the elderly, pregnant women, and immune-compromised individuals (McCabe-Sellers & Beattie, 2004). As Koechlin (2009) noted, “Unlike home-prepared food, infected foods prepared in restaurants have the potential for affecting more people” (p. 1). The cause of many foodborne illness outbreaks remains a mystery, in part because the origin of such incidents in private homes is often unreported. As Bryan (2002) noted,

> Besides those reported, many illnesses never come to the attention of health authorities. Many persons who develop gastroenteritis neither seek medical attention nor complain to health authorities. Even when medical assistance is sought, reports to health authorities are not always made. All reports are not investigated, and many of those that are investigated do not result in a conclusion as to (a) vehicle, (b) the mode of contamination and/or the source, and (c) the way the pathogen survived processing and grew to quantities sufficient to cause illness. (para. 11)

One cause of foodborne disease is inadequate hand washing. According to Todd, Grieg, Bartleson, and Michaels (2009), 40% of food-related disease is caused by food handlers not using gloves or proper hand-washing techniques when handling ready-to-eat food products. Allwood, Jenkins, Paulus, Johnson, and Hedberg (2004) studied restaurants in Minnesota and found that food workers’ ability to use proper hand-washing procedures was related to a manager’s knowledge of hand-washing requirements and the existence of a training program. The researchers also found that establishments using live demonstrations of proper hand washing had better outcomes than did those that used other means such as signs, posters, or video.

In Maryland, five of the state's 24 counties require foodservice facilities operating under medium- or high-priority food permits to have a CFM on the premises while the establishment is open for business. Certification consists of 16 hours of training in safe food handling, followed by passing an examination approved by the NRA. In Maryland, that is the SERVSAFE exam. Certification lasts for 3 years.

Statement of the Problem

Millions of Americans contract pathogens that cause foodborne illnesses and thousands die each year because of these diseases, which often result from improper food-handling practices in restaurants and other food-service establishments (Jones & Angulo, 2006; Roberts, 2008). Maryland lacks a statewide policy requiring food services to employ CFMs as a defense against foodborne illnesses. Instead, individual counties are on their own to implement food manager certification requirements. The result is that only five of the state's 24 counties have such a requirement. It is unknown how requiring restaurants to have CFMs has affected the operation of those establishments and the extent to which that requirement has resulted in improved food handling safety. That lack of knowledge is the problem the current study addressed by a comparison of Maryland restaurants with and without a CFM requirement. This problem is important because food manager certification represents an additional expense for restaurant owners, and it is necessary to know whether the requirement results in greater safety for restaurant patrons.

Purpose of the Study

The purpose of this quantitative study was to determine whether there are differences in foodborne disease outbreaks at Maryland medium- and high-priority restaurants employing an onsite CFM compared to establishments without such managers. CFMs are food workers who receive at least 16 hours of safe food-handling training and pass a comprehensive certification examination given by SERVSAFE. A larger purpose of the proposed study is to provide restaurant owners with information that will help them reduce the incidence of foodborne disease and thus improve public health.

Nature of the Study

This quantitative study was based on a cross-sectional design. The independent variable was the presence or absence of CFMs at a given foodservice establishment. The dependent variable was the difference in the proportion of foodborne illness outbreaks between the two groups of restaurants. Data collection involved collecting information from the Maryland Department of Health and Mental Hygiene for the period 2004 to 2013, which was used to compare foodborne illness outbreaks from the five counties that require CFMs and the 19 counties without this requirement. The counties that require CFMs started enforcement in 2004. The original plan was to subject data to inferential statistical analysis using a one-way ANOVA and independent-samples *t* tests to compare the two groups of restaurants. At the end, this method was not appropriate for my data analysis, and the two sample proportion test was deemed more appropriate instead.

The current research design was chosen because it promised to be cost effective and yield a quick turnaround in data collection. A qualitative design was also considered. Doing interviews would have resulted in richer data, but that depth would have been achieved at the expense of the breadth that can be attained through document research, which enables a researcher to employ a much larger sample.

Research Question and Hypothesis

The current study was based on one overarching research question: What is the relationship between foodborne illness outbreaks and the presence of CFMs in Maryland medium- and high-priority food establishments? This question led to the following hypothesis, which is stated in both null and alternative form:

> H_0: There are no statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such a requirement.
>
> H_1: There are statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such a requirement.

Theoretical Basis of the Study

This study was based on the theory of planned behavior (TPB), which is an attempt to account for behavioral intent. TPB focuses on intent rather than actual behavior (Ajzen, 1991). Unlike the theory of reasoned action (TRA), on which it is based, TPB is founded on an assumption that individuals are not necessarily in full control of their behavior (Blue, 1995). Another difference between the two theories is that TRA is applicable when formal skill or social cooperation is not required, whereas when those factors are included, TPB is more appropriate (Roberts, 2008). TPB will be further described in Chapter 2.

Definitions of Terms

Foodborne illness outbreak: “An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness” (CDC, 2011, para. 1).

Food-handling practices: Steps employed by food processers and manufacturers in managing products in their establishments (Baltimore County Department of Health [BCDH], 2011).

High-priority food establishment: A food facility that cooks then cools food from 135° F to 70° F within 2 hours and 70° F to 41° F within 4 hours, then reheats it to 165° F. Reheated food is kept in a warmer at 135° F until served. Any food product that does not meet the above requirements is discarded (BCDH, 2011).

Medium-priority food establishment: A food facility that cooks food, holds it at 135° F, and serves it immediately (BCDH, 2011).

Pathogen: Bacteria, virus, or other microorganism causing an illness or disease (FDA, 2012).

Assumptions

This study is based on the assumption that information provided by the Maryland Department of Health and Mental Hygiene was accurate, reliable, and timely compared to self-reported data from restaurant operators.

Scope and Delimitations

This study was confined to the state of Maryland. That geographical area was chosen for two reasons. First, because Maryland lacks a statewide policy regarding the presence of an onsite CFM at restaurants, the state represents an appropriate site to compare the effects of counties that require such a manager with those that do not. Second, I live and work in Maryland. I am familiar with the state's food service industry, and it was convenient for me to conduct the study there.

This study was further confined to restaurants defined as medium- and high-priority food service establishments. Both kinds of restaurant sell food that is cooked onsite. The distinction between the two has to do with holding times and temperatures (see Definitions of Terms). Excluded from the study are low-priority establishments, which sell prepackaged food and beverage items that require no preparation, refrigeration, or reheating. Low-priority facilities were not included in the study because food safety considerations pertaining to what such establishments sell have to do with where the products were manufactured and packaged, which may be outside of Maryland.

Finally, the current study was limited to the period from 2004 to 2013. This time frame was selected because it was in 2004 that five Maryland counties instituted a requirement that all medium- and high-priority restaurants employ an onsite CFM, and 2013 is the most recent year for which comprehensive data on foodborne illnesses are available. Because this study was confined to Maryland counties, and because individual states, counties, and municipalities are free to establish their own food safety policies, it will not be possible to generalize the results of this study to other states, counties, or municipalities.

Limitations

A potential limitation for the current study is my own professional status as a registered environmental health specialist, in which capacity I formerly supervised the professional regulators who inspect food establishments in Maryland. Because of my former job, I may have been subject to personal bias based on my specialized knowledge of Maryland’s food service industry. Appropriate steps were taken to minimize such bias; these are described further in Chapter 3.

One potential threat to the internal validity of the current study is the possibility that factors other than the independent variable could have affected the dependent variable. It was not possible to control for all other potential confounder variables. As noted above, one threat to external validity is the fact that Maryland’s current food safety policy lacks a statewide requirement for CFMs in medium- and high-priority food establishments, which limits the extent to which the study’s findings can be generalized to states that have a uniform requirement. For example, in 1985 California lawmakers saw the need for “uniform and statewide health and sanitation standards governing retail food facilities throughout the state,” (Taber, 2004, p.7) and enacted two laws—the California Uniform Retail Food Facilities Law (CURFFL) and California Health and Safety Code, §113700 through §114455—“to ensure food products consumed by the public are pure, safe and unadulterated” (Taber, 2004, p. 7).

Significance of the Study

Foodborne illness is a public health problem that results in pain and suffering, absences from work, lost wages, and reduced economic productivity. Foodborne illnesses affect some 48 million people annually in the United States, resulting in about 3,000 deaths and costing $77.7 billion (CDC, 2014). Although it is unknown how many instances of foodborne illness are caused by restaurant meals, according to a recent survey adults in the United States eat an average of 4.8 meals per week in restaurants (United Press International, 2011).

The majority of foodborne illnesses are preventable, and the food service industry has a major responsibility in reducing such illnesses (Jones & Angulo, 2006). Averett, Nazir, and Neuberger (2011) called for more effective education for food handlers. Chukwuocha et al. (2009) found that training in safe food-handling practices resulted in reductions in foodborne illness outbreaks.

The results of this study can contribute to positive social change by informing the efforts of restaurant owners and managers to improve food-handling safety in their establishments. The study outcome can assist community health educators as they provide information on safe food handling. The study will also benefit legislators and policy makers as they formulate laws and guidelines to improve the safety of the nation's food supply. The net effect of these changes will be fewer hospitalizations and deaths, reduced pain and suffering, and greater economic productivity. This study will also provide a basis for further research on the important topic of food safety.

Summary

Foodborne illness, although largely preventable, continues to be a significant public health problem in the United States. Because a large percentage of meals are eaten in restaurants, the food industry can play a significant role in reducing foodborne illness outbreaks. In the absence of federal requirements governing food handling in commercial establishments, individual states are left to formulate their own policies. In Maryland, five of the state's 24 counties have instituted a requirement that a CFM be on duty whenever the establishment is open for business.

The purpose of this quantitative study was to determine whether there are differences in foodborne disease outbreaks at Maryland medium- and high-priority restaurants based on the presence of an onsite CFM. Another purpose was to determine if restaurant owners' attitudes toward food safety are influenced by the presence or absence of a CFM requirement. The study was based on the theory of planned behavior. Data collection consisted of obtaining reports from the Maryland Department of Health and Mental Hygiene regarding the incidence of foodborne illness outbreaks associated with the state's restaurants. Data were statistically analyzed using a one-way ANOVA and independent-sample *t* tests used to test differences between the two groups.

Chapter 2 of this dissertation consists of a review of the relevant literature on foodborne illness, along with a discussion of the theory of planned behavior. In Chapter 3, the study's methodology will be presented, including research design, data collection and analysis procedures, and ethical protections. In Chapter 4, the results are summarized, and in Chapter 5 conclusions and recommendations are offered.

Chapter 2: Review of the Literature

Introduction

Foodborne illnesses affect about 48 million Americans a year, resulting in 128,000 hospitalizations and 3,000 deaths (CDC, 2014). A foodborne illness outbreak results when more than one person gets sick from eating the same contaminated food (FDA, 2012). Because of the greater potential scale of those affected, outbreaks are more consequential when they result from food consumed at restaurants. Adults in the United States eat an average of 4.8 meals per week in restaurants (United Press International, 2011). This suggests that food-service establishments have a large responsibility in reducing incidences of foodborne illness. According to Pilling, Brannon, Roberts, Shanklin, & Howells (2009), food-handling safety training can result in “improved attitudes, food safety behaviors, and employees’ knowledge” (p. 192).

