University of Alberta

Identifying risk factors for food poisoning in commercial eateries: A retrospective case-control study of health inspection records for food establishments in the Capital Health Region, Alberta, Canada, 2003.

by

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Dedication

I dedicate this work to my family.

Abstract

The present study seeks to identify significant risk factors for foodborne illness through systematic analyses of health inspection records. Edmonton area eateries with biologically-plausible food poisonings were compared with control facilities not having a food poisoning event. Both univariate and multivariate logistic regression techniques were employed to determine significant risk factors for two restaurant classifications. Results indicate differential risk factors for fast-food as opposed to full-service establishments. *Employee hygiene* and *sanitation violations* were pre-eminent for the former category, while *inadequate temperature control*, *missing thermometers*, and *chemical hazards* proved most significant for full-service establishments. *Public complaints* were significantly associated with food poisoning events, and *food safety programs* afforded salient preventative measures for both restaurant categories. This study demonstrates that electronic data management systems may be used as highly effective surveillance tools for identifying problem areas.

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The **Food Protection Group**
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Inspiration

"The general strategy of prevention is to understand the mechanisms by which contamination and disease transmission occur well enough to interrupt them." Robert Tauxe - 1997

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List of Abbreviations and Nomenclature

AV	Astrovirus
APHA	American Public Health Association
BP-SFBI	Biologically plausible suspected foodborne illness (CASES)
CDC	Centers for Disease Control and Prevention
CDSS	Communicable Disease Surveillance Sub-group
CIOSC	Canadian Integrated Outbreak Surveillance Centre
CIPHI	Canadian Institute of Public Health Inspectors
CNPHI	Canadian Network of Public Health Intelligence
CSC	Centre of Surveillance Coordination
EH	Environmental Health
EHO	Environmental Health Officer
EOO	Executive Officer's Order
EV	Enterovirus
FBI	Foodborne Illness
FDA	Food and Drug Administration
FEP	Food Establishment Permit
FSIS	Food Safety and Inspection Service
FSP	Food Safety Program
FSU	Former Soviet Union
HACCP	Hazard Analysis Critical Control Point
HAV	Hepatitis A virus
HC	Health Care
HCW	Health Care Workers
IAMFES	International Association of Milk Food and Environmental Sanitarians
IS	Information Systems
LR	Logistic Regression
MAP	Modified Atmosphere Packaging
MMWR	Morbidity and Mortality Weekly Report
MOH	Medical Officer of Health
NDR	Notifiable Disease Report
NEHA	National Environmental Health Association

NLV	Norwalk-like Virus
NRA	National Restaurant Association
PFGE	Pulsed-field gel electrophoresis
PH	Public Health
PHA	Public Health Act
PHI	Public Health Inspector
PLPH	Provincial Laboratory of Public Health
PSP	Paralytic Shellfish Poisoning
RHA	Regional Health Authority
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
RV	Rotavirus
SES	Socio-Economic Status
SFBI	Suspected Foodborne Illness
SR#	Service Request Number
TMS	Total Management System
USDA	United States Department of Agriculture
WHO	World Health Organization

Chapter 1: Background and context

1.1 Burden of foodborne disease

Gastroenteritis remains one of the leading causes of morbidity and mortality worldwide. The World Health Organization (WHO) estimates that approximately 2.5 to 3.3 million deaths occur each year in developing countries from diarrheal diseases, the highest case fatality rates being in the youngest age groups (Bresee *et al.* 2002) (Gurerrant *et al.* 2002). In South America, as in many other developing nations, diarrheal illness is still among the five leading causes of death in infants under one year of age, and remains among the highest ranking cause of death in children aged one to four (Anon. 1983).

In affluent and developed regions of the world, enteric illness is no longer considered to be a dominant cause of mortality. Most deaths from diarrheal illnesses arise from dehydration; a loss of fluid and electrolytes from the body. Consequently, the use of simple, cost-effective measures such as Oral Rehydration Therapy (ORT) have resulted in dramatic decreases in the case fatality rates in areas where such remedies are available (Gurerrant *et al.* 2002). Other factors responsible for the reported declines in death rates from gastrointestinal/enteric illness in the developed world include: improvements in sanitation, water treatment, and food safety; better disease surveillance for early detection and intervention of outbreaks; increased public awareness about foodborne illness; stricter legislative controls, and improved public health infrastructure (Nelson *et al.* 2001) (Reynolds 2001) (Kaferstein & Abdussalam 1999) (Altekruse & Swerdlow 1996)

Despite these factors, foodborne illnesses remain an important source of both morbidity and lost productivity in even the wealthiest nations. The annual cost to the Canadian economy is estimated to be over two billion dollars (CAN.) (Campbell *et al.* 1998). In the U.S., the economic burden attributed to foodborne illness is estimated to be in excess of five billon dollars (U.S.) each year (Altekruse & Swerdlow 1996) – down from estimates of 28 billion (U.S.) for treatment and lost productivity costs as recently as 1985 (Nelson *et al.* 2001). The CDC estimates that six to 80 million cases, 60,800 to 325,000 hospitalizations, and 1,800 to 9,000 deaths occur each year in the U.S. (Bresee *et al.* 2002) (Herikstad *et al.* 2002) (Angulo *et al.* 1998) (Altekruse & Cohen 1997). This wide range in estimates is explained on the basis that they are calculated from a variety of surveillance systems, each with its own sensitivity and underlying set of assumptions. Higher numbers, for example, are often based on foodborne illnesses caused by agents that have not been positively identified (Bryan 2002b). It may be argued, however, that these figures are more representative. Although outbreaks are more likely to make the news, the majority of foodborne infections in the community occur as individual or sporadic cases that are seldom clinically-confirmed (Tauxe 1997) (Altekruse & Swerdlow 1996). According to a recent population-based estimate of the burden of diarrheal illness in the U.S., a mere 12% of individuals suffering from diarrheal illness seek medical attention, and of those only 21% have a stool sample ordered by the attending physician (Herikstad *et al.* 2002). Common sense further dictates that many of the foodborne pathogens considered common today were unrecognized twenty years ago, and that laboratory tests of sufficient sensitivity / specificity may not exist or be used (particularly if the agent is new or rare). Consequently, foodborne illness is grossly underreported.

1.2 The impact of commercial eateries on foodborne illness

Public health agencies and the Centers for Disease Control and Prevention (Centers for Disease Control and Prevention) have identified commercial eateries as being among the primary sources of foodborne illness (Lee & Middleton 2003) (Cotterchio *et al.* 1998) (Altekruse & Cohen 1997) (Collins 1997) (Corber *et al.* 1984). The proportion of foodborne outbreaks attributed to the mishandling or mistreatment of food in a food establishment setting is 75 to 80 percent by some estimates (Bryan 2002a). This should come as no surprise. Food service outside the home is big business. The restaurant industry employs nearly 12 million people in the United States alone (Anon. 2003a) (Anon. 2003c). In 1996, it was estimated that the restaurant industry's share of the food dollar was 46%, and the typical consumer (defined as a person over eight years of age) ate greater than four meals per week away from home (Collins 1997). In 2003, growth in the food service industry was 4.4%, with estimated sales of more than $440.1 billion dollars U.S. (Anon. 2003a). These trends are largely reflective of societal changes (a factor that will be discussed along with other determinants of foodborne illness incidence in an upcoming section).

As usage of the burgeoning food service industry increases, so too does the potential for exposure to foodborne pathogens present as a result of improper food handling practices or other deficiencies at these facilities. The economy, and the workforce that runs much of the food industry often accentuate these problems. The restaurant industry is competitive, which encourages businesses to save money wherever they can. This can result in foregoing upgrades to the food processing / storage areas of the food establishment when they are required (because they are not visible to the patrons). It can also result in hiring less experienced staff. Entry-level workers are often young, with little food handling experience or training. In many instances, the food service industry also offers the first employment opportunities for new immigrants, many of whom may be unfamiliar with food safety legislation and have difficulty adjusting because of language, literacy, and/or cultural barriers. While it is improving because of recent changes public health legislation, insufficient training of food handlers by the food service industry also continues to be a problem. Much of the training offered by restaurant employers is focused on customer service rather than food safety. Left unchecked, these issues may increase the risk of food poisoning to consumers.

1.3 The role of public health in foodborne illness prevention

The role of public health (PH) is best described as providing primary prevention and advocacy to protect those most vulnerable in the population (Tichner 2002). Food protection initiatives undertaken by Environmental Health (a department of PH) exemplify each of these roles. Duties include inspection and permitting of food establishments, enforcement of pertinent legislation, disease surveillance, public and food-handler education, investigating food poisoning outbreaks, liaising with provincial and national counterparts, networking with provincial laboratories, and conducting research (Koren & Bisesi 1995) (Bryan 2002a). An example of such a program is presented in the following section.

1.4 Environmental health food safety programs (Capital Health)

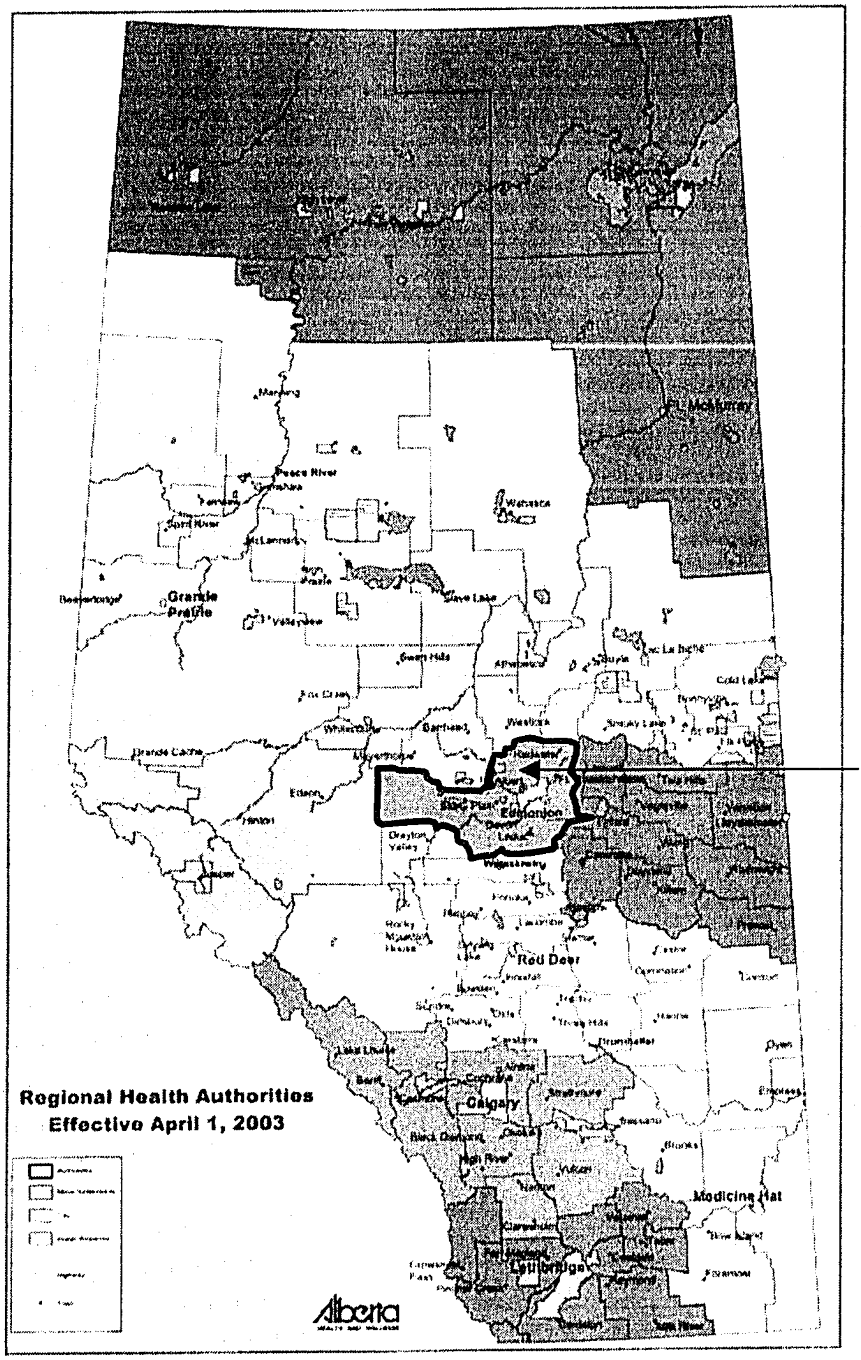
Food safety programs vary considerably from region to region. Staffing levels, available infrastructure, program goals, the legislative framework under which an Environmental Health program operates, and the education level required of its inspectors (PHI/EHO) have each been demonstrated to influence program outcomes (Wodi & Mill 1985) (Allwood *et al.* 1999). The following section describes the Environmental Health Food Protection Program for the Capital Health region of Alberta, Canada.

1.4.1 The Capital Health Region

Capital Health is Canada's largest integrated academic health region, providing complete health services to residents in the cities of Edmonton, Fort Saskatchewan, Leduc, Spruce Grove and St. Albert, the counties of Leduc, Parkland, Strathcona and Sturgeon, the Town of Devon, and communities in the eastern part of Yellowhead County. It is one of nine Regional Health

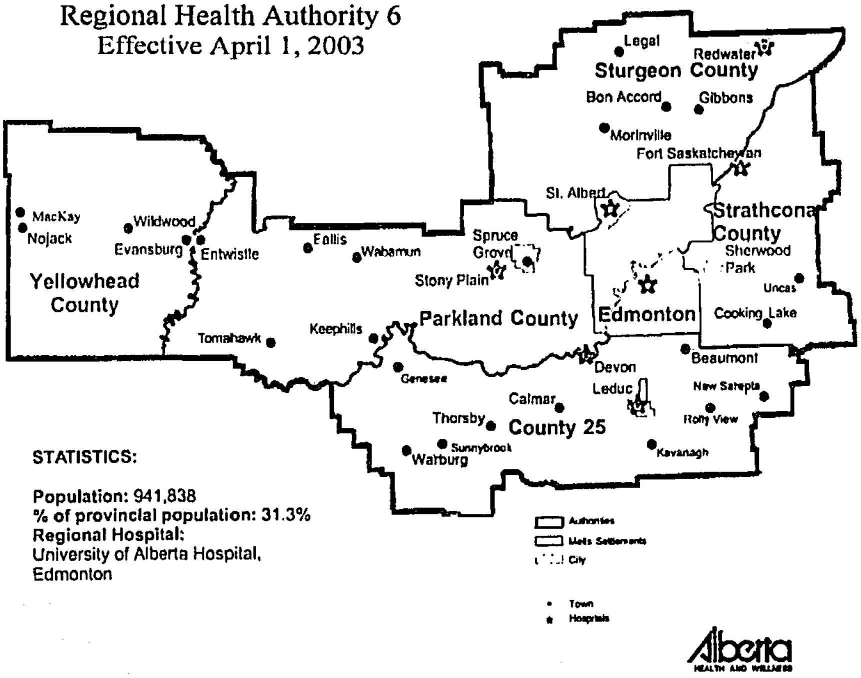
Authorities (RHAs) in the Province of Alberta (Figure 1.4.1). While not as large as many of the other regions geographically, persons residing within its borders account for nearly one third of the total population for the province. The Capital region recently surpassed one million individuals, and the population expected to grow by more than 115,000 people by 2010 (Capital Health News release, April 2005). The region is diverse; it has a large urban population centered around the Capital city of Edmonton, as well as an extensive rural component as depicted in Figure 1.4.2. Economically, the region and province are prospering, which has resulted in substantial growth and development over the past five years. This is particularly true for the City of Edmonton. Such growth has placed increased demands on EH programs, including inspection services and food protection initiatives.

Figure 1.4.1 Regional health authorities of Alberta



Capital Health

Figure 1.4.2 Map of the Capital Health Region



1.4.2 Staff / training

The ability of inspectors to competently perform their job duties is closely tied with sufficient training and experience (Isaacs *et al.* 1999). While they may come from varied backgrounds, inspectors must understand the underlying scientific principals of food safety in order for them to understand the rationale for regulations and interpret them for others (Bryan 2002b). As such, the practice of employing staff that lack the technical skills to adequately perform food safety inspections has been openly criticized (Allwood *et al.* 1999) (Bryan 2002b). In Canada, Public Health Inspectors (PHIs) / Environmental Health Officers (EHOs) must be certified by the Canadian Institute of Public Health Inspectors (CIPHI) and be designated an Executive Officer under the Public Health Act before they can work in the field. This requires specialized training, and a minimum of four to six years of university education. In Alberta, qualifications for executive officers are stipulated in provincial regulations. In Capital Health, 17 field staff work in the Food Protection Program. Most have Bachelor's degree in science, arts or technology plus an additional after-degree in environmental health (public health). In addition, one has a Masters degree in laboratory technology, and another has a M.D. degree.

Each inspector working in food protection is responsible for all inspections, referrals and investigations of food establishments located in their allocated district. In keeping with program goals, every inspector is required to complete six inspections per 7 ¾ hour day on average. It is further expected that all administrative duties, including data entry, phone calls, meetings and reports, be completed within this allocated time. In addition to these duties, field research is performed on a voluntary basis and if schedules permit. Inspectors in Capital Health typically work Monday to Friday, 8:30am to 5:00pm; weekend and evening inspections are also routinely conducted in facilities where these are required.

1.4.3 Registration and approval of food establishments

In Canada, the registration and approval of food establishments is largely under provincial jurisdiction. For example, under section 3(1) of the Public Health Act (PHA) Food and Food Services Regulation, being 328/2003 of the statues of Alberta, any facility that wishes to sell, manufacture, store, and/or distribute food to the general public is required to have a valid food establishment permit (FEP) (Public Health Act, Food and Food Establishment Regulation 2003). Operating without a FEP is an offence under the PHA, and violators may be subject to closure or fines. In Capital Health, owners must apply for FEP in advance of opening. Once an application is made, the facility must be inspected to ensure it is suitable for the purposes intended. Inspections are conducted by certified PHIs/EHOs holding Executive Officer status as defined by section 17 or 23(3) of the Alberta PHA. Upon successful inspection, the EHO will issue the permit with any restrictions s/he sees fit (eg. "Single-service utensils only" for establishments lacking proper dishwashing facilities).

1.4.4 Risk rating of food establishments (Class I, Class II, Class III)

In September 2002, a standardized hazard rating system for food establishments was adopted by all RHAs in Alberta. Similar rating systems exist in other areas of Canada, the U.S. and Europe (Buchholz *et al.* 2002) (Wodi & Mill 1985). In Alberta, this hazard rating (a.k.a. facility class) determines the amount that a food establishment is charged per year for their permit, as well as the frequency at which it is routinely inspected. These ratings are based on the degree of food preparation conducted and the demographics of the population served. Under this system, a facility selling pre-packaged foods rates differently from a full-scale restaurant, and a food establishment located in a seniors lodge rates higher than an eatery of similar size that caters to the general community because their inherent risks are different. A sample of various types of food establishments and their respective ratings is provided in ***Appendix I.***

1.4.5 Electronic record management system

A computerized tracking system is a valuable tool for EH programs wanting to store and analyze information gathered from health inspections (Mowat 1999). Health departments using such systems have found that inspection activities can be more easily planned, tracked, and evaluated (Barni *et al.* 2003). The present study utilized an existing electronic record management system to assess trends at food establishments over time to see if certain violations and other characteristics were significant predictors of foodborne illness.

The Total Management System (TMS) database is a non-research oriented, longitudinal data set that, among other things, is responsible for recording inspection activities for the Food Protection Division of Environmental Health Services, Capital Health. Each permitted food establishment in the Capital Health region is entered into the database. Environmental Health Officers returning from inspections in the field use TMS to track the date, type of inspection conducted, and any violations found or corrected. Violations are selected from a scroll-down menu using a click-and-drag function. Violation codes presented in the scroll-down menu are extensions of specific section(s) of the PHA Food Regulation. A complete list of violation codes is provided in ***Appendix II.*** Violations remain on the premise's file until they are corrected. While some violations may be corrected immediately, several re-inspections may be required in some instances. Upon successful completion, the violation code is removed from the outstanding violation list on the premise's file. All entries and revisions are tracked by the TMS system.

1.4.6 Inspection types

There are several types of inspections utilized by the Food Protection group, each with its own purpose and focus. The number of *routine inspections* a food establishment receives is determined by its hazard rating: Class I facilities are inspected once per year, Class II establishments twice a year, and Class III food establishments are inspected three times per year.

A food establishment may receive fewer inspections if there are too few inspectors, the facility changes ownership, or it opens part-way through the calendar year. Routine inspections are conducted unannounced, and are "complete" inspections (meaning that the EHO checks all temperatures and equipment, observes food handling practices, reviews cleaning procedures, and the like). Each routine inspection typically results in one or more *re-inspections*. A re-inspection focuses largely on past problems, and is conducted to monitor the progress or completion of corrective measures required of food establishment operators in response to cited deficiencies. Re-inspections do not count toward the total number of inspections a facility receives per year, and they often occur within set timeframes (48 hours, 7 days, 30 days...) or on specific dates. The inspector sets timeframes for correction when s/he first cites the violation(s). More than one re-inspection may be scheduled from a single routine inspection, suspected foodborne illness (SFBI) or complaint investigation – especially if multiple violations exist.

Demand inspections fall into several categories. All are initiated following a service request from an individual or group. *Initial inspections* are conducted on new food establishments that have not yet opened. Such inspections are much like a routine inspection, but with greater emphasis on structure and equipment since the inspector must determine if the establishment is suitable for the purposes intended. *Complaint investigations* are conducted in response to information received by the department that allege condition(s) exist that are departures from accepted regulatory requirements. Complaints may be filed in response to the manner in which food was handled, general sanitation, employee hygiene, pest infestation, and numerous other issues.

Suspected foodborne illness (SFBI) and *outbreak* investigations are also demand inspections. The terms are not synonymous. An outbreak of foodborne illness is defined as an incident in which five or more individuals, or more than one dining party, are epidemiologically linked in terms of place and time. These individuals cannot live in a common household, exclusive of an institutional setting. Outbreak investigations are collaborative in nature, often involving authorities at both local and provincial levels – inspectors, nurses, epidemiologists, as well as the provincial laboratory of public health (PLPH). Foodborne outbreak investigations are also quite structured, since they closely follow established guidelines set forth by the International Association of Milk Food and Environmental Sanitarians (IAMFES) and the Centers for Disease Control and Prevention (Centers for Disease Control and Prevention). SFBI investigations are similarly investigated. However, they rely less on the collaborative efforts of several departments and are reserved for single cases, households, and small dining parties. The principal investigator of an SFBI is usually the PHI/EHO who regularly inspects the facility where the illness is thought to have occurred. At the time a SFBI is received, relevant details of the alleged incident are recorded, including: the name and location of the food establishment, the date and time of the implicated meal, what foods were eaten, the date and time of onset, what symptoms occurred (in what order, their severity, and for what duration), as well as other pertinent information (e.g. are clinical or food samples available, was a physician consulted). A 48-hour food history and information on others in the dining party are also gathered, but this information is often incomplete. Much of this information was used in this study to determine if the reported SFBI was biologically plausible, and therefore suitable for inclusion as a case.

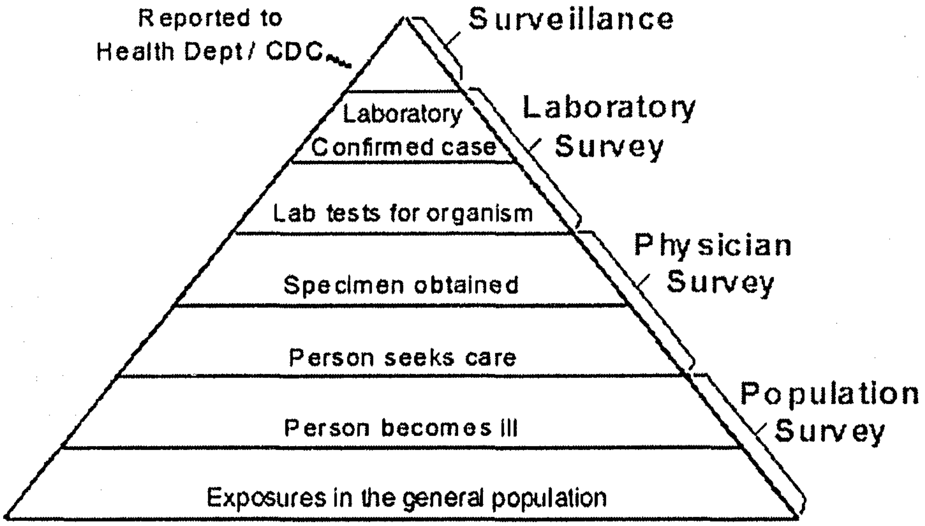
While they are defined differently, the goals of outbreak and SFBI investigations are remarkably similar. First, investigators must determine *where* and *when* exposure likely occurred, *who* is at risk (i.e. who was exposed), and *what* agent is most likely responsible (Reingold 1998) (Koren & Bisesi 1995) (IAMFES 1987). Such determinations are often made on incomplete epidemiological information, and in the absence of food or clinical samples. Irrespective of this, these determinations are necessary to prevent further exposure and to control the spread of disease in the short term. A more challenging task is often what investigators must try to determine next: *why* and *how*. A common misconception is that the singular goal of outbreak and SFBI investigations is to identify the food product believed responsible so that it may be removed from the menu or store shelves. While under rare circumstances this does occur, the primary focus of most investigations is to successfully define the chain of events that allowed contamination to occur in the first place, and further, what conditions permitted the growth of the organism (or the elaboration of toxins) to levels capable of causing illness (Reingold 1998) (Majkowski 1997) (Koren & Bisesi 1995). Only then can strategies be devised to prevent similar events from occurring in the future.

Chapter 2: Rationale and study objectives

2.1 Rationale

The principal researcher in this study has worked in the field of Environmental Health for seven years. During that time, he observed incidental trends when conducting suspected foodborne illness investigations at local eateries, and further recognized that no formal profile for a food establishment at greatest risk of having a food poisoning had ever been developed. It was further observed that the department took great care in tracking health code violations. A closer review of related research revealed that no study of this kind had ever been conducted and published in Canada. Moreover, it was felt that the proposed design for this study could offer a more rigorous assessment of reported cases of foodborne illness, associated with commercial food establishments within a defined region and time period, than other studies done to-date. Research focusing on the analysis of surveillance data, for example, relies on clinically confirmed cases identified by public health laboratories. While researchers conducting these studies have the benefit of knowing the agent responsible, there are inherent drawbacks to the exclusive use of laboratory confirmed data. First and foremost, only a fraction of individuals affected by enteric illness are represented by this group, as shown in Figure 2.1.1. In England, for example, it is estimated that one in six individuals with enteric illness visit their doctor, and only one in 136 cases of enteric illness is captured by their national surveillance program (Wheeler *et al.* 1999).

Figure 2.1.1 The triad model for disease surveillance initiatives.



SOURCE: www.cdc.gov

This study evaluates food poisonings that occur at the "Population" level versus the "Laboratory" or "Surveillance" levels. Cases are not required to be clinically confirmed. Instead, information on exposure and the clinical presentation of illness (symptoms, incubation period) are used to help determine which SFBI cases are biologically plausible, and therefore are suitable for further analysis.

Other factors also threaten the representativeness of laboratory and surveillance data. Provincial and national enteric surveillance data are normally collected for reportable illnesses only. Consequently, it is not representative of etiological agents such as *Norovirus (NLV), C. perfringens, B. cereus* or staphylococcal food poisonings, which are not captured by these surveillance initiatives. Selection bias would therefore be introduced into any study claiming to be representative of "food poisoning" that relied on these sources of data. Another drawback of incidence and prevalence data provided by laboratory surveillance systems is that associations between exposure and disease cannot always be determined or are less clear. There are several reasons for this:

- There are many vehicles of transmission for enteric diseases other than food (fecal-oral, contaminated water, person-to-person, and zoonotic). Surveillance systems track enteric illnesses by the etiologic agent responsible, not by exposure indices.
- Like SFBIs most enteric illnesses occur as sporadic cases (the difference being that they are not part of any formal investigation like an SFBI unless they are part of an identified outbreak); and most importantly
- Notifiable disease report (NDR) follow-ups consist of a telephone interview with the affected person that is often conducted weeks (or months) after the exposure occurred.

In addition to the obvious concern of having more than one potential exposure being mentioned (and having no way of verifying such information), a lengthy delay between exposure and the time the person is interviewed increases the likelihood of recall bias.

The greatest contribution of the present study is that it expands upon the existing body of literature dealing with restaurant inspections and disease prevention. Several studies have assessed if *food handler education* and *frequency of inspection* are effective strategies for reducing health violations at restaurants (Badder *et al.* 1978) (Kaplan 1978) (Corber *et al.* 1984)

(Riben *et al.* 1994a) (Riben *et al.* 1994b) (Mathias *et al.* 1994) (Mathias *et al.* 1995) (Penman & Webb 1996) (Campbell *et al.* 1998) (Cotterchio *et al.* 1998) (Allwood *et al.* 1999) (Kaferstein & Abdussalam 1999) (Isaacs *et al.* 1999). While these are important first steps in measuring the effect of intervention strategies, both these study designs rely on a single basic assumption – a reduction in the number of health code violations results in fewer food poisonings. Few studies have attempted to test this relationship directly. Between 1980-2004 only six papers have been published on the association between information collected during restaurant inspections and reported cases of food poisoning that implicate these facilities (Irwin *et al.* 1989) (Penman & Webb 1996) (Cruz *et al.* 2001) (Mullen *et al.* 2002) (Buchholz *et al.* 2002) (Jones *et al.*, 2004). Among these there is little agreement. This research seeks to clarify the relationship between the aforementioned variables through improved methodology not attempted in previously published studies.

2.2 Objectives

This study has three main objectives:

1. **Create a profile for food establishments at greatest risk of causing food borne illness in the Capital Health region based on inspection records electronically stored in the TMS database.**
2. **Highlight strengths and weaknesses in existing food inspection and record-keeping strategies in the Capital Health region, particularly as they relate to inspection frequency and the tracking of violation codes electronically.**
3. **Create a template for other health agencies to follow *vis-à-vis* the analysis and interpretation of information collected on food establishments in their region.**

2.3 Research question

Do inspection records for food establishments that receive biologically-plausible suspected food poisoning complaints differ significantly from food establishments that do not receive food poisoning complaints?

- Do they receive more general complaints (i.e. those other than SFBIs or outbreaks)?
- Do they receive more violations *overall*, or of a *particular type*?

- Are they inspected more or less frequently in comparison to food establishments of equal class without SFBI?
- Are they more or less likely to be a member of a national food "chain" (i.e. McDonald's, KFC, Taco Bell...) with a recognized quality control or food safety program (FSP) in place such as HACCP?
- Are they more likely to have had enforcement action taken against them in the 12-month period prior to the SFBI?

2.4 Hypothesis

(H_0): There is no difference in inspection records for food establishments that have had a biologically-plausible case of food poisoning reported compared with food establishments that have not had such a report.

(H_1): There is a difference in inspection records for food establishments that have had a biologically-plausible case of food poisoning reported compared with food establishments that have not had such a report.

Chapter 3: Literature review

The primary literature search was conducted in October and November 2003. Additional references were obtained during 2004 and the Spring of 2005. For the review, the following databases were accessed: MedLine, PubMED, and Web of Science. Search criteria included combinations of the following words and phrases for articles published between 1980 and 2004: restaurant inspection(s); foodborne illness; disease prevention; environmental health; and public health inspections. General background information was obtained from relevant textbooks and online using the Google® search engine. Case reports that illustrate risk factors for foodborne outbreaks were obtained from the MMWR, CCDR, and other relevant journals. Potential sources that were reviewed, but did not yield useful information included the Cochrane Collection and the BMC Public Health database. Unpublished literature was gathered by soliciting references from PHI/EHO's in administrative, research, and supervisory roles in the Capital Health region.

3.1 The biology of foodborne illness

With the onset of gastrointestinal symptoms, most people consider only what food was consumed at their most recent meal. This is a mistake. Few foodborne pathogens cause illness within a few hours: most take a day or more, and some can take several weeks to elicit symptoms following exposure (examples being Giardiasis, HAV and typhoid).

3.1.1 Foodborne infections

There are two mechanisms by which organisms can cause foodborne illness in humans: infection and intoxication. Foodborne infection is caused by bacteria, viruses or parasites that enter the body and grow. It is the predominant form of foodborne illness in humans. While specific incubation periods vary, they are typically greater than 8-12 hours. Examples of foodborne pathogens capable of causing foodborne infections that are likely to be captured by suspected foodborne illness reports include: *Salmonella spp., Campylobacter spp., Bacillus cereus, Shigella spp., Vibrio parahaemolyticus, Norovirus (NLV), Rotavirus,* and some of the pathogenic *E.coli* strains. Gastrointestinal symptoms arise from a variety of mechanisms, including the attachment of the organism to the gut lining, and the production of enterotoxins by the organism following ingestion.

Salmonella spp.

The CDC estimates Salmonellosis causes 1.4 million illnesses annually in the U.S. (Toth *et al.* 2002). There are currently over 200 known serovars of Salmonella capable of causing illness in humans (American Public Health Association 2000), but *S. enteritidis* and *S. typhimurium* are the most commonly reported serovars for confirmed human cases in Canada (Health Canada 2003). Salmonella is gram negative facultative anaerobe that is often motile and does not form endospores (American Public Health Association 2000). Salmonella incubates 12-72 hrs, invades the intestinal mucosa of the host when infection occurs, and may become systemic (Health Canada 2003) (American Public Health Association 2000). Its normal habitat is the intestinal tract of humans and animals. Meat and poultry products (including whole-shell eggs) are particularly susceptible to contamination, although peanuts, raw vegetables and unpasteurized cheese have also been implicated in large foodborne outbreaks (Honish *et al.* 2005) (Toth *et al.* 2002) (Honish 2001) (Tauxe 1997) (Luby *et al.* 1993). One of the largest outbreaks of Salmonella occurred United States, where it is estimated that 224,000 persons the developed *S. enteritidis* gastroenteritis after eating Schwan's ice cream. Investigators determined that the ice cream associated with infection contained premix that had been transported by tanker trailers that had carried unpasteurized eggs immediately before (Hennessy *et al.* 1996). Cross-contamination and fecal-oral transmission from pets and infected food handlers is also well documented for these enteric pathogens (Health Canada 2003) (Tauxe 1997) (Hedberg *et al.* 1991).

Campylobacter spp.

Campylobacter is a gram-negative, microaerophilic, thermophilic rod that is reported to be the leading cause of foodborne illness in Canada (Health Canada 2003), the U.S. (Tauxe *et al.* 1988), Europe (Bryan 2002a), and Australia (Unicomb *et al.* 2003). Surveillance data collected by the CDC and Ontario Ministry of Health have reported incidence rates of 15 and 42.3 cases per 100,000 respectively in recent years (Lee & Middleton 2003). Interestingly, the majority of Campylobacter cases reportedly occur as isolated, sporadic events involving small family groups (rather than large outbreaks); the highest frequency of which occur in the summer months (Health Canada 2003) (Lee & Middleton 2003) (Tauxe *et al.* 1988). Data collected by the Canadian Institute of Health Information (CIHI) also show the highest percentage of infections occur in two age categories: children under the age of two years and young adults in their late twenties (Health Canada 2003) – a fact that is supported by several other sources (American Public Health Association 2000) (Tauxe *et al.* 1988). Symptoms of campylobacteriosis typically include diarrhea, cramping, abdominal pain, and fever. Bloody diarrhea may also occur, as well as nausea and vomiting. The incubation period is reported to be two to five days, with illness lasting approximately one week in most individuals (Koren & Bisesi 1995) (American Public Health Association 2000). However, both asymptomatic and serious life-threatening illness may also occur (the latter primarily being in immunocompromised individuals when the organism spreads to the bloodstream). Long-term consequences, including arthritis and Guillain-Barré syndrome, can also result from a Campylobacter infection. It is reported that Guillain-Barré syndrome occurs in approximately one in every 1000 reported campylobacteriosis cases, and is characterized by paralysis that occurs when an individual's immune system attacks the body's own nerves (American Public Health Association 2000) (Altekruse & Cohen 1997) (Tauxe *et al.* 1988). It usually requires intensive care, and may last several weeks.

Campylobacter is commonly present in the gastrointestinal tract of healthy animals commonly used as sources of food, including cattle, pigs, chickens, turkeys, duck, and geese. In 2003, the Food Standards Agency (FSA) in the U.K. identified Campylobacter in 50% of raw chicken sampled at the point-of-sale (Food Standards Agency, 2003). While it is heat-sensitive, Campylobacter can survive refrigeration and will grow if contaminated foods are left at room temperature. Foodborne transmission is the most commonly implicated vehicle for Campylobacter infections (American Public Health Association 2000). Consumption of undercooked poultry, or foods cross-contaminated with raw poultry products, has been demonstrated to place individuals at particular risk of disease. This said, other foods including unpasteurized milk, undercooked meats, eggs, cheese, and shellfish have also been associated with cases of human illness (Tauxe *et al.* 1988). Other vehicles of transmission for Campylobacter include contact with other infected individuals, pets, and contaminated recreational/drinking water sources.

Bacillus cereus

Bacillus cereus is an aerobic spore-former that is responsible for two distinct forms of food poisoning: diarrheal and emetic. Each form is caused by a separate and distinct enterotoxin produced by the organism. The diarrheal form of illness results from infection of the intestinal tract. When present in sufficient numbers, *B. cereus* produces a heat-labile enterotoxin which results in the onset of watery diarrhea, and abdominal cramps (American Public Health Association 2000) (Anon. 1994b) (Koren & Bisesi 1995). Nausea may accompany the diarrhea, but vomiting is rarely present. Symptoms occur six to15 hours after consumption of contaminated food, and persist for 24 hours in most instances with no long-term sequelae

(American Public Health Association 2000). Foods implicated in outbreaks of diarrheal illness caused by this organism include meats, milk, vegetables, and fish (American Public Health Association 2000). The emetic type of food poisoning caused by *B. cereus* is characterized by onset of nausea and vomiting within 0.5 to 6 hours of the implicated meal (American Public Health Association 2000) (Anon. 1994b) (Koren & Bisesi 1995). While abdominal cramps and/or diarrhea may also occur, the duration of symptoms is generally less than 24 hours. Outbreaks of emetic food poisoning linked to *B. cereus* have generally been associated with rice products and other starchy foods that have been improperly temperature-controlled after cooking (Anon. 1994b). Emetic symptoms are caused by a pre-formed heat-stable toxin produced by the organism (American Public Health Association 2000). Rapid onset times coupled with relevant food history are often used to diagnose this type of food poisoning. The etiological agent may be confirmed by the isolation of large numbers of a *B. cereus* from the suspect food if it is available. In such instances, greater than 10^6 organisms per gram is considered indicative of active growth and proliferation (American Public Health Association 2000).

Shigella spp.

Shigella are gram-negative, nonmotile, rod-shaped bacteria frequently found in water polluted with human feces. According to the CDC, shigellosis (or bacillary dysentery) accounts for less than 10% of the reported outbreaks of foodborne illness in the U.S. In Capital Health, most cases are associated with international travel to middle and low income countries, or acquired from contact with an infected person (Zazulak & Honish 2004). Foods commonly implicated in outbreaks of shigellosis include salads (potato, tuna, shrimp, macaroni, and chicken), raw vegetables, milk and dairy products, and poultry. Improper food handling is the most common cause of food contamination (i.e. staff do not properly wash their hands after using the washroom, and subsequently touch ready-to-eat food). The infective dose is small; as few as ten organisms are believed to be capable of causing illness. The incubation period for shigellosis is 12 to 50 hours, and infection lasts one to three weeks (American Public Health Association 2000). Symptoms include abdominal cramps, diarrhea, fever, nausea and vomiting. Blood, pus, and/or mucus may also be found in the stools of persons affected. This occurs when *Shigella spp.* penetrates epithelial cells of the intestinal mucosa, multiply, and spread resulting in tissue destruction. Some strains also produce toxins much like *E. coli* O157:H7. Infants, the elderly, and the infirm are susceptible to the severest symptoms of disease (American Public Health Association 2000). Left untreated, case fatality rates may be as high as 10-15% with some strains. Possible sequelae that may result in some permanent disability include Reiter's syndrome, arthritis, and haemolytic uremic syndrome (HUS).

Vibrio parahaemolyticus

Vibrio parahaemolyticus is found in most marine ecosystems – in the warmer months it is found free-floating in coastal waters and in marine life, and in the colder season they may be isolated from silt beds on the ocean floor. Gastroenteritis caused by *V. parahaemolyticus* is associated almost exclusively with the consumption of raw or inadequately cooked seafood products (American Public Health Association 2000). It is reported that the number of *V. parahaemolyticus* cases in Japan range from 10,000 to 14,000 annually (Koren & Bisesi 1995). In 1998, it was responsible for an outbreak in the U.S. associated with consumption of raw shellfish harvested from Connecticut, New Jersey, and New York (Centers for Disease Control and Prevention 1999). Symptoms typically include cramping and diarrhea; though dysentery-like illness, high fever, nausea and vomiting are reported some cases (American Public Health Association 2000). The average incubation period for *V. parahaemolyticus* is 12 to 24 hours with a range of four to 96 (Koren & Bisesi 1995). Illness lasts between one and seven days. Long term sequelae, systemic infection, and death are very rare. The illness is reportable, and isolation of 10^5 Kanagawa-positive organisms per gram from epidemiologically implicated foods is considered confirmatory for diagnosis (American Public Health Association 2000).

While rare in comparison to *Salmonella* or *Campylobacter*, the epidemiology of *V. parahaemolyticus* is reportedly changing. At one time *V. parahaemolyticus* was believed responsible for only sporadic and localized illnesses, unlike toxigenic *V. cholerae* O1 and O139. It was never associated with a pandemic. Despite this, there have been noted increases in the number of outbreaks involving *V. parahaemolyticus* in recent years (Chowdhury *et al.* 2000). Of the three emerging serotypes responsible for this increase, O3:K6 has been the predominant pandemic strain (Wong *et al.* 2000). In 1996, it was responsible for several Asian outbreaks (Chowdhury *et al.* 2000) (Daniels *et al.* 2000) (Wong *et al.* 2000). Two years later, the O3:K6 strain was responsible for the aforementioned outbreak in the U.S. (Centers for Disease Control and Prevention 1999).

Norovirus (NLV)

Norovirus was recently approved as the official genus name for the group of small, single-stranded RNA viruses provisionally described as "Norwalk-like viruses" (NLV) and "small round-structured viruses" in the family Caliciviridae. Norovirus is estimated to be the most common cause of foodborne disease, accounting for an estimated 23 million cases of acute gastroenteritis every year, or two-thirds of all food-related illnesses in the U.S. (Bresee *et al.* 2002) (Anon. 2003b). Until recently, the epidemiologic features and disease burden associated with NLV have been poorly understood because of the lack of sensitive detection assays, and the underutilization of available diagnostic tools. In the last ten years, however, diagnosis of Norovirus has improved with the increased use of reverse transcriptase polymerase chain reaction (RT-PCR) to identify the virus in stool specimens taken from suspected cases (Lopman et al. 2003). This application of molecular techniques to investigate outbreaks of acute gastroenteritis in recent years has allowed health agencies to better illustrate the contribution of NLV to the overall burden of foodborne disease (Bresee *et al.* 2002). In a review of 90 outbreaks of non-bacterial gastroenteritis reported to the CDC over an 18 month period, 96% could be attributed to NLV (Bresee *et al.* 2002). Similarly, Norovirus was identified as the agent responsible in 58% of reported gastrointestinal outbreaks requiring laboratory investigation in Alberta conducted between January 1999 and the end of 2004 (Lee & Pang 2005). Several factors are believed responsible for this: NLV survives well in the environment, it has a low infectious dose (as few as 10 viral particles thought to be sufficient cause illness), it has several routes of transmission (fecal-oral, foodborne, waterborne, and person-to-person), and there is no lasting immunity. Most foodborne outbreaks of NLV arise though direct contamination of ready-to-eat food by an infected food handler (Lopman *et al.* 2003) (Kassa 2001). Consequently, cold foods, including various salads, sandwiches, and bakery products are frequently implicated in outbreaks of NLV (Hislop & Steinbru 2003) (Bresee *et al.* 2002). Food can also be contaminated at its source. Shellfish harvested from waters contaminated by human sewage have been associated with widespread outbreaks of NLV (Le Guyader *et al.* 2000) (American Public Health Association 2000). Similarly, produce and berries (often eaten raw) may become contaminated by polluted irrigation water prior to harvest and subsequently cause widespread outbreaks once they are distributed (Bresee *et al.* 2002). The incubation period for Norovirus-associated gastroenteritis is usually between 24 and 48 hours (median 33 to 36), but illness has been known to occur within 12 hours of exposure (Anon. 2003b) (Bresee *et al.* 2002). Norovirus infection usually presents as acute-onset of vomiting, watery non-bloody diarrhea accompanied by abdominal cramps and nausea. Low-grade fever is also frequently reported. Dehydration is the most common complication, especially among the young and elderly. Symptoms are self-limiting without specific treatment and usually last 24 to 60 hours. Recovery is usually complete, with no serious long-term sequelae (Anon. 2003b) (Lopman *et al.* 2003) (Bresee *et al.* 2002) (American Public

Health Association 2000). Unlike other leading causes of enteric illness, Health Canada and the CDC do not conduct active surveillance to monitor outbreaks of gastroenteritis caused by NLV. It is only recently reportable, and is not routinely screened for due to the specialized nature of the tests required. Some passive surveillance of NLV does occur when provincial or state health departments send clinical samples for testing, or when outbreaks are reported directly by local health agencies to their federal counterparts. Moreover, a system called CaliciNet, based on the PulseNet model, was recently developed to store and disseminate Norovirus sequences identified from outbreaks in order to link cases over large geographic areas. Further information on Norovirus can be obtained online at http://www.cdc.gov/ncidod/dvrd/revb /gastro/norovirus-factsheet.htm.

Rotavirus

Rotavirus is a small round-structured double stranded RNA virus that is responsible for acute gastroenteritis – particularly in infants and young children (Koren & Bisesi 1995). In many respects, the clinical presentation of rotavirus is similar to NLV. In countries with a temperate climate (such as Canada) the disease has a seasonal pattern, with annual epidemics occurring in the winter months (November to April) (American Public Health Association 2000). The primary mode of transmission is fecal-oral. Large numbers of the virus are excreted from persons with the disease, and the infective dose is small (10-100 viral particles). Asymptomatic excretion of this virus is well documented. Consequently, sufficient numbers to cause illness can be readily acquired through contaminated hands, surfaces, or ready-to-eat foods prepared by infected food handlers.

Once exposed, the incubation period ranges from one to three days. Symptoms, if they occur, start with vomiting, followed by three to eight days of watery diarrhea, fever and abdominal pain. The illness is self-limiting and persons affected typically make a full recovery. A common complication of Rotavirus infection is dehydration, which may require hospitalization. Immunity after infection is believed to be incomplete, but subsequent infections are thought to be less severe than the original.

Rotavirus is quite stable in the environment. Sanitary measures adequate for bacteria and parasites have been found to be largely ineffective. This is supported by reports that a similar incidence of the illness is found in both developed and developing countries (American Public Health Association 2000). Despite its persistence, rotavirus cannot be isolated from food samples. Consequently, it is rarely confirmed as an etiologic agent in foodborne outbreaks. Given the characteristics of the virus, however, it is suggested that it is likely responsible for many of the "undetermined" GI outbreaks and sporadic cases of foodborne illness described by health authorities each year. Further information on Rotavirus can be obtained online at http://www.cdc.gov/ncidod/dvrd/revb/gastro/rotavirus-factsheet.htm.

3.1.2 Foodborne intoxications

Organisms responsible for foodborne intoxications were once considered to be the predominant cause for foodborne illness in humans. Today, it is well understood that such illnesses are more frequently reported to health agencies because of acute onset times; while specific incubation periods vary, symptoms may develop within a few minutes of ingestion of the implicated food (American Public Health Association 2000). Foodborne intoxication occurs when enterotoxins are elaborated in food prior to consumption. This can occur in one of two ways; the first and most common being when perishable foods are stored or displayed at temperatures that promote bacterial growth (Canadian Restaurant and Food Services Association 2003) (Tortora *et al.* 1989). Several documented outbreaks of *Staphylococcus aureus* (Anon. 1986) (Jones *et al.* 2002), *Bacillus cereus* (Anon. 1994b), *Clostridium perfringens* (Anon. 1994a), *Scombroid* (Anon. 1988), and *Clostridium botulinum* (Anon. 1995) have been associated with foods held in the "danger zone" for extended periods of time. The "Danger Zone" is defined as temperatures between 4°C (40F) and 60°C (140F) (Public Health Act, Food and Food Establishment Regulation 2003) (National Center for Infectious Diseases 2003) (Partnership for food safety 2003). Many of the toxins produced during these periods are heat-stable, meaning subsequent re-heating or cooking may not destroy them. This explains why the temperature control of potentially hazardous foods is of critical importance to food safety (Canadian Restaurant and Foodservices Association 2003).

Another way chemical or biological toxins may be introduced into food products prior to consumption is via the accumulation and amplification of such toxins in the body tissues of an animal from the environment while it is alive (American Medical Association, Centers for Disease Control and Prevention, *et al.* 2001) (American Public Health Association 2000) (Angulo *et al.* 1998) (U.S. Food & Drug Administration 1992). Examples include paralytic shellfish poisoning (PSP) and Ciguatera. PSP is a foodborne illness caused by consumption of mussels, clams, cockles, or scallops that contain heat-stable toxins elaborated by planktonic algae that the shellfish feed on. Symptoms of this illness develop rapidly (0.5 to 2 hours after ingestion of the shellfish), and are varied depending on the type of toxin(s) present and the amount of toxin consumed. The effects of PSP are predominantly neurological and include tingling, burning, numbness, drowsiness, and slurred speech. In severe cases, respiratory paralysis and death may occur if respiratory support is not provided. Outbreaks, while infrequent, have been reported in Canada, the U.S., and Guatemala; the latter involving 187 cases and 26 deaths as a result of ingestion of clam chowder (U.S. Food & Drug Administration 1992) (Anon. 1991).

The most commonly reported marine toxin disease in the world is Ciguatera. Ciguatera is a form of human poisoning caused by the consumption of contaminated tropical marine fish (American Public Health Association 2000). The toxins are known to originate from several dinoflagellate species that are common to areas such as Hawaii and the Caribbean. Because the toxins are lipid-soluble, they accumulate through the food chain and may be present in harmful amounts in larger predatory fish such as barracuda, snapper, grouper, mackerel and triggerfish (CFSAN 2005).

Ciguatoxins are odourless, colourless, tasteless, and are unaffected by cooking, drying, salting, or freezing. Ciguatera presents primarily as an acute neurological disease manifested by gastrointestinal, neurological, and cardiovascular symptoms two to five hours after eating contaminated fish (American Public Health Association 2000). Symptoms can appear sooner and be more severe with repeated exposures. With ingestion of contaminated fish, the attack rate has been reported to be 73%-100% without any apparent age-related susceptibility (CFSAN 2005). Acute fatality, due to respiratory failure or circulatory collapse, is reportedly less than 1%. Clinical procedures capable of providing differential diagnosis of ciguatera in humans are not presently available. Consequently, diagnosis is based entirely on clinical presentation and recent dietary history. Because of these factors, the true worldwide incidence of Ciguatera is unknown.

3.2 Factors affecting the epidemiology of foodborne illness

Several factors affect the incidence and severity of foodborne illness. These include: recent changes in human demographics and behavior, advances in technology, growth of industry, the widespread distribution of food products, increases in international travel and commerce, microbial adaptation, economic development and land use, climate change, and the breakdown of public health measures/infrastructure. Several of these variables are interdependent.

3.2.1 Human demographics

Demographic variables such as age, socio-economic status (SES), and underlying health status have been demonstrated to dramatically affect the epidemiology of foodborne illness in both developing and industrialized (developed) nations (Altekruse & Cohen 1997) (Altekruse & Swerdlow 1996) (Anon. 1983) (Kaferstein & Abdussalam 1999) (Nelson *et al.* 2001). Those individuals who are impoverished, at the extremes of the age spectrum, or have underlying health conditions are at greatest risk of severe, recurrent, and/or persistent foodborne infections and their sequelae (American Public Health Association 2000) (Hayes *et al.* 2003) (Smith 1997). In developing nations, this describes the vast majority of the population.

In developed countries, enteric illness is no longer considered to be a predominant cause of mortality (Thomas & Hrudey 1997). It does, however, put a significant burden on the health care system, and remains a cause of premature death in even the wealthiest nations. Changes to the social demographics of industrialized nations in recent decades have resulted in a heightened susceptibility to severe, recurrent, and/or persistent foodborne infections amongst a growing proportion of the population (National Intelligence Council 2000) (Kaferstein & Abdussalam 1999) (Altekruse & Cohen 1997) (Collins 1997) (Hall 1997) (Smith 1997) (Altekruse & Swerdlow 1996).

Our aging society…

During the 20th century, the median age of the U.S. population steadily increased (Altekruse & Swerdlow 1996). In 1900, less than five percent of the population in the U.S. was reportedly over the age of 65. In contrast, by 2040 it is estimated that 20% of the population will be 65 or older (Altekruse & Cohen 1997). The impact and public health significance of this trend is highlighted by several recent publications (Altekruse & Swerdlow 1996) (Smith 1998) (Kaferstein & Abdussalam 1999) (National Intelligence Council 2000). In a U.S. study of 87,181 cases of gastroenteritis, for example, only 17% occurred in persons 70 years of age or more, yet 67.5% of the 514 illness-related deaths reported were from this same age group (Smith 1998). Several factors contribute to the increased incidence, morbidity, and mortality due to foodborne infection in the elderly: an overall age-associated decrease in immune status, age-related changes in the intestinal tract such as the decreased production of gastric acid and intestinal motility, malnutrition, lack of exercise, and increased use of medications (Smith 1998).

Underlying health status…

Underlying health status is an important indicator for the incidence, duration, and severity of foodborne illness. Persons who are at the extremes of age, are pregnant, malnourished, or are immunocompromised are more susceptible to infection by enteric pathogens. They are also more likely to have prolonged illness, experience associated complications, and are more likely to die (Hayes *et al.* 2003) (Bresee *et al.* 2002) (American Public Health Association 2000) (Kaferstein & Abdussalam 1999) (Angulo *et al.* 1998) (Altekruse & Cohen 1997).

The HIV epidemic has had a significant impact on underlying health status globally (Nelson *et al.* 2001). Researchers recently estimated that a total of 39.4 million cases of HIV infection, and ten million cases of AIDS, existed worldwide (WHO 2004). Ninety percent of these infections are expected to have occurred in developing regions least capable of caring for the people afflicted not only with this disease, but the opportunistic infections that accompany it as well (including enteric pathogens). Consequently HIV is, and will likely remain, an important determinant of health in both the developed and developing world. Several studies have demonstrated a higher incidence of diarrheal illness amongst HIV-infected patients compared with the general population (Altekruse & Cohen 1997) (Gilson & Buggy 1996). A high incidence amongst HIV and immunocompromised individuals in the 1993 cryptosporidiosis outbreak in Milwaukee offers one example. Marked increases in the severity of such illness amongst HIV-infected groups have also been reported (Hayes *et al.* 2003) (Hoxie *et al.* 1997). HIV-infected persons who contract *Salmonella*, for example, are at greater risk for recurrent nontyphoidal septicaemia (American Public Health Association 2000). High death rates amongst HIV-infected individuals were also reported following the aforementioned cryptosporidiosis outbreak in Milwaukee (Hoxie *et al.* 1997).

In Canada and other developed countries, the reported increase in the proportion of people with underlying chronic disease is largely due to advances in medical technology, including improvements in organ transplantation, the detection and treatment of cancer, and the use of new therapies to delay the onset of AIDS. In the past decade, for example, the death rate from breast cancer decreased by 25% in the United States while the incidence remained unchanged. Much of the decline in mortality is attributed to earlier detection and better treatment regimens (Arveux *et al.* 2003). Similar declines in mortality over time have been reported in France between 1980-1999 (Arveux *et al.* 2003) and Ontario, Canada between 1971-1996 (Chairelli *et al.* 2000). The effect of these medical procedures on the incidence of opportunistic infections (including foodborne illness) is highlighted extensively in clinical and epidemiological research (Smith 1997) (Gilson & Buggy 1996).

3.2.2 Human behaviour

Human behaviour has wide-reaching implications *vis-à-vis* the epidemiology of foodborne disease. Behavioral factors shape prevailing attitudes toward food safety, affect the size and scope of outbreaks when they occur, and in many cases influence the success of intervention strategies implemented by health agencies.

Historical influences on today's attitudes...

Improvements in sanitation (sewage treatment and waste disposal), potable water quality/monitoring/treatment, food processing (e.g. pasteurization), health care, and regulatory measures relating to quarantine/exclusion, contact tracing, and food inspection have resulted in substantial progress in preventing foodborne illnesses (Tauxe 1997) (Nelson *et al.* 2001). Typhoid fever, cholera, and trichinosis, for example, were common place in the 18th and 19th centuries (Douglas & Haley 2002), but have been virtually eliminated as sources of morbidity and mortality in the U.S., Canada and the U.K. today (Bean *et al.* 1990) (Tauxe 1997) (Wallace *et al.* 2000) (National Intelligence Council 2000) (Herikstad *et al.* 2002) (Lee & Middleton 2003). An unfortunate consequence of this success, however, is the complacency that now exists surrounding issues related to foodborne illness in both the general public and the medical profession throughout the developed world. There are several examples of the effect this has: people can not accurately describe what food poisoning is; they do not understand the potential impact of emergent threats posed by antimicrobial resistance, re-emergence, and newly identified enteric pathogens; and they generally do not appreciate how serious foodborne illness can be unless they have been personally affected.

Societal influences on consumer knowledge and attitudes...

Societal changes that affect the way consumers purchase and prepare food are also believed to contribute to the increasing incidence of foodborne illness (Kaferstein & Abdussalam 1999). Changes in the family structure and where people eat have broad reaching implications with respect to the epidemiology of foodborne illness. According to researchers, changes in consumer's lifestyles have resulted in less time for food preparation. Several factors are believed to contribute to this growing trend, including increased numbers of single parent families, and a higher proportion of women working outside of the home. Today, 70% of women aged 25 to 44 years are in the workforce (Collins 1997). As a result, families have become increasingly reliant on convenience foods, eating out, and quick methods of food preparation. This is particularly true in North America where the market is driven by consumer demands for variety and immediate gratification. As an example, fast-food restaurants and salad bars were rare fifty years ago, but are now among the primary sources of food for people living "on-the-run" (Altekruse & Cohen 1997). This is substantiated by the U.S. National Restaurant Association, which claims the number of fast food restaurants in the U.S. doubled between 1972 and 1987; and served an estimated 45.8 million people on average each day during that period (Hedberg *et al.* 1991).

There are several fundamental consequences of these societal changes. For more than 25 years, the Food Marketing Institute (FMI) has surveyed consumers about their changing needs, attitudes and behaviors. Surveys by this and other organizations are testaments to changes in today's society, and the effects that these have on consumers. A survey designed to assess consumer food-safety awareness conducted at Cornell University, for example, documented a substantial lack of knowledge about safe food preparation practices (Collins 1997). Researchers in this study found that safe food practices were often followed for convenience, esthetics, or taste rather than for food safety considerations such as the prevention of illness. Similarly, the FMI found the public equated food safety with freshness, believed cooked food was generally safer than raw food (regardless of the manner in which it was stored), and did not understand the potential hazard posed by fresh produce (Food Marketing Institute 1996). These findings are consistent with related research. In a study of 1,000 adults commissioned by the American Meat Institute, for example, 98% of respondents in the U.S. knew that harmful bacteria could be present on raw meat and poultry, yet only two in five recognized that they may be present in fruits and vegetables (Collins 1997). Barriers to safe food handling behaviors go far beyond insufficient time or planning in today's hectic society. They also include historical (and cultural) practices, feelings of invulnerability, taste preferences, inadequate space, general laziness and ignorance. Food safety skills are developed by years of conditioning, observation, and reinforcement – sometimes from formal training, but most often from a parent or guardian. Unfortunately, convenience lifestyles have created fewer opportunities for adults to develop such skills, or to teach safe food handling practices to their children. This problem is compounded by the fact that more children are home preparing foods in the absence of their parents (Collins 1997), and schools have placed less emphasis on home economics and food safety education because of demands in other areas of the curriculum (Altekruse & Swerdlow 1996).

3.2.3 Urbanization

Through most of history, the humans have lived a rural lifestyle, one that is dependent on farming, hunting and animal husbandry. Since the 1800s, however, more people have moved from rural communities to urban centers in search of better jobs, amenities and improved access to health care (Douglas & Haley 2002). Today, a greater proportion of the population lives in large urban centers than at any other time in history (Anon. #89). In 2000, the U.N. estimated that 47% of the world's population lived in urban areas, with 411 cities having populations over one million. In contrast, a mere 14% of people lived in urban centers in 1900, and only 12 cities had one million or more inhabitants (Anon. #89). According to the United Nations this trend is expected to continue, particularly in developing regions of the world.

Globally, urbanization affects the epidemiology of gastrointestinal illness in several ways. History shows that rapid urbanization can quickly overwhelm a city's infrastructure, resulting in increased morbidity/mortality from poverty and disease. Conditions reported in London in the late 1800s (Douglas & Haley 2002) provides but one example of what still occurs in cities located in developing regions of the world that lack the necessary infrastructure to provide safe water, waste and sewer disposal, as well as sufficient food, work, and access to health care.

In developed countries, urbanization contributes to the growing alienation between farm-gate (food producers) and dinner plate (consumers). It also influences the marketing, production and distribution of food products (Altekruse & Cohen 1997), as well as the frequency with which gastrointestinal symptoms are reported to health agencies. According to a recent population-based estimate of the burden of diarrheal illness in the U.S., derived from the Foodborne Diseases Active Surveillance Network (FoodNet), self-reported diarrheal illness was more common amongst those living in urban areas (Herikstad *et al.* 2002). As such, a potential benefit of urbanization, where sufficient infrastructure exists to provide better access to healthcare, is an increased likelihood that cases will be detected by existing surveillance systems. This, in turn, improves the ability of health agencies to identify and respond to clusters of foodborne illness in a timely manner.

3.2.4 Foods

The types of foods eaten by consumers also impact the epidemiology of foodborne disease. Eating uncooked shellfish, raw fruits/vegetables, and minimally processed foods with long shelf lives, no preservatives, and low salt and sugar content has become increasingly common in the developed world (Kaferstein & Abdussalam 1999) (Zink 1997). Unfortunately, there are inherent risks with each of these products. Studies have shown that the consumption of raw shellfish carries a risk of exposure to naturally occurring microorganisms capable of inducing illness (*Vibrio spp.*, PSP, Ciguatera) (American Public Health Association 2000) (Altekruse & Cohen 1997), as well as enteric pathogens from human sewage (NLV, Rotavirus, HAV) (Le Guyader *et al.* 2000). Minimally processed foods lacking preservatives have been similarly implicated in serious outbreaks food poisoning in the U.S. and Canada. Outbreaks associated with the consumption of unpasteurized cheese and apple cider, for example, have demonstrated that E.coli O157:H7 can be transmitted through foods with a pH level less than 4.0 should contamination occur (Tauxe 1997). Interestingly enough, the Canadian federal government still permits the sale of unpasteurized (raw milk) cheeses without testing for E.coli O157:H7 or requiring producers to modify outdated manufacturing practices. This is largely because of political pressures by special interest groups. Finally, many consumers have increased their intake of raw, fresh fruit and vegetables as part of a healthier lifestyle (Collins 1997) (Zink 1997). Consumption of such products has the potential to expose the consumer to a variety of bacterial, viral, and protozoan pathogens introduced during growth, irrigation, harvesting, storage, distribution and/or processing (Sivapalasingam *et al.* 2004) (Robertson & Gjerde, 2000). The inadvertent contamination of raw fruits and vegetables is now believed to be among the fastest growing causes of foodborne illness in North America; a fact that is highlighted by several recent outbreaks in both the U.S. and Canada. (Sivapalasingam *et al.* 2004) (Honish 2001) (Herwaldt & Ackers 1997) (Tauxe 1997) (Rosenblum *et al.* 1990).

3.2.5 Travel & immigration

History is filled with examples of how travel and immigration can influence the epidemiology of infectious disease. Diseases from Europe that arrived with early settlers were responsible for the eradication of indigenous peoples in some areas. Today, immigration and international travel (including peace keeping missions abroad) continue to affect the epidemiology of enteric illness in several ways. Among the highest rates of infection for enteric illnesses are reported in displaced populations (Nelson *et al.* 2001) (National Intelligence Council 2000). Refugees of war and natural disasters are faced with many risk factors (poor sanitation, lack of potable water, lack of safe food) and little/no infrastructure to treat the ill or control the spread. Peacekeepers and foreign aid workers sent to help such groups are similarly exposed, may return home with enteric diseases, and infect others. Immigration and travel also contribute enteric illness rates. Studies suggest the numbers of international arrivals reported worldwide have increased significantly in recent years (Zuckerman 2002), thus allowing for the introduction of enteric illness from areas where it is endemic (the developing world) to areas of lower prevalence. Between 1993 and 1997, Africa and the Middle East boasted 44% and 46% increases respectively in international arrivals, and this trend is expected to continue (Zuckerman 2002). Today's technology permits people to travel vast distances in a matter of hours – and around the world in a matter of days. Thus, travelers exposed to enteric illnesses in developing regions may become symptomatic only after returning home. These observations present real challenges for public health professionals as diagnosis and treatment may be delayed, contact tracing may be difficult, and the likelihood of secondary exposure/cases is increased. This occurs, in part, because physicians may not suspect infection from certain diseases (such as cholera) that are uncommon in this part of the world. In the context of investigating suspected foodborne illness complaints, enteric infections with long incubation periods (Giardiasis, HAV) may be confused with infections with shorter incubation periods when clinical presentations are similar. This is particularly true for sporadic cases of gastroenteritis where clinical samples are usually unavailable.

3.2.6 Economic development & international commerce

Food retailers look increasingly to foreign markets to satisfy consumer demands for fresh produce, exotic fruits, and foreign delicacies year round. Many of these products originate from developing nations that do not have food safety standards comparable to those found in nations such as Canada (Altekruse & Cohen 1997) (Tauxe 1997). In areas where enteric illnesses are prevalent (and endemic) agricultural products are at particular risk of contamination if irrigated with raw sewage or handled by infected workers. Moreover, the handling and transportation of foods (domestic or international) can further increase the risk of inadvertent contamination prior to purchase by a consumer. Unfortunately, it is not feasible for government agencies to test every product coming across its border. As a result, contaminated products do make their way into retail stores. In 1992, for example, imported coconut milk from southeast Asia was found to be responsible for an outbreak of cholera in Maryland (Taylor *et al.* 1997). Similarly, in 1996 an outbreak of Cyclospora in the Eastern U.S. and Canada was attributed to imported Guatemalan raspberries (Herwaldt & Ackers 1997).

Global trade provides an avenue for contaminated food to travel vast distances, and be responsible for outbreaks of foodborne illness over large geographic areas. In similar fashion, changes in food manufacturing practices, the scale of production plants and livestock operations, have been demonstrated to have similar affects on the incidence and distribution of enteric disease (Koren & Bisesi 1995). Consolidated food supplies, designed to effectively distribute food to large populations, may by their success expose large numbers of people to foodborne pathogens if and when contamination occurs. The *salmonella* outbreak associated with Shwan's Ice Cream, offers one example of this (Hennessy *et al.* 1996). Other factors, such as the use of preservatives and Modified Atmosphere Packaging (MAP), can increase the shelf-life and range that certain products can be distributed (Canadian Restaurant and Food Services Association 2003).

3.2.7 Technology

Advances in technology influence the incidence, scope, and the identification of foodborne illness. New and/or improved diagnostic techniques allow staff at public health laboratories to identify agents responsible for foodborne illness that were previously unrecognized. Between 1983 and 1987, the etiologic agent in foodborne disease outbreaks was not determined in 62% of documented outbreaks (Bean *et al.* 1990). These numbers have significantly improved in the last decade, in part due to advances in laboratory techniques. The recent ability of some labs to positively identify NLV is but one example of this (Bresee *et al.* 2002).

Technology also plays a role in food safety. The consumer's desire for good health, and their aversion to chemical preservatives, has required food processors to seek new preservation technologies for their products. Some of these technologies include ohmic heating, high-pressure processing, pulsed electrical field processing, and UV light (Zink 1997). Other, somewhat older methods also continue to be used, including competitive microbial inhibition (such as the use of lactic acid bacteria in certain meat/dairy products), pasteurization, dehydration, food irradiation, and modified atmosphere packaging (MAP) (Hall 1997). Each of these methods has its strengths and weaknesses. Irradiation, for example, is arguably the most effective method to reduce or eliminate a wide variety of unwanted pathogens (Frenzen *et al.* 2001). It can be used on a variety of food products (meat, poultry, fruits/berries/vegetables, spices...) and is endorsed by many prestigious organizations, including the WHO, American Medical Association, and the FDA (Feltes 1999) (Henkel 1998). Problems with public perception, however, currently prohibit its widespread use (Frenzen *et al.* 2001) (Feltes 1999) (Henkel 1998). MAP, on the other hand, extends the shelf-life of ready-to-eat foods by preventing the growth of aerobic bacteria. Although the absence of oxygen prohibits the growth of most spoilage organisms and foodborne pathogens, these products are not without their inherent risks. First, should the packaging be compromised, all protection provided by the MAP is lost. Another risk posed by these foods is that anaerobic bacteria can survive, and grow in a CO_2 environment if introduced during processing or packaging. Some anaerobic bacteria, such as *Clostridium botulinum,* are capable of causing severe illness and death (American Public Health Association 2000). Viruses and chemicals are similarly unaffected by MAP, and while growth will not occur, each may still be present in sufficient quantities for the food to cause illness should contamination occur prior to packaging.

3.2.8 Environmental conditions

There are several examples of how environmental conditions can affects the incidence of foodborne disease. In a recent study, seasonal changes were found to affect the proportion of shellfish contaminated with enteric viruses able to persist in the environment; including hepatitis A virus (HAV), Norwalk-like virus (NLV), enterovirus (EV), rotavirus (RV), and astrovirus (AV) (Le Guyader *et al.* 2000). Using reverse transcription-PCR, researchers found that although there were some seasonal differences among the viruses, contamination was most frequently observed in the winter months in shellfish samples collected in areas routinely impacted by human sewage (Le Guyader *et al.* 2000). Other researchers have described seasonal variations in the incidence of viral gastroenteritis as well. NLV, for example, was described in the literature decades before the technology was developed to identify the agent responsible (Alder & Zickl 1969).

Like seasonal changes, events capable of influencing global weather patterns and temperatures are known to have profound affects on the incidence of enteric and foodborne illness. A number of studies, for example, have reported pronounced increases in the incidence of epidemic diarrheal diseases such as dysentery and cholera in parallel with the phenomenon known as El Niño (Kovats *et al.* 2003) (Health Canada 1998). Climate change is believed responsible for similar trends. Researchers have reported that the incidence of foodborne illness is significantly influenced by warmer temperatures (Health Canada 1998). This is plausible given warmer temperatures can improve the survival capabilities of pathogenic microorganisms, and promote bacterial growth in food and water (Kovats *et al.* 2003) (National Intelligence Council 2000). In one study, conducted by Bentham & Lanford in 1995, data collected for reported cases of food poisoning was analysed over a nine-year period. Regression analysis was used to establish if associations existed between the monthly incidence of food poisoning, and temperatures for the same and previous month. Researchers found they did. Projections for annual temperatures in the future were then applied to the statistical models developed, and it was estimated that 179,000 additional cases of food poisoning in England and Wales would occur each year as a direct result of climate change by 2050 (Bentham & Lanford 1995). It was further reported that average summer temperatures would increase 2.1°C by 2050, and that episodes of extreme temperatures would become more frequent in the U.K. (Bentham & Lanford 1995). This is consistent with other projections, including that of the U.N. Intergovernmental Panel on Climate Change which forecast that the average *global* temperature will increase 3.1°C over 1995 levels by the year 2090 (Kaferstein & Abdussalam 1999).

Climate change and El Niño are also believed to contribute to the frequency of extreme weather events (EWE): hurricanes, floods, drought and fire (Kovats *et al.* 2003). The significance of these events, in the context of the present example and regardless of underlying causes, is that they are often associated with an increase in enteric illness (Health Canada 1998) (Bentham & Lanford 1995). Several factors are responsible for this. Extreme weather events strain public health infrastructure and displace residents, both of which limit their access to health care (HC) and other services. They also negatively impact food and water safety since general sanitation during and following such events is compromised. Poor sanitation is known to increase the likelihood of food contamination as well as fecal-oral transmission of enteric illness. Extreme weather events may also result in the loss of power; a condition that may disrupt access to potable water and also allow harmful bacteria to grow in refrigerated foods to numbers capable of causing illness. Floods and storms, in particular, are capable of compromising sewage treatment facilities and contaminating potable water supplies. The outbreak of E.coli O157:H7 in Walkerton, for example, was preceded by periods of heavy rain which is believed responsible for the contamination of a shallow well with surface runoff containing fecal matter from a nearby farmer's field. Other EWE, including earthquakes, tsunami, and drought may similarly disrupt or restrict access to sufficient quantities of potable water for human consumption and/or fresh water needed for agriculture.

3.2.9 Public health infrastructure

It is widely recognized that a lack of public health infrastructure adversely affects population health. This is particularly apparent in developing regions, where access to health care may be restricted and basic health services are often not available (Hall 1997). Enteric diseases that would be considered easily treatable by Canadian standards are often associated with high morbidity and mortality rates in developing areas – particularly in children (Gurerrant *et al.* 2002). The resurgence of communicable disease following the collapse of the former Soviet Union (FSU) is another example of the effect that a lack of infrastructure can have. According to a report prepared by the U.S. National Intelligence Council in 2000, the deterioration in healthcare and other services in the FSU as a result of the economic decline experienced in the 1990's in that region was largely responsible for the sharp rise in the incidence of dysentery and cholera (National Intelligence Council 2000). Reports from the WHO and CDC, have also described widespread epidemics of diphtheria, TB and HIV (Vitek & Wharton 1998) (Pinner 1996).

While less dramatic, the effect of infrastructure on food safety and public health in the context of developed nations is also apparent. The breadth of health services, including: the frequency of health inspections, the ability to conduct research, the degree of enforcement, and acquiring the resources to provide health education programs directed at food safety concerns for both industry and the public are all largely determined by budgetary restraints and staffing levels.

3.2.10 Antimicrobial resistance

Antimicrobial resistant foodborne illnesses are becoming increasingly prevalent on the world stage. Many factors are believed responsible for this trend, including the misuse of antibiotics by the public (Nelson *et al.* 2001), and the use of antibiotics as growth promoters in the agriculture industry (Tauxe 1998) (Nelson *et al.* 2001). Several studies have cited temporal associations between the emergence of fluoroquinolone resistant strains of Campylobacter, and the use of this class of antibiotics by the veterinary industry in food production animals (Unicomb *et al.* 2003). The public health significance of the increasing incidence of foodborne illness caused by antibiotic resistant bacteria is that they are more difficult and expensive to treat, and are associated with higher morbidity and mortality rates.

3.3 Surveillance of foodborne illness & outbreaks

Surveillance enables health professionals to assess trends related to the prevalence of outbreaks caused by specific etiologic agents or vehicles of transmission. Knowledge of such trends is useful in resource allocation – be it personnel, funds, or research into the development of new intervention strategies. At a deeper level, however, surveillance also provides insight into disease causation and thus provides an opportunity for illness prevention and control. It is the latter which is of greatest interest to public health, and as such is the focus of this study.

3.3.1 FoodNet

Surveillance of foodborne illness occurs at the local, national, and international levels. FoodNet is the foodborne diseases component of the CDC's Emerging Infections Program (Angulo *et al.* 1998). It provides a network for responding to emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying their potential source. Foodnet relies on the active surveillance of laboratories, physicians and the public (Nelson *et al.* 2001) (Yang *et al.* 1998). Data collected by this surveillance system is used in many ways. The CDC uses the data to identify emerging foodborne pathogens and to monitor the incidence of foodborne illness. The Food Safety and Inspection Service (FSIS) uses it to evaluate the effectiveness of new food-safety programs and regulations designed to reduce foodborne pathogens in meat and poultry. Finally, the FDA uses the data to evaluate its efforts to reduce foodborne pathogens in seafood, dairy products, fruits and vegetables.

3.3.2 PulseNet

PulseNet is the National Molecular Subtyping Network for Foodborne Disease Surveillance at the CDC (Anon. #84). In the U.S., the network is comprised of 50 state and five local public health laboratories, seven FDA laboratories, and one USDA FSIS lab. Canada is represented by six provincial laboratories, and the national lab in Winnipeg. Together, this network of public health laboratories performs DNA "fingerprinting" on foodborne bacteria using pulsed-field gel electrophoresis (PFGE) (Nelson *et al.* 2001). The network permits rapid dissemination of these fingerprint patterns, for comparison purposes, through an electronic database. In short, PulseNet is a passive surveillance tool that provides critical data for the early recognition of related outbreak events that otherwise may appear sporadic and unrelated.

3.3.3 MMWR

Several systems have developed out of surveillance tools to rapidly disseminate the information collected, analyzed, and interpreted to those who need to know, so that appropriate action can be taken to properly identify and mitigate risks to the public. One of the first means of communicating and distributing data on outbreak investigations and epidemics by the CDC was the use of widely available publications such as the MMWR (Nelson *et al.* 2001). Today, secure web-based systems and electronic formats allow information to be shared broadly, accurately, and in real-time. Two of the U.S. based systems (FoodNet and PulseNet) have already been discussed; a third, based out of Canada, is discussed below.

3.3.4 CIOSC. – Health Canada

The Canadian Integrated Outbreak Surveillance Centre (CIOSC), developed as part of the Canadian Network for Public Health Intelligence (CNPHI) by Health Canada, is a secure web-based application that provides a rapid reporting system for enteric, foodborne, respiratory and waterborne disease outbreaks across Canada. The CIOSC website is intended to be used by public health professionals for "posting" epidemiological information on suspected outbreaks of enteric and respiratory illness currently under investigation that may be of significance to regions outside of their own. The system therefore allows epidemiologists to see what is going on in other jurisdictions, to spot occurrences which may be similar to something happening locally, and to coordinate both investigative efforts and mitigation measures with those similarly affected.

3.3.5 Local surveillance initiatives

Active surveillance requires public health agencies to actively solicit information from outside sources. As such, it is the most accurate and resource demanding form of surveillance. Local examples of active surveillance include the use of absentee rates at sentinel schools and sales of diarrheal medication at sentinel pharmacies to detect outbreaks, and monitor their spread in a community.

In the traditional sense, surveillance typically refers to the tracking of disease. It is suggested, however, that the inspection of food establishments may similarly be described as the active surveillance of risk factors believed to be responsible for adverse health outcomes – they are purposeful, the collection of data is continuous, and collectively they are population based. The purpose of a restaurant inspection is to identify conditions believed to contribute to the incidence of foodborne disease, and to take reasonable steps to mitigate those risks. Information gathered during inspections is measured or observed directly by the EHO, or is solicited from employees present. All violations and corrective actions are recorded by EHOs on inspection reports and a regional electronic database. To date, review of such records collectively has been limited to the assessment of workload indicators by management for performance evaluations of field personnel. The present study utilizes inspection records for a considerably wider purpose: to determine if particular violations and other premises characteristics (either alone or in combination) are significant predictors of biologically-plausible and reported cases of foodborne illness in commercial eateries located in the Capital Health region.