No federal legislation specifies requirements for food-handling safety at commercial food services. Consequently, states and municipalities are on their own to implement such requirements. In Maryland, five of the state’s 24 counties have addressed food safety by requiring all medium- and high-priority food facilities to employ an onsite CFM, who is responsible for overseeing the safety of food-handling procedures. Because the efficacy of food managers in reducing foodborne illness has not been studied in Maryland, the current study was designed to compare the counties requiring food managers with those that lack this requirement. The study was based on document review of foodborne illness outbreaks collected by the Maryland Department of Health and Mental Hygiene from 2004 to 2013.

I began the literature review by consulting several databases: Google Scholar, Sage, and ProQuest. Searches were conducted with the following terms: *food safety, food processing, food handler education, food temperature, foodborne disease, foodborne illness, foodborne illness outbreaks, public policy and food safety, food workers, food handlers, food training, food hazards, food handling practices, food contact surfaces, sanitization process, food equipment cleaning, food storage, hand washing, pathogens, salmonella poisoning, listeria, listeriosis, escherichia coli, shiga, e-coli, norovirus, campylobacter, certified food managers, trained food handlers,* and *food regulation in Maryland.* The literature search involved no date parameters, but in selecting sources for review, preference was given for those published in the last 10 years. Preference was also given to peer-reviewed journal articles and doctoral dissertations.

Theory of Planned Behavior

The TPB, which was derived from the TRA, was developed by Ajzen and Fishbein (1977, 1980). TPB attempts to account for an individual's "intention to perform a given behavior" (Ajzen, 1991, p. 181). The emphasis is on intent: "trying to perform a given behavior rather than . . . actual performance" (Ajzen, 1991, p. 182). Pilling et al. (2009) stated that TPB is useful in assessing a person's behavior in light of his or her intentions. TPB is consonant with Bandura's (1977) notion of self-efficacy, which affects performance preparation and effort. Conner and Armitage (1998) lauded TPB for its frugality in suggesting behavioral determinants.

According to Ajzen (1991), TPB is based on the assumption that behavioral intentions are affected by three things: attitude, subjective norms, and perceived behavioral control (see Figure 1). Subjective norms are social influences to engage in or refrain from engaging in a particular behavior. Perceived behavioral control refers to the anticipated difficulty or challenges associated with a specific behavior and is affected by both internal factors (abilities, emotions, knowledge) and external influences (time, financial means, cooperation from others). A positive attitude, supportive subjective norms, and perceived self-efficacy will increase the likelihood of a person engaging in the behavior under consideration.

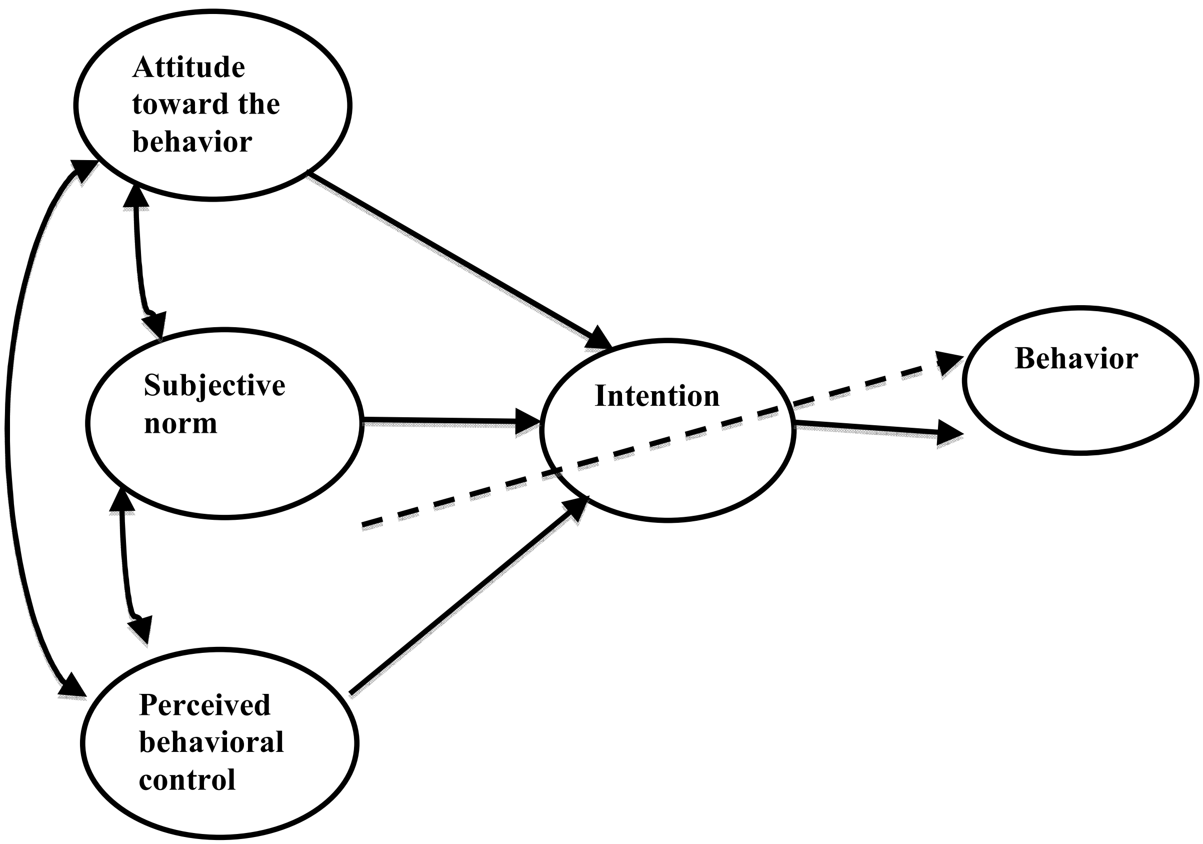

Figure 1. Theory of planned behavior.

According to Blue (1995), TRA is based on the assumption that an individual is in full control of a particular behavior, whereas TPB operates on the assumption that people are not necessarily in control of their behavior. For example, if a restaurant worker did not receive adequate training in food-handling procedures, that person would not understand the implications of his or her behavior and would thus not be in full control of the behavior. Another difference between the two theories is that TRA is applicable when formal skill or social cooperation is not required, whereas when those factors are included, TPB is more appropriate (Roberts, 2008).

Bagozzi, Baumgartner, and Yi (1992) used TPB in a study of consumers' use of coupons in grocery shopping. The researchers distinguished between a state and action orientation, which differ according to a capacity for acting on stated intentions. Bagozzi et al. found that a low capacity for action (state orientation) was associated with subjective norms, whereas a higher capacity (action orientation) was marked by an emphasis on attitudes. "State-oriented individuals form their intentions on the basis of normative expectations, whereas action-oriented individuals arrive at their intentions through attitudinal considerations" (Bagozzi et al., 1992, p. 507).

Pilling et al. (2009) used TPB in a study of restaurant employees' beliefs about food safety. The researchers used a survey and focus groups to determine employees' attitudes toward washing hands, using thermometers, and sanitizing work surfaces. Participants described several benefits of hand washing: better personal hygiene and food safety along with reduced cross-contamination. Disadvantages of hand washing included inconvenience and dry skin. Actually washing hands, as opposed to merely intending to, was affected by availability and location of sinks, along with training on how to wash hands properly. Regarding thermometers, participants noted that they can give a false sense of security about food safety. The chief barrier to sanitizing work surfaces was a perception of insufficient time.

Another study that considered the dynamics of hand washing was conducted by Rosen, Zucker, Brody, Engelhard, and Manor (2009), who explored the effects of an intervention program in 40 Jerusalem preschools. The intervention consisted of lectures, printed matter, and experiential learning. The researchers measured attitudes, beliefs, knowledge, and self-efficacy. They concluded that knowledge was affected by the intervention. “The combination of positive attitudes toward handwashing among educators and the program’s effectiveness in imparting knowledge helped to create a sustained social norm of handwashing among many children in disparate locations” (p. 686).

In a cross-cultural study of attitudes toward hygiene, Curtis, Danquah, and Aunger (2009) found that the primary motivations for hand washing were disgust and comfort. Disgust is triggered when one’s hands are soiled with dirt, feces, bodily fluids, or other deleterious substances. Comfort is achieved when one’s hands are clean and free from stains. Curtis et al. found that in Uganda, Senegal, Kenya, and Peru, increased hand washing was motivated by a cholera outbreak. However, when people perceived that the threat of disease had subsided, they reverted to their previous hygiene habits. The researchers also found that hand washing was affected by religious beliefs and social factors such as local cultural norms, family practices, governmental pronouncements, schools, and the media. Curtis et al. concluded that planned behavior is influenced by numerous factors but that once a behavior, such as hand washing, becomes common, it can no longer be regarded as the result of individual planning.

TRA and TPB have been used in numerous other studies on topics ranging from searching for a job to losing weight to exercising to getting drunk. Ajzen (1991) compared the results of 16 studies according to intention, attitude, subjective norm, and perceived behavioral control (see Table 1).

Table 1

Predicting Behavioral Intention

Study	Intention	AB_1	SN_1	PBC_1	AB_2	SN_2	PBC_2	R_2
Van Ryn & Vinokur (1990)	Search for a job	.63	.55	.20	.48	.35	.07	.71
Doll & Ajzen (1990)	Play six video games Mean within-subjects	.92	.54	.87	.46	.17	.43	.94
Schlegel et al. (1990)	Get drunk	.63	.41	.58	.41	.15	.36	.72
Ajzen & Driver (in press)	Five leisure intentions Mean within-subjects	.59	.70	.80	.28	.09*	.62	.85
Watters (1989)	Participate in election*	.39	.13*	.30	.32	.03*	.20	.43
Netemeyer, Burton, & Jognston (1990)	Participate in election*	.33	.34	.62	.10*	.10*	.54	.64
Schifter & Ajzen (1985)	Lose weight	.62	.44	.36	.79	.17	.30	.74
Madden, Ellen, & Ajzen (in press)	10 common activities	.52	.36	.37	.43	.22	.26	.63
Ajzen & Madden (1986)	Attend class	.51	.35	.57	.32	.16	.44	.68
	Get an A in a course	.48	.11*	.44	.50	-.09*	.45	.65
Beck & Ajzen (in press)	Cheat, shoplift, lie	.68	.40	.77	.29	.05*	.59	.81
Netemeyer, Andrews, & Durbasula (1990)	Give a gift	.51	.38	.44	.36	.08*	.20	.56
Parker et al. (1990)	Commit traffic violations	.26	.48	.44	.15	.28	.33	.60
Beale & Manstead (1991)	Limit infants' sugar intake	.41	.33	.52	.26	.16*	.40	.60
Godin, Vezina, & Leclerc (1989)	Exercise after giving birth	.50	- .01*	.60	.76	-.24	.84	.94
Godin et al. (1990)	Exercise after coronary	.42	.13*	.50	.25	.01*	.39	.55
Otis, Godin, & Lambert (in press)	Use condoms	.62	.42	.29	.52	.26	.17	.69

Note. AB = attitude toward behavior, SN = subjective norm, PBC = perceived behavioral control
1 = correlations, 2 = regression/coefficients

Foodborne Illness

Scallan et al. (2011) estimated that 31 different pathogens are acquired in the United States each year and that these are responsible for 9.4 million cases of foodborne illness, resulting in 55,961 hospitalizations and 1,351 deaths. Approximately 5.5 million foodborne illnesses are due to viruses, 3.6 million are bacteria-related, and 0.2 million are caused by parasites. The most frequent cause of viral infection is norovirus, whereas campylobacter and salmonella account for the greatest number of bacterial infections (see Table 2). The deadliest foodborne illnesses are salmonella, Listeria, Toxoplasma gondii, and norovirus (see Table 3). The pathogen most likely to result in hospitalization and death is Listeria (see Tables 4 and 5).