3.4 Related studies in public health & environmental health research

Some of the first examples of rank and prevalence data for specific risk factors that contribute to foodborne illness in commercial food establishments are evaluations of outbreak reports written in the 1970's and 1980's (Bryan 2002b). Similar systematic reviews continue to be conducted by health agencies to this day. Regardless of location or review period, the ranking of these risk factors remains remarkably similar: *improper cooling procedures*, *food handler contamination of ready-to-eat foods*, *cross-contamination between raw foods of animal origin and cooked products*, and *insufficient cooking temperatures* top the list (Bryan 2002a) (Bryan 1999) (Yang *et al.* 1998). For some pathogens, contamination at the source is also frequently identified (Le Guyader *et al.* 2000) (Taylor *et al.* 1997) (Anon. 1991). Outbreaks of gastroenteritis associated with the consumption of raw shellfish, imported fruit, and unpasteurized cheese are prime examples of this.

Increased inspection frequency and improved food handler education have each been demonstrated to reduce the presence of violations in commercial eateries. Allwood *et al.* (1999) reported that inspection scores decreased significantly among establishments that were inspected four times one year and either three or two times in the following year. Moreover, the mean number of food temperature violations increased significantly in restaurants inspected less frequently (Allwood et al. 1999). Similar findings have been reported by other researchers (Campbell *et al.* 1998) (Mathias *et al.* 1995) (Riben *et al.* 1994) (Kaplan 1978) (Badder *et al.* 1978), although it would appear that the cost / benefit of more frequent inspections diminishes after six inspections per year (Corber *et al.* 1984).

The presence of food handlers who are properly trained in aspects of food safety has also been demonstrated to improve overall inspection scores, and to reduce the frequency with which certain violations are cited (Campbell *et al.* 1998) (Cotterchio *et al.* 1998) (Mathias *et al.* 1995) (Riben *et al.* 1994). In response to these findings, a number of programs have been developed to educate food handlers about food-related and personal behaviors that affect food safety. In the U.S., the National Restaurant Association has a food-safety program intended to educate foodservice workers about Food Code requirements, safe food handling and hygiene called *Serve Safe*. Similar programs, including Serve Safe, are required of food handlers working in the industry here in Canada. In Alberta, one person in a supervisory role at each restaurant must complete a course in Food Sanitation and Hygiene approved by the Minister of Health.

3.5 Critical appraisal of related studies to-date

As indicated in the introductory section, few studies have attempted to determine the extent to which there is an association between information collected during restaurant inspections and reported cases of food poisoning that implicate these facilities. Six related to this topic – the only papers identified by the specified literature search – are discussed in the following section.

The first of these studies, conducted by (Penman & Webb 1996), is the least rigorous of those reviewed. Researchers conducted a case-control study following two outbreaks of food poisoning associated with food establishments located in Alabama and Mississippi. They observed that both facilities had passed recent inspections, and that inspection scores were not different from nearby eateries where no outbreak occurred. Similar findings were described years later by Scottish researchers (Mullen *et al.* 2002) conducting a similar study. In both instances, researchers concluded that the inspections had "failed". Upon review of their findings, however, it is clear that the inspections were not necessarily at fault. In one instance, for example, researchers described an outbreak of gastroenteritis in an adjoining nursing home that is consistent with the clinical presentation of Norovirus in the week prior to the suspected foodborne illness outbreak. Although none of the restaurant staff was reported ill, the possibility that the outbreak occurred in patrons as a result of contact with "contaminated" surfaces in the common areas is a real possibility. Such capabilities are well-documented today (Anon. 2003b) (Kuusi *et al.* 2002) (Love *et al.* 2002). Further, if staff preparing the food were asymptomatic, this could not have been "corrected" by the inspector or management on-site, beyond that of enforcing universal precautions such as hand washing. In addition, both studies lack sufficient breadth and size to make meaningful generalizations about inspection services.

A somewhat better attempt to assess the usefulness of restaurant inspections in predicting foodborne outbreaks was conducted by (Cruz *et al.* 2001). For the study, inspection reports of restaurants implicated in foodborne outbreak investigations (N=51) were compared with randomly-selected controls that did not have outbreaks associated with them (N=76). These controls were matched by year and month at a ratio of two controls per case. Analysis consisted of matched odds ratios and 95% confidence intervals for risk factors obtained from inspection reports. Variables associated with outbreaks at the univariate level were then entered into conditional logistic regression models to control for confounding. Results revealed cases and controls did not differ by overall inspection score or mean number of violations. This said, case restaurants were 3.3 times more likely to have insect/vermin problems [95%CI: 1.1, 13.1] and have larger seating capacities (>50). The limitations of this study are similar to those described for Irwin *et al.*(1989) below. They include a *limited sample size*, and *the use of a single inspection* to assess exposure. Further, the method used to select eligible cases brings into question the representativeness of the case and control groups – even for the Miami-Dade area where the study was conducted. Cases were selected on the basis of *confirmed etiology* and the *availability of the last inspection report*; 51/187 (a mere 27%) met these criteria. Similarly, Cruz *et al.*(2001) were forced to exclude 26 of 102 controls because of a lack of information. The loss of such large numbers of cases and controls jeopardizes the validity of their findings.

The Los Angeles County Department of Health Services also looked at whether certain characteristics of restaurants make them more likely to be associated with outbreaks of foodborne illness (Buchholz *et al.* 2002). Researchers conducted a retrospective cohort study of 10,267 restaurants inspected between July 1, 1997 and November 15, 1997. Case restaurants were defined as those that subsequently had a SFBI reported between July 1997 and June 1998 (N=158). Non-case facilities were defined as those that did not (N=10,109). Univariate and multivariate techniques were utilized to assess potential associations. Researches identified several factors, including *restaurant size*, *previous SFBIs*, *lower overall inspection score*, *improper food storage*, *the reuse of food*, *improper hand washing*, and *a lack of thermometers* as being significant predictors of these commercial eateries becoming a "case". Limitations of the study stem from the use of dichotomous variables to represent the presence or absence of violations, and the assessment of a single inspection to represent "exposure" (the details of which are discussed in the critique of Irwin *et al.* (1989)).

The largest and most recent study assessing whether past restaurant inspection scores are positively associated with outbreaks of foodborne illness was conducted by the Tennessee Department of Health in conjunction with the Vanderbilt University School of Medicine (Jones *et al.*, 2004). This study used state-wide restaurant inspection data from over 29,000 food establishments in Tennessee collected between January 1993 and April 2000. Information gathered from their electronic records database included: the facility identification number, overall inspection score, specific violations cited, county, date of inspection, inspector, and the duration of the inspection. A total of 167,574 inspections, conducted by 248 different inspectors over the study period, were reviewed. Results focused on the mean and distribution of inspection scores, as well as the ranking of violation codes according to the frequencies they were cited within the study period. Researchers reported that ***none*** of the 12 most commonly cited violations were "critical", and noted that a similar rank order amongst the violations was observed in food establishments with and without a foodborne outbreak. It was also reported that the mean score of the last inspection conducted before the outbreak was not significantly different from the mean score previous to it, nor from the mean inspection score of all restaurant inspections conducted over the entire study period. Routine inspection scores were found to vary considerably over time, by region, and by the person performing the inspection. Researchers concluded restaurant inspection scores alone did not predict the likelihood of a foodborne outbreak occurring in a food establishment. Several limitations were identified and discussed by the researchers that conducted it. First, the number of reported outbreaks within the study period was admittedly small (n=49). The intensity of surveillance can markedly influence the number of outbreaks identified. Second, researchers questioned the value of inspection "scores" to identify problem eateries, pointing to the fact that a substantial number of restaurants with scores above 90% had critical violations, and below 80% had no critical violations. Other drawbacks of the study, not discussed, included:

- Only the results of routine inspections were used, meaning demand inspections conducted in response to consumer complaints or follow-up inspections conducted in response to violations being cited were excluded. Further, facilities considered by the researchers as "difficult to classify" were similarly omitted. Each of these factors challenge how representative the study is.

- The data analysis was not sufficiently rigorous to make meaningful conclusions about statistical associations between independent variables and the outcome of interest; only average scores, distribution ranges, and rank-order data were presented.

A 1989 study conducted by researchers in Seattle-King County has been the topic of considerable debate – drawing both praise (Riben *et al.* 1994b) and criticism (Hatfield 1989) (Hatfield 1990) in peer-reviewed journals. Similar to Cruz *et al.* (2001), Irwin *et al.* (1989) utilized a matched case-control design to analyze the association between the results of routine inspections and foodborne outbreaks. This study was limited to permitted food establishments in the Seattle-King County area. Cases were identified from outbreaks occurring between January 1986 and March 1987. Twenty-eight of 36 outbreaks identified during that period were eligible for inclusion in the study (N=28). Two control restaurants with no reported outbreaks were matched by health district and inspection date (±30 days; N=56). Details of the restaurant inspection were obtained from computerized records. Forty-two different violation codes were independently assessed. Data on each outbreak and additional risk factors were collected from investigation files and interviews with restaurant operators (respectively) after obtaining informed consent. The interval between the last inspection and the outbreak in case restaurants was 3.7 months on average, but a wide range was reported (2.0 to 14.1 months). The article is silent on potential changes to program focus or other events that could affect inspection results. It does not appear that this was controlled for. Each violation cited by inspectors on the visit preceding the illness event was recorded as a dichotomous independent variable (i.e. either present or absent). Odds ratios and 95% confidence intervals for matched case-control analysis were calculated using SAS software (Irwin *et al.* 1989). When odds ratios in the matched analysis were indeterminate, unmatched odds ratios were calculated. Irwin concluded that restaurants with a "score" of less than 86 were five times more likely to be involved in an outbreak. Those receiving permit suspensions and unsatisfactory ratings were three times more likely. *Improper temperature control of perishable food*, *improper equipment maintenance*, and *any critical violation* were significant predictors of food poisoning for eateries included in the study. There are several factors to consider when reviewing these, and other, findings.

1. "Scores" given to food establishments are traditionally based on demerit points. These points, which are typically subtracted from a total score of 100, are assigned arbitrary values for which there is little scientific validity. Consequently, their use is frowned upon by many health professionals (Dundes & Rajapaksa 2001) (Zaki *et al.* 1977).

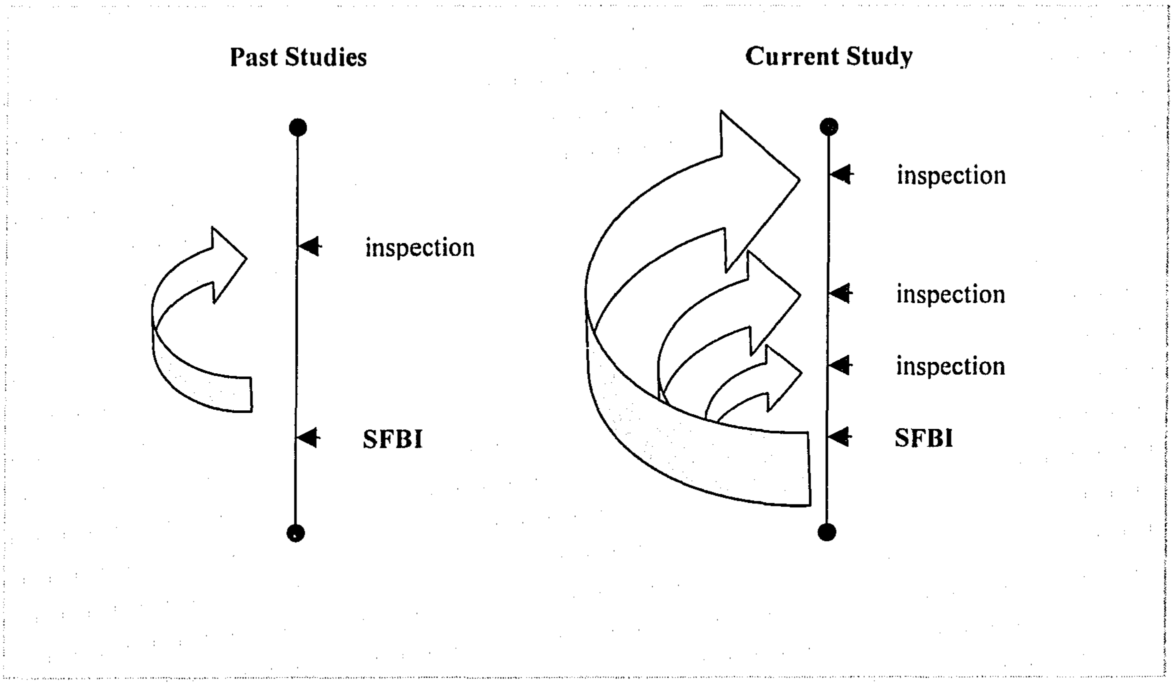
Further, the ability of restaurant owners, the public, and court officials to correctly interpret or understand these scores has been poor (Dundes & Rajapaksa 2001).

2. Sample sizes are extremely small, and the 95% CI are large. This increases the likelihood of spurious associations between independent variables and disease outcome.

3. There are more opportunities for "critical violations" to be identified at larger restaurants where there is more diversity and food handling. The size of the food establishment was not controlled for in this study design.

Moreover, restaurants with more than 150 seats, having corporate owners, and inspections lasting longer than 36 minutes were also found to be predictors of adverse outcomes. Similar associations were reported by (Buchholz *et al.* 2002) and (Cruz *et al.* 2001). There are several explanations to consider when reviewing these findings as well. First, all three factors are highly correlated; large restaurants are more likely to be corporate stores, and large facilities take longer to inspect than their smaller counterparts regardless of presenting problems. Another factor to consider is the variation between inspectors themselves. An EHO visiting a food establishment for the first time, or an inspector new to the field, will often take longer to conduct an inspection than someone familiar with the position and the facility. A final limitation inherent in the study design is the manner in which inspection data were collected and compared. As with every other study reviewed, researchers relied on the assessment of only a single inspection to assess exposure (Figure 3.5.1). These factors are not considered in the analysis or write-up, which casts doubt on the validity of these findings.

Figure 3.5.1 Comparative assessment of inspection histories.



A single inspection is a poor indicator of compliance because it represents only a single "snapshot" in time. The timing of the inspection (day, month, and hour) influences what an EHO may observe during an inspection. For example, activities, personnel, and general sanitation will change in any given food establishment over the course of the day. Because of this, an inspection conducted during a period of food preparation (i.e. shortly before lunch or supper-hour) is likely to result in very different findings than an inspection conducted when the establishment first opens, after a delivery, or during a lull mid-afternoon. Consequently, a better assessment of food establishments can be made by observing trends over time (several inspections that are conducted at different times) and measuring the relative frequency with which certain violations are cited (Figure 3.5.2). Most of the studies conducted to-date have failed to do this.

Figure 3.5.2 The assessment of restaurant activities at various points in time.

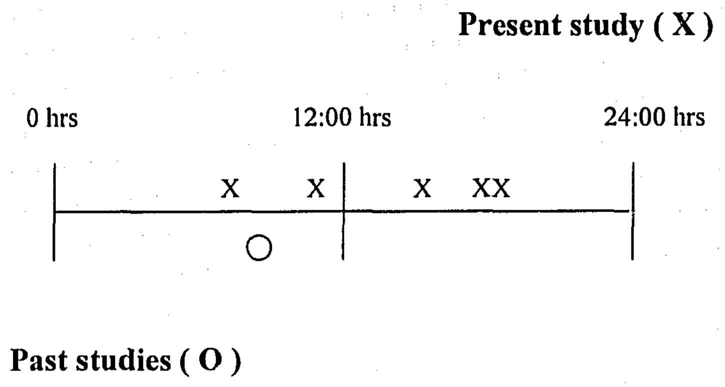


Figure 3.5.2 The assessment of restaurant activities at various points in time.

The review of more than one inspection offers a better assessment of conditions in local eateries because they are conducted at different times. As discussed, there can be considerable variation throughout the day or week as a result of how busy the restaurant is, who is on duty, when deliveries to the eatery are made, and whether a supervisor or manager is present. The bar in the figure above represents a 24-hour timeline. Data points marked by a "X" represent inspections conducted at various times throughout the day – made possible by the assessment of trends over time. The data point marked by a "O" is representative of past studies.

Chapter 4: Methods

4.1 Study design

Several methodological approaches were considered in undertaking this study. Although researchers conducting similar studies in the past have utilized cross-sectional techniques, there are serious concerns surrounding the use of a single inspection to assess the association between proposed risk factors (exposures) and the outcome of interest (foodborne illness). Further, dichotomous variables, used to represent the presence/absence of violations at food establishments, cannot be analyzed by as informative or powerful statistical techniques as what continuous or categorical data can.

Using a cohort design was also considered. Cohort studies establish a clear temporal association between exposure and disease, and allow for more precise estimates of risk than cross-sectional techniques. Unfortunately, cohort studies do not lend themselves to studying the effects of multiple exposures occurring over different periods of time as required by the present study. They are also subject to problems that reduce their effective sample size such as loss to follow-up. Moreover, cohort studies consume considerably more time and resources to complete, and given the topic, it was felt that serious ethical considerations would almost certainly prohibit such a study from taking place.

Nested case-control studies have been widely used in recent years as an alternative to traditional matched case-control designs (Szklo & Nieto, 2000). Suitable controls are selected from the available cohort at the time each case is identified. A problem with this design, in the context of the current study, is that every case and control would not be assessed for the same length of time (they are "matched" for this at the analysis stage). Further, there is a risk of losing potential cases due to insufficient data, as an adequate inspection history would not necessarily be available for those facilities having a BP-SFBI early in the study.

Given the potential problems with the aforementioned techniques, a restricted case-control design was selected for the present study (see section 4.3). All *Class II* and *Class III* food establishments inspected by the Food Protection Division of Environmental Health Services (Capital Health), in operation between January 1, 2002 and December 31, 2003 were eligible for inclusion in the study. This included the majority of eateries preparing food in the greater Edmonton area, including St. Albert and Sherwood Park (see Figure 1.4.2). Owing to inherent differences between these facility types, control selection and analysis were carried out separately for these respective groups.

4.2 Ethical considerations and the protection of personal privacy

Ethics approval was sought from the University of Alberta Health Research Ethics Board for the collection and analysis of data relevant to this study. A proposal was submitted in the early spring, and approval was obtained in March, 2004. Permission from the Environmental Health Division of Capital Health to use the TMS database for the retrieval of necessary inspection data were obtained prior to this time. Corporate approval for the use of Capital Health resources was secured in May, 2004.

4.3 Control of confounding

Confounding is a function of the complex interrelationships that exist between exposure and disease. It can result in an overestimate or underestimate of the true association between the exposure and outcome of interest. As such, controlling for known confounders is vital to any epidemiological study. There are three methods that can be used to help control confounding in the design of epidemiological studies: randomization, restriction, and matching (Hennekens & Buring 1987 p.293). Further steps to help control the effects of confounding between independent variables of interest are available at the analysis stage. The following section discusses each in the context of the present work.

4.3.1 Restriction

Confounding cannot occur if the potential confounders do not vary across exposure or disease categories. One way to achieve this is to restrict the admissibility criteria for subjects entering the study (Hennekens & Buring 1987 p.293). Another is to separate data such that independent categories are analyzed. In the context of the present example, both techniques are used. First, only *Class II* and *III* food establishments inspected by the food protection program were eligible for inclusion in the study. *Class I, non-permitted,* and *temporary food establishments* were excluded because of inherent differences within these groups, namely:

(a) they account for a small proportion of the SFBIs received each year;
(b) they lack sufficient inspection history to accurately assess trends over time; and/or

(c) they are often limited to the sale of pre-packaged, non-perishable foods – making them very different from full-service restaurants where a full range of food handling activities generally occur.

It was imperative that food establishments included in the study were equally involved in relevant food preparation activities, and that sufficient records of such activities existed. Food handling and temperature control violations, for example, are among the most critical a food establishment can receive. Studies have shown that these factors are frequently credited with being the cause of foodborne outbreaks in commercial eateries (Allwood *et al.* 1999) (Hedberg *et al.* 1991) (Irwin *et al.* 1989) (Luby *et al.* 1993). Most Class I food establishments would never receive either of these violations because such activities do not occur. It would therefore be inappropriate to compare these facilities with full-service food establishments and expect meaningful results.

4.3.2 Separation of data for analysis purposes

While the potential confounder must be predictive of the occurrence of disease, it need not be causal. In the present study, *facility class* had the potential to act as a confounder; particularly as it relates to the number of inspections conducted, and the types of violations that a food establishment was likely to receive. Owing to these inherent differences, it was decided to analyze Class II and III food establishments independently using logistic regression techniques.

4.3.3 Analysis

Confounding and interaction between independent variables can make results difficult to interpret. In the present study, confounding between independent variables being analyzed was controlled for using multivariate logistic regression (refer to section 4.7.2). Two multivariate models were developed; one for each facility class. Interactions between variables in each main effects model were similarly tested, and included in the final model if found to be significant.

4.4 Selection of cases and controls

All food establishments for whom a suspected foodborne illness (SFBI) complaint was registered between January 1, 2003 and December 31, 2003 were selected as *potential cases* (see Fig.4.4.1). SFBI reports for each facility were transcribed and checked by research assistants onto FORM A in order to remove personal identifiers (see ***Appendix III***). At no time did the same individual transcribe and verify the same report. Next, two public health professionals independently scrutinized each SFBI: the principal researcher and another experienced EHO. Each SFBI was then discussed to determine its validity according to set parameters listed in Table 4.4.1(a). *I.A.M.F.E.S. Procedures to Investigate Foodborne Illness* and the *Control of Communicable Diseases Manual (17th Edition)* published by the APHA were both used to assist assessors in making this decision.

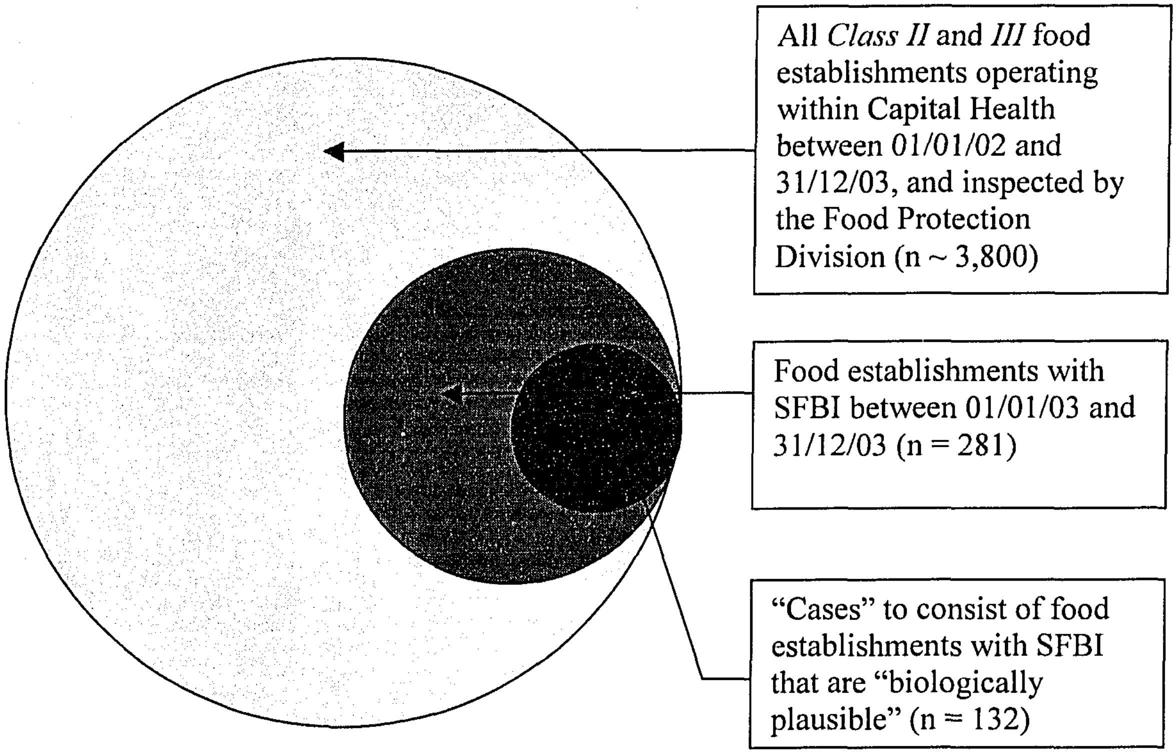
(a) Information presented in Table 4.4.1 was gleaned by the principle researchers from a variety of health resources, including relevant journals articles, online websites, the aforementioned CDC Manual and IAMFES guidelines, and Microbiology textbooks.

Table 4.4.1 Suspected food poisoning categories

Suspected Foodborne Illness Group	Description	Examples	Inclusion criteria met
Category A : Categorized by acute onset (less than eight hours from ingestion of implicated meal)	The clinical presentation is consistent with illness caused by toxins elaborated by bacterial growth or bioaccumulation in food before consumption (American Public Health Association 2000)	*Bacillus cereus* *Staphylococcus aureus* *Scombroid* (toxin) *P.S.P.* *Ciguatera* (toxin)	Yes (BP-SFBI)
Category B: Categorized by acute onset (immediate to less than six hours from ingestion of implicated meal)	The clinical presentation is consistent with the presence of metals or chemicals at levels capable of inducing acute illness. Predominant symptom = vomiting.	Copper Cadmium Antimony Tin Iron Zinc Cleaners	Yes (BP-SFBI)
Category C Categorized by onset of gastroenteritis following consumption of the implicated meal. Incubation times vary considerably, but are typically greater than six hours.	The clinical presentation is consistent with infection of the lower intestinal tract. Predominant symptoms are cramping and diarrhea. Specific etiologies described in (American Public Health Association 2000)	Nontyphoidal *Salmonella spp.* *Campylobacter jejuni / coli* *Bacillus cereus* *Clostridium perfringens* *Shigella spp.* *Vibrio parahaemolyticus* *Norovirus (NLV)* *Rotavirus* *E.coli**	Yes (BP-SFBI)
Category D (not biologically plausible)	The clinical presentation is inconsistent with that of foodborne illness **or** The incubation period does not fit with the symptoms described.	Respiratory illnesses Zoonotic diseases Onset of diarrhea less than six hours from implicated meal.	Not included

It is often difficult to positively identify the agent responsible for food poisoning (Collins 1997). This occurs for a variety of reasons. No samples may be available for testing, laboratory involvement may be delayed, the technology may not be available to identify the pathogen responsible, or the lab technician may be unable to isolate the organism from the food and clinical samples provided. Further, some agents are not sought through routine testing, including: Norovirus, HAV, Scombroid, P.S.P., Ciguatera, *Vibrio parahaemolyticus*, chemicals, and heavy metals. This leaves inspectors dependent upon epidemiological evidence gathered from interviews and on-site inspections to determine the majority of illness-related events in the field.

Facilities determined to have a biologically plausible suspected foodborne illness (BP-SFBI) by <u>*both reviewers*</u> were considered to be eligible cases for the purposes of the study. In instances where there was disagreement between the two reviewers in the application of the selection criteria, an opinion of a third healthcare professional (an Environmental Health Epidemiologist) was obtained. When this was required, a facility's inclusion in the study was based on the decision of this third individual. The epidemiologist considered the SFBI valid if at least one individual within the dining party had an onset of symptoms consistent with foodborne illness, and the illness was plausible in terms of the incubation time and the foods eaten. Food establishments with implausible SFBIs were excluded from further participation in the study.



All *Class II* and *III* food establishments operating within Capital Health between 01/01/02 and 31/12/03, and inspected by the Food Protection Division (n ~ 3,800)

Food establishments with SFBI between 01/01/03 and 31/12/03 (n = 281)

"Cases" to consist of food establishments with SFBI that are "biologically plausible" (n = 132)

Figure 4.4.1. Selection of cases and controls.

Cases were tracked by *service request number* (SR#) – a unique identification number assigned to each SFBI at the time it is received by the health department. A list of eligible cases was provided to an Information Systems (Data) Specialist with Environmental Health. These were screened by computer to ensure that all eligibility criteria were met, namely:

- the facility was either a Class II or III food establishment (excluding temporary and seasonal)
- the facility was in operation for a minimum of one year prior to the SFBI;
- the facility was NOT included more than once (the earliest SFBI being the default); and
- the facility did not close within the eligibility period defined for controls (before January 1, 2004).

Prior to the selection of controls, cases were separated by facility class. This was done for two reasons. First, it was felt that inherent differences (heterogeneity) between the respective facility classes could introduce confounding. Differences include the frequency with which inspections are done, and the complexity of food handling activities that routinely occur. It was also felt that by conducting separate analyses, differences in risk factors for food poisoning for the respective classes may be revealed. Second, stratifying by facility class negated the need for conditional logistic regression techniques that otherwise would have been required to analyze the data if matching had been used.

Controls were identified and selected by computer to reduce bias. To be eligible as a control, a food establishment:

- needed to be either Class II or III (excluding temporary and seasonal);
- could NOT have received a SFBI at any time during 2002 or 2003; and
- had to be in operation for that two-year period.

Any food establishment meeting these criteria was suitable as a potential control for any case of equal class. Three controls of the same facility class were randomly selected for each case. Selections were manually verified for accuracy prior to further data being extracted from inspection records.

4.5 Data collection

Several independent variables were extracted by computer from inspection records. A principal measure of interest was the relative frequency with which specific violations were cited in the case and control groups. Inspection history in each case and set of controls was assessed for the same *critical period,* defined as the 12-month period **preceding** the date of the BP-SFBI (see

Figure 4.5.1). While the same operational period was used to assess cases and controls, inspection dates within this time period were NOT matched. Controls were selected such that any 12-month period between January 1, 2002 and December 31, 2003 could be assessed (Sec. 4.3.1). All cases and controls were assessed for the same length of time. Many case-control studies recruit controls in this manner, and time-matched analyses are almost never performed. Consequently, logistic regression techniques were used.

Figure 4.5.1 Defining the "critical" (12-month observation) period for cases and controls.

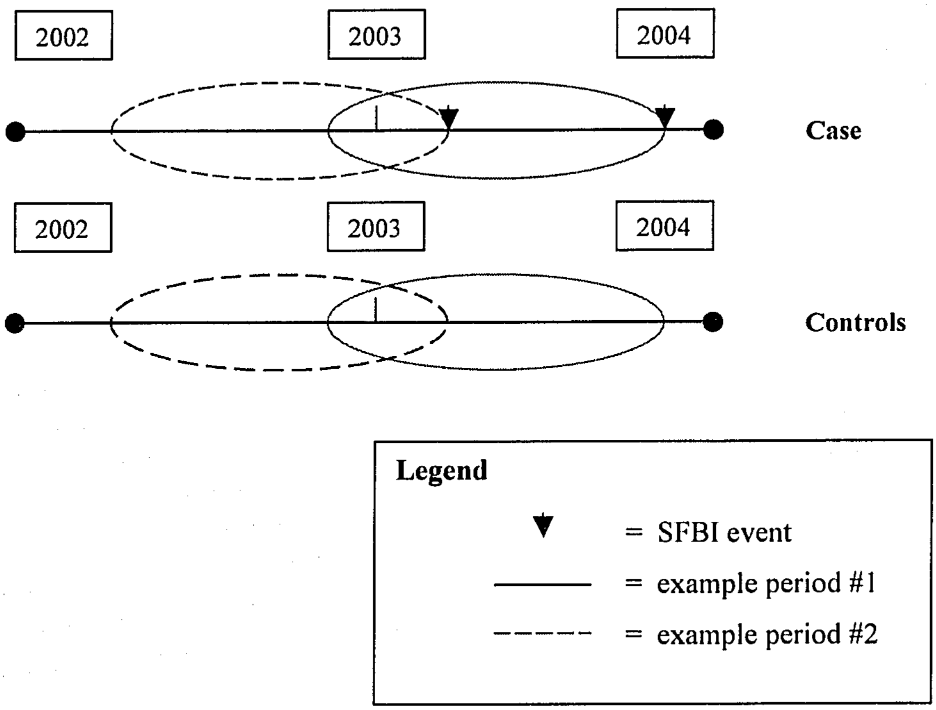


Figure 4.5.1 This diagram demonstrates how the critical period was selected for each case and set of controls. Food poisoning events were recruited between January 1, 2003 and December 31, 2003. The date of the food poisoning was used to identify the start of the critical period. Violation history for each case and set of controls was assessed for the same 12-month period preceding this date. Two time periods (each representing a case and set of controls) are highlighted by the ovals in the figure above. All inspections within a defined critical period were used for analysis purposes, however their frequency and interval within this timeframe remained random.

Violation codes cited by district Environmental Health Officers (EHOs) in this one-year period were extracted from the TMS database by computer. A violation code counted toward the total number if: (a) it was *cited* within the specified timeframe for the study; (b) it was *not removed* on a subsequent re-inspection conducted within the allocated 12-month period; or (c) it was imported into the critical period and was not removed on the first inspection conducted within that period (see Table 4.5.1). An "imported violation" was defined as any violation that was cited prior to the critical period, but was corrected during the critical period such that it contributed towards the total number of violations cited for a particular food establishment.

Table 4.5.1 – Calculating the number of violations cited.

Facility A			
Routine Inspection	Conducted 04/04/2003	*Unsanitary food-contact surfaces found*	1
Re-Inspection	Conducted 11/04/2003	- violation NOT corrected	1
Re-Inspection	Conducted 14/04/2003	- violation NOT corrected	1
Re-Inspection	Conducted 15/04/2003	Violation CORRECTED	0
Demand	Conducted 23/10/2003	*Unsanitary food-contact surfaces found*	1
Re-Inspection	Conducted 26/10/2003	Violation CORRECTED	0
		TOTAL	4
Facility B			
Routine Inspection	Conducted 04/04/2003	*Unsanitary food-contact surfaces found*	1
Re-Inspection	Conducted 11/04/2003	Violation CORRECTED	0
		TOTAL	1
Facility C			
Re-Inspection	Conducted 04/04/2003	Violation NOT corrected	1
Re-Inspection	Conducted 11/04/2003	Violation CORRECTED	0
Routine Inspection	Conducted 23/10/2003	Violation not cited.	0
		TOTAL	1

Table 4.5.1 illustrates how the total number of violations of a particular type is calculated for each food establishment in the study. **Facility A** and **Facility B** have the same violation cited on a routine inspection (*unsanitary food-contact surfaces*). **Facility A** subsequently fails to correct the noted violation on two subsequent re-inspections, so the violation is counted again (each time) toward the total. **Facility A** also receives the same violation again later in the year. The violation cited at **Facility B** is counted only once because it is corrected before the next inspection. **Facility C** depicts how imported violations contribute to the total number cited (i.e. any time a previously cited violation is not removed on the first inspection conducted within the critical period).

The number of inspections conducted within the critical period was recorded as a continuous variable. The presence of *consumer complaints*, and *the use of enforcement* by the health department within the study period were recorded as dichotomous variables, with 1=YES and 0=NO. Enforcement action was defined as any order, charges, or closure of the food establishment during the critical period. Both raw inspection data and service request archives were used to determine the presence of consumer complaints within the critical period. A registered complaint at either of these locations was considered to be a positive result. Food establishments belonging to a national food chain with a recognized food safety program (FSP) were defined *a priori* (see ***Appendix IV***). To maintain anonymity and reduce bias, these facilities were identified and verified by a research assistant who was independent and blinded to the purpose of the study. Values were recorded as a dichotomous variable with *not* having a recognized FSP being the reference category. These records were kept separate from the rest of the premises' information until after potential cases were evaluated for plausibility because of the potential for FSP status to influence this decision and introduce bias.

Prior to data entry or analysis, information returned to the principal researcher was checked for completeness and accuracy. To ensure that data for all cases were present, printouts provided by the data specialist were first compared to the original list prepared by the principal researcher to ensure that service request numbers (SR#) matched. Control printouts were reviewed to ensure three facility identification numbers of equal class (II or III) appeared under each SR#. To ensure that the critical period was accurate for each case and set of controls, dates of inspections listed on the raw data printouts were reviewed to make sure they fell within the *critical period* (identified as the 12-month period preceding the BP-SFBI for the case). Following this, inspection data were reviewed to ensure all on-site inspection types within the critical period had been correctly identified by the search algorithm. Raw data were then transcribed onto a Microsoft Excel® spreadsheet by the principal researcher, and were verified manually by another individual.

Health code violations were analyzed in several ways. Past studies have been openly criticized for analysing categories of violations without any attention to the individual violations within the set. Consequently, this research examined violations alone as well as in combination at the univariate level. Prior to multivariate analysis, violations extracted from the TMS database were combined into seventeen pre-defined categories (A-Q). This was done to render the data set more manageable, and the results more generalizable to areas outside the Capital Health region. The allocation of individual violations into the respective categories is self-evident; like violations were grouped together. A list of the violation categories is provided in Table 4.5.2. Violation codes combined to form each category are presented in Chapter Five.

Table 4.5.2 Pre-defined violation categories.

Set	Description of violation category	Number of violation codes	
		Planned	*Actual*
A	Temperature Control Violations	11	8
B	Cross-Contamination Violations	5	5
C	Unfit Foods	7	2
D	Infestation Pests / Vermin	2	1
E	Chemical & Biological Hazards	4	3
F	Food Storage / Packaging Violations	8	7
G	Cooking Equipment Violations	4	4
H	Dishwashing / Utensil violations	9	7
I	Test Equipment Violations	3	3
J	Maintenance / Sanitation Violations	8	7
K	Staff Hygiene Violations	5	4
L	Hand Sink Violations	2	2
M	Nuisance	1	1
N	Customer Contamination	1	1
O	Food Manager Certification / Training	1	1
P	Food Transportation	3	1
Q	Public Washroom Violations	2	2
Z	*Other Violations*	--	--

**Other Violations* used in multivariate analysis because of the limited sample size available in violations sets C, M, N, O, and P.

The *planned* number of violation codes reflects the number originally selected for each violation category (defined *a priori*). The *actual* number reflects the quantity used in the study. Certain variables were not cited within the sample population during the study period (see Chapter Five).

4.6 Sample size / power

Sample size was limited only by the number of SFBI complaints received by the Department in 2003. Approximately 3,800 permitted food establishments in the Capital Health region were eligible to participate. Two hundred eighty-one SFBIs were assessed as potential cases. Forty-seven percent of these SFBIs were determined to be biologically-plausible, translating into 132 cases for potential use in the study. A further 27 of these failed to meet eligibility criteria for the study and were dropped (see results section). One-hundred five food establishments, comprising of 38 Class II and 67 Class III facilities, were used. A sample size estimate using methods described by Schlesselman (1982) is presented below.

The estimated probability for exposure (defined as greater than three violations per year for the purposes of the calculation) was conservatively estimated to be 30% in the control group. Based on this figure, the approximate number of cases required to detect differences between food establishments with and without a BP-SFBI would be 90 (with 80% power, at a 5% level of significance, assuming a ratio of one case to three controls and an odds ratio of 2.0 on a two-sided test). An odds ratio of 2.0 was selected because past research has reported high estimates for OR values for many potential risk factors of SFBI (Irwin *et al.* 1989) (Buchholz *et al.* 2002). Consequently, this value may be considered to be a very conservative estimate as actual OR values are likely to be far higher.

In light that the total number of cases equalled 105 *before* the division of the data set into the respective facility classes, the study power was calculated for each facility classification using methods described by Dupont, WD (1988). As shown in Table 4.6.1, the study power was calculated across several odds ratios.

Table 4.6.1. Power calculations for Class II and Class III food establishments at various odds ratios

Facility Class	O.R. = 2.0	O.R.= 2.5	O.R.= 3.0	O.R.= 3.5	O.R.= 4.0
Class II (*n*=38)	0.371	0.604	0.772	0.877	0.936
Class III (*n*=67)	0.617	0.861	0.958	0.989	0.997

Calculations for table 4.6.1 were based on the following constant values: the level of significance $\alpha = \mathbf{0.05}$; the expected rate of exposure in the control group $\rho_0 = \mathbf{0.30}$; the number of controls per case $m = 3$; and the number of food establishments (n) in each facility class. Shaded areas identify values below 0.80 which can be considered too low to effectively detect differences between case and control groups.

4.7 Statistical methods & analysis

Analysis was conducted using SPSS v.11.5 software. Descriptive statistics were used to describe the respective facility classifications (II/III), as well as case and control groups selected for the study. To test the null hypothesis of no association, both univariate and multivariate statistical techniques were utilized. Because the data set consisted of several independent variables, and had a binary outcome, logistic regression was used.