The pathogens that cause foodborne illnesses flourish in environments of improper temperature control and are spread by "infected food handlers, contaminated raw ingredients, and cross-contamination" (Rooney et al., 2004, p. 427). According to Harris et al. (2003), the pathogens responsible for foodborne illness outbreaks find their way into the food chain during "food production, harvest, processing, transporting, and more especially in retail and foodservice establishments such as restaurants and cafes" (p. 79). A pathogen's potential to cause an infection is a function of its ability to survive on food surfaces or surfaces that come in contact with food. According to Todd et al., (2009), enteroviruses can survive at room temperature for up to 2 weeks and in refrigerated conditions for up to 2 months. Whereas pathogens found in the human body thrive in moist conditions, rotavirus and skin bacteria flourish under dry conditions and in low-moisture foods.

Table 2

Estimated Annual Episodes of Domestically Acquired Foodborne Illnesses

Pathogen	Total	Domestically acquired	Foodborne, %
Bacteria			
Bacillus cereus	63,623	63,411	100
Brucella spp.	2,003	1,679	50
Campylobacter spp.	1,322,137	1,058,387	80
Clostridium botulinum	56	55	100
Clostridium perfringens	969,342	966,120	100
STEC O157	96,534	93,094	68
STEC non–O157	168,698	138,063	82
ETEC, foodborne	39,781	17,897	100
Diarrheagenic *E. coli*	39,871	39,739	30
Listeria monocytogenes	1,662	1,607	99
Mycobacterium bovis	208	63	95
Salmonella spp.	1,229,007	1,095,079	94
S. enterica serotype	5,752	1,897	96
Shigella spp.	494,908	421,048	31
Staphylococcus aureus	241,994	241,188	100
Streptococcus spp.	11,257	11,219	100
Vibrio cholerae	277	84	100
V. vulnificus	207	203)	47
V. parahaemolyticus	44,950	40,309	86
Vibrio spp.	34,585	30,727	57
Yersinia enterocolitica	116,716	108,490	90
Subtotal	**4,883,568**	**4,330,358)**	
Parasites			
Cryptosporidium spp.	748,123	678,828)	8
Cyclospora cayetanensis	19,808	11,522	99
*Giardia intestinali*s	1,221,564	1,121,864	7
Toxoplasma gondii	173,995	173,415	50
Trichinella spp.	162	156	100
Subtotal	**2,163,652**	**1,985,785**	
Viruses			
Astrovirus	3,090,384)	3,089,868)	<1
Hepatitis A virus	35,769	21,041	7
Norovirus	20,865,958	20,796,079	26
Rotavirus	3,090,384	3,089,868	<1
Sapovirus	3,090,384	3,089,868	<1
Subtotal	30,172,879	30,086,723)	
Total	**37,220,098**	**36,402,867**	

Note. From Scallan et al., 2011. Used with permission.

Table 3

Estimated Hospitalizations and Deaths from Common Pathogens

Pathogen	Hospital. rate	Hospitalizations	Death rate	Deaths
Bacteria				
Bacillus cereus	0.4	20	0	0
Brucella spp.	55.0	55	0.9	1
Campylobacter spp.	17.1	8,463	0.1	76
Clostridium botulinum	82.6	42	17.3	9
Clostridium perfringens	0.6	438	<0.1	26
STEC O157	46.2	2,138	0.5	20
STEC non-O157	12.8	271	0.3	0
ETEC, foodborne	0.8	12	0	0
Diarrheagenic *E. coli*	0.8	8	0	0
Listeria	94.0	1,455	15.9	255
Mycobacterium bovis	55.0	31	4.7	3
Salmonella spp.	27.2	19,336	0.5	378
S. enterica serotype	75.7	197	0	0
Shigelle spp.	20.2	1,456	0.1	10
Staphylococcus	6.4	1,064	<0.1	6
Streptococcus spp.	0.2	1	0	0
Vibrio cholera	43.1	2	0	0
V. vulnifricus	91.3	93	34.6	36
V. perahaemolyticus	22.5	100	0.9	4
Vibrio spp.	37.1	83	3.7	8
Yersinia enterocolitica	34.4	533	2.0	29
Subtotal		**35,756**		**861**
Parasites				
Cryptosporidium	25.0	210	0.3	4
Cyclospora cayetanensis	6.5	11	0.0	0
Giardie intestinalis	8.8	225	0.1	2
Toxoplasma gondii	2.6	4,428	0.2	327
Trichinella spp.	24.3	6	0.2	0
Viruses				
Astrovirus	0.4	87	<0.1	0
Hepatitis A virus	31.5	99	2.4	7
Norovirus	0.03	14,663	<0.1	149
Rotavirus	1.7	348	<0.1	0
Sapovirus	0.4	87	<0.1	0
Subtotal		**15,284**		**157**
Total		**55,961**		**1,351**

Note. From Scallan et al., 2011. Used with permission.

Table 4

2011 Pathogen-Caused Illnesses and Deaths

Pathogen	Deaths	Cases	CFR
Campylobacter	2	6,746	0.03
Listeria	22	134	16.42
Salmonella	24	7,763	0.31
Shigella	2	1,514	0.13
STEC O157	2	463	0.43
STEC non-O157	1	509	0.20
Vibrio	5	154	3.25
Yersinia	3	158	1.90
Cryptosporidium	6	1,334	0.45
Cyclospora	0	22	0.00
Total	67	18,797	0.36

Note. From CDC (2011) FoodNet report. Used with permission.
CFR = case fatality ratio.

Table 5

2011 Pathogen-Caused Hospitalizations

Pathogen	Hospitalizations	Cases	% Hospitalization
Campylobacter	1,001	6,746	14.84
Listeria	127	134	94.78
Salmonella	2,174	7,763	28.00
Shigella	321	1,514	21.20
STEC O157	201	463	43.41
STEC non-O157	90	509	17.68
Vibrio	49	154	31.82
Yersinia	56	158	35.44
Cryptosporidium	268	1,334	20.09
Cyclospora	3	22	16.64
Total	4,290	18,797	22.82

Note. From CDC (2011) FoodNet report. Used with permission.

Morris (2011) posed the question of whether the U.S. food supply was safer in 2011 than in 2000. He pointed to the FoodNet system, which was created to assess the effect of 1995 U.S. Department of Agriculture (USDA) regulations codified in the Hazard Analysis and Critical Control Point (HAACP) system. “FoodNet provides annual data from designated sentinel surveillance sites on numbers of laboratory-diagnosed cases of 10 predominantly foodborne bacterial and parasitic pathogens” (para. 5). These data, according to Morris, showed an initial drop in infection rates after the USDA regulations were implemented, “followed by leveling off in subsequent years” (para. 5).

Many foodborne illnesses go unreported, making it difficult to acquire complete data on their frequency and type. The CDC’s foodborne illness surveillance network is an attempt to compile comprehensive data based on reports from states, counties, and municipalities. In 2004, a multistate foodborne illness outbreak resulted in about 600 cases of salmonella, 154 of which required hospitalization. The major transmission vehicles were roma tomatoes and ground beef (CDC, 2008). The same year, five Maryland counties reported 178 cases of foodborne illness caused by norovirus, bacillus cereus, clostridium perfringens, and scombroid toxi. Of these, 17 cases occurred in private homes and 161 resulted from eating at restaurants. Foods implicated in these illnesses included smoked salmon, chicken, crab, fried rice, fish sandwiches, iced tea, seafood salad, beef, and pizza (CDC, 2008).

Salmonella is the most common bacterial infection in the United States (see Tables 2 and 3). Many U.S. cases of salmonella infection result from food consumed in other countries. For example, Kimura et al. (2004) attributed 50% of cases in one outbreak to food eaten in Mexico. Domestically, the most common means of salmonella infection are undercooked chicken and eggs.

Food Handling Safety Training

Foodborne illnesses result from a variety of causes: undercooked food, improper food storage, contaminated food preparation surfaces, poor food handler hygiene, and food obtained from unapproved or unsafe sources (Hedberg, Churas, Radke, Selman, & Tauxe, 2008). Chukwuocha et al. (2009) estimated that 10-20% of foodborne illness is due to improper food handling. Roberts et al. (2008) claimed that 59% of foodborne illnesses can be traced to restaurant operations. Roberts, Barrett, and Sneed (2005) found that among both chain and independently-owned restaurants, many lack explicit policies regarding such food safety practices such as using gloves, washing hands, and taking the temperature of foods after cooking. Todd et al. (2009) reported on a self-report survey of U.S. food workers in which it was found that a fourth of those surveyed said they do not always wash their hands before handling food and a third said they do not consistently change gloves after handling raw meat. Given these facts, it is incumbent upon food service establishments such as restaurants to improve food handling safety. Perhaps the most obvious way to do so is through employee education.

Studies on the effects of food handling safety training have yielded mixed results. Wright and Feun studied how inspection scores at restaurants were affected by a certification process for food service managers and found no significant differences between pre- and posttest scores (as cited in Roberts et al., 2008). Mathias et al. studied the effects of food safety education and found that "the number of food handlers trained in food safety had no significant effect on food safety inspection violations" (as quoted in Roberts, 2008, p. 253). In their own study, Roberts et al. administered pre- and posttraining assessments to employees from 31 restaurants in Iowa, Missouri, and Kansas. The assessments addressed three components of food safety: personal hygiene, time and temperature of food storage, and cross-contamination. The researchers found that knowledge and compliance with behavioral standards improved with training. However, when particular practices were examined individually, only hand-washing knowledge and behavior improved significantly. Roberts et al. concluded that "training can improve knowledge and behaviors, but knowledge along does not always improve behaviors" (p. 252).

Chukwuocha et al. (2009) studied food handlers in Nigeria and found that about half of their 430 participants displayed inadequate knowledge of food sanitation. Knowledge was affected by educational level and job status, but the researchers found "no significant difference in attitude and practice between trained and untrained food handlers" (p. 240). Howes, McEwen, Griffith, and Harris (1996) found food safety training did not necessarily result in safe food handling behavior. Campbell et al. (1998) reviewed eight studies of food handler training programs. Six studies showed an improvement in post training assessment measures.

Cohen, Reichel, and Schwartz (2001) tested the effect of a food handling training program on food quality at a large food service company. They found a significant improvement in microbiological quality after the training program, although the results varied by department. Cotterchio, Gunn, Coffill, Tormey, and Barry (1998) assessed the effectiveness of a training and certification program for food managers at 94 restaurants. At restaurants where managers were required to attend the program, inspection scores improved, and the results held during a 2-year follow-up period.

Hedberg et al. (2006) evaluated data from the Environmental Health Services Network collected from 2002 to 2003. The researchers compared 22 restaurants where foodborne disease outbreaks had occurred with 347 restaurants that had no outbreaks. The two groups of restaurants were similar in the percentage that offered training for food workers. The presence of a certified kitchen manager was associated with reduced outbreak risks. Of the restaurants where an outbreak occurred, 32% had a certified manager, compared with 71% at restaurants with no outbreaks. On the other hand, "neither the presence of a CKM nor the presence of policies regarding employee health significantly affected the identification of an infected person or carrier as a contributing factor" (Hedberg, 2006, p. 2699).

Hammond, Brooks, Schlottmann, Johnson, and Johnson (2005) assessed the effectiveness of food worker training in Florida. Results were mixed. Some contributing factors to foodborne illness outbreaks increased after training, while others decreased. The authors concluded that it was impossible to make definitive statements about Florida's food worker training program. They noted that one ongoing challenge for restaurants is the high turnover rate among employees.

Cates et al. (2009) studied the effect of certified kitchen managers at 4,461 Iowa restaurants and found mixed results. The presence of a certified manager resulted in decreases for some inspection violations (food handling, equipment requirements, dishwashing) but not others (temperature control, water, and sewage). The researchers concluded that

> kitchen managers who have successfully completed a food safety training and certification program are knowledgeable about the relationship between foodborne illness risk factors and safe food handling and preparation practices and thus may be more likely to follow and enforce recommended practices to control foodborne illness risk factors. (p. 388)

Egan et al. (2007) reviewed 46 studies of food safety training published between 1969 and 2003. Countries where the studies were conducted included the United States (43%), United Kingdom (32%), Canada (4%), Italy (4%), Malaysia (4%), Australia (2%), Bahrain (2%), New Zealand (2%), Nigeria (2%), and Saudi Arabia (2%). The majority of studies involved food handlers (65%), with the rest involving food managers. The studies addressed both attitudes and behavior. Training interventions included home study, as well as on- and off-site courses and workshops. In studies that used pre- and posttraining tests of knowledge, only one reported no significant differences. Only four studies included retraining programs. Egan et al. reported that "the majority of food handlers and managers expressed a positive attitude to food safety but this was not supported by self-reported practices" (p. 1186).

Lynch, Elledge, Griffith, and Boatright (2003) surveyed restaurant managers in Oklahoma County, Oklahoma, regarding their knowledge of food safety practices. The survey addressed experience, sources of training, and certification. Results showed that those three factors affected food safety knowledge, but there was no relationship between hours of training and knowledge, nor did the time elapsed since training affect knowledge.

Averett, Nazir, and Neuberger (2011) studied the effects of mandatory food handler training imposed by the Kansas City, Missouri Health Department. Training consisted of a 2-hour lecture conducted by health department personnel that covered hand washing, dishwashing, hazardous materials, expiration dates, food storage, reheating, and general hygiene. The researchers compared rates of food-handler violations before and after implementation of the mandatory training. Although results showed some decreases in violations after training, Averett et al. concluded that the training program as a whole produced "no measurable benefit" (p. 14).

Food Industry Regulations

Many industries chafe at regulations, complaining that they hamper trade and reduce profits. Goldsmith, Turan, and Gow (2003) compared how Europe and the United States have responded to foodborne illness outbreaks, arguing that European governments have generally taken an active and coordinated role, whereas the United States "has opted for a more ad hoc and incremental approach" (p. 2), which has been widely criticized. Goldsmith et al. cited a 2002 U.S. Government Accounting Report that faulted the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) for inadequate oversight: "Although plants are required to take corrective action each time a violation is cited, the number of repetitive violations in various plants—109 in one plant alone—shows that FSIS has not ensured that recurring violations were eliminated" (as quoted in Goldsmith, 2002, p. 2).

Regarding meat safety, Goldsmith et al. (2002) argued that in the United States "there have been numerous failures of the system yet reform of the industry and novel regulation is not apparent" (p. 5). Europe, on the other hand, practices "full meat traceability and an animal passport system" (Goldsmith et al., 2002, p. 5). Goldsmith et al. attributed the more lax approach in the United States to that country's emphasis on individual rights, which makes the judicial system the arbiter of food safety, whereas in Great Britain such arbitration is the role of Parliament. The result, argued Goldsmith et al., is that "food safety is essentially a legal issue" (p. 6) in the United States and "essentially a regulatory issue" (p. 6) in the United Kingdom. The authors concluded that because "the U.S. system involves government operating more tangentially to industry" (p. 10) than in Europe, "organizations like the USDA have conflicting roles, supporting the industry through its grades and standards, while at the same time attempting to challenge errant practices" (p. 10).

Yasuda (2010) called the U.S. government's system of food safety oversight a "patchwork of . . . bureaucracies" (p. 202). At the federal level, that system comprises some 15 agencies, including the FDA, USDA, and CDC. The distribution of responsibility among these entities can seem somewhat arbitrary. For example, "The USDA inspects meat, poultry, eggs, and the processing plants for these products, and the

FDA inspects the rest of foodstuffs and their plants" (Yasuda, 2010, p. 202). Consumer advisories are issued by both state and federal agencies, and restaurant inspections can be carried out by state, county, or municipal government agencies. Foodborne disease outbreak statistics are compiled by the CDC but also by some state governments.

According to Yasuda (2010), although restaurant inspections account for a considerable expenditure of resources, the effectiveness of those inspections is poorly understood. Yasuda noted that "disease statistics are not collected separately or disaggregated by local jurisdiction. There are no data regarding the strictness of restaurant sanitary standards and their enforcement among different jurisdictions" (p. 207). Yasuda cited several studies about the results of restaurant inspections and argued that they "have failed to show that restaurants with poor inspection scores cause more food poisoning complaints than restaurants with better inspection scores" (p. 207).

Martinez, Fearne, Caswell, and Henson (2007) noted that foodborne illness outbreaks are a political and economic, as well as a public health, issue. The researchers documented a trend towards coregulation of food safety that involves both government and private regulatory agencies. As public resources for food safety regulation dwindle, state and local governments are increasingly willing to join with the private sector to form coregulatory bodies. However, such ventures are complex and are threatened by a variety of legislative obstacles.

Another approach to improving food safety is self-regulation in the food industry. Sharma, Teret, and Brownell (2010) noted that self-regulation has had a checkered history. In the tobacco industry, it has largely failed, but in others, such as fishing and forestry, it has been more successful. Sharma et al. evaluated the food industry's pledge to self-regulate advertising geared to children. The researchers proposed three criteria by which to evaluate several specific industry claims: transparency, meaningful objectives and benchmarks, and accountability and objective evaluation. Using these criteria, Sharma et al. considered the soft drink industry's promise "to limit portion sizes of beverages and set standards for the caloric and nutritional content of beverages to be sold in schools, with greater restriction in elementary and middle schools than in high schools" (p. 242). The researchers judged this promise largely unfulfilled, charging that

> the process of establishing nutrition criteria was not transparent and did not involve objective input from the scientific community. An example of flawed criteria is that high schools, where much of the sugared-beverage intake occurs, are subject to far less restriction than are elementary schools, where little intake occurs. (Sharma et al., 2010, p. 242)

Sharma et al. (2010) also considered the effectiveness of the 2007 Children's Food and Beverage Advertising Initiative, a voluntary program to impose restrictions on advertising to children in which healthy dietary choices and lifestyles are promoted. The authors' skepticism about this effort is reflected in their question, "Will depicting Ronald McDonald, Captain Crunch, or the Trix Rabbit being physically active make it permissible to promote unhealthy products to children?" (p. 244). Sharma et al. charged that self-regulation in the food industry, as in other spheres, is motivated more by external threats than by altruism. Given that fact, the authors concluded that "successful self-regulation requires standards that industry can attain to earn the trust of the public, the public health community, and government" (p. 246).

One strategy for promoting food safety in food-serving facilities is known as hazard analysis of critical control point (HACCP). HACCP was developed by the National Aeronautics and Space Administration (NASA) to maintain the safety of food consumed by astronauts while in space. The FDA (2014) defined HACCP as "a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product" (para. 1). FDA guidelines for implementing HACCP stress the importance of training employees in their role in maintaining food safety. HACCP includes seven principles:

- Conduct a hazard analysis.
- Determine critical control points.
- Establish critical limits.
- Establish monitoring procedures.
- Establish corrective actions
- Establish verification procedures.
- Establish record-keeping and documentation procedures. (FDA, 2014)

Zulkifly, Zahari, Jalis, and Othman (2009) studied the effectiveness of HACCP in small and medium-sized enterprises in Malaysia, a country with a poor record of food safety. The researchers interviewed managers of food-manufacturing companies about their experience implementing HACCP. Results showed that most implementations were in response to customer demand. HACCP implementation resulted in improved productivity and employee commitment and morale. The chief barriers to implementing HACCP were entrenched attitudes and a lack of technical and financial resources.

Almanza and Nesmith (2004) noted that safety training for food handlers in the United States varies by state. Such training usually ends with an examination, and successful trainees receive a certificate. Where certification is required, usually one CFM is required at every site. Certification typically lasts for 5 years. Traditionally, a local health department is the main regulatory body to enforce the certification requirement.

In Maryland, there is no statewide requirement regarding CFMs. Five of the state's 24 counties require such a manager on site at any medium- or high-priority food facility. These managers undergo 16 hours of training, followed by an exam. Certification is good for 3 years, after which completion of a 1-day recertification training is required.

Maryland also maintains a system of restaurant inspections, which are performed by professional staff who have at least a 4-year degree and have undergone field training prior to being licensed by the National Environmental Health Association. Every 3 years they must account for having completed 20 hours of continuing education on food safety. Inspectors must be familiar with state, county, and municipal regulations. Some restaurants in Maryland post their inspection reports online so that patrons can make an informed decision about whether to dine at a particular facility.

Public Policy and Foodborne Illness

According to he National Association of County and City Health Officials (NACCHO), "Foodborne illness remains a major threat to public health, and local health departments serve as the frontline defense against foodborne disease outbreaks" (p. 2). NACCHO stated that reducing foodborne illness outbreaks depends on "improving consumer education, strengthening reporting requirements, and building local health department capacity" (p. 2). More specifically, NACCHO recommended establishing an effective communication apparatus linking local health departments; forming an outbreak team that includes epidemiologists, environmental health laboratories, regulatory agencies, food industries, and agriculture departments; and conducting surveillance investigations following outbreaks. One practical suggestion is to increase the number of employers providing paid sick leave, which encourages sick employees to stay home and thus limits the spread of foodborne illnesses.

A national nonprofit public health organization that advocates for improved public policy is STOP Foodborne Illness. Created in 1994 in response to a West Coast E. coli outbreak, STOP provides public testimony for proposed legislation and lobbies federal agencies such as USDA, FDA, and CDC. The organization also provides mentoring and counseling for victims of foodborne illness.

Summary

Foodborne illness continues to be a significant public health problem, resulting in thousands of hospitalizations and deaths annually. The majority of reported foodborne illnesses result from food consumed in restaurants. Because the federal government does not specify food safety measures, states, counties, and municipalities have instituted a variety of practices and means of assessment. That variety makes it difficult to evaluate particular measures, such as the presence at a restaurant of a CFM. Studies of how food safety training for managers and employees affects food safety have yielded mixed results.

In Maryland, five of the state's 24 counties require that a CFM be on duty during a restaurant's hours of operation. The effectiveness of that requirement has not been studied, hence the need for the current study. In the next chapter, the study's methods will be presented, including research design, data collection and analysis procedures, and ethical protections.

Chapter 3: Methods

Introduction

Food safety is a major public health problem in the United States. The federal government does not mandate specific food safety practices, leaving states, counties, and municipalities to implement their own requirements. In Maryland, five of the state's 24 counties require that a CFM be on duty at all medium- and high-priority restaurants. The effectiveness of that requirement has not been assessed. Accordingly, the current study was designed to determine whether CFMs in Maryland have affected the incidence of foodborne illness in the state. The study, based on the theory of planned behavior, involved reviewing state public health data on foodborne-illness outbreaks in Maryland between 2004 and 2013. In the remainder of this chapter, the study's design, data collection and analysis procedures, and ethical protections will be described.