4.7.1 Univariate analysis

Univariate analysis was used to determine whether specific violations, categories of violations, or any of the other individual characteristics extracted from inspection records were significantly associated with food poisoning in commercial eateries. Chi-square tests were conducted on data collected for each facility class. Two-by-two tables were analyzed using the Fisher's Exact Test because some of the cell values were determined to be less than five. The remaining data analyses were conducted using logistic regression, the results of which are presented as the odds ratio of BP-FBI in relation to the reference category. For most of the independent variables, this reference category was the absence of exposure. For *inspection frequency*, however, the reference category was the expected number of inspections. Ninety-five percent confidence intervals and levels of significance (*p-values*) accompany reported odds ratios for all logistic regression analyses.

4.7.2 Multivariate analysis

Each facility class was assessed separately. Purposeful selection, as described by Hosmer and Lemeshow (2000), was used to determine which independent variables would be fit into the final model. Independent variables significant at $p<0.25$ in univariate analyses were selected and fit into a multivariate model. Variables found to be statistically significant in the multivariate model ($p<0.05$) were identified, and fit into a reduced model to allow the significance of those removed to be assessed. Statistically non-significant variables were removed one at a time, and a likelihood ratio test was used to compare the full and reduced models. Confounding was determined by assessing the change in beta coefficients (β) for variables included in the reduced model, after removing each of those not found to be significant one at a time. A "removed" variable was kept in the reduced model if any beta values changed by more than 15%. Once significant confounders were identified and put back into the *main effects model,* it was then fitted with clinically plausible first-order interaction effects between the variables remaining. Such interaction effects were tested one at a time to determine if any were statistically significant ($p<0.05$). Any first-order interactions proving to be significant were subsequently added to the main effects model to form the *final multivariate model* reported in the results section.

Chapter 5: Results

5.1 Case selection / description of data set

All suspected food poisonings (SFBIs) registered by Capital Health during 2003 that occurred in Class II or Class III food establishments inspected by the Food Protection Program were reviewed (n=281). Reviewers consisted of a Food Protection/Disease Control Specialist with Capital Health (the principal researcher), and a senior health inspector holding a Master's Degree in Laboratory Science. The agreement rate between the reviewers in the application of the selection criteria for potential cases was 90.7% (255/281). Twenty-six SFBIs (9.3%) went to a third reviewer, an Environmental Health Epidemiologist. Of these SFBIs, 22/26 (84.6%) were identified as potential cases on the basis that at least one person in the dining party reported symptoms consistent with foodborne illness, and both the implicated meal and incubation time were plausible.

Altogether, 132 biologically-plausible suspected food poisonings (BP-SFBI) were identified as potential cases. Twenty-seven of these BP-SFBIs were excluded for failing to meet eligibility criteria: ten restaurants were already cases (had another foodborne illness earlier in 2003), four restaurants went out of business before December 31, 2003, and 13 restaurants had been open less than 12 months at the time the BP-SFBI occurred. One-hundred five facilities, consisting of 38 Class II establishments and 67 Class III establishments were identified as usable cases. Three hundred fifteen controls were selected at random by computer from the TMS database that did not have a SFBI in 2002 or 2003. Of the 420 eateries participating in the study, 152 (36.2%) were Class II and 268 (63.8%) were Class III (Figure 5.1.1). Inspection data were available for 100% of these food establishments.

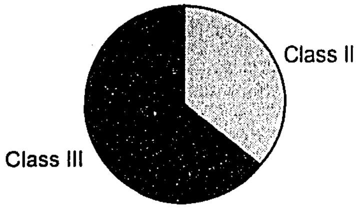


Figure 5.1.1 Ratio of Class II to Class III food establishments.

5.2 Descriptive and univariate analysis of independent variables

Several independent variables of interest were extracted from inspection records for each food establishment. They included:

- the number of inspections conducted within the study period;
- the presence of a recognized food safety program (FSP);
- the use of enforcement in the past year (orders, administrative hearings, charges, or closure);
- the presence of one or more customer complaints in the past 12 months; and
- information on 76 different violation codes.

The descriptive and univariate analysis of each of these variables is presented in sections 5.2.1 through 5.2.6.

5.2.1 Number of inspections

Descriptive data for inspection frequency is presented in ***Appendix V***. For analysis purposes, inspection frequency was measured categorically. Ranges selected for each of the categories were based on program expectations for the respective food establishment classes (equal to the number of routine inspections required for the facility class, plus one re-inspection for each routine conducted). They are presented in Table 5.2.1.

Table 5.2.1 Inspection frequency of Class II and Class III food establishments.

Inspection Frequency	Number of Inspections	% Case	% Control	% Total
Class II		*(n=38)*	*(n=114)*	*(n=152)*
Below expected	1	2.6	28.1	21.7
Expected	2 - 4	57.9	50.0	52.0
Greater than expected	5 - 8	23.7	18.4	19.7
Much greater than expected	9 +	15.8	3.5	6.6
Class III		*(n=67)*	*(n=201)*	*(n=268)*
Below expected	1 - 2	1.5	19.9	15.3
Expected	3 - 6	49.3	61.2	58.2
Greater than expected	7 - 9	26.9	15.4	18.3
Much greater than expected	10 +	22.4	3.5	8.2

More than 75% of food establishments had the expected number of inspections (or greater) conducted within the 12-month observation period. Significant differences in inspection frequency between case and control groups were observed for Class II food establishments in the study [χ^2=15.770; p=0.001 at 3 df]. A similar association between inspection frequency and receiving a BP-SFBI was also observed for Class III food establishments [χ^2=37.838; p<0.001 at 3 df;].

5.2.2 Violation data

Information on 76 different violation codes was collected from electronic inspection records. Seventeen of the violations reviewed (22.4%) were not cited in either case or control groups within the study period [Table 5.2.2]. These violations were dropped from the analysis. The results of the descriptive analyses for the 59 remaining violations are presented in Tables 5.2.3 and 5.2.4.

Table 5.2.2 Violations not cited in either case or control groups within the critical period.

Violation Header (Descriptor)	Violation Set	Critical Violation in TMS
Cooking of Food	A	Yes
Bulk Ice Cream Temperature	A	Yes
Quick Freeze Facilities	A	No
Non-Potable Water	C	Yes
Convenience Food Expiry Dates	C	Yes
Unapproved Foods	C	Yes
Un-Inspected Foods	C	Yes
Re-Served Foods	C	Yes
Live Animal in Restaurant	D	Yes
Sewage	E	Yes
Metal Containers	F	Yes
Wood Dishes/Utensils	H	No
Unapproved Equipment (Dishwasher)	H	No
Required Sinks	J	No
Infection Control	K	Yes
Transportation of Food	P	Yes
Food Transportation – Protection	P	No

Table 5.2.2 lists all violations not cited in either case or control groups within the study period. Twelve of the seventeen (70.6%) were "*critical violations*"; a term reserved for those violations

believed to place the public at greatest risk of adverse outcomes. Similar violations were combined into predetermined categories (Violation Sets A-Q) for univariate and multivariate analysis (as described in Chapter 4). Nine of these categories lost one or more violations [Table 5.5.2]. Eight, violation sets (B, G, I, L, M, N, O, and Q) lost none. *Violation Set C* lost the greatest number and proportion of violation codes: five of seven (71%). Set A lost three out of eleven (27%), set D lost one out of two (50%), set E one out of four (25%), sets F and J both lost one out of eight (13%), set H two out of nine (22%), set K lost one out of five (20%), and set P lost two out of three (67%).

Table 5.2.3 Descriptive statistics for violation codes cited in Class II eateries.

	Violation and Description	Cases with violation			Controls with violation		
		N	Mean ± (SD)	Median (Range)	N	Mean ± (SD)	Median (Range)
A	**Temperature Control Violations**						
	Cold Storage of Food	3	1.7±0.58	2(1-2)	14	1.3±0.47	1(1-2)
	Food at Room Temperature	6	1.3±0.82	1(1-3)	8	1.1±0.35	1(1-2)
	Thawing of Food	2	1.5±0.71	1.5(1-2)	3	1.3±0.58	1(1-2)
	Hot Holding of Food	2	1.0±0.00	1(1-1)	4	1.5±0.58	1.5(1-2)
	Chilling of Food	0	--	--	0	--	--
	Freezer Temperature	2	1.0±0.00	1(1-1)	2	1.0±0.00	1(1-1)
	Cold Display of Food	0	--	--	2	1.0±0.00	1(1-1)
	Reheating of Food	1	1.0	1(1-1)	0	--	--
B	**Cross-contamination Violations**						
	Refrigeration Storage	3	1.7±1.15	1(1-3)	6	1.3±0.52	1(1-2)
	Cleaning Clothes	3	2.0±0.00	2(2-2)	4	1.3±0.50	1(1-2)
	Improper Food Handling	1	1.0	1(1-1)	5	1.2±0.45	1(1-2)
	Food Contact Surfaces	0	--	--	2	1.0±0.00	1(1-1)
	Unrelated Tasks	0	--	--	0	--	--
C	**Unfit Foods**						
	Food Unfit for Human Consumption	0	--	--	0	--	--
	Food Labelling	0	--	--	1	1.0	1(1-1)
D	**Infestation: Insects/Vermin**	3	1.3±0.58	1(1-2)	3	1.0±0.00	1(1-1)
E	**Chemical & Biological Hazards**						
	Poison Storage	1	1.0	1(1-1)	3	1.0±0.00	1(1-1)
	Poison Use	1	1.0	1(1-1)	1	1.0	1(1-1)
	Refuse Storage	2	2.0±1.41	2(1-3)	0	--	--
F	**Food Storage / Packaging**						
	Unacceptable Containers	2	1.0±0.00	1(1-1)	3	1.3±0.58	1(1-2)
	Separate Storage Space	3	2.3±1.15	3(1-3)	4	1.8±0.96	1.5(1-3)
	Unacceptable Packaging	2	1.0±0.00	1(1-1)	0	--	--
	Adequate Storage Space / Shelving	1	2.0±0.00	2(2-2)	1	3.0±0.00	3(3-3)
	Food / Storage Area Incursions	1	1.0	1(1-1)	1	2.0±0.00	2(2-2)
	Bulk Food Non-Perishable	0	--	--	0	--	--
	Food Storage in Washroom	0	--	--	1	2.0±0.00	2(2-2)
G	**Cooking Equipment Violations**						
	Food Equipment Unsanitary	8	2.4±0.74	2.5(1-3)	11	1.8±1.2	1(1-4)
	Food Equipment in Disrepair	4	3.0±1.63	3(1-5)	1	3.0±0.00	3(3-3)
	Ventilation System	1	4.0±0.00	4(4-4)	2	1.0±0.00	1(1-1)
	Utensils / Dishware Damaged	0	--	--	0	--	--
H	**Dishwashing/Utensil Violations**						

	Mechanical Procedures	2	2.0±0.00	2(2-2)	5	3.2±3.83	2(1-10)
	Dishes / Utensils Storage	0	--	--	2	1.0±0.00	1(1-1)
	Manual Procedures	6	1.5±0.55	1.5(1-2)	4	1.0±0.00	1(1-1)
	Machine Disrepair (Dishwasher)	2	3.0±1.41	3(2-4)	2	2.0±0.00	2(2-2)
	Dishes / Utensils Unclean	1	1.0	1(1-1)	1	1.0	1(1-1)
	Dipper Well	0	--	--	0	--	--
	Single Service Utensils Reused	0	--	--	1	2.0±0.00	2(2-2)
I	**Test Equipment Violations**						
	Thermometer Missing (Cooler or Hot Holding)	6	1.7±1.03	1(1-3)	14	1.4±0.76	1(1-3)
	Test Equipment – Temp / Chem. (Machine)	2	3.5±2.12	3.5(2-5)	3	1.3±0.58	1(1-2)
	Test Equipment – Temp / Chem. (Manual)	2	2.5±2.12	2.5(1-4)	7	1.3±0.49	1(1-2)
J	**Maintenance / Sanitation**						
	Floors, Walls & Ceilings (Sanitation)	9	2.7±2.83	2(1-10)	19	1.4±0.60	1(1-3)
	Non-Food Contact Surfaces Unsanitary	11	2.1±1.14	2(1-4)	13	2.0±1.5	1(1-6)
	Floors, Walls & Ceilings (Structural)	12	3.5±3.37	2.5(1-13)	11	2.0±1.41	1(1-4)
	Shelving	1	1.0	1(1-1)	2	1.0±0.00	1(1-1)
	Plumbing Maintenance	4	3.8±3.10	3(1-8)	3	1.7±0.58	2(1-2)
	Screen Doors / Weather stripping	4	3.3±2.63	2.5(1-7)	1	1.0±0.00	1(1-1)
	Water Supply		--			--	
K	**Staff Hygiene Violations**						
	Hand washing	9	1.6±1.01	1(1-4)	3	1.0±0.00	1(1-1)
	Food Worker Clothing	0	--	--	1	1.0	1(1-1)
	Personal Hygiene	0	--	--	1	1.0	1(1-1)
	Food Worker Hair Control	0	--	--	1	1.0	1(1-1)
L	**Hand Sink Violations**						
	Hand washing supplies	8	2.1±1.55	1.5(1-5)	24	1.7±1.63	1(1-8)
	Wash Basin (Missing / Inaccessible)	4	1.0±0.00	1(1-1)	3	1.3±0.58	1(1-2)
M	**Nuisance**	0	--	--	1	1.0	1(1-1)
N	**Customer Contamination**	0	--	--	0	--	--
O	**Food Manager Certification**	1	5.0±0.00	5(5-5)	3	2.0±1.7	1(1-4)
P	**Food Transportation (Unsanitary)**	1	2.0±0.00	2(2-2)	5	1.2±0.45	1(1-2)
Q	**Public Washrooms**						
	Washroom Sanitation	2	2.0±1.41	2(1-3)	4	1.8±0.95	1.5(1-3)
	Washroom Maintenance (Structural)	1	3.0±0.00	3(3-3)	2	1.0±0.00	1(1-1)

Table 5.2.4. Descriptive statistics for violation codes cited in Class III eateries.

	Violation and Description	Cases with violation			Controls with violation		
		N	Mean ± (SD)	Median (Range)	N	Mean ± (SD)	Median (Range)
A	**Temperature Control Violations**						
	Cold Storage of Food	28	3.1±4.32	2(1-24)	36	1.6±0.73	1.5(1-4)
	Food at Room Temperature	22	2.2±1.99	1.5(1-10)	18	1.5±0.71	1(1-3)
	Thawing of Food	14	1.9±1.23	1(1-5)	15	1.3±0.59	1(1-3)
	Hot Holding of Food	7	1.3±0.49	1(1-2)	5	2.0±1.73	1(1-5)
	Chilling of Food	9	1.8±1.30	1(1-5)	5	1.2±0.45	1(1-2)
	Freezer Temperature	3	1.0±0.00	1(1-1)	7	1.4±0.54	1(1-2)
	Cold Display of Food	4	3.3±4.50	1(1-10)	5	1.6±0.89	1(1-3)
	Reheating of Food	1	1.0	1(1-1)	1	1.0	1(1-1)
B	**Cross-contamination Violations**						
	Refrigeration Storage	12	2.6±2.87	1.5(1-11)	17	1.4±0.61	1(1-3)
	Cleaning Clothes	8	1.8±1.04	1.5(1-4)	10	1.3±0.48	1(1-2)
	Improper Food Handling	7	2.6±1.72	2(1-6)	5	1.0±0.00	1(1-1)
	Food Contact Surfaces	6	2.2±1.17	2(1-4)	9	1.1±0.33	1(1-2)
	Unrelated Tasks	4	1.3±0.50	1(1-2)	3	1.3±0.58	1(1-2)
C	**Unfit Foods**						
	Food Unfit for Human Consumption	0	--	--	3	1.7±0.58	2(1-2)
	Food Labelling	0	--	--	0	--	--
D	**Infestation: Insects/Vermin**	15	2.0±1.36	1(1-4)	15	1.9±0.96	2(1-4)
E	**Chemical & Biological Hazards**						
	Poison Storage	5	1.6±0.89	1(1-3)	2	1.0±0.00	1(1-1)
	Poison Use	5	1.8±0.84	2(1-3)	3	1.7±0.58	2(1-2)
	Refuse Storage	3	2.3±2.31	1(1-5)	2	1.0±0.00	1(1-1)
F	**Food Storage / Packaging**						
	Unacceptable Containers	14	2.1±1.35	1.5(1-5)	16	1.6±1.02	1(1-4)
	Separate Storage Space	10	1.9±1.60	1(1-6)	13	1.1±0.28	1(1-2)
	Unacceptable Packaging	9	1.4±0.73	1(1-3)	10	1.2±0.42	1(1-2)
	Adequate Storage Space / Shelving	4	2.0±0.82	2(1-3)	1	1.0	1(1-1)
	Food / Storage Area Incursions	1	1.0	1(1-1)	1	2.0	2(2-2)
	Bulk Food Non-Perishable	2	1.0±0.00	1(1-1)	2	2.0±0.00	2(2-2)
	Food Storage in Washroom	1	1.0	1(1-1)	0	--	--
G	**Cooking Equipment Violations**						
	Food Equipment Unsanitary	26	2.7±2.58	2(1-12)	48	1.9±1.01	1.5(1-4)
	Food Equipment in Disrepair	19	2.4±1.80	2(1-8)	16	1.6±0.89	1(1-4)
	Ventilation System	3	2.0±1.00	2(1-3)	2	2.0±0.00	2(2-2)
	Utensils / Dishware Damaged	2	1.5±0.71	1.5(1-2)	0	--	--
H	**Dishwashing/Utensil Violations**						

	Mechanical Procedures	15	2.3±1.67	2(1-7)	34	1.8±1.07	1(1-5)
	Dishes / Utensils Storage	8	1.4±0.74	1(1-3)	12	1.5±0.67	1(1-3)
	Manual Procedures	5	3.0±3.94	1(1-10)	6	1.3±0.52	1(1-2)
	Machine Disrepair (Dishwasher)	5	1.6±0.89	1(1-3)	9	1.8±1.20	1(1-4)
	Dishes / Utensils Unclean	5	2.0±1.41	1(1-4)	10	1.2±0.42	1(1-2)
	Dipper Well	6	1.5±0.55	1.5(1-2)	0	--	--
	Single Service Utensils Reused	0	--	--	0	--	--
I	**Test Equipment Violations**						
	Thermometer Missing (Cooler or Hot Holding)	30	2.2±1.56	2(1-8)	35	1.8±1.06	1(1-5)
	Test Equipment – Temp / Chem. (Machine)	11	2.3±1.62	2(1-5)	20	1.8±1.29	1(1-6)
	Test Equipment – Temp / Chem. (Manual)	2	8.5±9.19	8.5(2-15)	1	1.0	1(1-1)
J	**Maintenance / Sanitation**						
	Floors, Walls & Ceilings (Sanitation)	35	3.5±2.81	2(1-15)	68	2.2±1.63	2(1-8)
	Non-Food Contact Surfaces Unsanitary	23	2.5±2.37	1(1-10)	63	1.9±1.06	2(1-5)
	Floors, Walls & Ceilings (Structural)	21	3.3±2.44	3(1-11)	24	2.9±1.87	2.5(1-7)
	Shelving	5	3.0±2.00	2(1-6)	18	1.7±1.18	1(1-5)
	Plumbing Maintenance	11	1.7±1.01	1(1-4)	6	1.3±0.52	1(1-2)
	Screen Doors / Weather stripping	5	3.2±1.10	3(2-5)	5	1.2±0.45	1(1-2)
	Water Supply	1	2.0	2(2-2)	1	1.0	1(1-1)
K	**Staff Hygiene Violations**						
	Hand washing	10	1.5±0.97	1(1-4)	7	1.1±0.38	1(1-2)
	Food Worker Clothing	3	3.0±1.73	4(1-4)	1	2.0±0.00	2(2-2)
	Personal Hygiene	1	1.0	1(1-1)	2	1.0±0.00	1(1-1)
	Food Worker Hair Control	0	--	--	0	--	--
L	**Hand Sink Violations**						
	Hand washing supplies	19	2.3±1.49	2(1-5)	41	1.5±0.71	1(1-4)
	Wash Basin (Missing / Inaccessible)	5	1.4±0.89	1(1-3)	13	1.4±0.65	1(1-3)
M	**Nuisance**	2	1.5±0.71	1.5(1-2)	1	1.0	1(1-1)
N	**Customer Contamination**	0	--	--	4	2.0±0.82	2(1-3)
O	**Food Manager Certification**	4	2.5±1.91	2(1-5)	2	4.0±1.41	4(3-5)
P	**Food Transportation (Unsanitary)**	7	2.3±1.11	2(1-4)	11	1.6±1.03	1(1-4)
Q	**Public Washrooms**						
	Washroom Sanitation	5	1.8±1.30	1(1-4)	12	1.4±0.67	1(1-3)
	Washroom Maintenance (Structural)	4	1.8±0.96	1.5(1-3)	5	3.0±1.22	3(2-5)

Values in Tables 5.2.3 and 5.2.4 are representative of Class II and Class III food establishments respectively. The number of food establishments with the violation in the data set is represented by the column labeled [N]. Calculations for the mean, standard deviation, median, and range exclude facilities without the violation. For example, *"Cold Storage of Food"* is a component of *Temperature Control Violations* (set "A"). A total of 64 Class III food establishments had this violation code cited one or more times during the study period: 28 cases and 36 controls. Among the _case_ food establishments with the violation, it was cited a mean of 3.1 times (±4.32 S.D.), a median of twice, and a range of one to 24 times.

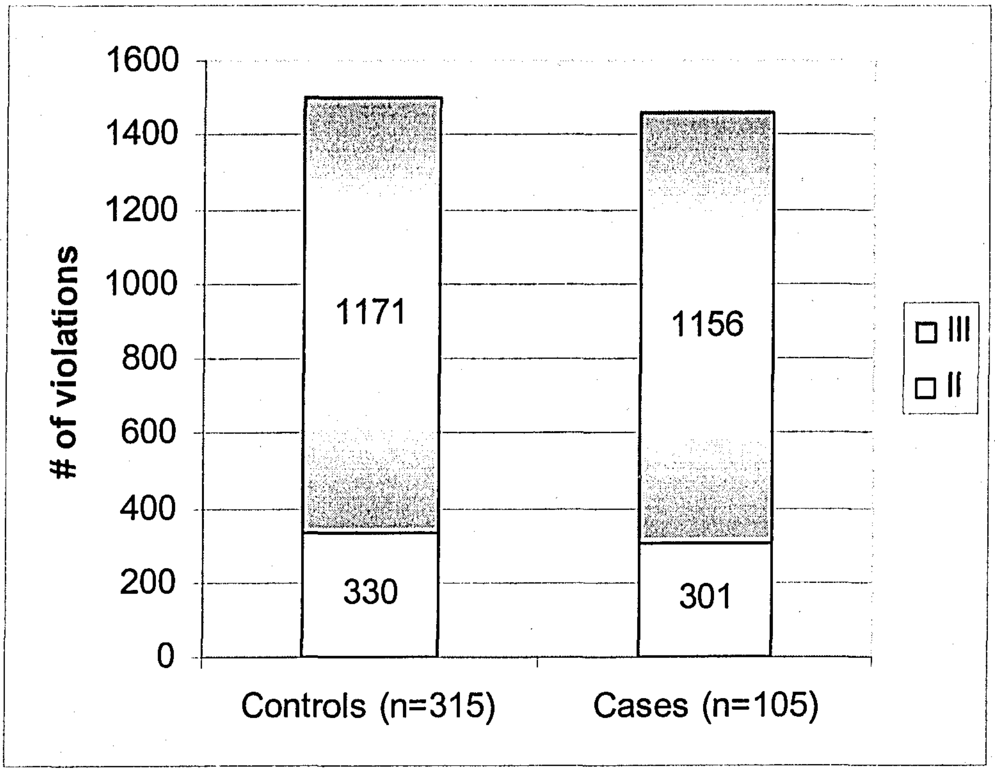
Taking each violation as a continuous variable, a total of 2,958 violations were cited in food establishments participating in the study: 631 among Class II food establishments, and 2,327 among Class III. On average, food establishments _not_ implicated in a BP-SFBI (controls) had fewer violations cited than eateries with a food poisoning (cases).

Table 5.2.5. The number, mean, and range of violations cited in case and control groups for Class II and Class III food establishments within the study period.

Facility Class	Number of violations	Mean # of violations	Range
Class II			
Cases (n=38)	301	7.9	0 - 63
Controls (n=114)	330	2.9	0 - 32
Class III			
Cases (n=67)	1,156	17.3	0 - 154
Controls (n=201)	1,171	5.8	0 - 36

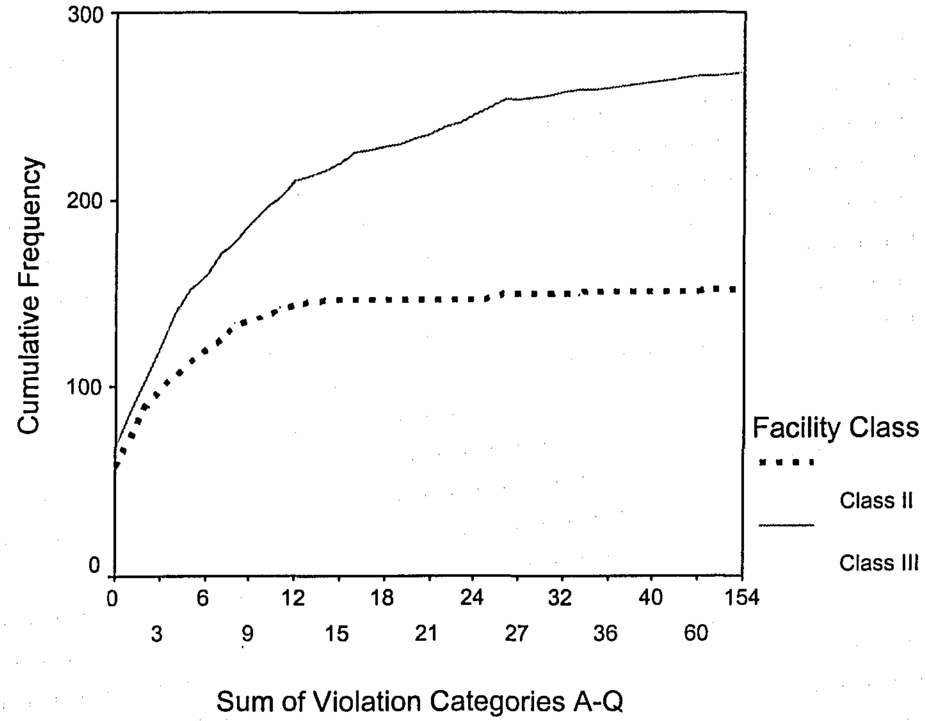
Class II controls had 330 violations cited with a mean score of 2.9 per food establishment and a range of zero to 32. Class II facilities with a BP-SFBI had 301 violations cited, with a mean score of 7.9 per food establishment and a range of zero to 63. Class III controls had 1,171 violations cited with a mean score of 5.8 per food establishment and a range of zero to 36. Class III facilities with a BP-SFBI had 1,156 violations cited with a mean score of 17.3 violations per food establishment and a range of zero to 154.

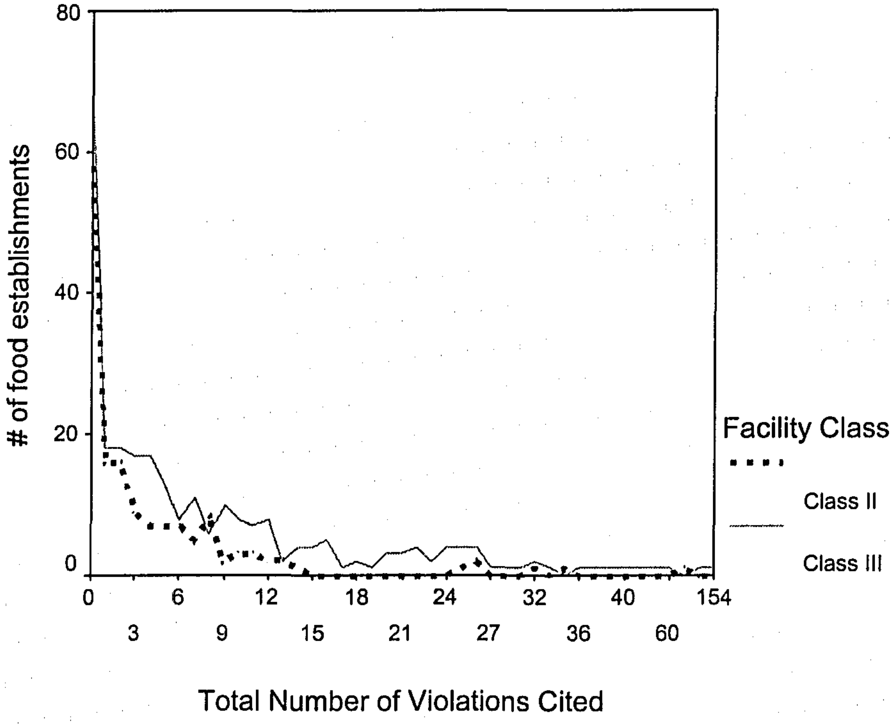
Figure 5.2.1 The respective number of violations cited in case and control groups for each facility class.



The total number of violations identified in case and control groups was remarkably close despite the fact that the controls outnumbered the cases 3:1 (Figure 5.2.1). It was also determined that the proportion of violations contributed by Class II and Class III facilities to the case and control groups were similar; Class III facilities having the larger of the two. Looking at the Figure 5.2.2, over 95% of Class II facilities had 12 violations cited or less. Proportionally, far fewer Class III food establishments had this number of violations. Outliers were observed in both case and control groups, highest being 63 violations for a Class II food establishment, and 154 for a Class III food establishment.

Figure 5.2.2 **Distribution and cumulative frequency of total violations cited in Class II and Class III food establishments.**





Univariate analysis of summary violation data

One categorical variable of interest in the study was whether or not a food establishment received any violation within the study period. Receiving any of the 59 different violation codes was considered to be a positive result for this dichotomous independent variable.

Class II

Looking only at Class II food establishments, 73.7% of cases and 57.9% of controls had at least one violation cited in the previous year (Table 5.2.6). This means receiving *"any violation"* cannot be considered significantly associated with BP-SFBI in this class of food establishment [χ^2=3.011 at 1df; p=0.122 (Table 5.2.6)]. This is supported by the results of univariate logistic regression where the odds of having a violation cited in the past 12 months failed to achieve statistical significance [OR=2.04; 95%CI: 0.90-4.59, p=0.086].

Class III

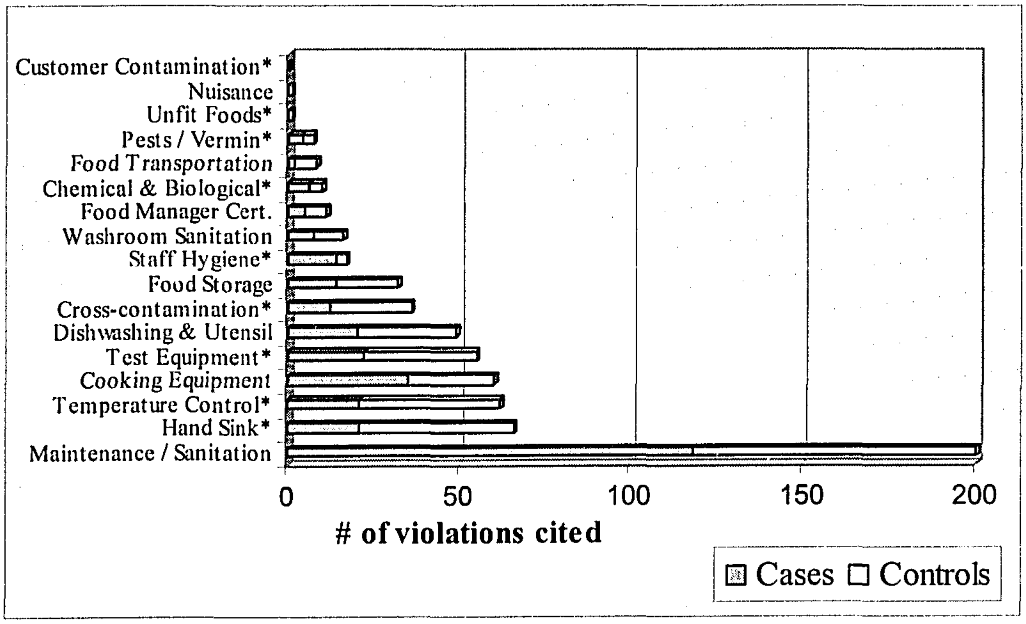
In Class III food establishments, one or more violations cited within the critical period *was* found to be significantly associated with BP-SFBI [χ^2=7.085 at 1df; p=0.009 (Table 5.2.7)]. Eighty-seven percent of cases had at least one violation cited in comparison to 70% of controls. Class III food establishments having one or more violations cited in the past 12 months were 2.7 times more likely to have a BP-SFBI when compared food establishments of equal class without a violation [OR=2.74; 95%CI: 1.28-5.89, p=0.01].

Rank order of violations

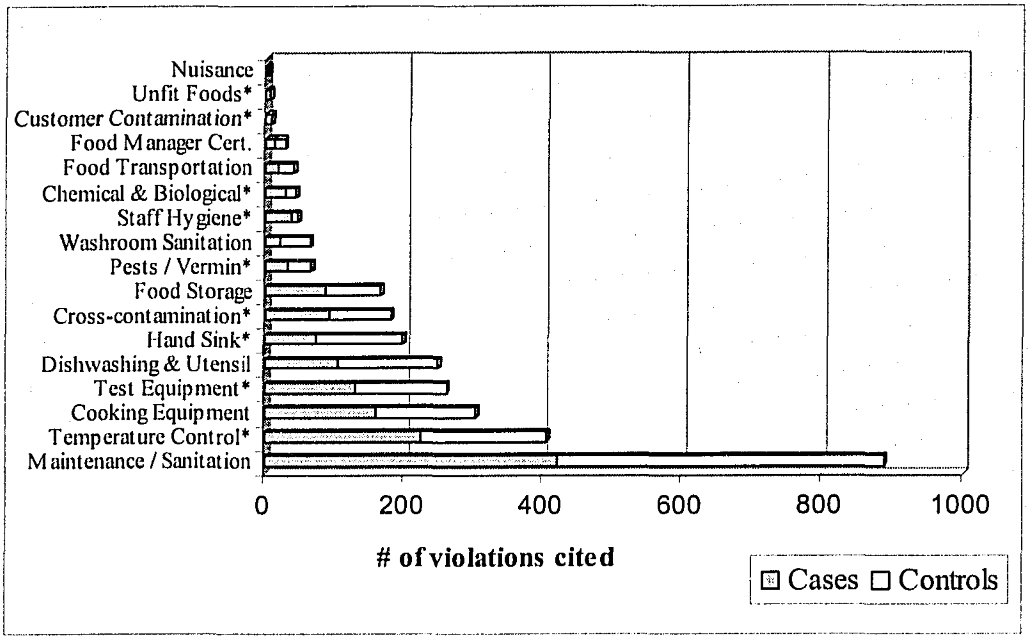
There has been considerable interest in the frequency with which inspectors cite specific kinds of violations within a defined geographic area and time period. Researchers in Tennessee, for example, analyzed statewide restaurant inspection data from January 1993 through April 2000 (Jones *et al.* 2004). Data collected for the present study was analyzed in a similar fashion to determine if trends within the Class II and Class III facilities (extracted from inspection records for food establishments in the Edmonton area during 2003) were similar. Results are presented in Figure 5.2.3.

Figure 5.2.3 The rank-order of different kinds of violations by the number of times they were cited during a 12-month period in Class II and Class III food establishments.

Class II



Class III



* indicates a violation category that contains critical violations.

Figure 5.2.3 comprises of nine categories containing one or more critical violations, and eight categories containing only non-critical violations. Subtle differences with respect to the rank-order of violations were observed between Class II and Class III facilities, and between case and control groups. Violations regarding general *maintenance / sanitation* were the most frequently cited, both in terms of the number of food establishments that had them, and the number of times these were identified within the study period. Critical violations, including those involving *temperature control of potentially hazardous foods*, *hand washing facilities in kitchen areas*, and *test equipment* (such as missing thermometers) were also amongst the most frequently cited. *Customer contamination of food products*, *nuisance*, and *foods unfit for human consumption* were cited the least frequently.

Univariate Analysis of Violation Codes

Taking each of the violations independently as a dichotomous variable, with the presence of the violation within the critical period equal to one and the absence of the violation within the critical period equal to zero, six (7.9%) were significantly associated with Class II facilities receiving a BP-SFBI ($p<0.05$; Table 5.2.6). Twenty-four violations (or 31.6%) were associated with Class III receiving a plausible food poisoning ($p<0.05$; Table 5.2.7). Cases were also more likely to have a *food safety program* (FSP), a higher than expected *frequency of inspection*, and a *public complaint* in the 12-month period preceding the BP-SFBI than controls of equal class assessed over the same time period (Table 5.2.6 and 5.2.7). Receiving *any violation* within the critical period was determined to be significantly associated with disease outcome in Class III food establishments, but not in Class II.

Table 5.2.6 The association between independent variables of interest and foodborne illness in Class II food establishments (n=152)

Violation Header (Descriptor)	% Case *(n=38)*	% Control *(n=114)*	*p-value*(a)
Recognized FSP	57.9	17.5	<0.001
Hand washing	23.7	2.6	<0.001
Inspection Frequency			0.001
Below Expected	2.6	28.1	
Expected	57.9	50.0	
Greater than Expected	23.7	18.4	
Much Greater than Expected	15.8	3.5	
Public Complaints	36.8	13.2	0.003
Floors, Walls & Ceilings (Structural)	31.6	9.6	0.003
Food Equipment in Disrepair	10.5	0.9	0.014
Screen Doors / Weather Stripping	10.5	0.9	0.014
Manual Dishwashing Procedures	15.8	3.5	0.016
Non-Food Contact Surface Dirty	28.9	11.4	0.019
Unacceptable Packaging (b)	5.3	0.0	0.061
Plumbing Maintenance (b)	10.5	2.6	0.066
Food Equipment Unsanitary (b)	21.1	9.6	0.088
Food Held at Room Temperature (b)	15.8	7.0	0.115
Any Violation (b)	73.7	57.9	0.122
Infestation Pests / Vermin (b)	7.9	2.6	0.165
Floors, Walls & Ceilings (Sanitation) (b)	23.7	16.7	0.341
Separate Storage Space (b)	7.9	3.5	0.367
Adequate Storage Space / Shelving (b)	2.6	0.9	0.439
Poison Use (b)	2.6	0.9	0.439
Cold Storage of Food (b)	7.9	12.3	0.564
Thermometer Missing (b)	15.8	12.3	0.585
Thawing of Food (b)	5.3	2.6	0.599
Unacceptable Containers (b)	5.3	2.6	0.599
Hot Holding of Food (b)	5.3	3.5	0.640
Refrigeration Storage (b)	7.9	5.3	0.691
Food Handler Clothing (b)	0.0	0.9	1.000
Food Manager's Course (b)	2.6	2.6	1.000
Improper Food Handing (b)	2.6	4.4	1.000
Poison Storage (b)	2.6	2.6	1.000
Chilling of Food (b)	--	--	--
Dipper Well (b)	--	--	--

(a) p-values reported are from analysis using Fisher's Exact Test except for inspection frequency which is significant at 3 degrees of freedom.

(b) designates variables found to be significant for Class III food establishments.