Research Design

Sociological research can be classified as qualitative, quantitative, or mixed-methods. A qualitative design is appropriate for studies of how people behave and for exploring the meaning behind a particular phenomenon. Qualitative studies typically involve a small number of participants and often interviews or focus groups. A qualitative study involves describing and explaining participants' lived experience (Babbie, 2007; Maxwell, 2005; Trochim & Donnelly, 2006).

Quantitative studies usually involve arriving at generalizations based on numerical data. They often address the relationship between two or more variables. Quantitative research can be descriptive or experimental. Experimental studies are based on comparing a treatment group and a control group. Nonexperimental research usually involves variables that are not manipulated by the researcher (Mann, 2003; Trochim & Donnelly, 2006). Mixed-methods studies employ both qualitative and quantitative techniques. A mixed-methods researcher might start by administering a survey, then conduct follow-up interviews with a subset of the original sample.

Quasi-experimental and cross-sectional designs are similar. Both are weaker on internal validity compared to experimental designs. In the case of quasi-experimental designs, “researchers can randomly select samples from a population, but do not require the random assignment of individual cases to the comparison groups” (Nachmias & Nachmias, 2008, p. 118). Both designs allow researchers to conduct studies in “natural, real-life settings using probability samples” (Nachmias & Nachmias, 2008, p. 133), and so improve external validity. Quasi-experimental designs “involve the study of more than one sample,” and the study can continue for an extended period (Nachmias & Nachmias, 2008, p. 130).

Despite the similarities between quasi-experimental and cross-sectional designs, the latter was more appropriate for the current study because it is relatively quick and does not require extensive follow-up. Data on all variables are collected once. Cross-sectional designs can use existing data instead of survey data (Olsen & St. George, 2004; Public Health Action Support Team [PHAST], 2011). A cross-sectional design is appropriate for describing the “pattern of relation between variables” (Nachmias & Nachmias, 2008, p. 116), such as the relationship between foodborne illness outbreaks and CFMs. Cross-sectional designs are good for descriptive analysis—that is, describing the group that is being studied—and are able to measure prevalence for all factors being studied (PHAST, 2011). This study employed inferential statistics to compare the two groups of restaurants being studied.

The current research was a nonexperimental study based on document analysis. The independent variable was the presence or absence of CFMs. The dependent variable was the difference in average number of foodborne illness outbreaks between the two groups of restaurants from 2004 to 2013. A foodborne illness outbreak is defined as an "incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness" (CDC, 2011, para. 1). Data were analyzed with two sample proportion tests when the original plan to use independent-sample *t* test and ANOVA was found inappropriate for my data. The documents analyzed were reports from the Maryland Department of Health and Mental Hygiene relating to foodborne disease outbreaks from 2004 to 2013 in the state's medium- and high-priority restaurants.

A qualitative study was considered but rejected. There are five main types of qualitative design. In ethnographic approach, "cultural groups are studied in their natural setting for a prolonged period through observation and interviews" (Creswell, 2009, p. 13). Grounded theory involves "interaction grounded in the views of participants through the use of multiple stages of data collection, refinement and interrelationships of categories of information" (Creswell, 2009, p. 13). In a case study, a researcher explores "programs, events, activities" (Creswell, 2009, p. 13) by using a variety of data collection procedures for an extended period. In a phenomenological study, a researcher explores the importance of "human experiences about a phenomenon" (Creswell, 2009, p. 13) as described by participants. In a narrative study, a researcher studies the way individuals live and asks them to tell stories about their lives (Creswell, 2009, p. 13). Although a study involving individual interviews would produce richer data than is possible in one based on a survey, the greater depth that could be achieved with a qualitative design would come at the expense of the breadth that a quantitative study offers.

Research Questions and Hypotheses

The current study was based on one overarching research question: What is the relationship between foodborne illness outbreaks and the presence of CFMs in Maryland medium- and high-priority food establishments? This question led to the following hypothesis, which is stated in both null and alternative form:

> H_0*:* There are no statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such a requirement.
>
> H_1*:* There are statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such a requirement.

Population and Sample

The target population for this study was all U.S. states that do not have uniform requirement for restaurant CFMs. The accessible population was all restaurants in 24 Maryland counties—the five counties that require CFMs and the 19 counties that do not. Based on an effect size equivalent of 0.3 (one-tailed), an alpha of 0.05, and a power (1-beta) of 0.80, it was determined that a sample size of at least 64 was needed for the current study, based on a G-Power calculation (Ellis, 2010, p. 139; Ellis, 2012, p. 25). However, I used the entire data of 288 provided by Maryland DHMH. Each of the two groups had a different sample size. The counties that require CFMs had 139 samples, while no CFM counties had 149 restaurants, with an 80% chance of detecting an effect and a 20% chance of avoiding a Type II error (Ellis, 2012, p. 25). Type II errors occur when a false null hypothesis is accepted. Type I errors occur when a true null hypothesis is rejected. The possibility of detecting an effect increases as the sample size increases (Ellis, 2012).

The sample was drawn from all medium- and high-priority restaurants in Maryland's 24 counties. Counties report incidents of foodborne illness outbreaks to local health departments, which forward them to the state. Based on the FoodNet surveillance network system, reports are presented statewide despite the fact that monitoring takes place within individual counties. FoodNet surveillance began in Maryland in 1998 and expanded to include the entire state in 2002 (DHMH, 2002).

Data Collection

A letter was sent to the Maryland Department of Health and Hygiene requesting permission to conduct the study (see Appendix A). Approval to conduct was also obtained from the Walden University Institutional Review Board (IRB) with approval number 04-30-15-0254919. Data were collected from the Vital Records Division of Maryland's Department of Health and Hygiene. These data consisted of information on foodborne illness outbreaks in the state from 2004 to 2013: where and when they occurred, and how many people were affected. This information is provided to the state by local regulatory agencies or counties. Specifically, data from medium- and high-priority food establishments from the Maryland five counties requiring CFMs and the 19 counties lacking such a requirement were reviewed and the average of foodborne illness outbreaks in the two groups were compared. The 2004-2013 period was chosen because 2004 was when five Maryland counties began requiring the presence of a CFM in restaurants, and 2013 is the most recent year for which disease information is available. Permission was obtained from the Maryland Department of Health and Mental Hygiene and Walden University's IRB before data collection began.

Data Analysis

Data collected from the Maryland Department of Health and Hygiene were subjected to statistical analysis. The plan was to calculate means and standard deviations for the two groups, followed by a one-way ANOVA to determine if there was a significant difference between the means of the two groups. Data were further planned to be analyzed using independent-samples *t* tests, with an alpha value of .05, one-tailed, and 95% confidence level. The *t* test was also supposed to be used to compare the means of the two groups of restaurants. However, these statistical methods were found inappropriate for the analysis of data collected. Data analysis was performed with two sample proportion test instead of SPSS, which was originally chosen because it has the capability of handling large amounts of data.

Role of the Researcher

As the primary researcher for this study, I was responsible for collecting and analyzing the data and interpreting the results. Because of my professional role as a registered environmental health specialist, I was subject to potential bias. Part of my former job was supervising the staff that inspects restaurants in Maryland. To minimize bias, I bracketed any preconceived opinions before conducting the study.

Ethical Protections

Permission to conduct the study and IRB approval number 04-30-15-0254919 were obtained before I began data collection. All data have been stored securely. Hard copies are kept in a locked file cabinet. Electronic data are stored on a password-protected personal computer. All data will be destroyed 5 years after completion of the study.

Summary

In this chapter, I described the methods for a quantitative study designed to determine the effectiveness of a CFM requirement in Maryland medium- and high-priority restaurants. Data collection was based on statistics regarding foodborne-illness outbreaks from 2004 to 2013. Data were statistically analyzed using a two sample proportion test because the original plan to employ one-way ANOVA and independent-samples *t* tests used to check for average number of foodborne illness outbreak differences between two groups were found inappropriate for my data.

Chapter 4: Results

Introduction

The purpose of this quantitative study was to determine the effect of an onsite CFM on the incidence of foodborne disease outbreaks at Maryland medium- and high-priority restaurants. Five Maryland counties require that food services employ CFMs; the other 19 counties lack such a requirement. The requirement of CFMs by the Maryland five counties had been in place during the period of this study. Baltimore County, for instance, began enforcement of CFM in medium –and high-priority establishments in 2004. The study was based on one overarching question: What is the relationship between foodborne illness outbreaks and the presence of CFMs in Maryland medium-and high-priority food establishments? This question led to the following hypothesis: the null hypothesis stated that there are no statistically significant differences between foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such requirement. The alternative hypothesis states that there are statistically differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such requirements. Data on foodborne disease outbreaks between 2004 and 2013 were collected from the Maryland Department of Health and Mental Hygiene. The analysis results and data description and summary of this study are explained in the next sections.

Data Collection

The data for this study were collected from the Vital Records' Division of Maryland Department of Health and Mental Hygiene. Data collected consisted of information on foodborne illness outbreaks in the state from 2004 to 2013: where and when they occurred and how many people affected. These data were specifically from medium and high-priority food establishments from the Maryland five counties requiring CFMs and the 19 counties lacking such a requirement.

The proposed plan in chapter three was to conduct sampling from the existing data for 288 medium and high-priority food establishments collected from the Maryland Department of Health and Mental Hygiene. That plan was modified and the entire data, comprising of 139 samples from counties requiring CFMs and 149 samples from counties without such requirement were used for the study. Data collected represents the larger population of restaurants in Maryland’s 24 counties.

Results

Data were separated into two groups: counties requiring CFMs (see Table 6) and counties not requiring CFMs (see Table 7). Tables 6 and 7 list the number of restaurants in each county reporting at least one outbreak of foodborne illness and the number of restaurants not reporting outbreak of foodborne illness during the reporting period (2004-2013). Two counties that did not require CFMs, Caroline and Somerset, reported no outbreaks. The five Maryland counties that require CFMs had a total of 12,531 medium - and high - priority food establishments in operation during the period of study, and 139 of them reported 139 foodborne illness outbreaks, averaging 1.0 per restaurant. That means a total of 12,392 restaurants from these counties did not report incidents of foodborne outbreaks during the same period (see Table 6). On the other hand, the 19 Maryland counties not requiring CFMs had 8,265 medium - and high – priority food establishments in operation during the study period and 149 reported 157 foodborne illness outbreaks averaging 1.1 per restaurant. The information from this data means that Maryland counties that do not require CFMs had 8,116 restaurants that did not report foodborne illness outbreaks during the study period (see Table 7). The significance of this data, cannot be overlooked. For instance, the 19 Maryland counties not requiring CFMs had the lowest number of restaurants and reported the highest number of foodborne illness outbreaks. However, the five Maryland counties that require CFMs had the highest number of restaurants and lowest number of foodborne outbreaks during the same period.

Data shows for example, 27 foodborne illness outbreaks reported by Baltimore County, one of the CFM Counties in 2004-2013 (see Table 6), came from 27 different restaurants in that county. However, Anne Arundel, a non-CFM County, had 35 foodborne outbreaks reported by 34 restaurants during the same period (see Table 7).

The first statistical assumption for this study is that sample proportion one is equal to sample proportion two; that is, proportion one minus proportion two equals zero. The second assumption is that proportion one is not equal to proportion two, meaning that proportion one minus proportion two does not equal zero.