Table 5.2.7 The association between independent variables of interest and foodborne illness in Class III food establishments (n=268)

Violation Header (Descriptor)	% Case (n=67)	% Control (n=201)	*p-value*[(a)]
Food Held at Room Temperature	32.8	9.0	<0.001
Thermometer Missing (Cooler or Hot Holding)	44.8	17.4	<0.001
Plumbing Maintenance	16.4	3.0	<0.001
Dipper Well	9.0	0.0	<0.001
Food Equipment in Disrepair	28.4	8.0	<0.001
Recognized FSP	23.9	1.5	<0.001
Public Complaint(s)	40.3	18.4	<0.001
Inspection Frequency			<0.001
Below Expected	1.5	19.9	
Expected	49.3	61.2	
Greater than Expected	26.9	15.4	
Much Greater than Expected	22.4	3.5	
Cold Storage of Food	41.8	17.9	<0.001
Floors, Walls & Ceilings (Structural)	31.3	11.9	0.001
Chilling of Food	13.4	2.5	0.002
Hand washing	14.9	3.5	0.002
Infestation Pests / Vermin	22.4	7.5	0.002
Thawing of Food	20.9	7.5	0.005
Unacceptable Containers	20.9	8.0	0.006
Floors, Walls & Ceilings (Sanitation)	52.2	33.8	0.009
Any Violation	86.6	70.1	0.009
Hot Holding of Food	10.4	2.5	0.012
Improper Food Handing	10.4	2.5	0.012
Poison Storage	7.5	1.0	0.012
Adequate Storage Space / Shelving	6.0	0.5	0.015
Poison Use	7.5	1.5	0.025
Food Equipment Unsanitary	38.8	23.9	0.026
Unacceptable Packaging	13.4	5.0	0.027
Food Manager's Course	6.0	1.0	0.036
Refrigeration Storage	17.9	8.5	0.041
Separate Storage Space	14.9	6.5	0.043
Food Handler Clothing	4.5	0.5	0.049
Screen Doors / Weather Stripping (b)	7.5	2.5	0.127
Manual Dishwashing Procedures (b)	7.5	3.0	0.149
Non-Food Contact Surface Dirty (b)	34.3	31.3	0.653

(a) p-values reported are from analysis using Fisher's Exact Test except for inspection frequency which is significant at 3 degrees of freedom.

(b) designates variables found to be significant for Class II food establishments.

Analysis and Description of Violation Sets

Descriptive and univariate analyses of violation sets A-Q are presented in sections 5.2.2.1 to 5.2.2.13. Relevant tables precede these sections. Descriptive statistics are presented in Tables 5.2.8 through 5.2.10. Univariate logistic regression analysis of each *dichotomous variable* is presented in Table 5.2.11. Univariate logistic regression analysis of each *categorical variable* is presented in Table 5.2.12.

Table 5.2.8. Descriptive analysis of violation sets (A-Q) for Class II food establishments.

Violation and Description		Cases with violation (*n=38*)			Controls with violation (*n=114*)		
		N	Mean ± (SD)	Median (Range)	N	Mean ± (SD)	Median (Range)
A	Temperature Control Violations	13	1.6±1.12	1(1-5)	27	1.5±1.01	1(1-5)
B	Cross-contamination Violations	6	2.0±0.89	2(1-3)	10	2.1±1.97	1(1-7)
C	Unfit Foods	0	--	--	1	1.0	1(1-1)
D	Infestation: Insects/Vermin	3	1.3±0.58	1(1-2)	3	1.0±0.00	1(1-1)
E	Chemical & Biological Hazards	4	1.5±1.00	1(1-3)	4	1.0±0.00	1(1-1)
F	Food Storage / Packaging	8	1.8±1.16	1(1-4)	7	2.6±2.88	2(1-9)
G	Cooking Equipment Violations	11	3.2±2.36	3(1-9)	14	1.8±1.12	1(1-4)
H	Dishwashing/Utensil Violations	7	2.9±2.54	2(1-8)	13	2.2±2.59	1(1-10)
I	Test Equipment Violations	10	2.2±1.48	1.5(1-5)	23	1.4±0.66	1(1-3)
J	Maintenance / Sanitation	24	4.9±7.66	3(1-38)	36	2.3±1.86	2(1-10)
K	Staff Hygiene Violations	9	1.6±1.01	1(1-4)	6	1.0±0.00	1(1-1)
L	Hand Sink Violations	10	2.1±1.45	1.5(1-5)	26	1.7±1.64	1(1-8)
M	Nuisance	0	--	--	1	1.0	1(1-1)
N	Customer Contamination	0	--	--	0	--	--
O	Food Manager Certification	1	5.0	5(5-5)	3	2.0±1.73	1(1-4)
P	Food Transportation	1	2.0	2(2-2)	5	1.2±0.45	1(1-2)
Q	Public Washrooms	2	3.5±3.54	3.5(1-6)	5	1.8±0.84	1(1-3)

Table 5.2.9. Descriptive analysis of violation sets (A-Q) for Class III food establishments.

Violation and Description		Cases with violation *(n=67)*			Controls with violation *(n=201)*		
		N	Mean ± (SD)	Median (Range)	N	Mean ± (SD)	Median (Range)
A	Temperature Control Violations	45	4.5±6.99	3(1-47)	65	2.1±1.53	2(1-11)
B	Cross-contamination Violations	24	3.4±2.89	2(1-11)	32	1.7±0.89	1.5(1-4)
C	Unfit Foods	0	--	--	3	1.7±0.58	2(1-2)
D	Infestation: Insects/Vermin	15	2.0±1.36	1(1-4)	15	1.9±0.96	2(1-4)
E	Chemical & Biological Hazards	12	2.0±1.54	1(1-5)	7	1.3±0.49	1(1-2)
F	Food Storage / Packaging	27	2.7±2.19	2(1-10)	35	1.7±0.96	1(1-4)
G	Cooking Equipment Violations	32	3.9±4.46	2(1-21)	59	2.0±1.22	2(1-5)
H	Dishwashing/Utensil Violations	27	3.2±3.67	2(1-16)	57	2.0±1.28	1(1-6)
I	Test Equipment Violations	33	3.3±3.06	2(1-16)	46	2.1±1.69	2(1-10)
J	Maintenance / Sanitation	47	6.4±6.52	5(1-41)	112	3.4±2.79	3(1-19)
K	Staff Hygiene Violations	12	2.1±2.35	1(1-9)	10	1.2±0.42	1(1-2)
L	Hand Sink Violations	24	2.1±1.42	2(1-5)	47	1.7±0.90	1(1-4)
M	Nuisance	2	1.5±0.71	1.5(1-2)	1	1.0	1(1-1)
N	Customer Contamination	0	--	--	4	2.0±0.82	2(1-3)
O	Food Manager Certification	4	2.5±1.91	2(1-5)	2	4.0±1.41	4(3-5)
P	Food Transportation	7	2.3±1.11	2(1-4)	11	1.6±1.03	1(1-4)
Q	Public Washrooms	7	2.3 ±1.25	3(1-4)	15	2.1±1.46	2(1-6)

Table 5.2.10 Associations between violation categories and disease outcome (BP-SFBI) for Class II and III food establishments using Fisher's Exact Test.

	Violation Set and Description	% within Cases	% within Controls	*p-value*
Class II		*(n=38)*	*(n=114)*	
A	Temperature Control Violations	34.2	23.7	0.209
B	Cross-contamination	15.8	8.8	0.232
C	Unfit Foods	0.0	0.9	1.000
D	Infestation Pest/Vermin	7.9	2.6	0.165
E	Chemical & Biological Hazards	10.5	3.5	0.108
F	Food Storage / Packaging Violations	21.1	6.1	0.013
G	Cooking Equipment	28.9	12.3	0.023
H	Dishwashing & Utensil Violations	18.4	11.4	0.276
I	Test Equipment: Temp/Chem.	26.3	20.2	0.496
J	Maintenance / Sanitation	63.2	31.6	0.001
K	Staff Hygiene Violations	23.7	5.3	0.003
L	Hand Sink Violations: Kitchen	26.3	22.8	0.664
M	Nuisance	0.0	0.9	1.000
N	Customer contamination	0.0	0.0	N/A
O	Food Manager Certification	2.6	2.6	1.000
P	Food Transportation	2.6	4.4	1.000
Q	Washroom Sanitation/Maintenance	5.3	4.4	1.000
Z	Other* (C+M+N+O+P)	5.3	7.9	0.732
Class III		*(n=67)*	*(n=201)*	
A	Temperature Control Violations	67.2	32.3	<0.001
B	Cross-contamination	35.8	15.9	0.001
C	Unfit Foods	0.0	1.5	0.575
D	Infestation Pest/Vermin	22.4	7.5	0.002
E	Chemical & Biological Hazards	17.9	3.5	<0.001
F	Food Storage / Packaging Violations	40.3	17.4	<0.001
G	Cooking Equipment	47.8	29.4	0.007
H	Dishwashing & Utensil Violations	40.3	28.4	0.094
I	Test Equipment: Temp/Chem.	49.3	22.9	<0.001
J	Maintenance / Sanitation	70.1	55.7	0.044
K	Staff Hygiene Violations	17.9	5.0	0.003
L	Hand Sink Violations: Kitchen	35.8	23.4	0.055
M	Nuisance	3.0	0.5	0.155
N	Customer contamination	0.0	2.0	0.575
O	Food Manager Certification	6.0	1.0	0.036
P	Food Transportation	10.4	5.5	0.166
Q	Washroom Sanitation/Maintenance	10.4	7.5	0.446
Z	Other* (C+M+N+O+P)	16.4	9.0	0.111

Table 5.2.11 Univariate logistic regression of dichotomous independent variables for Class II and Class III food establishments.

Dichotomous Data		Class II (n=152)			Class III (n=268)		
Violation Set and Description		O.R.	95% C.I.	*p-value*	O.R.	95% C.I.	*p-value*
A	Temperature Control Violations	1.68	0.76 - 3.72	0.204	4.28	2.37 - 7.72	<0.001
B	Cross-contamination	1.95	0.66 - 5.78	0.228	2.95	1.58 - 5.51	0.001
D	Infestation Pest/Vermin	3.17	0.61 - 16.43	0.169	3.58	1.64 - 7.80	0.001
E	Chemical & Biological Hazards	3.24	0.77 - 13.63	0.110	6.05	2.27 - 16.10	<0.001
F	Food Storage / Packaging Violations	4.08	1.37 - 12.15	0.012	3.20	1.74 - 5.89	<0.001
G	Cooking Equipment	2.91	1.19 - 7.14	0.020	2.20	1.25 - 3.88	0.006
H	Dishwashing & Utensil Violations	1.75	0.64 - 4.78	0.272	1.71	0.96 - 3.04	0.070
I	Test Equipment	1.41	0.60 - 3.32	0.428	3.27	1.83 - 5.85	<0.001
J	Maintenance / Sanitation	3.71	1.72 - 8.01	0.001	1.87	1.03 - 3.38	0.039
K	Staff Hygiene Violations	5.59	1.84 - 16.97	0.002	4.17	1.71 - 10.16	0.002
L	Hand Sink Violations	1.21	0.52 - 2.81	0.660	1.83	1.01 - 3.32	0.047
O	Food Manager Certification	1.00	0.10 - 9.91	1.000	6.32	1.13 - 35.31	0.036
Q	Washroom Sanitation/Maintenance	1.21	0.23 - 6.52	0.823	1.45	0.56 - 3.72	0.443
Z	Other Violation (C+M+N+O+P)	0.65	0.13 - 3.14	0.590	2.00	0.89 - 4.48	0.093
	Any Violation	2.04	0.90 - 4.59	0.086	2.74	1.28 - 5.89	0.010
	Public Complaint(s)	3.85	1.64 - 9.04	0.002	2.99	1.63 - 5.48	<0.001
	Food Safety Program (FSP)	6.46	2.89-14.45	<0.001	20.71	5.81-73.80	<0.001

Table 5.2.12 Univariate logistic regression of categorical independent variables.

Categorical Data	Class II (n = 152)				Class III (n = 268)			
Violation Set and Description	N	O.R.	95% C.I.	p-value	N	O.R.	95% C.I.	p-value
A Temperature Control Violations								
0	112	1.00			158	1.00		
1	27	1.47	0.57 - 3.74	0.425	33	2.69	1.13 - 6.41	0.026
2-3	10	2.32	0.61 - 8.87	0.219	50	2.91	1.38 - 6.13	0.005
4-5	3	--	--	--	17	11.33	3.80 - 33.77	<0.001
6+	0	--	--	--	10	24.73	4.93 - 124.15	<0.001
B Cross-contamination								
0	136	1.00			212	1.00		
1	8	1.08	0.21 - 5.63	0.924	23	1.72	0.67 - 4.44	0.263
2-3	6	6.50	1.14 - 37.14	0.035	23	2.53	1.03 - 6.23	0.044
4-5	1	--	--	--	5	5.90	1.00 - 36.39	0.056
6+	1	--	--	--	5	x	x	x
D Infestation Pest/Vermin								
0	146	1.00			238	1.00		
1	5	2.14	0.34 - 13.17	0.422	14	6.44	2.07 - 20.04	0.001
2-3	1	--	--	--	10	0.89	0.18 - 4.34	0.890
4-5	0	--	--	--	6	7.15	1.28 - 40.15	0.025
6+	0	--	--	--	0	--	--	--
E Chemical & Biological Hazards								
0	144	1.00			249	1.00		
1	7	2.43	0.52 - 11.38	0.261	12	4.94	1.51 - 16.17	0.008
2-3	1	--	--	--	5	5.29	0.86 - 32.46	0.072
4-5	0	--	--	--	2	--	--	--
6+	0	--	--	--	0	--	--	--
F Food Storage / Packaging Violations								

0	137	1.00			206	1.00		
1	8	5.94	1.34 - 26.31	0.019	30	2.08	0.90 - 4.78	0.086
2-3	5	2.38	0.38 - 14.89	0.355	22	3.46	1.40 - 8.57	0.007
4-5	1	--	--	--	7	5.53	1.19 - 25.71	0.029
6+	1	--	--	--	3	--	--	--
G Cooking Equipment								
0	127	1.00			177	1.00		
1	11	0.82	0.17 - 4.04	0.810	37	1.12	0.47 - 2.66	0.799
2-3	11	6.48	1.77 - 23.78	0.005	34	2.84	1.31 - 6.18	0.008
4-5	1	--	--	--	14	1.62	0.48 - 5.48	0.436
6+	2	--	--	--	6	x	x	x
H Dishwashing & Utensil Violations								
0	132	1.00			184	1.00		
1	11	1.22	0.31 - 4.89	0.777	42	1.44	0.68 - 3.07	0.344
2-3	5	2.17	0.35 - 13.59	0.407	29	1.62	0.69 - 3.83	0.272
4-5	2	--	--	--	7	0.60	0.07 - 5.13	0.641
6+	2	--	--	--	6	18.00	2.04 - 158.51	0.009
I Test Equipment Missing								
0	119	1.00			189	1.00		
1	20	1.08	0.36 - 3.25	0.886	32	2.39	1.05 - 5.41	0.037
2-3	11	1.22	0.30 - 4.91	0.781	30	2.28	0.98 - 5.31	0.056
4-5	2	--	--	--	11	12.16	3.07 - 48.22	<0.001
6+	0	--	--	--	6	9.12	1.60 - 51.82	0.013
J Maintenance / Sanitation Violations								
0	92	1.00			109	1.0		
1	20	2.39	0.79 - 7.27	0.125	36	1.07	0.41 - 2.80	0.884
2-3	26	2.95	1.10 - 7.92	0.032	51	1.09	0.47 - 2.53	0.849
4-5	8	9.29	1.99 - 43.33	0.005	32	1.74	0.70 - 4.33	0.233
6+	6	11.14	1.86 - 66.75	0.008	40	4.92	2.24 - 10.81	<0.001
K Staff Hygiene Violations								
0	137	1.00			246	1.00		
1	12	3.72	1.12 - 12.41	0.032	16	3.47	1.25 - 9.68	0.017
2-3	2	--	--	--	4	--	--	--

4-5	1	--	--	--	1	--	--	--
6+	0	--	--	--	1	--	--	--
L Hand Sink Violations: Kitchen								
0	116	1.00			197	1.00		
1	24	0.83	0.28 - 2.42	0.729	35	1.64	0.75 - 3.62	0.219
2-3	7	2.36	0.50 - 11.17	0.280	28	1.43	0.59 - 3.48	0.427
4-5	4	--	--	--	8	5.97	1.37 - 25.98	0.017
6+	1	--	--	--	0	--	--	--
Q Washroom Sanitation / Maintenance								
0	145	1.00			246	1.00		
1	3	--	--	--	10	1.33	0.33 - 5.30	0.687
2-3	3	--	--	--	9	1.55	0.38 - 6.39	0.544
4-5	0	--	--	--	2	--	--	--
6+	1	--	--	--	1	--	--	--
Z Other Violation (C+M+N+O+P)								
0	140	1.00			239	1.00		
1	7	x	x	x	12	1.09	0.29 - 4.16	0.900
2-3	3	--	--	--	10	4.90	1.34 - 17.99	0.017
4-5	2	--	--	--	6	0.65	0.08 - 5.71	0.701
6+	0	--	--	--	1	--	--	--
Inspection Frequency								
Expected	78	1.00			156	1.00		
Below Expected	42	0.85	0.36 - 2.02	0.710	41	0.09	0.01 - 0.70	0.021
Higher Than Expected	27	0.78	0.28 - 2.19	0.631	49	2.16	1.08 - 4.34	0.030
Much Higher Than Expected	5	0.68	0.07 - 6.42	0.735	22	7.99	3.01 - 21.20	<0.001

(x) = insufficient data in one or more cells resulting in unstable estimates
(--) = less than five facilities; estimates not reported

The results of the descriptive and univariate analysis for each violation category (or set) are summarized in the following sections. The mean, standard deviation, and range were calculated for both case and control groups in each facility class. Values presented are only representative of food establishments with the violation. Associations between BP-SFBI and each violation set were calculated by analyzing two-by-two tables using Fisher's Exact Test. Analysis of independent dichotomous and categorical data was also conducted using univariate logistic regression.

5.2.2.1 Temperature control violations

Eight critical violations were combined to form this category: improper "*thawing of food*"; improper "*chilling of food*"; inadequate "*reheating of food*"; inadequate "*hot holding of food*"; "*perishable food at room temperature*"; "*cold display of food*"; "*cold storage of food*"; and "*freezer temperature*". None of these violations were significantly associated with foodborne illness for Class II food establishments [Table 5.2.6]. Different results are reported for Class III eateries, where *inadequate hot holding of food* (p=0.012), *improper thawing of food* (p=0.005), *improper chilling of food* (p=0.002), *perishable food at room temperature* (p<0.001), and *cold storage of food* (p<0.001) were each significantly associated with disease outcome [Table 5.2.7].

Forty Class II food establishments had one or more temperature control violations cited within the critical period: 13/38 cases and 27/114 controls [Table 5.2.8]. In Class II food establishments where temperature control violations were found, they were cited a mean of 1.6 (S.D. ± 1.12) times, and a range of one to five times if the facility was a case. For food establishments *without* a BP-SFBI, temperature control violations were cited a mean of 1.5(±1.01), and a range of one to five times. Temperature control violations were *not* found to be significantly associated with food poisoning in Class II eateries at the univariate level using Fisher's Exact Test [Table 5.2.10] or logistic regression [Table 5.2.11; Table 5.2.12].

Descriptive statistics for Class III food establishments are presented in Table 5.2.9. One-hundred ten eateries had one or more temperature control violations cited within the critical period: 45/67 cases and 65/201 controls. In Class III facilities where temperature control violations were found, they were cited a mean of 4.5(±6.99) times, and a range of one to 47 times. Without a food poisoning, temperature control violations were cited a mean of

2.1(±1.52) times, and a range of one to eleven times. Temperature control violations were significantly associated with disease outcome in Class III eateries [p<0.001; Table 5.2.10]. The odds of having a BP-SFBI with one or more temperature control violations cited in the past 12 months was over four times higher when compared to facilities with no such violations [OR=4.28; 95%CI: 2.37-7.72, p<0.001 (Table 5.2.11)]. Taken as a categorical variable, having more temperature control violations was associated with an increased risk of having a BP-SFBI [Table 5.2.12].

5.2.2.2 Cross-contamination violations

This violation set is comprised of five critical violations: "*improper food handling*"; "*food contact surfaces unsanitary, unsuitable for the purposes intended, or in disrepair*"; "*improper refrigeration storage practices*"; "*cleaning cloths unsanitary*"; and "*unrelated tasks performed by a food handler*". While none of these violation codes were significantly associated with foodborne illness for Class II food establishments [Table 5.2.6], *improper food handling* (p=0.012) and *refrigeration storage* (p=0.041) were each significantly associated with BP-SFBIs for Class III food establishments [Table 5.2.7].

Sixteen Class II food establishments had one or more cross-contamination violations cited within the critical period: 6/38 cases and 10/114 controls [Table 5.2.8]. In food establishments where cross-contamination violations were found, they were cited a mean of 2.0(±0.89) times, and a range of one to three times over a 12-month period – assuming the facility was a case. Such violations were cited a mean of 2.1(±1.96), and a range of one to seven times if the facility was a control. Cross-contamination violations were <u>not</u> significantly associated with disease outcome using Fisher's Exact Test [Table 5.2.10]. As a dichotomous variable, cross-contamination violations similarly failed to achieve statistical significance in univariate logistic regression [Table 5.2.11]. Taken as a categorical variable, more cross-contamination violations were associated with an increased risk of having a BP-SFBI, though in some range categories this association failed to achieve statistical significance [Table 5.2.12]. For example, Class II food establishments with two to three cross-contamination citations in the past year were 6.5 times more likely to have a BP-SFBI than Class II food establishments without such violations [Table 5.2.12].

Different results are reported for Class III food establishments. Fifty-six eateries had one or more cross-contamination violations cited within the critical period: 24/67 cases and 32/201 controls. In facilities with a BP-SFBI, cross-contamination violations were cited a mean of 3.4(±2.89) times, and a range of one to eleven times. Without a food poisoning, cross-contamination violations were cited a mean of 1.7(±0.89) times, and a range of one to four times. In univariate analysis, cross-contamination violations were found to be significantly associated with disease outcome [p=0.001; Table 5.2.10]. Class III food establishments with one or more cross-contamination violations cited in the past 12 months were nearly three times more likely to have a BP-SFBI than facilities of the same class without such violations [OR=2.95; 95%CI: 1.58-5.51, p<0.001]. Taken as a categorical variable, more cross-contamination violations were associated with an increased risk of having a BP-SFBI. Similar to Class II food establishments, however, this association failed to achieve statistical significance in some range categories [Table 5.2.12].

5.2.2.3 Infestation of insects or vermin

This critical violation was not combined with any other violation code. Six Class II food establishments had pest control violations cited one or more times within the critical period [Table 5.2.8]. In the three Class II food establishments where evidence of insects or vermin was found, the violation was cited a mean of 1.3 (±0.58) times and a range of one to four times over a 12-month period. The violation was not cited more than once in any of the Class II controls.

Thirty Class III eateries had one or more pest control problems cited within the critical period: 15/67 cases and 15/201 controls. In Class III food establishments where pest control violations were found, they were cited with similar frequency in case and control groups [2.0(±1.36) and 1.9(±0.96) respectively; Table 5.2.8 and Table 5.2.9].

An infestation of insects or vermin was significantly associated with BP-SFBI for Class III food establishments [Table 5.2.10]. A similar association was not observed for Class II eateries. Results of univariate logistic regression reveal Class III food establishments with one or more pest control violations cited in the past 12 months were 3.6 times more likely to have a BP-SFBI than those assessed over the same time period without insect or vermin infestations [OR=3.58; 95%CI: 1.64-7.80, p<0.001]. A similar odds ratio was observed for

Class II food establishments, but it failed to achieve statistical significance [OR=3.17; 95%CI: 0.61-16.43, p>0.05]. Taken as a categorical variable, a stronger association was found in Class III food establishments with pest control violations cited four to five times per year than in restaurants of similar class that only had the violation cited once in a 12-month period (see Table 5.2.10).

5.2.2.4 Chemical & biological hazards

This violation set is comprised of two critical ("*poison storage*" and "*poison use*") and one non-critical violation ("*garbage containment*"). None of these violations were significantly associated with foodborne illness for Class II food establishments [Table 5.2.6]. However, *poison storage* (p=0.012) and *poison use* (p=0.025) were each significantly associated with BP-SFBIs for Class III food establishments [Table 5.2.7].

In Class II eateries, four out of 38 cases, and four out of 114 controls had one or more chemical or biological hazards cited within the critical period. In food establishments where evidence of chemical or biological hazards were found, they were cited a mean of 1.5 (±1.00) times, and a range of one to three times in a 12-month period – assuming the establishment was a *case*. Controls receiving this kind of violation did so no more than once in the study period.

Although the odds of having a BP-SFBI was three times higher in Class II facilities with one or more *Chemical & Biological Hazards* cited in the past 12 months, this association did not achieve statistical significance [OR=3.24; 95%CI: 0.77-13.36, p>0.05]. This finding is supported by the results of the Fisher's Exact Test, which similarly failed to demonstrate that *Chemical & Biological Hazards* were significantly associated with disease outcome [Table 5.2.10]. Insufficient data were available to analyze *Chemical & Biological Hazards* as a categorical variable for Class II eateries [Table 5.2.12]. Consequently, the relationship between having several of these violations cited over a 12-month period and BP-SFBI could not be assessed.

Nineteen Class III eateries had one or more *Chemical & Biological Hazards* cited within the critical period: 12/67 cases and 7/201 controls. In facilities with a BP-SFBI, *Chemical & Biological Hazards* were cited a mean of 2.0(±1.53) and a range of one to five times.

Without a food poisoning, *Chemical & Biological Hazards* were cited an average of 1.3(±0.49) and a range of one to two times in facilities where this violation was found [Table 5.2.9]. *Chemical & Biological Hazards* were determined to be significantly associated with disease outcome [Table 5.2.10]. Class III food establishments with *Chemical & Biological Hazards* cited in the past 12 months were six times more likely to have a BP-SFBI when compared to facilities without violations of this kind [OR=6.05; 95%CI: 2.27-16.10, p<0.001]. Taken as a categorical variable, more *Chemical & Biological Hazards* were associated with an increased risk of having a BP-SFBI in Class III facilities, though this association failed to achieve statistical significance [Table 5.2.12].

5.2.2.5 Food storage / packaging violations

This violation set is comprised of two critical violations (*unacceptable food packaging, unacceptable food containers*) and five non-critical violations (*inadequate storage space for food products, failure to provide separate storage space for food and non-food items, food storage area incursions, bulk food storage* and *food storage in bathrooms or lavatories*). None of the individual violations were significantly associated with foodborne illness for Class II food establishments [Table 5.2.6]. For Class III food establishments, however, *unacceptable containers* (p=0.006), *adequate storage space* (p=0.015), *unacceptable packaging* (p=0.027) and *separate storage space* (p=0.043) were each significantly associated with disease outcome [Table 5.2.7].

A greater percentage of facilities with a BP-SFBI had *Food Storage/Packaging Violations* compared to controls regardless of facility class [Table 5.2.10]. Looking specifically at those establishments that were found to have *Food Storage/Packaging Violations*, the number of times they were cited in the Class II facilities was often greater in the control group than the case group. This is reflected in the mean and range values [Table 5.2.8]. The opposite was found for Class III food establishments [Table 5.2.9].

Class III food establishments with one or more food storage / packaging violations cited in the past 12 months were 3.2 times more likely to have a BP-SFBI when compared to facilities of the same class without such problems [OR=3.20; 95%CI: 1.74-5.89, p<0.001]. Taken as a categorical variable, more food storage violations were associated with an increased risk of having a BP-SFBI, though in the lowest category this association failed to achieve statistical significance (see Table 5.2.12). A similar association between BP-SFBIs and *Food Storage/Packaging Violations* was also found for Class II food establishments. Facilities with these violations were four times more likely to have a food poisoning when compared to establishments of equal class without food storage / packaging problems [OR=4.076; 95%CI:1.367-12.150, p<0.01]. As a categorical variable, this association was only found to be statistically significant if the violation was cited on one occasion in the past 12 months (see Table 5.2.12).

5.2.2.6 Cooking equipment violations

This violation set comprised of four non-critical violations: *ventilation deficiencies*, *food equipment in disrepair*, *food equipment unsanitary*, and *damaged dishes / utensils*. Food equipment being in disrepair was significantly associated with foodborne illness for both Class II and Class III food establishments [p=0.014 and p<0.001 respectively]. Unsanitary food equipment was also significantly associated with BP-SFBIs, but only for Class III food establishments [p=0.026; Table 5.2.7].

Twenty-five Class II and 91 Class III food establishments had one or more equipment violations cited within the critical period. In food establishments where evidence of equipment problems was found, they were cited with greater frequency in facilities *with* a BP-SFBI compared to controls. These are reflected in the mean and range estimates presented in Tables 5.2.8 and 5.2.9.

Cooking equipment violations were significantly associated with disease outcome in both Class II and Class III facilities [p=0.023 and p=0.007 respectively; Table 5.2.10]. The odds of having a BP-SFBI in a Class III food establishment with one or more equipment violations cited in the past 12 months was 2.2 times higher than eateries of the same class without equipment problems [OR=2.20; 95%CI: 1.25-3.88, p<0.01]. A similar association was found for Class II food establishments, though in this instance facilities with cooking equipment violations were 2.9 times more likely to have a BP-SFBI identified [OR=2.91; 95%CI: 1.19-7.14, p<0.05].

Taken as a categorical variable, more cooking equipment violations were associated with an increased risk of having a BP-SFBI for both Class II and III food establishments, though this association often failed to achieve statistical significance [Table 5.2.12].

5.2.2.7 Dishwashing and utensil violations

Seven non-critical violations were combined to form this violation set: *dipper well* (off or absent), *dishes/utensils unclean*, *dishes/utensils improperly stored*, *single service utensils reused*, *manual dishwashing practices incorrect*, *mechanical procedures* (meaning the dishwasher was not adequately sanitizing dishes or utensils), and *dishwasher in disrepair*. *Improper manual dishwashing procedures* were significantly associated with foodborne illness for Class II food establishments (p=0.016) but not for Class III. An ineffective dipper well was not found in any Class II food establishment, or Class III control within the critical period. As a result, this violation was significantly associated with BP-SFBIs, but only for Class III food establishments [p<0.001; Table 5.2.7]. No other violation in this set was significantly associated with food poisoning for either facility class.

Twenty Class II food establishments had one or more dishwashing or utensil violations cited within the critical period: 7/38 cases and 13/114 controls. The mean and range that improper dishwashing / utensil violations were cited in Class II food establishments was similar in case and control groups [Table 5.2.8]. In Class III facilities, mean and range estimates differed [Table 5.2.9] – the higher being in food establishments where food poisonings were identified. Eighty-four Class III eateries had one or more dishwashing / utensil violations: 27/67 cases and 57/201 controls.

The odds of having a BP-SFBI did not appear to increase with the identification of violations of this kind: Class II or III food establishments with one or more dishwashing or utensil violations cited in the past 12 months were not significantly more likely to have a food poisoning than facilities of equal class without dishwashing or utensil violations (p>0.05). Nevertheless, the odds ratios and 95% confidence intervals did appear to increase as more violations of this type were reported (see Table 5.2.12).

5.2.2.8 Test equipment violations

Three violation codes were combined into this category. Thermometers are required in restaurants to monitor temperatures of coolers and hot hold units. It is a critical violation if they are absent. Two separate violation codes are used to track infractions dealing with the test equipment that is required to monitor the sanitizing cycle of commercial dishwashers. Both are considered non-critical violations. Test papers are used to measure the concentration of chemical sanitizer in low temperature machines. A gauge is used to determine the temperature of the rinse water in high-temperature machines. Both techniques perform the same function in that they inactivate pathogens that may exist on the surfaces of dishes, utensils and other equipment.

Of the test equipment violations, only *missing thermometers for coolers and/or hot holding units* was found to be significantly associated with foodborne illness for Class III food establishments ($p<0.001$). A similar association was *not* observed for Class II establishments. The remaining test equipment violations were not significantly associated with BP-SFBI for either facility class.

Twenty Class II and 79 Class III eateries had one or more *testing equipment violations* cited within the critical period [Tables 5.2.8 and 5.2.9]. Mean and range estimates differed between case and control groups, and for the respective facility classifications – the higher being in Class III food establishments, and in eateries where food poisonings were identified (*cases).*

Test equipment violations were not significantly associated with disease outcome in Class II facilities [Table 5.2.10]. Class II food establishments with one or more test equipment violations cited in the past 12 months were not more likely to have a BP-SFBI than facilities without them [Table 5.2.11]. The opposite is true for Class III facilities, where the odds of having a BP-SFBI was determined to be over *three times higher* for facilities with test equipment violations when compared to food establishments without them [OR=3.27; 95%CI: 1.83-5.85, $p<0.001$]. Taken as a categorical variable, more test equipment violations were associated with an increased risk of having a BP-SFBI for both Class II and III food establishments, though in some range categories this association failed to achieve statistical significance (see Table 5.2.12).

5.2.2.9 Maintenance / sanitation violations

Data from seven non-critical violations was combined into this category: the *structural maintenance* and *general sanitation* of floors, walls & ceilings; *shelving* (insufficient, unsuitable or in disrepair); *dirty non-food contact surfaces*; *damaged or absent screen doors / weather stripping*; *insufficient water supply*; and *plumbing maintenance*. Descriptive analyses of each variable are presented in Tables 5.2.6 and 5.2.7. Using Fisher's Exact Test, *structural problems* with the floors/walls/ceilings (p=0.003), *missing screens or weather stripping* (p=0.014), and *dirty non-food contact surfaces* (p=0.019) were each significantly associated with foodborne illness for Class II food establishments [Table 5.2.6]. In Class III food establishments, *floors, walls & ceilings (sanitation)* (p=0.009); *floors, walls & ceilings (structural)* (p=0.001); and *plumbing maintenance* (p<0.001) were each significant [Table 5.2.7].

Irrespective of group allocation or facility class, maintenance and sanitation violations were cited with the greatest frequency. Sixty Class II and 159 Class III food establishments had one or more maintenance / sanitation violations cited . In food establishments where maintenance / sanitation violations were found, mean and range estimates differed between case and control groups, and between the respective facility classifications. The highest mean and range scores were found in Class III food establishments, and in eateries where food poisonings were identified.

Having one or more maintenance / sanitation violations cited in the past 12 months was significantly associated with a BP-SFBI for both Class II and III food establishments (p=0.001 and p=0.044 respectfully). For a Class II food establishment, the odds of having a BP-SFBI was 3.7 times higher in facilities with one or more maintenance / sanitation violations than ones without maintenance or sanitation problems [OR=3.71; 95%CI: 1.72-8.01, p=0.001]. Class III eateries with maintenance / sanitation violations were nearly twice as likely to have a BP-SFBI when compared to those without such problems [OR=1.87; 95%CI: 1.03-3.38, p<0.05]. As a categorical variable, more maintenance / sanitation violations were associated with an increased risk of having a BP-SFBI for both Class II and III food establishments, though this association often failed to achieve statistical significance [Table 5.2.12].

5.2.2.10 Staff hygiene violations

Four violation codes were combined into this category: "*hand washing*"; "*personal hygiene*"; "*food worker clothing*" and "*food worker hair control*". *Hand washing* and *personal hygiene* are both critical violations. The first is cited if a food handler fails to wash their hands at the start of their shift; before handling ready-to-eat food; after smoking, eating, going to the restroom, or handling any item in the kitchen that may contaminate their hands (such as money, dirty dishes or other soiled surfaces, garbage, or raw meat/poultry/seafood). Personal hygiene violations are cited if the food handler is discovered smoking while preparing food, or fails to wear gloves over cuts, rashes, or sores on their hands while preparing food. *Food handler clothing* and *hair control* are both non-critical violations. Employee clothing violations are commonly cited if garments are soiled, if aprons or uniforms are not being worn, or if food handlers are not removing jewellery when preparing food. Food handlers must ensure their hair is effectively under control at all times to prevent the inadvertent contamination of their hands, or physical contamination of food by loose hair follicles. This can be accomplished with the use of hair nets, hats, elastics, or hair style.

Of the staff hygiene violations, only *hand washing* was significantly associated with foodborne illness for both Class II (p<0.001) and Class III (p=0.002) food establishments (see Tables 5.2.6 and 5.2.7 respectively). *Food handler clothing* was also marginally associated with food poisoning (p=0.049) for Class III food establishments, but not for Class II. The remaining staff hygiene violations were not significantly associated with BP-SFBI for either facility class.

As a set, staff hygiene violations were significantly associated with BP-SFBIs (p=0.003) and did not vary by facility class [Table 5.2.10]. Univariate LR analysis revealed that Class II food establishments with one or more staff hygiene violations cited were 5.6 times more likely to have a BP-SFBI than facilities without staff hygiene violations [OR=5.59; 95%CI: 1.84-16.97, p<0.01]. A similar relationship is reported for Class III food establishments, where the odds of having a BP-SFBI was over four times higher for facilities with one or more staff hygiene violations cited compared to those without [OR=4.17; 95%CI: 1.71-10.16, p<0.01]. Insufficient data was available to determine if more staff hygiene violations corresponded to an increased likelihood of foodborne illness for either facility class [Table 5.2.12].

5.2.2.11 Hand sink violations (kitchen)

Two violation codes were combined into this category: "*hand washing supplies*" and "*wash basin missing or inaccessible*". *Hand washing supplies* is cited in instances where soap and/or single-use towels are not available for food handlers to use at the dedicated hand washing sink. The other violation is cited when the hand basin is not accessible, or has been removed. Descriptive data for each of these variables are presented in Tables 5.2.6 and 5.2.7. Individually, failing to provide *an accessible hand sink* or *a hand sink properly equipped with soap and single-use towels* were not significantly associated with BP-SFBI for either facility class. A similar relationship between hand sink violations (as a set) and BP-SFBI in Class II food establishments was also observed [Table 5.2.8]. Hand sink violations were marginally associated with disease outcome in Class III facilities [$p=0.055$; Table 5.2.9].

Fifteen Class II and 22 Class III eateries had one or more *hand sink violations* cited within the critical period [Tables 5.2.8 and 5.2.9]. In restaurants where hand sink violations were found, the number of times *hand sink violations* were cited was only slightly greater in restaurants with a BP-SFBI in comparison to controls. This is reflected in the mean and range values presented in Tables 5.2.8 and 5.2.9.

The odds of having a BP-SFBI was not significantly greater in Class II food establishments with one or more hand sink violations when compared to facilities without the violation assessed over the same time period [Table 5.2.11]. In Class III food establishments, those facilities having one or more test equipment violations cited in the past 12 months were nearly *twice* as likely to have a BP-SFBI than food establishments with none cited [OR=1.83; 95%CI: 1.01-3.32, $p<0.05$]. Taken as a categorical variable, more hand sink violations were associated with an increased risk of having a BP-SFBI, though this effect failed to achieve statistical significance in most category ranges [Table 5.2.12].

5.2.2.12 Public washrooms: sanitation and maintenance

The public often gauges the cleanliness and safety of a food establishment by looking at the public restrooms. Two non-critical violation codes were combined into this category: *washroom maintenance* and *washroom sanitation*. The terms are self-explanatory.

Seven Class II and twenty-two Class III food establishments had one or more public washroom violations cited within the critical period. In Class II food establishments where such violations were found, they were cited a mean of 3.5(±3.53) times in eateries with a BP-SFBI, and 1.8(±0.84) times in eateries without a BP-SFBI [Tables 5.2.8 and 5.2.9]. In Class III facilities, problems with public washrooms were cited 2.3(±1.3) times on average if the facility was a case, and 2.1(±1.5) times if the place was a control.

No public washroom violation was found to be significantly associated with BP-SFBI for either facility class using Fisher's Exact Test [$p>0.05$; Table 5.2.10]. Moreover, the odds of having a BP-SFBI was not significantly higher in Class II or III food establishments with one or more public washroom violations cited in the past 12 months when compared to food establishments of the same class without the violation [Table 5.2.11]. More public washroom violations were associated with an increased odds of having a BP-SFBI for Class III food establishments, though this association failed to achieve statistical significance in any category range [Table 5.2.12]. Washroom violations were not cited more than once in any Class II food establishment.