Table 6

Foodborne Outbreaks in Maryland Counties Requiring CFMs (2004-2013)

County	Foodborne illness outbreaks	The number of county restaurants reporting outbreaks	The number of county restaurants that did not report outbreaks
3. Baltimore	27	27	2,805
13. Howard	13	13	955
15. Montgomery	48	48	2,829
16. Prince George's	22	22	2,369
24. Baltimore City	29	29	3,434
Total	**139**	**139**	**12,392**

Table 7

Foodborne Outbreaks in Maryland Counties Not Requiring CFMs (2004-2013)

County	Foodborne illness outbreaks	The number of County Restaurants Reporting Outbreaks	The number of County Restaurants that did not Report Outbreaks
1. Allegany	5	5	338
2. Anne Arundel	35	34	1,129
4. Calvert	9	9	256
5. Caroline	0	0	95
6. Carroll	12	12	533
7. Cecil	5	4	423
8. Charles	7	7	469
9. Dorchester	2	2	169
10. Frederick	24	22	1,024
11. Garrett	4	3	217
12. Harford	16	16	783
14. Kent	1	1	137
17. Queen Ann's	3	3	262
18. St. Mary's	5	5	371
19. Somerset	0	0	95
20. Talbot	8	7	221
21. Washington	13	11	682
22. Wicomico	5	5	315
23. Worchester	3	3	597
Total	**157**	**149**	**8,116**

Thus, the foodborne illness data reported by 149 restaurants in non-CFM Counties and 139 from CFM Counties were used for the study. First, the groups were separated between CFM and non-CFM counties, then subjected to statistical analysis.

Data Analysis

During the proposal stage, it was assumed that data to be collected would be normally distributed, and *t* test and ANOVA would be appropriate for the analysis. In effect, however, the data analysis showed that the assumption of normality, necessary in order to use these statistical tests appropriately, was not achieved. One of the study groups had zero variance. Consequently, it was determined that both ANOVA and independent sample *t* test would not be appropriate for the analysis of the data. The results of ANOVA and independent sample *t* test that were originally proposed for this study were deemed inappropriate (see Appendix C).

Therefore, it became necessary to conduct data analysis by employing a two-sample proportion test using Minitab as the appropriate statistical method for this study. The purpose of two-sample proportion test for this study was to determine whether there was significance in foodborne illness outbreaks between five Maryland counties that require CFMs and 19 counties without such requirement for their medium-and high-priority food establishments.

The summarized data from county restaurants without CFMs showed 157 reported foodborne outbreaks out of 8,265 restaurants, $p1$, below, while samples from counties that required CFMs had 139 foodborne outbreaks from 12,531 restaurants, $p2$, below.

$p1$ = sample proportion of county restaurants without CFMs: 157/8,265 = 0.01899577, approximately 0.0190, where 157 is the number of foodborne outbreaks reported from 2004 to 2013 out of 8,265 restaurants from 19 Maryland counties without CFMs.

$p2$ = sample proportion of county restaurants that require CFMs: 139/12531 = 0.01108718, approximately 0.0111, with 139 indicating the number of foodborne outbreaks reported during the study period out of 12,531 restaurants from five counties that require CFMs.

The question becomes is p (1) statistically higher than p (2); that is, does a relationship exist between foodborne illness outbreaks and the presence of CFMs in Maryland medium-and high-priority food establishments. In order to address this question, it becomes necessary to test the hypotheses:

H_0: There are no statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 counties without such a requirement. The alternative hypothesis for my study is:

H_1: There are statistically significant differences in foodborne illness outbreaks between the five Maryland counties that require CFMs in medium- and high-priority food establishments and the 19 Counties without such a requirement. The difference between sample proportions for non-CFM counties was greater than the CFM counties ($p1 > p2$; $p1 - p2 > 0$).

Therefore, using summarized data of 157 foodborne outbreaks from counties without CFMs out of 8,265 restaurants and 139 foodborne illness outbreaks from counties that require CFMs out of 12,531 restaurants, the null and alternative hypothesis were tested. The result of the two-sample proportion test appears in Table 8.

Table 8

Test and CI for Two Proportions

Sample	X	*N*	Sample *p*
Non-CFM (1)	157	8,265	0.018996
CFM (2)	139	12,531	0.011092

Difference = *p* (1) - *p* (2)
Estimate for difference: 0.00790327
95% lower bound for difference: 0.0049932
Test for difference = 0 (vs > 0): $z = 4.71$ *p* value = 0.000

Fisher's exact test: *p* value = 0.000

$p < .05$ and alpha value = 0.05

Since the *p* value is less than alpha value, the null hypothesis is therefore rejected. Therefore, there is evidence to suggest that there is a significance difference in the proportion of foodborne illness outbreaks between county restaurants that require CFMs and those without such a requirement: a 95% confidence and a lower bound at 0.005 0.008(95% CI, 0.005), $z = 4.71$, $p = 0.000$.

The study's results show that there is a relationship between foodborne illness outbreaks and the presence or absence of CFMs in restaurants operating as medium- and high-priority food establishments. Counties employing on-site CFMs had fewer incidents of foodborne illness outbreaks than did counties without such a requirement. The question arises whether one foodborne outbreak on average over a ten-year period is significant enough to consider a change in current regulations. This can be answered affirmatively because when it comes to foodborne outbreak, one outbreak is enough to send thousands of people to hospitals and may even lead to death.

Summary

In this chapter, the results were presented for a quantitative study designed to determine the effect of CFMs on the incidence of foodborne illness outbreaks in Maryland medium- and high-priority restaurants. Data analysis consisted of computing descriptive statistics and conducting a two-sample proportion test. Results indicated that restaurants without CFMs were more likely to experience a foodborne illness outbreak (Sample proportion = 0.0190) than were restaurants with CFMs (Sample proportion = 0.0111). The results obtained by analyzing data using a two-sample proportion test suggest that there is significance difference in foodborne illness between county restaurants that require CFMs and those without such requirement. In the next chapter, these results will be discussed, and recommendations will be made.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this quantitative study was to determine whether the presence of an onsite CFM affects the number of foodborne disease outbreaks reported at Maryland medium- and high-priority restaurants. The nature of study was quantitative, based on a cross-sectional design. The independent variable was the presence of CFMs at a given food service establishment. The dependent variable was the difference in the proportion of foodborne illness outbreaks between the two groups of restaurants. Data were collected from the Maryland Department of Health and Mental Hygiene for 2004-2013. A total sample of 139 foodborne illness outbreaks from 12,531 restaurants in the five Maryland counties requiring CFMs was compared to 157 foodborne outbreaks from 8,265 restaurants in the 19 Maryland counties without such a requirement. Results showed that restaurants without CFMs reported a significant difference of 0.008 foodborne disease outbreaks, more than restaurants with CFMs. This result is significant because five counties requiring CFMs have more food establishments during the study period, 12,531, than the 19 counties without this requirement, with 8,265. Data shows that CFM counties reported fewer foodborne outbreaks compared to non-CFM counties. Consequently, when this result is compared to data analysis using a two-sample proportion test, the outcome of 0.008(95% CI, 0.005), $z = 4.71$, p =0.000 suggests that there is significance difference in regard to foodborne disease outbreaks between county restaurants that require CFMs and those without such requirement.

Discussion

This study was based on TPB, which is based on TRA. The difference between the two theories is that TRA theorists assume that people are usually in control of a particular behavior, whereas TPB theorists assume that people are not necessarily in control of their behavior. According to Roberts et al. (2008), TPB is appropriate when formal skills, such as education and social cooperation, are required. Applying TPB to the topic at hand yields the conclusion that if a restaurant worker does not receive adequate training in food-handling procedures, that person will not understand the implications of his or her behavior and thus will not be in full control of the behavior.

According to Scallan et al. (2011), approximately 9.4 million cases of foodborne illness are reported in the United States each year, resulting in 55,961 hospitalizations and 1,351 deaths. Harris et al. (2003) stated that the pathogens responsible for foodborne illness outbreaks find their way into food chain during “food production, harvest, processing, transport, and more especially in retail and food service establishments such as restaurants and cafes” (p. 79). Many foodborne illnesses go unreported, making it difficult to acquire complete data on their frequency and type. The CDC’s foodborne illness surveillance network is an attempt to compile comprehensive data based on reports from states, counties, and municipalities.

According to Roberts et al. (2008), 59% of foodborne illnesses can be traced to restaurant operations. Roberts et al. (2005) found that many chain and independently-owned restaurants lack explicit policies regarding food safety practices. Todd et al. (2009) reported that one fourth of U.S. food workers in a survey said they do not always wash their hands before handling food, and a third said they do not consistently change gloves after handling raw meat. These facts make it clear that food service establishments need to improve food handling safety through better employee education and monitoring of food handling behavior.

Conclusions

The research question on which this study was based asked, “What is the relationship between foodborne illness outbreaks and the presence of CFMs in Maryland medium- and high-priority food establishments?” The results showed that between 2004 and 2013, facilities operating with onsite CFMs reported fewer cases of foodborne illness outbreaks (Sample proportion = 0.0111) than did facilities without CFMs (Sample proportion = 0.0190), a statistically significant difference of 0.008(95% CI, 0.005), $z = 4.71$, $p = 0.000$.

The two-sample proportion method was deemed more appropriate for data analysis than the proposed ANOVA and independent sample *t* test where one sample group has zero variance. The results show that the *p* value was less than alpha value of 0.05, and therefore, the null hypothesis was rejected.

Limitations

This study was limited to medium- and high-priority food establishments in a single state: Maryland. The results cannot be generalized to other states or to other types of food services. The study was based on foodborne illness outbreaks reported to the Maryland Department of Health and Mental Hygiene from 2004 to 2013. Because not all incidences of foodborne illness are reported, it cannot be assumed that the data on which this study was based were comprehensive and complete.

Contribution of the Study to Social Change

Foodborne illnesses affect 48 million people annually in the United States, resulting in about 3,000 deaths and costing $77.7 billion (CDC, 2014). U.S. adults eat an average of 4.8 meals per week in restaurants (United Press International, 2011). Given these statistics, the safety of food eaten in restaurants is an important matter of public health. Results of the current study suggest that people living in Maryland counties without a requirement that medium- and high-priority restaurants employ an onsite CFM are at greater risk of exposure to pathogens that cause foodborne illness than are state residents living in counties with such a requirement.

Results of this study can be used to make a case that Maryland should adopt a statewide requirement that all foodservice establishments require the presence of an onsite CFM whenever an establishment is open for business. This study's results can also be used to confirm the importance of training in proper food-handling techniques for foodservice workers and for improved supervision and monitoring of those workers. CFMs improve food safety and thus contribute to improved public health, in turn reducing expenses for medical treatment, reducing pain and suffering, and reducing time missed at work and the accompanying lost wages for the nation's workforce.

Chukwuocha et al. (2009) found that training in safe food-handling practices resulted in reduction of foodborne illness outbreaks. Averett et al. (2011) called for more effective education for food handlers. Results of the current study confirm the conclusions of this earlier research and can help reduce the number of hospitalizations and deaths resulting from preventable foodborne illnesses. Such reductions will improve the economic status of potential disease victims by reducing disease-treatment costs and lost wages as well as foodservice establishments by reducing lawsuits.