5.2.2.13 Other violations

Violation sets cited in fewer than 25 food establishments within the 12-month observation period were combined into a single category for analysis purposes [Table 5.2.10]. "*Other violations*" is comprised of three critical and four non-critical violations. Critical violations included: "*food unfit for human consumption*" (a violation cited when rotten, expired, or unwholesome foods are found), "*customer contamination of food*", and "*improper food labelling*". Non-critical violations included in this category were: "*nuisance*", "*food transportation (unsanitary)*", and "*food manager certification*" (a violation cited when no person in a supervisory role has food safety training in a premises where it is required).

Individually, none of the violations making up this category were significantly associated with BP-SFBI in Class II food establishments. *Food manager certification* was significantly associated with the outcome of interest for Class III facilities [$p=0.036$; Table 5.2.7]. As a set, *other violations* were not significantly associated with identified food poisonings in either Class II or Class III eateries [Table 5.2.10].

Having one or more “other violations” cited in the past year was *not* found to significantly increase the odds of BP-SFBI when compared to facilities without these violations [Table 5.2.11]. This said, the odds of having a BP-SFBI in a Class III food establishment with one or more *food manager certification* violations cited in the past 12 months was over 6 times higher than eateries without the violation [OR=6.32; 95%CI: 1.13-35.31, $p<0.05$]. *Food manager certification* was not analyzed as a categorical variable because of insufficient data. As a combined category, *other violations* were found to be associated with an increased risk of having a BP-SFBI as the number of times they were cited in the past 12 months increased. This association was observed for Class III food establishments, but only between the first and second categories [Table 5.2.12]. A similar association could not be determined for Class II food establishments because data was too sparse.

5.2.3 Food safety program (FSP)

The presence of a FSP was measured as a dichotomous variable. Regardless of facility class, the presence of a FSP was significantly associated with food establishments where a BP-SFBI was identified: χ^2=23.206 at 1df ($p<0.0001$) for Class II eateries, and χ^2=38.237 at 1df ($p<0.0001$) for Class III [Tables 5.2.6 and 5.2.7 respectively]. The odds of identifying a BP-SFBI in a Class II food establishment with a FSP was over six times more likely than in a similar facility without such a program [OR=6.46; 95%CI: 2.89-14.45, $p<0.001$]. An even greater association was found for Class III food establishments, where commercial eateries with a FSP were 20 times more likely to have a food poisoning identified than ones without such a program [OR=20.71; 95%CI: 5.81-73.80, $p<0.001$] (see Table 5.2.11).

5.2.4 Public complaints

Having one or more *public complaints* cited in the past year was found to be strongly associated with Class II and Class III food establishments that subsequently had a BP-SFBI identified [χ^2=10.355 at 1 df; p=0.003 (Table 5.2.6) and χ^2=13.247 at 1 df; $p<0.001$ (Table 5.2.7) respectively]. At the univariate level (using logistic regression), the odds of having a BP-SFBI was 3.8 times higher in a Class II food establishment with one or more consumer complaints during the past 12 months when compared to a similar facility with no public complaints [OR=3.85; 95%CI: 1.64-9.04, $p<0.01$]. A similar association was found for Class III food establishments, where food establishments with a complaint in the past year were nearly 3 times more likely to have a BP-SFBI than facilities without a complaint [OR=2.99; 95%CI: 1.63-5.48, p<0.001] (see Table 5.2.11).

5.2.5 Enforcement

Enforcement action in the preceding 12 months was not found to be a significant predictor of foodborne illness. Only one food establishment (a case) had an executive officer's order (EOO) issued within the 12-month observation period. No other enforcement actions in either the case or control groups were noted.

5.2.6 Number of different violations cited

Aside from specific violation codes, the number of *different* violations a food establishment received within the study period was also analyzed. Class II food establishments received a mean of 2.4(±2.89) different violations within the 12-month observation period; the range being zero to 15 and the median being one. Class III food establishments received a mean of 4.4(±4.76) different violations, the range being zero to 26 and the median being three.

Table 5.2.13 The breakdown of distinct violation codes observed in Class II and Class III food establishments within the 12-month critical period (n=1,531).

# of different violations	Class II % Case (n=38)	 % Control (n=114)	 % Total (n=152)	Class III % Case (n=67)	 % Control (n=201)	 % Total (n=268)
0	26.3	42.1	38.2	13.4	29.9	25.7
1 to 3	31.6	36.0	34.9	25.4	29.4	28.4
4 to 6	23.7	15.8	17.8	12.0	22.9	20.2
7 to 9	7.9	6.2	6.6	15.0	9.5	10.9
10 to 15	10.4	0.0	2.8	22.4	8.0	11.5
16 or more	0.0	0.0	0.0	11.9	0.5	3.4

The number of different violations cited was divided into six categories for analysis purposes. Each facility class was independently assessed. A wider variety of violations was found in Class III food establishments rather than Class II. Nearly 75% of Class II food establishments had fewer than four different violations cited, compared to 54% of Class III facilities. Class III food establishments were the only facilities to receive greater than 16 different violations in a single year. They also had more food establishments with 10-15 different violations than their Class II counterparts (Figures 5.2.6 through 5.2.9). The highest number of distinct violations was reported in Class III eateries with a BP-SFBI. Controls had the fewest violations, regardless of facility classification.

Figure 5.2.4 The number of different violations observed in Class II food establishments with a BP-SFBI (cases).

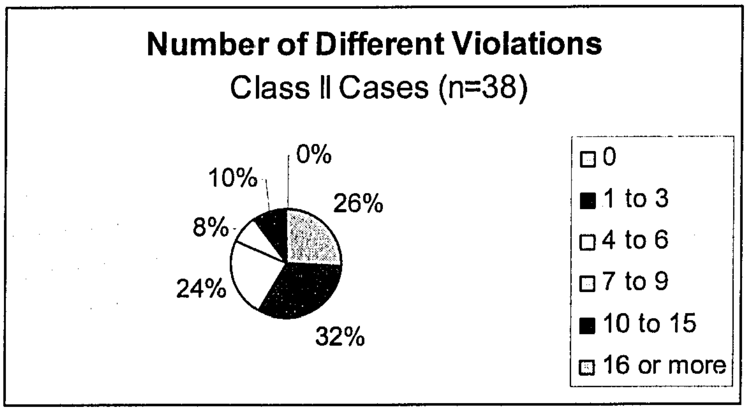


Figure 5.2.5 The number of different violations observed in Class II food establishments without a BP-SFBI (controls).

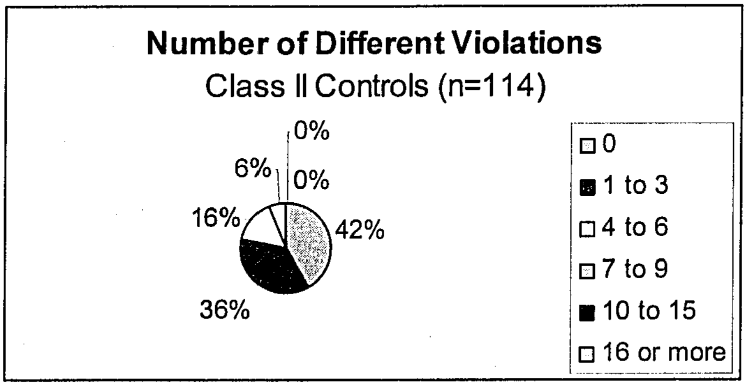


Figure 5.2.6 The number of different violations observed in Class III food establishments with a BP-SFBI (cases).

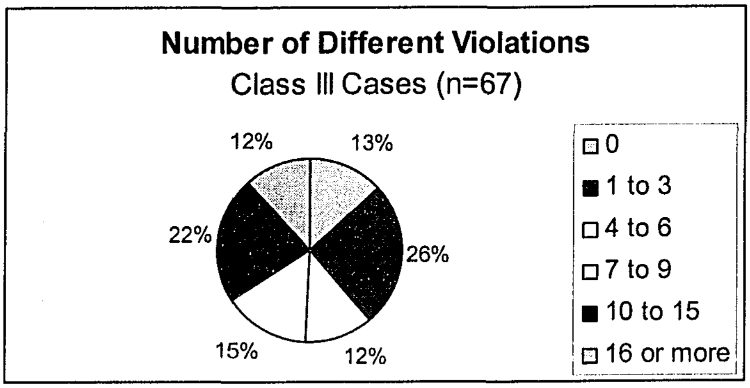
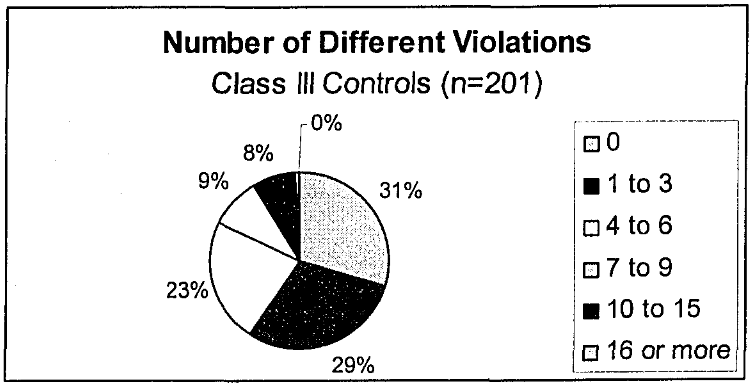


Figure 5.2.7 The number of different violations observed in Class III food establishments without a BP-SFBI (controls).



In univariate analysis, the number of different violations cited in the past year was found to be significantly associated with BP-SFBI for Class III food establishments [χ^2=47.217; p=0.001 at 22 df], but not for Class II food establishments [χ^2=19.197; p=0.097 at 13 df]. As was the case for "*Any Violation*", the "*Number of Different Violations*" was not included as a variable for the final model in multivariate analysis.

5.3 Multivariate analysis

Class II and Class III food establishments were independently assessed using logistic regression. Violation sets cited in fewer than 25 food establishments were combined into a single violation category (Z) for model building purposes. These included violation sets C, M, N, O and P (see Table 4.5.2). Dichotomous variables found to be significant to $p<0.25$ in univariate analysis were selected for the multivariate model. Purposeful selection was then used to determine which dichotomous and categorical variables fit into the final model for each facility class (refer to methods section). Results of this analysis are presented for the respective facility classifications in the sections below.

5.3.1 Class II food establishments

5.3.1.1 Development of final model

Independent dichotomous variables significant to $p<0.25$ in univariate analysis, and used for model building purposes for Class II food establishments, included *public complaints* and *violation sets* A, B, D, E, F, G, J and K. No categorical variables were used because of insufficient sample size, which resulted in "zero cell problems" in one or more of the category range when used. Variables considered for multivariate analysis for Class II food establishments are presented in Table 5.3.1. To test if these factors taken together were significantly associated with foodborne illness, they were fit into a multivariate model.

Table 5.3.1 Independent variables selected for multivariate analysis (Class II)

	Univariate LR		
Variable	**O.R.**	**95%CI**	***p-value***
Maintenance / Sanitation Violations(J)	3.71	1.72-8.01	0.001
Staff Hygiene Violations (K)	5.59	1.84-16.97	0.002
Public Complaints	3.85	1.64-9.04	0.002
Food Storage / Packaging Violations(F)	4.08	1.14-12.15	0.012
Cooking Equipment Violations(G)	2.91	1.19-7.14	0.020
Chemical & Biological Hazards (E)	3.24	0.77-13.63	0.110
Infestation Pests / Vermin (D)	3.17	0.61-16.43	0.169
Temperature Control Violations (A)	1.68	0.76-3.72	0.204
Cross-contamination Violations (B)	1.95	0.66-5.78	0.228

Collectively, independent variables significant to $p<0.25$ in univariate analysis were found to be significantly associated with identified cases of foodborne illness in Class II establishments [$\chi^2=26.422$; p=0.002 at nine degrees of freedom]. Alternatively, the "Omnibus Test of Model Coefficients" from SPSS may also be used to assess this relationship [$\chi^2=24.621$; p=0.003 at nine degrees of freedom].

Looking at the p-value for each independent variable after being fit into the multivariate model (Table 5.3.2), it is determined that only *complaint status* remains significantly associated with the outcome of interest (p=0.05).

Table 5.3.2 Independent variables significant to p<0.25 in univariate analysis for Class II food establishments tested together in a multivariate model.

Variable	β	O.R	95%C.I.		*p-value*
			Lower	Upper	
Public Complaints	0.999	2.71	0.99	7.43	0.052
Staff Hygiene Violations (K)	1.187	3.28	0.84	12.82	0.088
Maintenance / Sanitation Violations (J)	0.713	2.04	0.78	5.31	0.144
Food Storage / Packaging Violations (F)	0.865	2.37	0.68	8.29	0.175
Cooking Equipment Violations (G)	0.471	1.60	0.54	4.75	0.396
Chemical & Biological Hazards (E)	0.659	1.93	0.34	11.10	0.460
Cross-contamination Violations (B)	-0.543	0.58	0.11	2.98	0.515
Infestation Pests / Vermin (D)	0.701	2.02	0.22	18.19	0.532
Temperature Control Violations (A)	-0.276	0.76	0.26	2.23	0.616

To test the significance of the variables removed, the difference between the full and reduced models was assessed using the likelihood ratio test. Variables were removed one at a time in order of least significance. The significance of variables remaining in the model was re-assessed at each stage. *Maintenance / Sanitation Violations* (J) became significantly associated with BP-SFBI in a model already containing *complaint status* after the removal of violation sets A,D,B,E,G and F. *Staff hygiene violations* (K) were also marginally significant

($p=0.063$), but were not added to the preliminary main effects model. With the addition of *maintenance / sanitation violations* (J), remaining variables listed in Table 5.3.1 were re-assessed to test the hypothesis [Ho: $\beta_i = 0$ | Complaint, Set J] before a test for confounding was conducted. No other significant variables were identified ($p>0.05$). Full and reduced models incorporating all variables removed were then compared. As $\chi^2=7.626$; $p=0.367$ at seven degrees of freedom, it was concluded that remaining variables in the stated multi-factorial design were ***not*** significantly associated with BP-SFBI when placed into a model already containing *maintenance / sanitation violations* and *complaint status*. Insignificant variables ($p>0.05$) were removed from the model if they were not confounders for *complaint status* or *maintenance / sanitation violations*.

5.3.1.2 Assessment of confounding

Before variables failing to achieve statistical significance in the multivariate model can be dropped, they must be tested to determine if they are significant confounders. Beta coefficient values for complaint status and facility maintenance / sanitation were compared for full and reduced models for each variable. As shown in Table 5.3.3, *staff hygiene* and *cooking equipment* violations each changed beta coefficient values greater than 15% when removed. *Food storage / packaging violations* approached statistical significance, but were not used. Remaining variables did not change beta coefficient values significantly, and were also dropped from the main effects model.

Table 5.3.3 Assessment of confounders for Class II food establishments.

Independent Variable	Complaint **% difference (Δβ)**	Facility Maintenance / Sanitation (J) **% difference (Δβ)**
Temperature Control Violations (A)	1.7	1.7
Cross-contamination Violations (B)	1.1	1.4
Infestation of Pests / Vermin (D)	3.3	7.2
Chemical & Biological Hazards (E)	1.5	6.5
Food Storage / Packaging Violations (F)	4.3	14.9
Cooking Equipment Violations (G)	1.2	18.4
Staff Hygiene Violations (K)	23.1	11.8

Although both *Staff Hygiene* and *Cooking Equipment* violations should have been added to the main effects model at this stage, only the former was used. There were several reasons for this:

1. The model containing all four variables was found to have zero cell problems resulting from an insufficient sample size with the addition of *cooking equipment violations* (Set G).
2. Alternative model building strategies (Forward Stepwise and Backward LR) each identified *staff hygiene violations* as being included in the final model, but not *cooking equipment violations*.
3. *Staff hygiene violations* were a stronger confounder for complaint status than cooking *equipment violations* were for *maintenance / sanitation problems*.
4. *Cooking equipment violations* were the least significant of the four variables (Complaint, J, K and G) at the univariate level, and after being fit into a multivariate model with the other selected terms (Tables 5.3.1 and 5.3.2 respectively).
5. *Staff hygiene* problems are more biologically-plausible in terms of causing certain types of food poisoning, such as Norovirus, than *cooking equipment* violations.

Thus, the main effects model for Class II food establishments consists of three independent variables: *public complaints, maintenance/sanitation violations* (Set J), and *staff hygiene violations* (Set K). Together, these characteristics were determined to be significantly associated with BP-SFBI [χ^2=20.424; p<0.001 at three degrees of freedom].

To determine the final model, clinically-plausible interaction effects between the variables in the main effects model were tested one at a time. None were determined to be statistically significant. Therefore, the final model consists of three main effects and no interaction terms. A summary table is presented below.

Table 5.3.4 Summary table for Class II food establishments

	Univariate LR			Multivariate LR		
Variable	**O.R.**	**95%CI**	**p-value**	**O.R.**	**95%CI**	**p-value**
Maintenance / Sanitation (J)	3.71	1.72-8.01	0.001	2.71	1.20-6.12	0.017
Staff Hygiene Violations (K)	5.59	1.84-16.97	0.002	3.19	0.94-10.86	0.063
Public Complaints	3.85	1.64-9.04	0.002	2.37	0.92-6.09	0.074
Food Packaging (F)	4.08	1.14-12.15	0.012			
Cooking Equipment (G)	2.91	1.19-7.14	0.020			
Chem.& Bio. Hazards (E)	3.24	0.77-13.63	0.110			
Infestation Pests/Vermin (D)	3.17	0.61-16.43	0.169			
Temperature Control (A)	1.68	0.76-3.72	0.204			
Cross-contamination (B)	1.95	0.66-5.78	0.228			

5.3.1.3 Diagnostics for final model

The goodness of fit for the final model was assessed in several ways. First, a Hosmer and Lemeshow (H-L) Test was used. A good model has observed and expected values that that are close. These values are presented in the contingency table below.

Table 5.3.5 Observed and expected values in case and control groups.

Contingency Table for Hosmer and Lemeshow Test

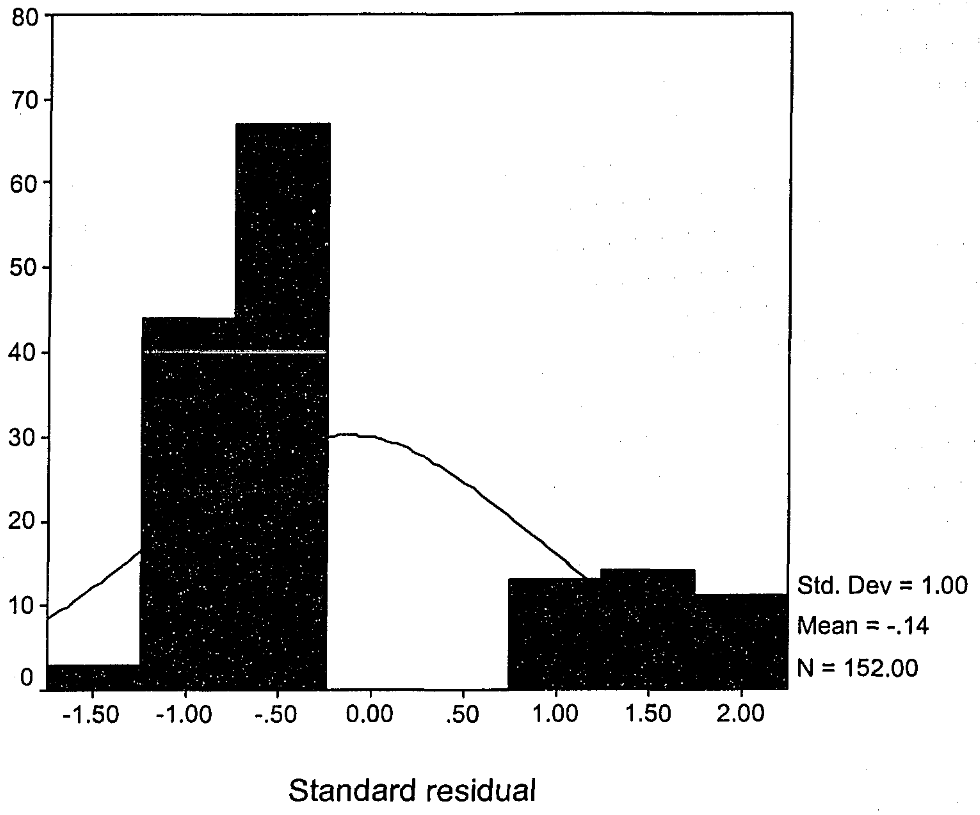
	Controls		Cases		
	Observed	Expected	Observed	Expected	Total
1	67	67.894	11	10.106	78
2	8	7.394	2	2.606	10
3	27	27.083	11	10.917	38
4	9	8.340	6	6.660	15
5	3	3.289	8	7.711	11

As $\chi^2=0.436$; $p=0.933$ at three degrees of freedom, we fail to reject the null hypothesis for the H-L test and conclude that the data fits the model.

5.3.1.4 Standardized residuals for Class II food establishments

The original sample size was calculated for the data set as a whole. Because each facility class was analyzed independently, it was important to run diagnostics on each model separately. Data on standardized residuals for Class II food establishments are presented in Figure 5.3.1.

Figure 5.3.1 Standardized residuals histogram – Class II



If the sample size is sufficiently large, then the standardized residuals should approximate a normal distribution. Though some features of a normal distribution are present in the figure above, it is admittedly skewed. This usually occurs as a result of a small sample size. Power and sample-size calculations presented in the *Methods* section support these findings. Despite this, the low standardized residuals presented in Figure 5.3.1 suggest a good fit for the final model.

5.3.2 Class III food establishments

5.3.2.1 Development of final model

While several categorical variables were found to be significantly associated with food poisoning in Class III food establishments ($p<0.05$), they were determined to have insufficient data for model-building purposes. Thus, only dichotomous independent variables were used. To be considered for the multivariate model, those variables significant to $p<0.25$ in univariate LR analysis were initially selected. *Public complaints* and *violation sets* A, B, D, E, F, G, H, I, J, K, L and Z fulfilled this requirement. Each of these variables is presented in Table 5.3.6.

Table 5.3.6 Independent variables selected for multivariate analysis and modeling for Class III food establishments.

	Score	df	Sig.
Public Complaints	13.247	1	.000
Temperature Control (A)	25.186	1	.000
Cross Contamination (B)	12.040	1	.001
Insects / Vermin (D)	11.261	1	.001
Chemical & Biological Hazards (E)	15.880	1	.000
Food Storage / Packaging Violations (F)	14.800	1	.000
Cooking Equipment (G)	7.593	1	.006
Dishwashing & Utensil Violations (H)	3.329	1	.068
Test Equipment Violations (I)	16.806	1	.000
Maintenance / Sanitation (J)	4.335	1	.037
Staff Hygiene (K)	11.158	1	.001
Hand Sink Violations (L)	3.992	1	.046
Other Violations (Z)	2.900	1	.089
Overall Statistics	49.062	13	.000

To test if these factors taken together were significantly associated with foodborne illness, they were fit into a multivariate model. Since $\chi^2=47.581$; $p<0.001$ at 13 degrees of freedom, the null hypothesis of no association is rejected. When taken together, these factors are significantly associated with plausible food poisonings identified at Class III food establishments in the Capital Health region.

Looking at the p-values for each independent variable after being fit into the multivariate model (Table 5.3.7), it was determined that *public complaints*, *temperature control violations* and missing *test equipment* each remained significantly associated with the outcome of interest ($p \leq 0.05$). These variable selections are consistent with those determined by forward LR techniques.

Table 5.3.7 Multivariate model containing all variables significant in univariate analysis ($p<0.25$) for Class III food establishments.

			95%C.I.		
Variable	**β**	**O.R.**	**Lower**	**Upper**	***p-value***
Temperature Control Violations (A)	1.18	3.24	1.55	6.78	0.002
Public Complaints	.975	2.65	1.31	5.38	0.007
Test Equipment Missing (I)	.705	2.02	1.00	4.12	0.052
Chemical & Biological Hazards (E)	1.09	2.97	0.89	9.95	0.077
Food Storage / Packaging Violations(F)	.432	1.54	0.67	3.54	0.309
Other Violations (Z)	-.533	0.59	0.20	1.71	0.329
Infestation Pests / Vermin (D)	.402	1.50	0.56	4.00	0.423
Hand Sink Violations (L)	-.261	0.77	0.35	1.68	0.512
Cooking Equipment Violations(G)	-.213	0.81	0.36	1.83	0.609
Maintenance / Sanitation Violations(J)	-.166	0.85	0.38	1.87	0.682
Staff Hygiene Violations (K)	.232	1.26	0.37	4.28	0.711
Dishwashing & Utensil Violations (H)	-.123	0.89	0.43	1.81	0.738
Cross-contamination Violations (B)	-.037	0.96	0.41	2.29	0.932

Taken together, these three variables were found to be significantly associated with disease outcome $\chi^2=40.110$; $p<0.001$ at three degrees of freedom [Table 5.3.8]. Remaining variables were not significantly associated with food poisonings when placed in a model already containing inspection frequency, public complaints, and temperature control violations [$\chi^2=7.471$; $p=0.680$ at ten degrees of freedom].

Table 5.3.8 Preliminary main effects model (Class III)

Variable	β	O.R.	95%C.I. Lower	95%C.I. Upper	*p-value*
Temperature Control Violations (A)	1.164	3.20	1.70	6.03	<0.001
Public Complaints	0.990	2.69	1.41	5.14	0.003
Test Equipment Missing (I)	0.785	2.19	1.16	4.15	0.016

Variables were removed in order of least significance beginning with cross-contamination concerns to test the hypotheses: **Ho: $\beta_i = 0$ | [Temperature Control (A), Test Equipment (I), Complaint Status]**. Differences between full and reduced models were assessed using the likelihood ratio test. The p-values of variables remaining in the reduced model were re-assessed at each step. "*Chemical & Biological Hazards*" (violation set E) became significantly associated with BP-SFBI ($p<0.05$) after the removal of violation sets B, H, K, J, G, D, L, and F. Set E was placed into the main effects model [see Table 5.3.9], and each of the original entries selected for multivariate analysis was reassessed. No additional variables were identified. Removed variables were subsequently analyzed to determine if they were confounders.

Table 5.3.9 Class III multivariate model *before* the assessment for confounding.

Variable	β	O.R.	95%C.I. Lower	95%C.I. Upper	*p-value*
Temperature Control Violations (A)	1.063	2.90	1.52	5.52	0.001
Public Complaints	0.922	2.51	1.30	4.86	0.006
Test Equipment Missing (I)	0.709	2.03	1.06	3.90	0.033
Chemical & Biological Hazards (E)	1.041	2.83	0.96	8.32	0.058

Together, complaint status and violations sets A, E and I are significantly associated with BP-SFBI [χ^2=43.779; $p<0.001$ at four degrees of freedom].

5.3.2.2 Assessment of confounding

Beta coefficient values for *complaint status*, *temperature control violations*, *test equipment violations*, and *chemical / biological hazards* were compared for full and reduced models for each of the remaining variables. Violations sets B, D, F, G, H, J, K, L, and Z were tested individually to determine their effect on the model when removed. As shown in Table 5.3.10, *none* of the variables changed beta values greater than 15 percent, and as such they were dropped from the preliminary main effects model.

Table 5.3.10 Assessment of confounders for Class III food establishments.

Independent Variable	**% difference (Δβ)**	Violation Sets **% difference (Δβ)**		
	Complaint	**A**	**E**	**I**
Cross-contamination Violations (B)	1.2	1.3	0.2	0.0
Food Storage / Packaging Violations (F)	2.8	7.2	6.4	9.1
Facility Maintenance / Sanitation (J)	2.4	5.2	4.2	5.5
Staff Hygiene Violations (K)	1.2	2.0	4.8	3.2
Infestation of Pests / Vermin (D)	5.6	1.5	7.5	7.3
Cooking Equipment Violations (G)	1.6	3.4	5.2	1.8
Dishwashing & Utensil Violations (H)	1.1	3.8	2.3	4.4
Hand Sink Violations (L)	2.3	3.3	2.2	5.2
Other Violations (Z)	7.1	5.3	6.6	5.0

No significant confounders were identified. Thus, the main effects model for Class III food establishments is presented in Table 5.3.9. Taken together, receiving a *public complaint*, one or more *test equipment violations*, *temperature control violations*, and *chemical / biological violations* during the last 12 months is significantly associated with identified BP-SFBI in Class III food establishments [χ^2=43.779; p<0.001 at four degrees of freedom].

To determine the final model, clinically-plausible interaction effects between the variables in the main effects model were tested one at a time. They comprised of:

Complaint*Temperature Control Violations (A); Complaint*Chemical & Biological Hazards (E); Complaint*Test Equipment Violations (I); Temperature Control Violations (A)* Chemical & Biological Hazards (E); Temperature Control Violations (A)*Test Equipment Violations (I) and Chemical & Biological Hazards (E)*Test Equipment Violations (I). None of the interaction terms were found to be statistically significant.

The final model for Class III food establishments consists of four main effects and no interaction terms. Variables included in the model are summarized in Table 5.3.11. Variables determined to be significantly associated with BP-SFBI in univariate analyses are also presented for summary purposes. Those variables not appearing in the table did not achieve statistical significance ($p<0.05$) in univariate logistic regression.

Table 5.3.11 Class III summary table for independent variables in the final model, and significant to $p<0.05$ in univariate logistic regression.

	Univariate LR			Multivariate LR		
Variable	O.R.	95%CI	p-value	O.R.	95%CI	p-value
Temperature Control (A)	4.28	2.37-7.71	<0.001	2.90	1.52-5.52	0.001
Public Complaints	3.00	1.63-5.48	<0.001	2.51	1.30-4.86	0.006
Test Equipment (I)	3.27	1.83-5.85	<0.001	2.03	1.06-3.90	0.033
Chemical & Biological Hazards (E)	6.05	2.27-16.10	<0.001	2.83	0.964-8.32	0.058
Food Storage / Packaging (F)	3.20	1.74-5.89	<0.001			
Cross-Contamination (B)	2.95	1.58-5.51	0.001			
Insects / Vermin (D)	3.58	1.64-7.80	0.001			
Staff Hygiene (K)	4.17	1.71-10.16	0.002			
Cooking Equipment (G)	2.20	1.25-3.88	0.006			
Any Violation [1]	2.74	1.28-5.89	0.010			
Food Manager Certification [1]	6.32	1.13-35.31	0.036			
Maintenance / Sanitation (J)	1.87	1.03-3.38	0.039			
Hand Sink Violations (L)	1.83	1.01-3.32	0.047			
Inspection Frequency [1, 2]						
Below Expected	0.09	0.01-0.70	0.021			
Greater than expected	2.16	1.08-4.34	0.030			
Much greater than expected	7.99	3.01-21.20	<0.001			

1 = not eligible for multivariate analysis

2 = values in comparison to the reference category (expected number of inspections)

5.3.2.3 Diagnostics for final model

The goodness of fit for the final model for Class III food establishments was assessed in the same manner as for Class II. Results of the Hosmer and Lemeshow (H-L) test indicate that the data fits the specified model. As $\chi^2=2.427$; $p=0.658$ at four degrees of freedom, the null hypothesis for the H-L test (Ho: Observed = Expected) is not rejected. This is further supported by the proximity of observed and expected values presented in the contingency table below:

Table 5.3.12 Observed and expected values in case and control groups.

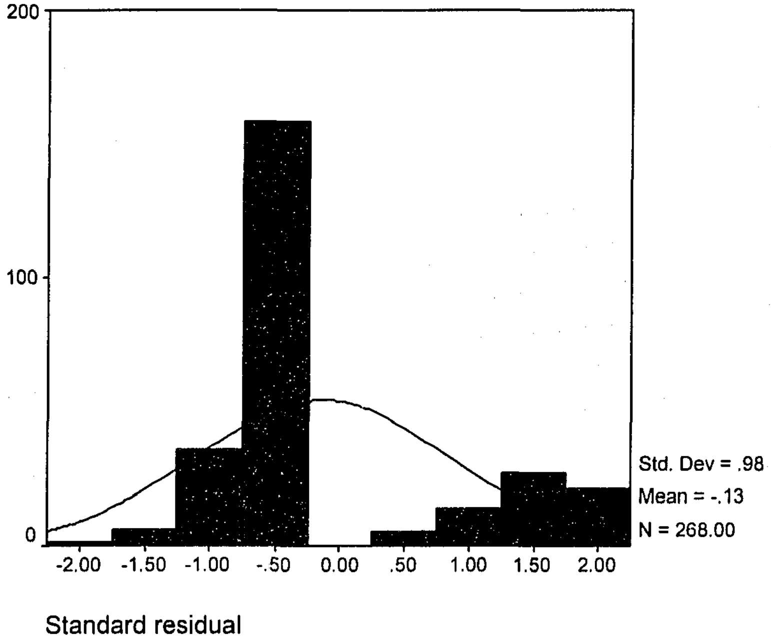
Contingency Table for Hosmer and Lemeshow Test

		Control		Case		
		Observed	Expected	Observed	Expected	Total
Step 1	1	95	93.847	9	10.153	104
	2	16	17.215	5	3.785	21
	3	21	21.972	7	6.028	28
	4	28	29.699	11	9.301	39
	5	24	20.909	10	13.091	34
	6	17	17.358	25	24.642	42

5.3.2.4 Standardized residuals for Class III food establishments

As shown in figure 5.3.2, the distribution of standardized residual values for Class III food establishments did approximate a normal distribution. It is therefore expected that there was sufficient sample size within this stratum. Moreover, as standardized residuals are moderate to low, this would suggest a good fit for the final model for Class III facilities.

Figure 5.3.2 Standardized residuals histogram – Class III



Chapter 6: Discussion

Several significant differences were observed between case and control groups in the present study. Differences were also observed at the univariate level and between the final multivariate models for the respective facility classes. Many factors are believed to contribute to these observations, including limited sample size resulting from the division of data by facility class, inherent differences in the breadth of food handling activities that take place and the frequency with which they occur, differences in the average educational level and number of years of experience held by the restaurant employees in the respective facility types, as well as the size and design of the food establishments themselves.

6.1 Inspection frequency

Many researchers have demonstrated that increased frequency of inspection results in improved inspection scores (Allwood *et al.* 1999) (Campbell *et al.* 1998) (Mathias *et al.* 1995) (Riben *et al.* 1994b) (Kaplan 1978). In comparison, few studies have attempted to determine if any association exists between inspection frequency and reported cases of food poisoning at food establishments. Improvements as a result of increased inspection frequency were not assessed as part of the present study. Instead, researchers felt it was important to identify what factors were determinants of increased inspection frequency in order to better understand potential interaction and confounding effects between this and other independent variables potentially associated with BP-SFBI. The statistical associations between "*any violation*", violation sets A-Q, *public complaints*, having a *FSP*, and *inspection frequency* are presented in Table 6.6.1.

Table 6.1.1 Associations between inspection frequency and other independent variables

Violation Set and Description	χ^2	*df*	*p-value*
CLASS II			
Maintenance / Sanitation Violations	50.150	3	<0.001
Any Violation	45.506	3	<0.001
Public Complaints	35.602	3	<0.001
Hand Sink Violations: Kitchen	29.189	3	<0.001
Cross-contamination	28.154	3	<0.001
Staff Hygiene Violations	21.811	3	<0.001
Temperature Control Violations	19.749	3	<0.001
Dishwashing & Utensil Violations	16.732	3	0.001
Cooking Equipment Violations	15.161	3	0.002
Food Storage / Packaging Violations	9.819	3	0.020
Infestation Pest/Vermin	8.187	3	0.042
Washroom Sanitation/Maintenance	6.644	3	0.084
Chemical & Biological Hazards	6.314	3	0.097
Test Equipment Missing: Temp/Chem.	5.882	3	0.117
Unfit Foods	4.094	3	0.252
Food Safety Program (FSP)	2.988	3	0.394
Food Transportation	2.912	3	0.405
Food Manager Certification	1.639	3	0.651
Nuisance Violation	0.930	3	0.818
Customer Contamination	--	--	--
CLASS III			
Cooking Equipment Violations	84.019	3	<0.001
Maintenance / Sanitation Violations	81.660	3	<0.001
Any Violation	70.423	3	<0.001
Temperature Control Violations	66.685	3	<0.001
Infestation Pest/Vermin	60.062	3	<0.001
Cross-contamination	52.903	3	<0.001
Chemical & Biological Hazards	51.387	3	<0.001
Food Storage / Packaging Violations	50.714	3	<0.001
Staff Hygiene Violations	49.169	3	<0.001
Test Equipment Missing: Temp/Chem.	48.022	3	<0.001
Hand Sink Violations: Kitchen	46.021	3	<0.001
Public Complaints	42.510	3	<0.001
Dishwashing & Utensil Violations	28.611	3	<0.001
Food Transportation	24.809	3	<0.001
Unfit Foods	15.236	3	0.002
Customer Contamination	8.868	3	0.031
Washroom Sanitation/Maintenance	7.685	3	0.053
Food Manager Certification	7.071	3	0.070
Food Safety Program (FSP)	4.272	3	0.234
Nuisance Violation	3.496	3	0.321

Although some differences were observed between the respective facility classes, *public complaints* and *most violation sets* were found to be strongly associated with increased inspection frequency. This accurately reflects the expected roles and responsibilities of EHOs within the Food Protection Program, and is therefore an indicator that the EH program is running well. As discussed in the introduction, demand inspections (i.e. complaints and SFBIs) result in an investigation, and often an on-site inspection, by the district PHI/EHO. Violations, particularly those dealing with *maintenance and sanitation concerns*, or critical violations such *as inadequate temperature control*, *improper food handling*, *equipment failure*, or *insect/vermin infestations* often require one or more re-inspections before they are satisfactorily corrected. In many instances, it is inappropriate to delay the reassessment of food establishments receiving such violations for prolonged periods.

There were, however, certain variables ***not*** found to be significantly associated with inspection frequency for either facility class. Having a manager certified in a food safety did not reach statistical significance due in part because inspectors require the operator to enrol in the next available course when this violation is cited. Furthermore, the inspector may verify attendance at such a course without returning to the food establishment. Nuisance violations, cited in only four food establishments within the critical period, were also not significantly associated with increased inspection frequency. This is not surprising given that nuisance violations are akin to a "miscellaneous" violation category to capture problems not specifically dealt with in the Food and Food Establishments Regulation, and are therefore infrequently used. The final variable not found to be significantly associated with inspection frequency for either facility classification was the presence of a FSP. This is understandable as the goal of such programs is to reduce the occurrence of risk factors commonly associated with foodborne illness, a topic discussed further in section 6.2.

Results of the univariate analyses demonstrated that inspection frequency was positively associated with identified food poisonings in both Class II and Class III food establishments. Commercial eateries with fewer problems and below the expected number of inspections were less likely to have a BP-SFBI. Inversely, facilities with a history of problems requiring more inspections were found to be at an increased risk of having a BP-SFBI. This relationship may at first appear to contradict what many may expect, namely that more inspections would result in *fewer* problems. Instead it reveals how inspection frequency is impacted by risk management initiatives used by EH programs to identify food establishments believed to be at greatest risk of causing a foodborne illness.

The success rate of EH initiatives, such as increased inspection frequency, are often difficult to assess because the number of BP-SFBIs averted remains unknown. What can be concluded is that risk management initiatives, of which increased inspection frequency is one, are not capable of averting food poisonings 100% of the time. This is understandable for several reasons. First, health inspections cannot prevent deliberate acts of sabotage by patrons or restaurant employees. Such acts occur, and while not prevalent, foodborne outbreaks resulting from intentional contamination have been documented (Torok *et al.* 1997). Second, it is the responsibility and goal of health departments to *reduce* the burden of foodborne illness – a feat accomplished largely through cooperative working relationships with food establishment operators, health education of food handlers, and sometimes through enforcement of food safety regulations. It is ultimately the legal responsibility of *restaurant owners* to ensure that their food establishment is in compliance with regulatory requirements, and that risk factors for food poisoning are minimized on a day-to-day basis. The reason for this is simple: the owners, or someone designated on their behalf, are present at all times when the food establishment is in operation. A PHI/EHO with the health department is not.