Although the focus of this study was on food safety in restaurants, its results can be used to inform public education directed toward reducing illnesses acquired from improper food-preparation techniques at home,the largest source of foodborne illnesses. Schools and public health centers can benefit from the results of this study in their educational efforts. Elected officials and policy makers can use the results of this study to guide legislative changes that will improve the safety of the food Americans eat. The result of all these efforts will be an improved quality of life and greater economic prosperity for the nation's citizens.

Recommendations for Action

The impact of foodborne illness outbreaks to the society should compel the government to become more involved in the education and certification of food workers rather than leaving it to individual state and local governments to monitor. I recommend the following actions be taken:

1. The federal government should play an active role in advising states about how to improve food safety, including the benefits of requiring CFMs in all restaurants. A federal presence is important because foodborne illness outbreaks are not constrained by geographical borders. Therefore, the FDA should provide clear guidance to states about how to reduce foodborne illness outbreaks. In the absence of federal action, individual states should implement requirements regarding the presence of CFMs in foodservice establishments.

2. Individual foodservice establishments should provide consistent and comprehensive training for all employees who handle food. Such training should include an emphasis on washing hands; wearing gloves; and observing safe practices for preparing, cooking, and storing food.
3. Consumers should take steps to ensure that the foodservice establishments they patronize employ safe food handling, preparation, storing, and serving procedures. Pressure from consumers will improve the implementation and monitoring of food safety practices.
4. Schools and public health agencies should increase and improve their efforts to educate the public about food safety.

Recommendations for Further Research

This subject is important in keeping our food supply chain safe and our community healthy. Therefore, I recommend that additional studies be conducted in the following areas:

1. This study was based on data from a single state: Maryland. The study could be replicated in other states and other parts of the United States.
2. Additional research could determine whether there are differences in foodborne illness outbreaks among urban, suburban, and rural areas.
3. The current study was quantitative. A qualitative or mixed-methods study could incorporate interviews with foodservice employees—both supervisors and front-line workers. Such interviews could address the quality and consistency of food safety training, as well as the potential disjuncture between what people are told and how they behave on the job.

4. A longitudinal study could track the progress of foodservice establishments that employ CFMs over a period of implementing such personnel.
5. Additional research is needed to determine whether there is a relationship between foodborne illness incidence in restaurants and private homes in a given area.
6. A study controlling for restaurant size could determine whether that variable affects the incidence of foodborne illnesses.

Summary

Foodborne illness represents an ongoing public health problem. Results of this quantitative study indicate that foodborne illness outbreaks were less frequent in Maryland medium- and high-priority restaurants that require onsite CFMs compared to state establishments without such a requirement. Results of the study can be used by legislators, educators, public health officials, and foodservice owners and operators to improve food safety, thereby improving public health, reducing health care costs and lost wages, and contributing to greater prosperity for both consumers and dispensers of food.

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Appendix A: Permission to Conduct the Study

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

June 22, 2015

To whom it may concern:

Mr. Alphonsus Korie received public information from our offices. He may use the data in the table included below for the purposes detailed in his dissertation proposal. I received the proposal submitted to Walden University dated March 2015.

County	Number of foodborne outbreaks
1. Allegany	5
2. Anne Arundel	35
3. Baltimore County	27
4. Calvert	9
5. Caroline	0
6. Carroll	12
7. Cecil	5
8. Charles	7
9. Dorchester	2
10. Frederick	24
11. Garrett	4
12. Harford	16
13. Howard	13
14. Kent	1
15. Montgomery	48
16. Prince George's	22
17. Queen Anne's	3
18. St. Mary's	5
19. Somerset	0
20. Talbot	8
21. Washington	13
22. Wicomico	5
23. Worcester	3
30. Baltimore City	29

201 W. Preston Street – Baltimore, Maryland 21201
Toll Free 1-877-4MD-DHMH – TTY/Maryland Relay Service 1-800-735-2258 Web Site: www.dhmh.maryland.gov

Sincerely,

Alvina Chu, MHS
Chief, Division of Outbreak Investigation
cc: Clifford Mitchell, MD, ScM, MPH, Director, Environmental Health Bureau

Appendix B: Facilities and Counties Reporting Foodborne Outbreaks

Note: Facility represent restaurant, County or Co with 1 represent Allegany County (See Appendix A: above).

OutbreakID	LOCATION	CO
4984	Facility	1
2994	Facility	1
3479	Facility	1
3315	Facility	1
2980	Facility	1
3059	Facility A	2
3025	Facility A	2
5924	Facility	2
5413	Facility	2
4605	Facility	2
5966	Facility	2
4006	Facility	2
4773	Facility	2
5267	Facility	2
2926	Facility	2
3218	Facility	2
3392	Facility	2
2771	Facility	2
2938	Facility	2
5916	Facility	2
5652	Facility	2
3138	Facility	2
4198	Facility	2
3606	Facility	2
4399	Facility	2
2751	Facility	2
3438	Facility	2
2865	Facility	2
4808	Facility	2
4046	Facility	2
5409	Facility	2
4586	Facility	2
3008	Facility	2
6343	Facility	2

2860	Facility	2
2973	Facility	2
4394	Facility	2
3197	Facility	2
4917	Facility	2
3053	Facility	2
4122	Facility	3
6255	Facility	3
5671	Facility	3
5730	Facility	3
2772	Facility	3
4141	Facility	3
4685	Facility	3
3541	Facility	3
4228	Facility	3
4591	Facility	3
5852	Facility	3
3465	Facility	3
2949	Facility	3
3528	Facility	3
5664	Facility	3
4850	Facility	3
5400	Facility	3
5739	Facility	3
6308	Facility	3
4288	Facility	3
6315	Facility	3
6112	Facility	3
4933	Facility	3
3294	Facility	3
2832	Facility	3
5375	Facility	3
5392	Facility	3
3238	Facility	4
4367	Facility	4
3250	Facility	4
5010	Facility	4
2924	Facility	4
2916	Facility	4
4725	Facility	4

4594	Facility	4
6341	Facility	4
5237	Facility	6
6305	Facility	6
3324	Facility	6
4505	Facility	6
2747	Facility	6
2805	Facility	6
6235	Facility	6
4673	Facility	6
5915	Facility	6
2962	Facility	6
4380	Facility	6
2986	Facility	6
5243	Facility B	7
2929	Facility B	7
3998	Facility	7
4328	Facility	7
6275	Facility	7
2976	Facility	8
5897	Facility	8
4234	Facility	8
3357	Facility	8
4008	Facility	8
5911	Facility	8
6389	Facility	8
3999	Facility	9
5927	Facility	9
6279	Facility	10
5755	Facility C	10
3599	Facility C	10
4308	Facility	10
4468	Facility D	10
4045	Facility D	10
6176	Facility	10
6259	Facility	10
3445	Facility	10
5423	Facility	10
4015	Facility	10
3476	Facility	10

3455	Facility	10
4932	Facility	10
3249	Facility	10
3358	Facility	10
3602	Facility	10
3540	Facility	10
4669	Facility	10
5781	Facility	10
4562	Facility	10
4050	Facility	10
5992	Facility	10
5623	Facility	10
5253	Facility	11
3625	Facility	11
6284	Facility E	11
4296	Facility E	11
5997	Facility	12
2750	Facility	12
4432	Facility	12
5963	Facility	12
6302	Facility	12
5482	Facility	12
4582	Facility	12
3415	Facility	12
4273	Facility	12
5506	Facility	12
2757	Facility	12
3339	Facility	12
4112	Facility	12
4351	Facility	12
4022	Facility	12
2952	Facility	12
4545	Facility	13
2852	Facility	13
3623	Facility	13
5779	Facility	13
4079	Facility	13
5896	Facility	13
5393	Facility	13
2869	Facility	13

5805	Facility	13
6312	Facility	13
5234	Facility	13
5302	Facility	13
4660	Facility	13
3244	Facility	14
5672	Facility	15
3067	Facility	15
4864	Facility	15
3291	Facility	15
6331	Facility	15
4360	Facility	15
3604	Facility	15
3608	Facility	15
5390	Facility	15
3590	Facility	15
6029	Facility	15
4596	Facility	15
5861	Facility	15
6126	Facility	15
3587	Facility	15
4499	Facility	15
4039	Facility	15
5928	Facility	15
5444	Facility	15
4034	Facility	15
4662	Facility	15
4943	Facility	15
2921	Facility	15
4029	Facility	15
5224	Facility	15
6337	Facility	15
5692	Facility	15
2914	Facility	15
4374	Facility	15
6006	Facility	15
4390	Facility	15
4363	Facility	15
4389	Facility	15
2950	Facility	15

6280	Facility	15
4043	Facility	15
5520	Facility	15
5677	Facility	15
6153	Facility	15
6317	Facility	15
4576	Facility	15
3077	Facility	15
4539	Facility	15
4325	Facility	15
3579	Facility	15
3258	Facility	15
2905	Facility	15
4317	Facility	15
5312	Facility	16
5509	Facility	16
2975	Facility	16
3022	Facility	16
2758	Facility	16
5918	Facility	16
3287	Facility	16
5715	Facility	16
4035	Facility	16
4610	Facility	16
3055	Facility	16
3211	Facility	16
6270	Facility	16
3477	Facility	16
2897	Facility	16
3017	Facility	16
3441	Facility	16
2862	Facility	16
5703	Facility	16
5593	Facility	16
2972	Facility	16
2963	Facility	16
5670	Facility	17
2753	Facility	17
3601	Facility	17
3424	Facility	18

2944	Facility	18
3010	Facility	18
3469	Facility	18
3006	Facility	18
3099	Facility	20
3045	Facility	20
2748	Facility F	20
4150	Facility F	20
3295	Facility	20
5399	Facility	20
5694	Facility	20
3036	Facility	20
4347	Facility G	21
3351	Facility G	21
4318	Facility	21
2939	Facility	21
4401	Facility H	21
4311	Facility H	21
6152	Facility	21
6268	Facility	21
5711	Facility	21
5335	Facility	21
4206	Facility	21
3293	Facility	21
3986	Facility	21
5840	Facility I	22
4601	Facility I	22
2948	Facility	22
2907	Facility	22
5688	Facility	22
3240	Facility	23
2947	Facility	23
2884	Facility	23
3174	Facility	30
3016	Facility	30
4012	Facility	30
4882	Facility	30
3605	Facility	30
6327	Facility	30
5980	Facility	30

4903	Facility	30
3333	Facility	30
3207	Facility	30
2982	Facility	30
3370	Facility	30
4574	Facility	30
3021	Facility	30
4621	Facility	30
6297	Facility	30
4480	Facility	30
4578	Facility	30
6306	Facility	30
6310	Facility	30
4375	Facility	30
4948	Facility	30
5693	Facility	30
3352	Facility	30
4378	Facility	30
4557	Facility	30
2763	Facility	30
4024	Facility	30
5377	Facility	30

Appendix C: Results of proposed data analysis using ANOVA and Independent-Sample *t* test deemed inappropriate for data with one sample group with zero variance.

Data Analysis

Data analysis began with an independent-samples *t* test. The purpose of a *t* test is to determine the likelihood that a difference between two groups' averages occurred. The data were also subjected to a one-way ANOVA. Results of the two tests were similar. Consequently, ANOVA could not perform post-hock analysis for less than three variable groups and CFM counties have equal number of foodborne outbreaks and number of affected restaurants reported. On the other hand, one of the groups has zero variance; making it impossible to analyze data with both independent-sample *t*-test and ANOVA. Group statistics (see Table 8) revealed that the average number of foodborne illness outbreaks among the 149 restaurants without CFMs was 1.06 (SD = .24, SEM = .02), compared to a mean of 1.00 for the 139 restaurants with CFMs (SD = .00, SEM = .00). There were no data outliers, as shown in Figure 2. However, four point locations shown in Figure 2 may appear to be outliers because the showed up on the plot with characteristics of an outlier, but they are not. Data used for the analyses ranged from 1 to 2 in both groups and the four point locations shown in Figure 2 have values of 2. Therefore, they cannot be outliers.