In summary, most categorical variables were not used in multivariate analysis because of limited sample size in certain category ranges. While sufficient data may have existed in this instance, it was inappropriate to include inspection frequency in the multivariate model because the occurrence of violations and complaints determined if more inspections were needed. This is demonstrated by the strong associations reported between inspection frequency and many of the other independent variables in the study (Table 6.1.1). Despite not being included in the multivariate model, inspection frequency remains a good indicator for food establishments at increased risk of causing food poisoning. It is anticipated that future studies in this area will continue to explore the impact of inspection frequency on reducing the number of health code violations demonstrated to cause BP-SFBI in commercial eateries.

6.2 Food safety programs

The presence of a food safety program (FSP) in a food establishment was found to be strongly associated with identified BP-SFBIs. Despite this, it was excluded from the multivariate analyses and was not included in the final model for either facility class. The role of a FSP in a food establishment is to improve food quality, reduce the likelihood of food poisonings, and minimize associated liabilities. Many FSPs require the manager of the food establishment to contact health officials when the restaurant receives a foodborne illness complaint from the public. The result is more food poisonings are identified at these facilities in comparison to food establishments without such a program (a reporting bias). A strong association between FSPs and identified food poisoning in commercial eateries is therefore not necessarily one of causation. To test this hypothesis further, data were divided into facilities with and without FSPs to determine if food establishments with FSPs possessed more health violations (i.e. other potential risk factors for food poisoning) than their counterparts. Results of this analysis are presented in Tables 6.2.1 and 6.2.2. It is expected that some of these observations are a result of a limited sample size. Many of the violation categories appear as if they would become significantly associated with identified food poisonings for facilities with a FSP if more data had been available. Further research is warranted in this area.

Table 6.2.1 The strength of association between violation categories A-Q and BP-SFBI identified in Class II food establishments with and without food safety programs (FSPs).

		Class II: No FSP			Class II: FSP		
	Violation Set & Description	**% Case** (n=16)	**% Control** (n=94)	***p-value***	**% Case** (n=22)	**% Control** (n=20)	***p-value***
A	**Temperature Control**	31.3	27.7	0.769	36.4	5.0	0.022
B	**Cross-Contamination**	18.8	10.6	0.399	13.6	0	0.233
C	**Unfit Foods**	0	1.1	1.000	n/a	n/a	n/a
D	**Infestation Pest/Vermin**	12.5	3.2	0.153	4.5	0	1.000
E	**Chemical & Biological Hazards**	6.3	3.2	0.472	13.6	5.0	0.608
F	**Food Storage / Packing Violations**	18.8	7.4	0.159	22.7	0	0.049
G	**Cooking Equipment**	18.8	11.7	0.426	36.4	15.0	0.166
H	**Dishwashing & Utensil Violations**	18.8	12.8	0.455	18.2	5.0	0.346
I	**Test Equipment Missing**	31.3	20.2	0.335	22.7	20.0	1.000
J	**Maintenance / Sanitation**	62.5	30.9	0.022	63.6	35.0	0.121
K	**Staff Hygiene Violations**	6.3	5.3	1.000	36.4	5.0	0.022
L	**Hand Sink Violations**	18.8	26.6	0.757	31.8	5.0	0.047
M	**Public Health Nuisance**	0	1.1	1.000	n/a	n/a	n/a
N	**Customer Contamination**	n/a	n/a	n/a	n/a	n/a	n/a
O	**Food Manager Certification / Training**	0	3.2	1.000	4.5	0	1.000
P	**Food Transportation**	0	4.3	1.000	4.5	5.0	1.000
Q	**Public Washrooms**	6.3	3.2	0.472	4.5	10.0	0.598
--	**Any Violation**	75.0	58.5	0.273	72.7	55.0	0.336
--	**Public Complaint(s)**	18.8	12.8	0.455	50.0	15.0	0.023

Table 6.2.2 The strength of association between violation categories A-Q and BP-SFBI identified in Class III food establishments with and without food safety programs.

	Violation Set & Description	Class III: No FSP			Class III: FSP		
		% Case (n=51)	% Control (n=198)	*p-value*	% Case (n=16)	% Control (n=3)	*p-value*
A	Temperature Control	74.5	31.8	<0.001	43.8	66.7	0.582
B	Cross-Contamination	45.1	16.2	<0.001	6.3	0	1.000
C	Unfit Foods	0	1.5	1.000	n/a	n/a	n/a
D	Infestation Pest/Vermin	29.4	7.6	<0.001	n/a	n/a	n/a
E	Chemical & Biological Hazards	21.6	3.5	<0.001	6.3	0	1.000
F	Food Storage / Packing Violations	47.1	17.7	<0.001	18.8	0	1.000
G	Cooking Equipment	52.9	29.8	0.003	31.3	0	0.530
H	Dishwashing & Utensil Violations	47.1	27.8	0.011	18.8	66.7	0.155
I	Test Equipment Missing	60.8	23.2	<0.001	12.5	0	1.000
J	Maintenance / Sanitation Deficiencies	80.4	55.6	0.001	37.5	66.7	0.546
K	Staff Hygiene Violations	23.5	5.1	<0.001	n/a	n/a	n/a
L	Hand Sink Violations	43.1	23.7	0.008	12.5	0	1.000
M	Public Health Nuisance	3.9	0.5	0.107	n/a	n/a	n/a
N	Customer Contamination	0	2	0.584	n/a	n/a	n/a
O	Food Manager Certification	7.8	1	0.017	n/a	n/a	n/a
P	Food Transportation	13.7	5.6	0.064	n/a	n/a	n/a
Q	PublicWashrooms	11.8	7.6	0.395	6.3	0	1.000
--	Any Violation	92.2	70.2	0.001	68.8	66.7	1.000
--	Public Complaint(s)	35.3	18.2	0.013	56.3	33.3	0.582

Any Violation

Receiving a violation during the past 12 months was *not* found to be significantly associated with restaurant-acquired food poisonings in food establishments with a FSP for either facility class. It was, however, strongly associated with BP-SFBI in those *Class III facilities lacking* a FSP. A similar association was not observed in Class II facilities without a FSP.

Public Complaints

Public complaints had opposing effects on Class II and Class III food establishments with and without a FSP. Receiving one or more public complaints in the past year was significantly associated with restaurant-acquired food poisonings in Class II food establishments *with* a

FSP and Class III facilities *without* a FSP. Differences were similarly observed for the individual violation categories.

Violation Categories – Class II

In Class II establishments *with* a FSP, three violation sets were not identified in either case or control groups (these being *nuisance*, *unfit foods*, and *customer contamination*). Four additional sets (*cross-contamination*, *infestation insect/vermin*, *improper food storage*, and *inadequate food safety training*) were not identified in any Class II control with a FSP. *Maintenance / sanitation concerns* were the only violation category that was significantly associated with BP-SFBI in facilities without a FSP. *Temperature control, food storage, staff hygiene*, and *hand sink violations*, as well as *public complaints*, were significantly associated with disease outcome in facilities with a FSP.

Violation Categories – Class III

Significant differences with respect to health code violations cited on inspections conducted over a 12-month period were found to exist between Class III food establishments with and without a FSP. Fewer violation categories were positively associated with restaurant-acquired food poisonings in food establishments with a FSP compared to those without: 12 were identified in facilities without a FSP in place ($p<0.05$), yet none were identified in food establishments with a FSP [Table 6.2.2]. Seven of the violation categories were not cited in any Class III facility with a FSP for the critical period [Table 6.2.2]. Another seven violation sets were not cited in any of the controls with a FSP in place. Small sample size may be partially responsible for this trend.

Fewer differences were observed between Class II food establishments with and without a FSP when compared to Class III [Tables 6.2.1 and 6.2.2]. There are several possible explanations for this. First, owing to their limited menus, fewer staff, and smaller stores, there may be less opportunity for such differences to exist. Second, Class II food establishments pay poorly relative to full-service (Class III) eateries, and therefore have a higher turnover of staff. As a result, they rely more heavily on a young, transient, and often untrained workforce. This could offset any positive effects a FSP may have. Finally, observations may again be a result of a limited sample size. Many of the violation categories appear as if they could become significantly associated with identified restaurant-acquired food poisonings if more data had been available, particularly in facilities with a FSP.

In summary, having a FSP was found to be associated with more identified SFBI investigations, but fewer violations. It is therefore not suggested that food establishments with a FSP have more food poisonings, or possess more risk factors for them, despite the strength of the association reported between FSPs and restaurant-acquired food poisonings. Further research into the differences that exist between Class II and III food establishments with and without food safety programs seems warranted.

6.3 Public complaints

Past studies have shown that facilities implicated in a food poisoning are at higher risk of having another (Buchholz *et al.* 2002). A similar association with complaints from the general public is reported here. Public complaints were found to be significantly associated with identified BP-SFBI, irrespective of facility class at the univariate level. In multivariate analysis, receiving one or more public complaints in the previous year was among the main effects in the final model for both Class II and Class III food establishments.

Despite the apparent strength of association between complaint status and BP-SFBIs in the present study, and the similarity of these findings to other studies where the effect of past food poisonings were analyzed, it is not expected that the relationship between reported food poisonings and public complaints is a result of the two demand inspection systems inadvertently measuring the same thing. If a complainant mentions any ill effects following the consumption of a food product, the report is automatically classified as a SFBI. Complaints are reserved for poor sanitation or hygiene, pest concerns, odours, and other departures from food safety regulations NOT involving illness. It is therefore more likely that a complaint would be inadvertently recorded as a SFBI than the reverse.

In order to determine if there was an association between complaint status and other independent variables in the study, data collected were divided into facilities with and without public complaints. The percentage of food establishments in case and control groups was then tabulated to determine if food establishments with complaints possessed more health violations than their counterparts. To test if the significance of independent variables associated with identified food poisonings differed between facilities with and without complaints, a chi-square analysis was performed. Results of this analysis are presented in Tables 6.3.1 and 6.3.2.

Table 6.3.1 The strength of association between violation categories A-Q and BP-SFBI identified in Class II food establishments with and without public complaints.

	Violation Set & Description	Class II: No Complaint			Class II: Complaint		
		% Case (n=24)	% Control (n=99)	p-value	% Case (n=14)	% Control (n=15)	p-value
A	Temperature Control	25.0	20.2	0.587	50.0	46.7	1.000
B	Cross-Contamination	12.5	6.1	0.376	21.4	26.7	1.000
C	Unfit Foods	n/a	n/a	n/a	0.0	6.7	1.000
D	Infestation Pest/Vermin	8.3	3.0	0.251	7.1	0.0	0.483
E	Chemical & Biological Hazards	8.3	4.0	0.332	14.3	0.0	0.224
F	Food Storage / Packing Violations	25.0	3.0	0.002	14.3	26.7	0.651
G	Cooking Equipment	20.8	13.1	0.344	42.9	6.7	0.035
H	Dishwashing & Utensil Violations	12.5	11.1	1.000	28.6	13.3	0.390
I	Test Equipment Missing	20.8	22.2	1.000	35.7	6.7	0.080
J	Maintenance / Sanitation	50.0	29.3	0.089	85.7	46.7	0.050
K	Staff Hygiene Violations	8.3	5.1	0.621	50.0	6.7	0.014
L	Hand Sink Violations	16.7	22.2	0.781	42.9	26.7	0.450
M	Public Health Nuisance	0.0	1.0	1.000	n/a	n/a	n/a
N	Customer Contamination	n/a	n/a	n/a	n/a	n/a	n/a
O	Food Manager Certification / Training	0.0	3.0	1.000	7.1	0.0	0.483
P	Food Transportation	4.2	3.0	1.000	0.0	13.3	0.483
Q	Public Washrooms	4.2	4.0	1.000	7.1	6.7	1.000

Few violations were significantly associated with identified BP-SFBIs in Class II food establishments – with or without public complaints [Table 6.3.1]. Complaint status appeared to have little effect on the significance of most other independent variables within this facility classification. There were, however, exceptions. *Food storage / packaging violations* were more significantly associated with BP-SFBI in facilities without complaints. *Staff hygiene concerns*, *maintenance/sanitation deficiencies*, and *cooking equipment violations* were more significantly associated with disease outcome in facilities with complaints. Several factors may be responsible for these trends.

Violations involving *facility maintenance* and *employee hygiene* are aspects the general public can easily observe, and recognize without specialized training, when visiting a commercial eatery. Open kitchen designs, typical of fast food restaurants that make up the vast majority of Class II food establishments, provide the general public with the opportunity to observe such problems. In comparison, *cross-contamination*, *improper storage of chemicals*, *problems with insects/vermin*, and many of the other violations usually require an observer to be in the kitchen, receiving, or storage areas of the facility. Thus, there is less opportunity for these violations to be noticed by the public because these areas are usually restricted to authorized personnel. Further evidence to support this hypothesis is found in Table 6.3.2, where a similar association was not observed for Class III eateries (where open kitchen designs are less prevalent).

Aside from the physical layout, another factor that may prohibit patrons from recognizing certain problems is ignorance. Few people are aware that every food establishment is required to have one person in a supervisory role certificated in food safety and hygiene. Moreover, there is no requirement to post such qualifications for consumers to see. Another example of a violation which may not be recognized by the general public is *improper food storage / packaging*. This violation is often cited when materials coming into contact with food products while they are in storage are not clean or food-grade. It may also be cited when there is inadequate separation between raw meat and ready-to-eat foods (which can increase the likelihood of cross-contamination). The typical consumer is unlikely to recognize such problems.

Table 6.3.2 The strength of association between violation categories A-Q and BP-SFBI identified in Class III food establishments with and without public complaints

	Violation Set & Description	Class III: No Complaint			Class III: Complaint		
		% Case (n=40)	% Control (n=164)	p-value	% Case (n=27)	% Control (n=37)	p-value
A	Temperature Control Violations	65.0	31.1	0.000	70.4	37.8	0.013
B	Cross-Contamination	20.0	12.8	0.310	59.3	29.7	0.023
C	Unfit Foods	0.0	0.6	1.000	0.0	5.4	0.504
D	Infestation Pest/Vermin	15.0	4.9	0.035	33.3	18.9	0.246
E	Chemical & Biological Hazards	15.0	2.4	0.005	22.2	8.1	0.151
F	Food Storage / Packing Violations	35.0	15.9	0.013	48.1	24.3	0.064
G	Cooking Equipment	42.5	26.2	0.053	55.6	43.2	0.448
H	Dishwashing & Utensil Violations	37.5	26.8	0.243	44.4	35.1	0.604
I	Test Equipment Missing	47.5	22.6	0.003	51.9	24.3	0.035
J	Maintenance / Sanitation Deficiencies	62.5	53.7	0.376	81.5	64.9	0.170
K	Staff Hygiene Violations	15.0	3.7	0.015	22.2	10.8	0.300
L	Hand Sink Violations: Kitchen	32.5	20.7	0.142	40.7	35.1	0.794
M	Public Health Nuisance	2.5	0.6	0.354	3.7	0.0	0.422
N	Customer Contamination	0.0	0.6	1.000	0.0	8.1	0.257
O	Food Manager Certification	5.0	0.6	0.099	7.4	2.7	0.568
P	Food Transportation	7.5	4.3	0.415	14.8	10.8	0.712
Q	Washroom Sanitation / Maintenance	12.5	5.5	0.156	7.4	16.2	0.450

Seven violation categories were significantly associated with BP-SFBI in Class III eateries without a public complaint ($p<0.05$). Five categories were associated with disease outcome in Class III eateries with a complaint. Similar to Class II food establishments, few differences were observed in facilities with and without public complaints. Variables were likely to be similarly associated with disease outcome in facilities with regardless of complaint status.

In summary, receiving public complaints did not appear to reliably increase or decrease the likelihood that other risk factors for food poisoning would be identified in either case or control groups. This differs from what was observed for facilities with and without a FSP. This relationship (or lack thereof) suggests that the general public cannot identify many kinds of problems in food establishments, or facilities at greatest risk of causing foodborne illness. Nonetheless, there are clearly opportunities to explore these relationships in greater detail given that public complaints were part of the final model in multivariate analyses for both facility classifications. For instance, the nature of complaints received by food establishments was not part of the current study design. In the future, researchers may wish to categorize public complaints into various types in order to further explore these relationships. The number of complaints could also be assessed to determine if relationships are linear, and similarly increase with the volume of complaints received.

6.4 Trends in violation data

A principal outcome of interest in the present study was the identification of violations significantly associated with plausible food poisonings in commercial eateries using inspection records. The following sections are used to discuss trends in violation data, to compare these trends with those reported by past studies, and to speculate how this information may be used to improve EH programs and disease surveillance.

6.4.1 The rank order of violations in comparison to past studies

Past studies involving reviews of food inspection records have shown that the most frequently cited problems recorded by EHOs are often non-critical violations involving maintenance and general sanitation (Jones *et al.* 2004). Researchers in the past have also claimed that critical violations were not among the top ten most frequently cited violations over a given period, or in a given cross-sectional sample. The present study both confirms and rejects these past findings. While sanitation violations were the most frequently cited within the study period, ***temperature control violations***, ***a lack of hand wash supplies***, and ***missing thermometers*** were also cited with considerable frequency in both Class II and Class III facilities [Figure 5.2.3]. Each of these categories contains critical violations. And, while some differences were found to exist between the respective classes, and between case and control groups, critical violations were always amongst the most frequently cited. This is the first study of its kind to demonstrate these relationships. There are several possible explanations for this, the most likely of which are:

(a) the method by which food poisonings were identified (i.e. at the community level);

(b) the length of the observation period (one year versus one inspection);

(c) the assessment of a greater range of inspection types (routine monitoring inspections, re-inspections, and complaints investigations...); and

(d) the assessment of exposure in terms of the relative frequency that violations were cited (i.e. the use of categorical rather than dichotomous variables) whenever possible.

Several other reasons why a greater proportion of the most frequently cited violations in the present study were critical in comparison to past studies are also offered. These include differences in the educational training of local EHOs, differences in the focus of the local health department, and a general shift in ideology towards a risk assessment / outcome-based approach to restaurant inspections (rather than a "check-box" or regulatory approach) in recent years. Finally, these findings may simply reflect a higher percentage of poor restaurants locally compared to areas where similar studies have been conducted in the past. The low level of enforcement reported within the study group casts doubt on the latter of these explanations. To test these hypotheses, further research is needed.

6.4.2 Generic measures of health violations and their application to the EH field

Having "any violation" cited within the review period was found to be significantly associated with identified and plausible food poisonings in Class III food establishments at the univariate level ($p<0.01$). Similar findings have been reported in studies conducted in Seattle-King County and Los Angeles (Irwin *et al.* 1989) (Buchholz *et al.* 2002). While it is important to recognize this relationship from a statistical standpoint, the practical application of this information in the field is limited when compared with specific violation codes. Specific codes offer greater precision and specificity as they relate to risk identification and management initiatives, which are the driving force behind this research. For this reason, and as it was thought that "any violation" would correlate highly with specific violation categories, it was decided not to consider this generic variable for model building purposes. Nevertheless, when entered into a multivariate model along with the violation codes considered, "any violation" is not found to be significantly associated with the outcome of interest [OR: 0.877; p=0.825]. Moreover, it is not significant when fit into a reduced model already containing *temperature control violations*, *test equipment violations*, *chemical & biological hazards*, and *complaint status*, nor is it a confounder for any of these variables. As such, this factor would not have changed the main effects or final model for Class III establishments had it been considered.

A better generic indicator of risk than having any violation cited is measuring the number of distinct violation types a food establishment receives within a defined period. No previous study has attempted to do this. In the present example, the number of different kinds of violations received by a food establishment in a 12-month period was found to be positively associated with BP-SFBI at the univariate level for Class III food establishments. Differences in the range of violations cited were also observed between case and control groups for the data set overall (n=420). This suggests that EHOs are identifying risk factors for food poisoning at permitted establishments. It also substantiates claims that systems like TMS are effective tools for tracking inspection records and identifying at-risk food establishments, if properly managed. While all aspects related to the number of distinct violation codes cited within the study period cannot be directly compared to past studies, it is anticipated that this information will prove useful in any future development of foodborne illness surveillance initiatives targeting permitted food establishments in the region.

6.4.3 Size versus facility class

Differences between the current study and others conducted to-date can make direct comparisons difficult. Several studies have reported facility size and seating capacity as being positively associated with foodborne outbreaks in restaurants (Irwin *et al.* 1989) (Cruz *et al.* 2001) (Buchholz *et al.* 2002). Such data were unavailable for the current study. It is suggested, however, that these variables were intended to help researchers approximate, and thereby indirectly measure, the complexity of food handling activities that occur in these food establishments; and not merely act as an indicator for the number of people potentially impacted should a foodborne outbreak occur. This measure is akin to facility classification in the present study. Comparing the results of the two facility classes reviewed, differences were observed in:

- the number of significantly associated risk factors at the univariate level;

- the kinds of violations found to be significant at the univariate and multivariate levels of analysis;
- the variety of violations cited within the critical period; and
- how strongly inspection frequency was associated with disease incidence.

Such differences support previous findings that larger establishments with more staff, more food handling, and increasingly complex menus are more likely to have violations cited. Moreover, as a larger number of Class III premises were determined to have a BP-SFBI, this would appear to support past claims that larger restaurants are more likely to have SFBIs identified. It is suggested, however, that the present study also builds upon past work by clarifying these relationships through more precise identification and delineation of noted differences between the respective facility classes.

6.4.4 Violation categories

Several violation categories were found to be significantly associated with identified BP-SFBIs in Edmonton area food establishments. In the following sections, differences between the respective facility classifications are discussed. Results are also contrasted with past studies, and information is presented to help explain why certain categories are believed to be predictors of food poisoning in commercial eateries.

6.4.4.1 Violation sets found in the final model for Class II food establishments

While several violation sets were found to be significant at the univariate level for Class II eateries located in the Capital Health region, only *maintenance/sanitation concerns* achieved statistical significance in multivariate analysis. *Staff hygiene violations* were similarly included in the final multivariate model because they were found to be a significant confounder for complaint status. The following sections discuss each of these violation sets in the context of Class II food establishments in the Capital Health region.

HAND WASHING / STAFF HYGIENE

Failing to wash hands before, during, and after handling foods clearly contributes to the spread of foodborne diseases (National Center for Infectious Diseases 2003) (Centers for

Disease Control and Prevention 2002). Hands can spread disease-causing microbes from raw foods of animal origin and from infected food handlers to ready-to-eat foods. In a comprehensive review of 91 scientific articles, hand-washing practices were shown to significantly reduce enteric illnesses transmitted by the fecal-oral route. Researchers have similarly reported that improper hand washing among food handlers is the second leading cause of foodborne illness in commercial eateries (Collins 1997).

Because hand washing is deemed a critical component in reducing the inadvertent contamination of food, one would expect that studies of this kind would identify the lack of such activities to be associated with outbreaks of food poisoning involving commercial eateries. A review of the studies presented in the critical appraisal section of this thesis reveals only *one* where poor hygiene practices among food handlers were found to be significantly associated with disease outcome in univariate analysis. This review also shows that poor hygienic practices were never included in a multivariate model, if such analysis was done. Results of the current study appear to confirm reports that unhygienic practices by food handlers are positively associated with an increased risk of foodborne illness in commercial eateries. Lack of hand washing was found to be significantly associated with BP-SFBI at the univariate level regardless of facility class ($p<0.01$). In multivariate analysis, staff hygiene violations failed to achieve statistical significance and were not part of the final model reported for Class III food establishments. Since they were a significant confounder for complaint status, however, staff hygiene violations were included in the final model for Class II food establishments. Differences between the respective facility classes, with respect to staff hygiene violations, likely extend from the reliance on young inexperienced staff at many Class II restaurants, as well as open kitchen designs typical of most fast-food eateries which dominate this class. It is anticipated that these results will provide health educators with even more evidence to support why staff hygiene practices are pre-eminent in foodborne illness prevention.

MAINTENANCE / SANITATION VIOLATIONS

In the context of a commercial eatery, maintenance and sanitation violations are indicative of inadequate cleaning schedules or procedures. They may also occur as a result of an ineffective maintenance program. There are several consequences that may result from such conditions. In many respects, maintenance / sanitation violations act as a prerequisite for more serious problems. They may, for example, increase the likelihood that food, food contact surfaces/equipment, or an employees' hands will inadvertently become contaminated. Such contamination may be physical, chemical or biological in nature. Maintenance / sanitation violations may also provide conditions suitable for the entry and proliferation of pests, or create occupational hazards for workers.

In the present study, maintenance and sanitation concerns were the most frequently cited of any violation type. This is consistent with many of the related studies conducted to-date (Irwin *et al.* 1989) (Buchholz *et al.* 2002) (Jones *et al.* 2004). At the univariate level, maintenance/sanitation violations were positively associated with disease outcome. As a categorical variable, more maintenance and sanitation problems in a Class II facility corresponded with an increased likelihood of a BP-SFBI. A similar relationship was not observed at Class III eateries, where only those establishments receiving the violation six or more times in the past year were significantly associated with an identified food poisoning.

Maintenance / sanitation problems initially failed to achieve statistical significance in multivariate analysis for either facility class. With the removal of several less significant variables from the Class II model, however, maintenance / sanitation violations achieved statistical significance ($p<0.05$). Consequently, it was added to the Class II preliminary main effects model. Inclusion of maintenance / sanitation violation in the final model was verified using purposeful selection, forward LR, and backward elimination techniques.

Noted differences between the respective facility classes are largely attributed to style of Class II restaurants: fast food establishments with walk-up counters and open kitchens. It is not expected that sample size or other frequently cited factors significantly contributed to noted differences in this instance. Consequently, it is expected that the presence of maintenance / sanitation violations in Class II and Class III establishments will not be regarded differently in the application of these results to identify food establishments at greater risk of having BP-SFBIs in the field. What may change is the manner in which maintenance and sanitation data are collected. Most maintenance and general sanitation deficiencies are currently described as being non-critical violations. Based on the significance of these violations in multivariate analysis, and drawing from personal experiences in the field, however, it is recommended that PHI/EHOs be given the discretion to assign critical violation status to violations of this kind should conditions warrant it. This would allow electronic data management systems, such as TMS, to more accurately record conditions found, and identify high-risk food establishments with greater precision.

6.4.4.2 Violation sets found in the final model for Class III food establishments

Three violations sets were included in the final model with complaint status: *temperature control violations*, *test equipment violations*, and *chemical / biological hazards*.

TEMPERATURE CONTROL VIOLATIONS

Microbial growth is a function of time, temperature, and other environmental factors. To restrict microbial growth that may otherwise result in the proliferation of pathogens or the production of toxins to levels capable of causing foodborne illness, food safety regulations have historically required perishable foods to be maintained either below 4°C or above 60°C. Recent outcome-based health legislation has also permitted time to be used as a control mechanism to control microbial growth in potentially hazardous foods under certain conditions (Public Health Act, Food and Food Establishment Regulation 2003).

Human pathogens may be introduced, or remain in foods in several ways. Foods may become re-contaminated after cooking due to poor sanitation or employee hygiene, or they may already contain low numbers of harmful bacteria as a result of insufficient cooking. Even if both these conditions are satisfied, there is still a possibility that pathogens could be present. Spore-formers such as *Bacillus cereus* and *Clostridium perfringens*, for example, have adapted so they can survive the cooking process and reproduce rapidly during the cooling stage. Additionally, raw fruits and vegetables, fermented foods and cultured products have elevated microbial counts as part of their natural flora.

In this study, temperature control violations were recorded as a result of improperly maintained equipment (such as coolers, freezers, or hot holding units), improper cooling or thawing practices, and improper display of perishable foods for extended periods of time. At the univariate level these violations were significantly associated with identified food poisonings at Class II and III food establishments in the Capital Health region. While temperature control violations failed to achieve statistical significance in multivariate analysis for Class II food establishments, they were an important part of the main-effects and final model for Class III facilities. It was further demonstrated that as the odds of a BP-SFBI increased, so too did the number of temperature control violations cited over the past 12 months. This finding is both biologically-plausible and consistent with epidemiological studies conducted in the past. Until Norovirus was successfully identified, the most commonly reported improper food handling practice associated with outbreaks of foodborne illness was improper holding and storage temperatures for potentially hazardous (perishable) foods. Moreover, a similar association between temperature control violations being cited by a PHI/EHO on the most recent routine inspection and subsequent foodborne illness at a food establishment was reported in Seattle-King County (Irwin *et al.* 1989). Variations with respect to how significantly temperature control violations are associated with food poisonings is believed to extend from differences in the scope of food handling activities that take place in Class III food establishments compared with Class II. It is also conceivable that a smaller sample size in Class II establishments may have prevented temperature control violations from becoming statistically significant. Based on this, it is expected that EHOs will continue to handle time/temperature problems in the same manner irrespective of the type of food establishment they occur in. Also, despite its strength of association at both the univariate and multivariate levels of analysis, it is important to remember that not every foodborne outbreak can be averted with proper temperature control. Foods must be cooked thoroughly, and measures must be taken to prevent contamination post-processing. In some instances, excluding ill food handlers, encouraging all staff to wash their hands frequently, and covering food properly are the only ways food establishment operators can help ensure that their food does not become a vehicle for the transmission of disease.

TEST EQUIPMENT VIOLATIONS

The driving force behind the statistical significance of this violation set was clearly the absence of thermometers to monitor coolers and hot holding units. Test equipment used to determine the capacity of heat or chemical sanitizers to perform adequately were not found to be significantly associated with disease outcome for either facility class. Missing thermometers were, however, found to be significantly associated with identified food poisonings in Class III food establishments ($p<0.001$; at the univariate level when taken as a dichotomous variable). The same relationship was not observed in Class II eateries. It is suggested that the proportion of facilities with a food safety program (FSP) in the respective facility classes contributed to observed differences in the strength of association between test equipment violations and disease outcome. The reason is simple. Operators of food establishments with such programs routinely check cooler temperatures as part of their regular duties – often several times per day. Since thermometers are required for this, it is reasonable that facilities with a FSP would have this violation cited less frequently.

Class II food establishments not only had a higher proportion of food establishments with a FSP, they are also generally smaller, have fewer coolers and hot holding units requiring test equipment. Class II eateries are also more likely to use single-service dishes and utensils. Each of these factors reduces the number of thermometers and other test equipment needed in comparison to larger Class III food establishments. Consequently, it should be noted that test equipment violations were also not significantly associated with BP-SFBI in Class II facilities *without* a FSP (Table 6.2.2). The same cannot be said for Class III establishments (Table 6.2.3).

Given the influence of missing thermometers on this violation set, it is not surprising that test equipment violations were significantly associated with BP-SFBI in multivariate analysis for Class III establishments. Temperature control problems and test equipment violations are correlated. It is suggested that food establishment operators who have thermometers present are more aware of, and concerned with, proper holding temperatures for potentially hazardous foods, and are more likely to check cooler and hot holding units on a regular basis. In terms of related research, the present study is not the first to identify a lack of thermometers as being significantly associated with foodborne outbreaks in permitted food establishments. A study conducted in Los Angeles County in the late 1990s demonstrated a similar association with a lack of thermometers at the univariate level (Buchholz *et al.* 2002). Researchers in Seattle reported similar findings, namely that food establishments receiving foodborne illness complaints were twice as likely to have had missing thermometers cited on their most recent inspection, though this association failed to achieve statistical significance (Irwin *et al.* 1989). In the application of these findings to the field, it is not expected that significant differences in inspection strategies or mitigation measures will result. Environmental Health Officers will continue to require that thermometers be present, and that temperatures be monitored regularly regardless of facility type, so long as potentially hazardous foods are present.

CHEMICAL & BIOLOGICAL HAZARDS

Poisonous substances, including pesticides, solvents, painting supplies, degreasers, cleaners, and sanitizers, must be stored distinctly separate from food products. They must also be used safely in order not to contaminate food products, or any surface that may come into contact with them. Proper containment and removal of waste from the premises is similarly important. Aside from odours, solid and liquid waste is unsightly, can attract insects and vermin, and increase the likelihood of cross-contamination.

As a dichotomous variable, chemical and biological hazards had the highest odds ratio of any violation set for Class III food establishments in univariate analysis [OR:6.05; 95%CI: 2.27-16.10]. Sufficient data were collected to analyze chemical and biological hazards as a categorical variable, but only within the first two category ranges. Few facilities had these kinds of violations cited more than once because corrective actions typically require the operator of the food establishment to move (or remove) any substances that is at risk of causing harm immediately. Consequently, there is rarely an opportunity for these violations to be present on (or require) a subsequent re-inspection because they are corrected promptly before the inspector leaves. It is therefore expected that violations of this kind are under-reported, and that actual associations between this variable and the outcome of interest may actually be greater than reported here.

In multivariate LR analysis, chemical & biological hazards were one of three violation sets identified with complaint status for the Class III final model. Surprisingly, no other study conducted to-date has successfully identified this relationship. Upon closer examination, it would appear that most studies failed to assess these risk factors independently of other storage and cross-contamination concerns; one exception being the research conducted in Seattle-King County (Irwin *et al.* 1989). The latter reported a matched odds ratio of 1.9 for *"Toxic items improperly stored, labelled, or used"* in univariate analysis, though it appears this relationship failed to achieve statistical significance (95%CI: 0.5-7.4). A small sample size in Irwin's study is believed responsible for this.

In light of these findings, it is expected that chemical and biological hazards will retain their "critical violation" status, and play an increasingly important part of inspection initiatives. In future studies, researchers may choose to delineate this variable into separate violation categories in order to explore the respective contributions of chemical and biological hazards. In the present study, the analysis of individual violation codes at the multivariate level was prevented by insufficient sample size.

6.4.4.3 Violation sets not found to be statistically significant in multivariate analysis for either facility class.

CROSS-CONTAMINATION

Food must be handled in a manner designed to minimize the possibility of it becoming a vehicle for the transmission of disease. Cross-contamination can occur during transport, storage, preparation or service of food. It may result in the physical, chemical, or biological adulteration of food products, as well as the introduction of allergens. Each of these factors has the capacity to cause foodborne illness. Conditions known to increase the likelihood of cross-contamination in a restaurant setting include:

- The storage of raw foods of animal origin (i.e. meats/poultry/seafood) and potential ready-to-eat foods (i.e. vegetables, bread, desserts, cooked products) in close proximity in coolers and freezers. This is particularly true if products are not properly covered.
- The use of the same utensil, cutting board, or other food contact surface for both raw foods of animal origin and ready-to-eat foods.
- The failure of food handlers to change gloves or wash hands between duties such as handling garbage, dirty dishes, or raw meat, and then preparing a salad, dessert, or other ready-to-eat food.

In the present study, cross-contamination violations were analyzed as a categorical variable, and were significantly associated with foodborne illness in commercial eateries at the univariate level regardless of facility class. Class II food establishments with the violation cited two to three times in the previous year were 6.5 times more likely to have a BP-SFBI when compared to food establishments without the violation ($p=0.035$). Similarly, a higher proportion Class III eateries with a BP-SFBI had cross-contamination violations than their respective controls (Table 5.2.10). Subtle differences between the respective classes may be attributed to differences in sample size for the respective groups. In terms of related research, other authors have reported remarkably similar findings. While not to the same degree of significance, researchers in Los Angeles and Seattle both demonstrated an association between cross-contamination violations and foodborne illness at local restaurants (Buchholz, *et al.* 2002) (Irwin, *et al.* 1989). The importance of preventing cross-contamination from occurring is similarly highlighted in the Food Safety Code of Practice for Canada's Food Service Industry (CRFA 2003), the Alberta Public Health Act Food and Food Establishment Regulation, and various food safety programs.

It seems surprising that violations of this kind are not more significantly associated with the outcome of interest at the multivariate level. There are several possible explanations for this observation. First, they may be highly correlated with one or more of the other independent variables that are slightly more significant (i.e. temperature control). Also, as many of the violations are behavioural, there may be less of an opportunity for inspectors to identify such problems on routine (monitoring) and re-inspections because of the time of the day the inspection is conducted, the staff on duty at the time, or the amount of food being prepared (if any). The very presence of a PHI/EHO may also influence food handling behaviours; moreover it is suggested that this is indeed likely. A final reason why cross-contamination violation may not be identified as frequently as others involves how and when cross-contamination violations are usually corrected. Whereas a sanitation problem may take a week to complete, and require a re-inspection, cross-contamination concerns can (and often are) corrected at the time they are identified: foods in storage may be moved or discarded, food contact surfaces / equipment may be cleaned before further use, and improper food handling practices will be corrected at the time they are observed. This was discussed in the context of chemical & biological hazards in a preceding section. In light that cross-contamination has been associated with numerous foodborne outbreaks, it is expected that they will remain an important focus of food safety education, restaurant inspections and foodborne illness investigations in the future. However, as their role in sporadic restaurant-acquired food poisonings remains uncertain, more research in this area is clearly warranted.

PEST CONTROL

Taken as a dichotomous variable, having an infestation of insects or vermin in the past 12 months was found to be significantly associated with BP-SFBI in Class III food establishments at the univariate level ($p<0.001$). A similar association was not observed in

Class II food establishments. While an infestation of insects/vermin failed to achieve statistical significance at the multivariate level, its strong association with BP-SFBI at the univariate level is consistent with findings reported by (Cruz, *et al.* 2001). The study conducted in Seattle by Irwin *et al.* (1989) also demonstrated a positive association between rodent/insect infestations and subsequent outbreaks of food poisoning, though it failed to reach statistical significance [OR:6.5, 95%CI: (0.8-51.1)].

In addition to the epidemiological linkage, there is also a scientifically plausible explanation for why such an association is likely to exist. Insects and vermin act as vectors for a variety of human illnesses. Consequently, an infestation of insects or vermin in a commercial food establishment increases the likelihood that foods will become contaminated while in storage or during preparation. This may result from direct contact with the pest, or from indirect contact with a piece of equipment or other food contact surface contaminated by insect or rodent activities. In a recent study, researchers demonstrated that the common housefly *Musca domestica* was capable of transmitting *Aeromonas caviae* (Nayduch *et al.* 2001). Files have also been implicated as important mechanical vectors for the transmission of *Campylobacter,* and their control has been demonstrated to coincide with a lower incidence of diarrheal illness (Chavasse *et al.* 1999). Rodents and cockroaches have similarly been identified as carriers of enteric pathogens, including *Salmonella spp.* It is further suggested that the very presence of insects or vermin in a restaurant setting may be indicative of more widespread problems, including poor sanitation, improper food storage waste containment problems, and inadequate pest control measures. Each is a common precursor for infestation problems, and increases the risk of inadvertent food contamination by themselves. Correlations to this effect were not explored as part of the present research, but could reasonably form the basis for future studies in this area. Based on this collective evidence, infestations of insects / vermin will remain classified as a critical violation, and an important predictor of adverse outcomes (albeit complaints or SFBI reports) for permitted food establishments in the future.

FOOD STORAGE / PACKAGING VIOLATIONS

Food storage and packaging violations were marginal confounders for maintenance / sanitation violations in the main effects model for Class II food establishments. They were also found to affect the beta coefficients of factors remaining in the Class III multivariate model more than any other violation set when an assessment of confounding was done (though $\Delta\beta$ values were less than 10%). An initial response to these findings was one of uncertainty. Food storage / packaging violations were significantly associated with BP-SFBI in univariate LR analysis. Moreover, an increase in the number of food storage/packaging problems was shown to be associated with a similar increase in the likelihood of disease. Despite this, there was no obvious relationship between violations of this kind and the variables it was influencing at the multivariate level. Given that the connection was somewhat ambiguous, it was initially felt that these observed relationships may be spurious. Upon closer examination, however, it was noted that past studies have reported similar findings. Researchers in Los Angeles County, for example, identified incorrect food storage as being significantly associated with food poisoning in both univariate and multivariate analyses (Buchholz, *et al.* 2002). Based on this collective evidence, it is proposed that food storage / packaging violations correlate strongly with risk factors associated with cross-contamination during transport, storage and display. It is further suggested that the absence of proper containers / packaging, or sufficient storage space contributes to the introduction of foreign material into food products (i.e. physical, chemical or biological adulterants) which later result in foodborne illness. Differences in the strength of association between the respective facility types may be accounted for by a reduced sample size, and fewer dedicated food storage areas in Class II eateries. Additional research, incorporating a larger sample size, is required to explore this relationship further.