Table C1

Descriptive Statistics of Foodborne Outbreaks of Two Groups

					95% *CI* for *M*			
	N	*M*	*SD*	*SE*	Lower bound	Upper bound	Min.	Max.
Restaurants without CFMs	149	1.060	.239	.020	1.022	1.099	1.000	2.000
Restaurants with CFMs	139	1.000	.000	.000	1.000	1.000	1.000	1.000
Total	288	1.031	.174	.010	1.011	1.052	1.000	2.000

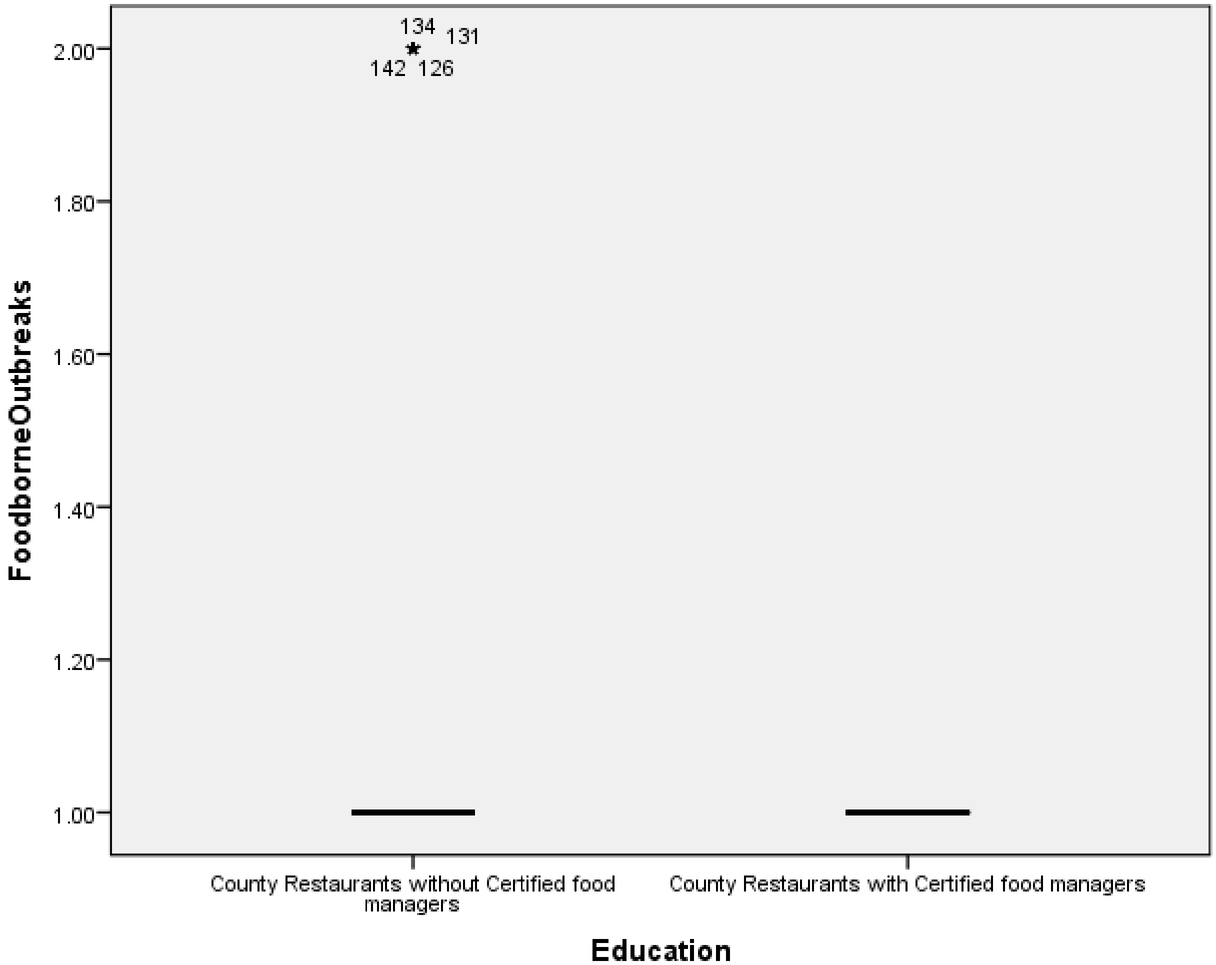

Figure C1. Boxplot showing no data outliers.

Data were assessed for normal distribution using the Shapiro Wilk test ($p < .05$) and the Kolmogorov-Smirnov test. That analysis revealed that foodborne illness outbreak scores for each group of restaurants were not normally distributed (see Table 9). The assumption of normality is necessary for statistical significance testing using independent-samples *t* test. However, the independent samples *t* test is considered "robust" to violations of normality. Therefore, some violations of this assumption can be tolerated, and the test will still provide valid results.

Table C2

Shapiro-Wilk Test of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	*df*	Sig.	Statistic	*df*	Sig.
Foodborne outbreaks[b]	Restaurants without CFMs	.539	149	.000	.253	149	.000

a. Lilliefors significance correction.
b. Foodborne outbreaks were constant for restaurants with CFMs.

Homogeneity of variances was not met, as assessed using Levene's test for equality of variances (p = .0005). Moreover, SPSS uses Levene's test of equality of variance and two differently-calculated Independent-samples t tests, which will give a valid result irrespective of whether this assumption is met or violated. A t test for equality of means indicates comparison of t distribution with 148 degrees of freedom, a t value of 3.09, and p = .002 (see Table 10).

Table C3

Levene's Test for Equality of Variances and T Test for Equality of Means

	Levene's test for equality of variances		*T* test for equality of means						
								95% *CI* of dif.	
	F	Sig.	*t*	*df*	Sig.*	*M* dif.	*SE* dif.	Lower	Upper
Foodborne outbreaks**	40.54	.00	2.98	286	.003	.0604	.0203	.0205	.1003
Foodborne outbreaks***			3.09	148.00	.002	.0604	.0196	.0217	.0991

*Two-tailed
**Equal variances assumed
***Equal variances not assumed

The null hypothesis for the current study was as follows:

H_0: There are no difference in foodborne illness outbreaks between the five Maryland counties that require certified food managers in medium- and high-priority food establishments and the 19 counties without such a requirement.

There was a statistically significant difference of .06 in mean foodborne outbreaks scores between county restaurants without CFMs and those with CFMs: 0.06(95% *CI*, 0.02 to 0.10), t (148.00) = 3.09, p = .002 (see Table 10). Based on this result, the null hypothesis is rejected. In other words, there is a relationship between foodborne illness outbreaks and the presence or absence of CFMs in restaurants operating as medium- and high-priority food establishments. The study's results show that Counties employing on-site CFMs had fewer incidents of foodborne illness outbreaks than did counties without such a requirement. A question may be raised whether one foodborne outbreak on average over a ten year period is significant enough to consider a change in current regulations. The answer is yes because when it comes to a foodborne outbreak, one outbreak is enough to send thousands of people to the hospital and even deaths. A plot of the foodborne outbreak means of the two groups (using ANOVA) indicates mean values ranging from 1.00 for restaurants with CFMs to 1.06 for restaurants without CFMs (see Figure 3).

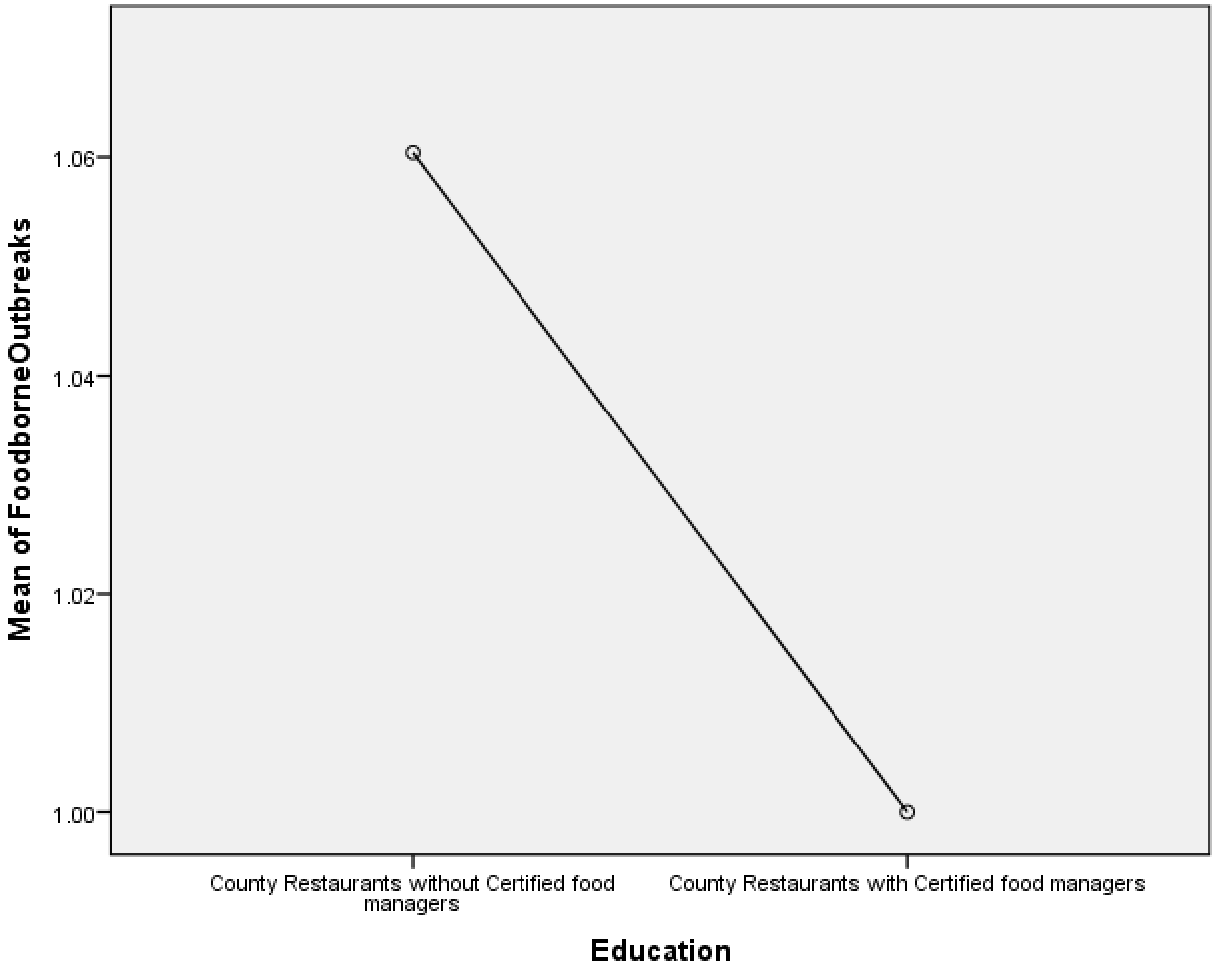

Figure C2. ANOVA plot of mean foodborne outbreaks.