COOKING EQUIPMENT VIOLATIONS

Cooking equipment used in the preparation, storage and service of foods must be kept in proper working condition and free from structural defects. It also must be maintained in a clean and sanitary condition to prevent the inadvertent contamination of food. Four violations were combined to form this category. Two were found to be significantly associated with BP-SFBI (unsanitary equipment and damaged equipment) in a chi-square analysis. Two were not (ventilation problems and damaged dishware/utensils). In univariate analysis, cooking equipment violations as a set were significantly associated with BP-SFBI regardless of facility class, but it failed to achieve statistical significance in either multivariate model. As a potential confounder, cooking equipment violations were demonstrated to be associated with maintenance / sanitation problems in Class II eateries. Since unsanitary equipment and damaged equipment are both components of cooking equipment problems, this relationship is understandable. Cooking equipment violations were not included in the final model for Class II eateries for reasons previously discussed.

In terms of related research, few studies have reported significant associations between most cooking equipment violations and foodborne outbreaks at permitted restaurants. It is thought that a limited sample size may be responsible for this in some instances. In others, as in the case of the Los Angeles study (Buchholz *et al.* 2002), marginal associations were found between disease outcome, the use of damaged utensils [RR:1.5; 95%CI: 1.0-2.2], and the presence of unclean refrigerators [RR: 1.3; 95%CI: 1.0-1.8]. Disagreement between the respective studies suggests that none of the violations in this category are strong predictors of foodborne illness from a surveillance standpoint. It is still important, however, that equipment be properly maintained, particularly as it relates to coolers, freezers and hot holding units. While these violations may not occur with sufficient frequency to achieve statistical significance at a multivariate level for sporadic cases of foodborne illness here, they have been routinely implicated in large outbreaks of food poisoning resulting from *Staphylococcus aureus*, *Bacillus cereus*, and *Clostridium perfringens*.

KITCHEN HAND SINK VIOLATIONS

As discussed, hand washing is an important part of foodborne illness prevention. While it is ultimately the responsibility of food handlers to practice good personal hygiene while on duty, it is the responsibility of the restaurant owner to supply the necessary equipment for this to occur. Permitted kitchens are required to have dedicated hand sinks supplied with hot and cold running water. These sinks must be accessible to staff, and be equipped with soap and single-use towels at all times. Supplementary supplies, such as alcohol-based hand sanitizers and disposable gloves, may also be provided, but not in lieu of hand basins as such items are not required under pertinent health legislation in Alberta.

In the present study, kitchen hand sink violations were found to be significantly associated with foodborne illness in Class III facilities, but only in instances where the problem was cited four to five times in a 12-month period. As a dichotomous variable, they remained only marginally significant. Such violations were not found to be significant in remaining categories, or in Class II facilities. In similar studies, hand sink violations were combined with hand washing activities making direct comparisons impossible. Consequently, authors of the present study believe that a strong association was not found because:

(a) The presence of a properly equipped and accessible hand basin, in itself, does not ensure its appropriate use;

(b) Staff who routinely wash their hands are likely to do so regardless if all items are available. For instance, they may use another sink, not use soap, or not dry their hands, and while not ideal these activities still reduce the number of bacteria on their hands;

(c) Glove use and the use of hand sanitizers in the food industry are becoming increasingly popular. Each supplements hand washing initiatives, and have no relation to the presence or accessibility of hand basins.

PUBLIC WASHROOMS

Contrary to popular belief, the condition of public washroom facilities in commercial eating establishments does not correlate well with known risk factors for food poisoning. In the present study, sanitation and maintenance violations occurring in public washrooms were analyzed separately from similar violations reported in other areas of the food establishment. This was done, in part, because of the popular belief that the condition of washrooms can be used to gauge aspects of food safety and sanitation in other areas of the establishment. The TMS system tracks such violations separately in recognition that there are different risks involved with having maintenance and sanitation violations in food storage or processing areas, as compared to having them in public restrooms. Analysis of washroom violations revealed they were not significantly associated with BP-SFBI, regardless of the number of times they were cited or the type of food establishment in which they occurred. This is consistent with past studies which similarly demonstrated no relationship between the maintenance or sanitation of toilet/lavatories and foodborne disease (Buchholz *et al.* 2002).

OTHER VIOLATION CATEGORIES

None of the remaining violations were found to be significantly associated with BP-SFBI at the multivariate level for either facility class when combined together to form a single category (Z). At the univariate level, other violations cited two to three times in the previous 12 months were found to be positively associated with identified food poisonings in Class III food establishments [O.R.: 4.9; 95%CI: 1.34-17.99; p=0.017]. No associations of statistical significance were observed in other categorical ranges for Class III facilities, or in any range for Class II food establishments. While it is believed that sample size may be at least partially responsible for this observation, the greatest contributing factor to this variation is thought to be the inherent differences in the scale and diversity of food handling practices at the respective food establishments. One indication of this is highlighted by the fact that Class III food establishments with a BP-SFBI were 6.3 times more likely to be lacking a person with recognized food safety training. Examples of courses approved by the Minister under the PHA include *FoodSafe* and *ServeSafe*, as discussed in the introduction. Based on these findings, it is recommended that health departments encourage the food service industry to improve upon internal training programs, ask that a greater proportion of food handlers become certified in approved food safety & hygiene courses (particularly in full-service / Class III eateries), and challenge state, provincial, and federal governments to provide additional funding for food safety and health education programs. As for EH programs, it is paramount that they continue to focus their limited health education resources on full-service and high risk facilities.

6.5 Validity

In studies of harm/causation, a principal measure of validity is ensuring that case and control groups are similar with respect to known determinants of outcome. Every effort was made to ensure that anticipated sources of bias and confounding were effectively controlled. Several of the measures incorporated into the study design have been discussed. Those remaining are described below.

Representativeness of food establishments

One of the most important aspects of any study is the selection of subjects that are representative of the entire population. In the present example, *all* Class II and III food establishments in operation for the specified time period inspected by the food protection division of Capital Health had an equal opportunity for inclusion in the study.

Validity of SFBI (cases)

Public health offices receive dozens of SFBI complaints every year that have no bearing on the facility being implicated: either the symptoms are inconsistent with foodborne illness, or the incubation period is inconsistent with the clinical presentation described. In essence, these reports are not SFBIs. Consequently, their inclusion in the study would introduce error, and compromise validity. To help overcome this, specific criteria for the selection of biologically-plausible suspected food poisoning complaints were used to select cases (see Table 4.3.1). These criteria were extracted from widely accepted diagnostic resource materials, and as such represent the best available tool to identify biologically-plausible cases of food poisoning reported in the Capital Health region during 2003 secondary to clinical confirmation.

6.6 Control of potential biases

Bias has been defined as "any systematic error in the design, conduct or analysis of a study that results in a mistaken estimate..." (Gordis 1996; pp.183). In the present study, surveillance bias, attrition, maturation and the Hawthorn effect were circumvented by its very design. Selection bias, on the other hand, was minimized by the use of clear definitions and inclusion criteria for cases and controls (as discussed in the methods section). Researcher (or investigator) bias was similarly reduced by blinding assessors of BP-SFBIs to the identity of the food establishment and food safety program (FSP) status, requiring more than one person to independently review SFBI forms to identify biologically-plausible cases, developing standardized protocols to make such assessments, and using a computer to randomly select and assign eligible controls. Not all sources of bias could be controlled. As the study relied on SFBI reports obtained from the general public, it is subject to recall bias. Inaccuracies in the information provided to the health department could result in the misclassification of cases and a reduction in study power. Observer bias was similarly not controlled for in the study design. Over 20 different EHOs performed the restaurant inspections upon which the study was based. It is felt, however, that any influence brought about by this variable would be non-differential in nature, and therefore impact results very little. Future studies, incorporating a larger sample size, may wish to explore the impact of individual inspectors on inspection scores and/or adverse outcomes further.

While considerable effort was made to clearly define cases and controls, the potential to inadvertently misclassify certain facilities still exists. It is well-known that foodborne illness is under-reported (Altekruse & Swerdlow 1996) (Jones *et al.* 2004). It is estimated that less than five percent of legitimate food poisonings are reported to local health agencies (Herikstad *et al.* 2002). Typically, SFBI reports are from those individuals with severe illness, or are from groups where more than one individual experienced the onset of gastroenteritis following a common meal or event. Because of this, facilities with unreported cases of food poisoning may inadvertently be classified as controls in the proposed study. While this may first appear to be a significant limitation, one must consider that

(a) it dilutes odds ratios towards the null, meaning actual associations may be greater than reported here; and
(b) it applies to all studies of this kind.

Nothing can be done with respect to the proportion of SFBI complaints received by the department from the community. The same limitations exist for studies examining laboratory-confirmed outbreaks of enteric diseases from which incidence and prevalence data are generated. The goal here is not to misrepresent what is being examined, but to conduct the most stringent study possible using data from *valid* and *reported* foodborne illness investigations conducted in the Capital Health region during 2003.

A second way misclassification may be influence results deals specifically with the cases. While food establishments may be implicated with a biologically-plausible food poisoning, they are not necessarily the source. This too serves to dilute the odds ratio towards the null, and may make certain associations difficult to ascertain. The only scenario where this type of misclassification may be avoided is in instances where the etiologic agent is positively identified, in sufficient numbers, in both clinical specimens and food samples. Such scenarios are extremely rare; occurring occasionally in large foodborne outbreak investigations, but infrequently in sporadic SFBI reports involving a few people.

A third way misclassification bias may be introduced into the study is from the secondary data source. If SFBI investigations are improperly coded in TMS by health inspectors, search algorithms designed to identify and extract necessary data will miss potential "cases". While possible in theory, the likelihood that this could occur and not be noticed is remote. Every complaint and SFBI is catalogued at the time it is received by support staff and assigned a service request number (SR#). It is then passed to the appropriate PHI/EHO for investigation. All reports entered into the TMS database must have the SR# attached. This is done for several reasons, but in the context of the present example is important only because it serves as a check/balance system. Management reviews workload indicators, including the number of SFBIs and complaints called into the department, on a monthly basis. Discrepancies in the number of demand inspections received by the department and the number recorded in the TMS database are therefore quickly identified and corrected.

6.7 Quality assurance

6.7.1 Sensitivity

The assessment of sensitivity is limited in this study; the number of true cases of food poisoning in the Edmonton region is not known, only the number reported to the department. Thus, the proportion of valid cases that are reported to the department cannot be calculated directly. A review of studies conducted on the incidence and surveillance of foodborne illness, however, suggests that this proportion is quite low. According to the 2001 guidelines for evaluating public health surveillance systems (PHSS) produced by the CDC, a PHSS that does not have high sensitivity can still be useful for monitoring trends as long as the sensitivity remains constant over time. Factors that influence sensitivity in PHSS include the introduction of new diagnostic techniques and changes in surveillance methods themselves. Neither of these occurred in the Edmonton area between January 1, 2002 and December 31, 2003.

6.7.2 Data quality

Data quality was another important factor that needed to be assessed given the use of a secondary data source. To assess the validity of information present in the TMS database, 25 files were selected at random using an online random number generator (Research Randomizer®). Field notes for the most recent routine inspection were compared with the electronic version upon which the study was based (TMS). Fifty-seven violations were cited in the reports viewed. The average number of violations cited per food establishment was 2.28, with a range of zero to eight. Analyzing the data as a dichotomous variable, agreement between these sources was very good [Kappa= 0.733; $p<0.001$]. As a continuous variable, a disagreement between inspectors' field notes and TMS was found in only three out of 2,225 occasions where a specific violation code was reviewed (0.13%).

6.7.3 Positive predictive value

Validation of BP-SFBI cases by laboratory confirmation was not possible in the vast majority of cases. Fewer than 30% of SFBIs reviewed indicated that any person within the dining party sought medical attention (n=38; 16 Class II and 22 Class III). Of these, 26% had clinical samples submitted (n=10; *five* Class II and *five* Class III). The etiologic agent was identified in two BP-SFBIs and five outbreaks that occurred in the study period. Positive predictive value (PPV) is therefore defined as the proportion of SFBIs reported that were valid and plausible in relation to the total number of SFBIs received by Capital Health in 2003.

$$\textbf{PPV} = \frac{\textbf{\# of biologically plausible SFBIs in 2003}}{\textbf{Total \# of SFBIs received by Capital Health in 2003}}$$

$$= \mathbf{132 / 281}$$

$$= \mathbf{0.470}$$

Approximately 47% of the SFBI reports received by Capital Health in 2003 are believed to be valid.

6.7.4 Pre-test of data retrieval algorithms

Several pre-tests of the extraction algorithm were conducted by the Data Specialist prior to running the study sample. The development and pre-testing of such extraction algorithms followed the approval of the proposal by the department and the completion of an ethics review. However, the primary researcher was not involved in this programming component.

6.8 Study strengths and limitations

6.8.1 Strengths

Any epidemiological study has inherent strengths and limitations that can influence the quality of data collected and the validity of results obtained. There are several benefits to the concept and design of the current study which are highlighted in the sections below. This is done to demonstrate how this research builds upon the limited work conducted in this area to-date, as well as to demonstrate the particular usefulness and relevance of this work to the fields of Environmental and Public Health in general.

6.8.1.1 Sample size and representativeness

This study benefited greatly from the location at which it was conducted. The Capital Health region accounts for nearly one-third of the provincial population of Alberta. The Edmonton area alone recently surpassed one million people, and boasts one of the largest food establishment-to-resident ratios in North America. The food protection program within Environmental Health Services is responsible for the majority of these food establishments; approximately 4,400 in total. This strengthens the study in many ways:

- The size and geographic range make the sample population more representative of restaurants inspected in the Capital region, and in Alberta.
- The sample size allows for more rigorous and powerful statistical techniques to be used at the univariate and multivariate stages of analysis.

Further to this, Capital Health is recognized as a leader in research and innovation. In keeping with this image, there was considerable interest in Capital Health to conduct epidemiological research looking at risk factors for food poisoning associated with local eateries. Such information is useful when projecting anticipated workloads for field staff, and is necessary if existing surveillance mechanisms are to be improved such that effective and timely intervention strategies can be implemented to reduce the burden of foodborne disease in the community. Moreover, it is anticipated that similar methods may be used in the future to evaluate both intervention and surveillance strategies used by EH programs.

6.8.1.2 Case selection

One of the greatest strengths of this study is the manner in which plausible restaurant-acquired food poisonings were identified. As discussed in the introduction, foodborne illness assessed at the community level rather than at the laboratory level provides the opportunity for enteric pathogens not reportable under provincial legislation to be captured and included in the study. As a result, using SFBIs rather than confirmed outbreaks of foodborne illness where the etiologic agent has been identified allows the researcher to extract data from a larger, and arguably more representative sample population (see Figure 2.1.1). This method is also representative of how EHOs and field Epidemiologists must ascertain an implicated "source" in the vast majority of sporadic food poisoning cases where food and clinical samples are unavailable. Moreover, with the use SFBIs rather than confirmed foodborne outbreaks, there is the risk of non-specificity (meaning the illness described, while plausible in terms of clinical presentation and incubation period, may not be caused by the implicated restaurant). While this may appear to be a drawback, it also serves to strengthen any positive associations found because it dilutes the odds ratios towards the null. In the present example, researchers were still successful in identifying risk factors significantly associated with foodborne illness from inspection records. It is therefore suggested that actual associations may be greater than presented herein.

6.8.1.3 Selection of controls

To maximize the rigorousness and power of the study, three controls were selected for each case (see Chapter 4). To be eligible as a control, any 12-month period between January 1, 2002 and December 31, 2003 had to be available for review, meaning the facility had to be in operation with no SFBIs at any time within that timeframe. This said, only the 12-month window preceding the date of the BP-SFBI for the case they were selected for was used for analysis purposes. This ensured cases and controls were assessed for the same length of time, had equal opportunity to receive health inspections, and have violations cited. The assessment of each set of controls in this manner also helped ensure proper temporal association, and helped control for time period which could have otherwise introduced confounding. Several factors closely associated with time period can influence the number and type of inspections conducted by the health department. A news story on a food safety or health issue may increase the number of complaints received by the department for several days or weeks after it airs. Similarly, demands in other areas of the EH program, brought about by *special events* (summer festivals), *staffing shortages*, and *emergency response* may reduce the frequency of routine inspections food establishments receive for a period of time. The kinds of violations cited may also be affected. Roof leaks, for example, are often best detected during spring runoff. Insects, on the other hand, are more likely to be present in the warmer summer months. Altogether, this helps explain why it was necessary to examine each case and set of controls for the same 12-month period. No two seasons are exactly the same.

6.8.1.4 Transferable methods

The assessment of epidemiological trends and the development of innovative surveillance strategies to assist EH programs are both challenging and time-consuming. Because of this, many regions short on expertise and manpower may choose not to undertake such initiatives. In the present example, initiatives were developed within the context of an existing electronic data management program used to track inspection records. Consequently, this work serves as an example of what can be done with health inspection data collected for an entirely different purpose. It also offers a practical example of field research to health departments wishing to identify the relative importance of food safety violations in their area, or to explore potential surveillance initiatives of their own. Researchers feel strongly that there is the potential for more regions to recognize the breadth of opportunities these data provide. Now that the use of electronic inspection records to identify risk factors for food poisoning has been successfully demonstrated, the current design should allow other regional health authorities to reproduce the study using their own data, provided that food establishments are regularly inspected.

6.8.1.5 Improved assessment of risk factors

An attractive feature of the present study is the manner in which independent variables were identified and tracked. By tracking the frequency with which violations are cited over a 12-month period, rather than the simple binary 'presence or absence' of a violation on a given inspection, allows researchers to better assess trends over time when compared to similar studies reported to date. The present study also provides researchers with the opportunity to determine if increases in the number of times a violation is cited translates into similar increases in the likelihood of having a BP-SFBI in a permitted food establishment.

The independent assessment of Class II and Class III food establishments was also tremendously beneficial. The independent assessment of the respective classes negated the need for a matched analysis, allowing instead unconditional logistic regression techniques to be used. More importantly, it allowed differences between the respective classes to be revealed. Such differences are of great importance from a field standpoint because they have the potential to influence changes to inspection strategies if they are consistently found. More research is warranted in this area.

6.8.1.6 Benefits of an electronic data management system (TMS)

Inspection techniques vary between individual inspectors, and from region-to-region, even when they are conducted under the auspices of the same legislation. The food protection group in Environmental Health has a standardized set of violation codes to select from in the TMS database. Such a system is necessary to effectively track program indicators.

In the current climate of budgetary pressures brought about by health reforms, EH programs are increasingly scrutinized to produce measurable outcomes. Because it is difficult to measure something that "never happened", as in the case of an adverted outbreak, many EH programs have opted to track violations cited and corrected by their inspectors. In Capital Health, this is done electronically using preset violation codes which correspond to regulatory requirements cited in the PHA Food and Food Establishments Regulation. Although on-site inspections and inspection reports will vary in format and style in the field, standardized violation codes entered into the TMS database are thought to vary considerably less.

There are other benefits to using an electronic data management system for research purposes. Accessibility to inspection data and its quality are considered to be two of the strongest benefits of using TMS. While there were initial setbacks with obtaining the data, owing to unforeseen demands on the data systems specialist in other departmental areas, few problems were experienced after receiving the raw data set extracted from electronic records. Most problems were easily corrected, and later identified by the data systems specialist as data entry errors by the field inspectors – one example being forgetting to enter a service request number for complaint inspections. Data algorithms designed to summarize inspection data, however, did not perform well, even after repeated attempts were made to weed out "bugs" in the system. In response to these difficulties, raw data were entered into the Microsoft Excel spreadsheet manually (as indicated in the methods section).

6.8.2 Limitations

Many weaknesses are an extension of a study's strengths. The following sections discuss various limitations of the present study, including issues surrounding case selection, representativeness, matching, analysis, generalizability, and the use of a secondary data source.

6.8.2.1 Selection of *cases* and *controls*

Because the selection of cases is based on the clinical presentation of illness rather than the positive identification of the agent responsible, the likelihood of misclassification increases. As discussed previously, the inadvertent misclassification of controls is also possible through the under-reporting of foodborne illness. It is believed, however, that misclassification will result in a dilution of reported odds ratios toward the null hypothesis should it occur, thus strengthening any positive associations found.

6.8.2.2 Representativeness

Another limitation of this study is that it does not assess foodborne illnesses with long incubation periods. Food histories taken in response to SFBI are limited to 48 hours from the time of onset, and may be incomplete because of recall bias. As such, infection with Cyclospora, Giardia, Cryptosporidium, HAV, *Yersinia* and certain pathogenic strains of *E.coli* will not be accurately assessed from SFBI data. It is important to reiterate, however, that the general public is not likely to associate gastrointestinal illness with an exposure that occurred several days or weeks prior to the onset of symptoms. Since infection with the aforementioned agents is often prolonged, recurrent, and may be severe, these cases are more commonly identified through Notifiable Disease Reports (NDRs) once persons seek medical treatment rather than through SFBI investigations.

6.8.2.3 Drawbacks of using a secondary data source

Despite the benefits outlined in the previous section, there are also problems inherent to the use of a secondary data source such as TMS. First, many different people enter the data – in this instance more than twenty. Consequently, the potential for missing or incomplete records, and individual differences in the use of certain violation codes during data entry (i.e. inspector bias) is increased. There is also the possibility (albeit unlikely) that program glitches may result in the loss of some inspection data. Both these sources of error are considered to be non-differential in nature, and it is assumed that they would affect both cases and controls equally if or when they occurred.

Another potential shortcoming of the study stems from the violation codes themselves. While the TMS system is excellent at tracking the number of times a particular violation was cited, when it was entered, and when it was removed, it may not always reflect the *severity* of the condition found on any particular occasion. For example, there is one violation code for inspectors to select when floor, wall or ceiling surfaces are found in an unsanitary condition during an inspection. Thus, conditions depicted in figure 6.8.1 would be tracked by TMS identically assuming the district inspector took no enforcement action, and conditions were rectified by the next inspection conducted.

Figure 6.8.1 Pictures portraying similar violations, but at varying levels of severity

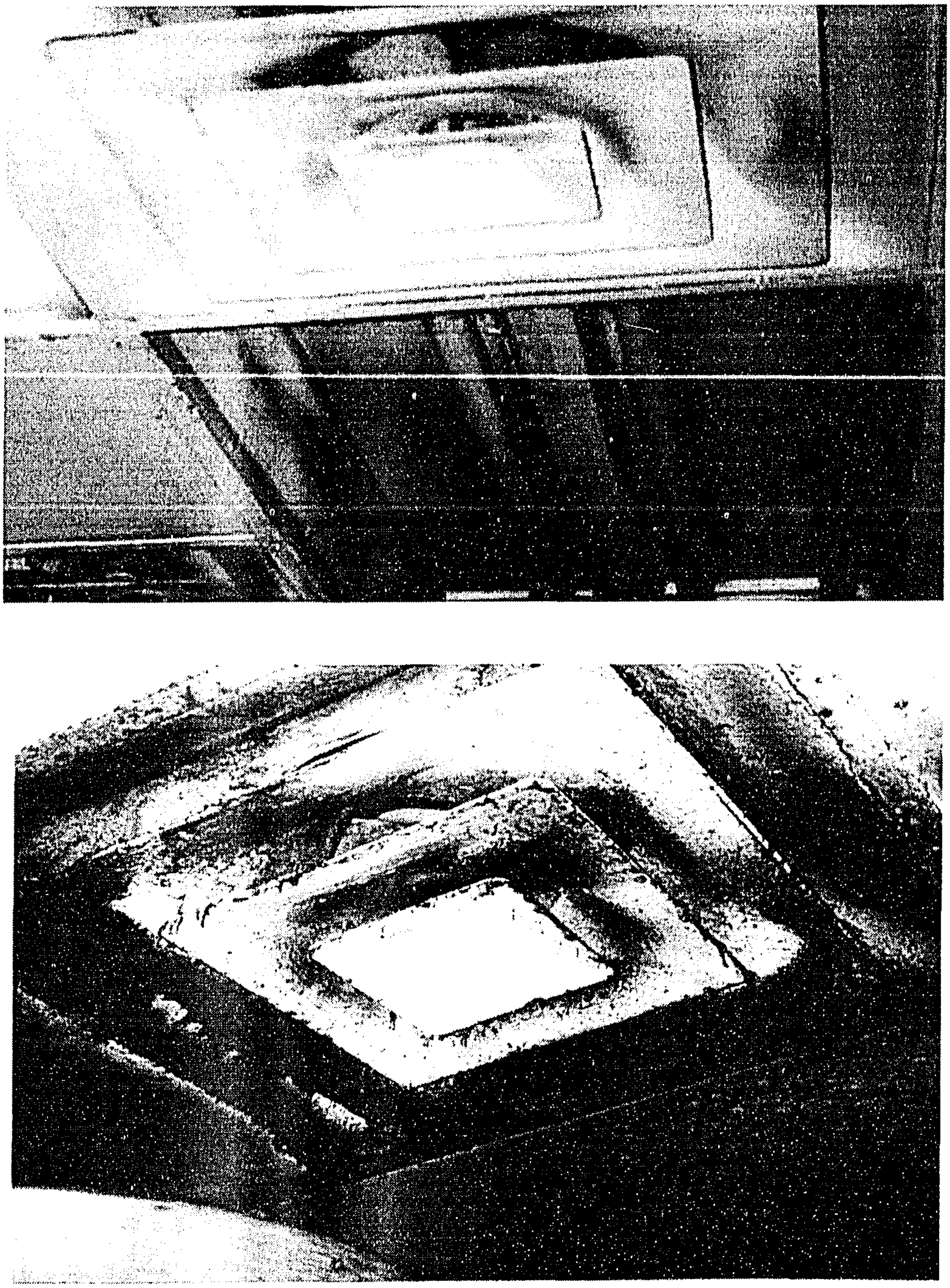


Figure 6.8.1 Floors, walls and ceilings in permitted food establishments are required to be maintained in a clean and sanitary condition. Unsanitary conditions are usually indicative of an ineffective maintenance / sanitation program, and may attract insects or result in the inadvertent contamination of food products. The photos above depict return air vents that require cleaning. Both conditions are coded identically by TMS. It is proposed that in the future, inspectors be given the opportunity to assign critical violation status to certain non-critical violations when conditions warrant it.

Severity scales, if incorporated into future versions of the TMS program, would have to be widely and consistently used by all inspectors for trends of this nature to be assessed.

6.8.2.4 The independent assessment of Class II and Class III facilities

Although the independent assessment of the respective facility classes was beneficial in many ways, it also had some important drawbacks. Each of the potential limitations introduced by the segregation of the respective classes for analysis purposes is discussed below in the context of the present study.

The effect on sample size...

Assessing the respective facility classes independently had a negative impact on sample size. Because data for each facility class was analyzed independently, the sample size was effectively cut in half. This adversely impacted the power of the study as demonstrated Table 4.6.1. As a consequence, the fact that certain independent variables were not statistically significant in multivariate analysis does not mean that they are not actually related to BP-SFBI in commercial eateries. While they truly may not be, the possibility of a Type II error cannot be disregarded under the present circumstances. Reduced power increases the likelihood that a null hypothesis will *not* be rejected when in fact it is false. Additional research using a larger sample population (or longer time period) is needed should individuals wish to verify or reject reported findings.

Limitations placed on statistical analyses...

Another drawback of analyzing Class II and III facilities independently was certain associations could not be assessed. While results for the respective classifications can be compared, an analysis of the effect of facility class on disease outcome cannot be conducted. Similarly, potential interaction effects between facility class and other exposures of interest cannot be calculated. Each of these represents a drawback to the study design.

The impact on the recruitment of controls...

It often becomes increasingly difficult to find suitable controls for research initiatives as more restrictions are placed onto the study population. Such is the case when sample sizes are small, cases and controls are matched on several variables, and recruitment of live subjects is required. Stratifying by facility class did reduce the effective sample size. However, because the study drew from a sample population of more than 3,800 food establishments, finding a suitable number of controls was not difficult.

6.8.2.5 Design & analysis

Case-control studies are limited in that they cannot conclusively determine cause and effect, only statistical associations between independent variables (violation codes,...) and the outcome of interest (biologically-plausible cases of foodborne illness reported in the Capital Health region). This is because disease outcome is already known, and risk factors are identified retrospectively. Despite this, it is felt that the benefits offered by a case-control design clearly outweigh this drawback in the present example. Cohort designs are not well-suited for rare outcome events, or for assessing multiple exposures over time. Case-control studies are.

The statistical analysis has its own set of limitations. The end result of using summary data is differences between certain sub-groups may be lost, or the strength of association weakened, when smaller components are combined. Such effects were apparent after violation codes were combined into larger sets (A-Q). In light of this, data on both violation codes (n=59) and violation sets (A-Q) were reported where feasible.

6.8.2.6 Restriction

A less representative sample of the reference population is a potential consequence of using restriction to increase internal validity. It is not anticipated that this was a problem in the present example. All Class II and III food establishments inspected by the food protection division in operation for the time period in question were eligible for inclusion in the study. Consequently, the sample is only unrepresentative insofar as it does not include Class I facilities, and food establishments not in consecutive operation between January 1, 2002 and December 31, 2003 in the Capital Health region.

6.8.2.7 Generalizability

One of the objectives listed for the proposed study is to provide an example of how data collected by food protection programs can be analyzed for surveillance purposes. This said, there may be certain limitations with respect to how generalizable and reproducible the study is in regions lacking the necessary expertise to analyze epidemiological trends, or resources to conduct regular inspections and track program indicators (i.e. inspections, violations, and facility demographics). It is expected that this study would be difficult to replicate on a large scale without the assistance of a computerized tracking system. Regions lacking the resources required to develop and maintain such a database would be required to manually review reports for each food establishment and tabulate the results before analysis would be possible. In addition to being both cost and time prohibitive, this process would likely introduce bias and error. Related studies on the development and use of electronic data management systems confirm the necessity of a computerized recording system to point out the most common infractions, and track program indices (Barni *et al.* 2003).

Chapter 7: Recommendations and conclusions

7.1 Recommendations

Recommendations emerging from this study are discussed in two different contexts: immediate applications to the field of EH, and directions for future research. Each is discussed below.

7.1.1 Applications to the field of environmental health

7.1.1.1 General applications: risk identification & management

There are several immediate and long-term applications for the findings of this research. First and foremost, variables identified as being significantly associated with BP-SFBI in commercial eateries can be used to help identify which food establishments in the region are at greatest risk of causing foodborne outbreaks. In response to the identification of these facilities, health authorities have the opportunity to better allocate existing staff and resources, and implement control measures designed to mitigate the increased risk of foodborne illness. As discussed, measures shown to reduce the number of cited health violations in commercial eateries include *food handler education*, and *increased inspection frequency*. Closure is also effective at eliminating imminent risk, but there is insufficient evidence that it, or other forms of enforcement (i.e. orders, fines or prosecutions), are effective risk management strategies over the long-term. A closer look at these relationships is warranted.

7.1.1.2 Improvements to electronic data management and tracking systems

It is suggested that electronic tracking systems offer the most practical and consistent means of tracking risk factors and identifying problem eateries. Ideally, such a system would be of greatest practical value if: (a) it is used over a large geographic area, (b) it is incorporated into an existing electronic database already used to track program indicators in the region, and (c) the specified risk factors could be changed over time (should subsequent studies reveal changes to risk factors at the univariate or multivariate level).

At the present time it is difficult to compare outcomes of restaurant inspections across different regions of Canada. Even within Alberta, several electronic data management systems are currently used. Some RHAs lack computer systems altogether. It is recommended that provincial health regions move towards standardizing electronic tracking systems for their health inspection programs. This would permit better comparisons between regions, allow RHAs and Alberta Health to track epidemiological trends, and improve overall disease surveillance. It is proposed that the DC9 Council of Managers, Alberta Health, and the Canadian Institute of Public Health Inspectors (CIPHI) work collectively towards the development and implementation of such a program. This interdisciplinary approach to the development of such a platform is likely to benefit the field in other ways, including fostering new ideas, providing opportunities for research, and improving the surveillance of risk factors for foodborne illness.

In Capital Health, discussions with the Information Systems Specialist to upgrade the existing TMS system have already begun. Upgrades to the program are in the preliminary stage. However, the plan is to have the colour of the food establishment change on the main screen as more factors found to be significantly associated with BP-SFBI are satisfied. It is proposed at the present time to have three alert levels for each facility class (low, medium and high). A council of senior EHOs in food protection will meet before the release of the new initiative to decide which mitigation strategies will be implemented. Such strategies will be in addition to the regular inspection activities, and will be cumulative as risk levels increase. Consequently, these proposed initiatives will focus greater emphasis on Edmonton area eateries that offer the greatest potential risk to restaurant patrons – a response that has long been advocated in EH literature (Wodi *et al.* 1985) (Zaki *et al.* 1977). It is anticipated that this initiative will undergo a trial and evaluation period prior to widespread utilization within the region.

7.1.1.3 Methods

Another application of this research to the field of EH is the potential for the study design to be used by other health departments to analyze data collected by their own food protection programs. As well as allowing regions to identify local trends, and implement risk management strategies in response to them, work of this kind could also assist in the advancement of epidemiological research. Specifically, it could allow results from two different regions to be compared, since it is currently unknown if identified risk factors reflect conditions found in other cities or municipalities. While it is anticipated that identified risk factors may change with time, district, city, or region, this may not in fact be the case. In the interim, food inspection data collected in Capital Health and analyzed for the purposes of this study can be considered representative only of food establishments located in Edmonton and surrounding areas inspected under the auspices of the Food Protection Program.

7.1.2 Future research

There are several opportunities for further research stemming from the results of this study. Many of these examples have been discussed in previous sections; they include:

- repeating the study in another RHA in order to compare factors found to be significant using logistic regression;
- examining more closely the associations between certain independent variables used in this study;
- exploring the reason(s) behind observed differences between certain health violations and disease outcome for the respective facility classes;
- assessing the long-term impacts of enforcement on compliance with health regulations; and
- studying the content and application of food safety programs currently utilized by national restaurant chains, and investigating their impact on reducing the number of foodborne illness reports a food establishment with such a program receives.

Many other avenues also seem worthy of exploration. Because the methods used to conduct this study are new, in that several inspections were used retrospectively to determine exposure, repeated use of these techniques should provide evidence that the study is reproducible. Conducting the study again locally in a few years would allow researchers to identify changes to the final multivariate model, and determine if the strength of associations between independent variables and BP-SFBIs had changed. This approach offers epidemiologists one way to assess temporal differences and to evaluate the impact of changes in the food protection program – including mitigation strategies implemented in response to the initial study.

Future studies may also choose to more closely assess the impact of other independent variables not considered in the present study design. Such factors include:

- specific styles of cuisine (e.g. Asian, East-Indian, Western)

- the use or presence of more formal HACCP programs
- the seating capacity of the restaurant,
- the primary language of the operator of the food establishment,
- the number of years the restaurant has been in operation (with the existing owner),
- the number of years the owner has worked in the food service industry, and
- controlling for individual inspectors, or areas of the city.

With the addition of such variables, steps to ensure adequate sample size would likely be needed in order for determinants of foodborne illness to achieve statistical significance.

There are inherent consequences to lengthening the observation period, or expanding the geographic area of a study, in order to increase its effective sample size. Prospective designs are prone to loss-to follow-up which can affect how representative a study is. As the geographic area expands, so does the likelihood that differences will exist in the application of inspection services or food protection initiatives. Limited staff and competing program interests in many rural areas, for example, often make it difficult for local inspectors to meet provincially-set standards for inspection frequency. As such, the validity of any study failing to control for these factors could be compromised as combined groups would not necessarily be homogeneous. A second consequence that is expected to occur with increased sample size, is the rigor/usefulness of the information obtained from the mere presence or absence of particular violations. Common sense suggests that as the study period lengthens, so too does the likelihood that a violation will eventually be cited within the study period. Eventually, differences between case and control groups will be diminished to a point where the analysis of violation codes as dichotomous variables is no longer warranted. Only through the analysis of independent variables in terms of the number of times they are cited (i.e. in categorical or continuous form) will indicators for foodborne illness be revealed.

7.2 Broader implications of epidemiological research in the field of Environmental Health

7.2.1 Staffing

Given the lack of rigorous epidemiological research in this area to date, there is clearly a need for more epidemiologists in the fields of Food Protection, EH, and Public Health. Ideally, these individuals should receive certification as an EHO in addition to their medical training so that the respective complexities of each role can be understood. The need for certified personnel for the surveillance, investigation, and reporting of foodborne illness was echoed in a recent article published in Emerging Infectious Diseases (Hoffman *et al.* 2005). In this paper, the capacity of state and territorial health agencies to prevent foodborne illness and respond to outbreaks was examined. Researchers surveyed 48 heath departments identifying barriers to investigating foodborne outbreaks, submitting samples, and conducting disease surveillance. Researchers also collected information on the number of staff each state health department had, as well as the qualifications of inspectors, epidemiologists, and other personnel who may be called upon to conduct foodborne illness investigations. The authors concluded that by addressing shortages in the number of dedicated foodborne disease epidemiologists capable of performing analytic studies, and working to reduce delays in reporting to agencies such as the CDC, the capacity of state health departments to respond to foodborne illness could be improved. In Canada, it is expected that similar delays and inconsistencies in reporting are experienced between the local health authorities, the provincial government, and Health Canada. Therefore, it seems logical to conclude that similar staffing changes could also benefit regional health authorities across Canada.

7.2.2 Improvements to accountability

In the early spring of 2005, the Governor General's Office began auditing food protection programs for selected regional health authorities in Alberta. In light of this current political climate, which requires health departments to produce measurable outcomes and demonstrate greater fiscal responsibility, it is expected that epidemiological research and expertise will become increasingly important to the field of EH. Current data management systems used by EH departments allow RHAs to track workload indicators for field staff, including the number of inspections conducted, the number of violations cited and corrected, the number of complaints received, and the number foodborne illness outbreaks investigated. It is suggested, however, that a closer evaluation of inspection databases, and the translation of these findings into improved surveillance and inspection initiatives, could result in increased efficiency and improved cost-effectiveness for local inspection programs – a sentiment shared by authors of related research. While some risk factors for food poisoning have been highlighted by the present work, there are clearly some resource-intensive activities that do not appear to be associated with adverse health outcomes (including the identification of some violations). There is an opportunity here for regional health authorities to revise inspection strategies in response to new risk assessment initiatives offered by this kind of research.

7.3 Conclusions

Food inspection services provided by Environmental Health departments play a critical role in the primary prevention of foodborne illness.

This study demonstrated significant differences between inspection records for permitted food establishments with and without a BP-SFBI. Researchers were successful in identifying risk factors for food poisoning in commercial eateries using electronic health inspection records. Differences between Class II and Class III food establishments in the Capital Health region with respect to these risk factors were similarly highlighted. Results suggest that *public complaints*, poor *staff hygiene*, and *maintenance / sanitation violations* are of particular importance to Class II food establishments when they occur together. In comparison, *public complaints*, *temperature control violations*, *a lack of thermometers*, and *chemical / biological hazards* are of particular importance to Class III food establishments. The results of univariate analysis further suggest that as the number of different violations a food establishment receives increases, so too does the likelihood that it will be responsible for a BP-SFBI.

In addition to meeting the primary objectives listed in the methods and introduction sections, the present study demonstrates that inspectors working in the food protection division of Capital Health are meeting program expectations for inspection frequency, are identifying critical violations on monitoring inspections of food establishments under their care, and are appropriately focusing their efforts on "problem" facilities that warrant more attention. The study also highlights the positive influence that food safety programs can have, and the importance of food safety training for food handlers. Commercial eateries with FSPs were better at reporting suspected food poisonings when they occurred, and generally had fewer health code violations than food establishments without such a program. In full-service restaurants (Class III facilities), the odds of causing a BP-SFBI was greater in facilities lacking staff trained in food safety. In light of these findings, it is recommended that food handler education continue to be required, and that increased attention be placed on the development of food safety programs in permitted food establishments where these are currently lacking. An interdisciplinary approach to the implementation of such programs is most likely to achieve the greatest success. Ideally, programs should be developed, implemented, and evaluated *collaboratively* with government agencies and industry representatives (i.e. restaurant owners, operators, and associations). If nothing else, FSPs provide the necessary prerequisite programs and framework for HACCP – an internationally recognized food safety system originally developed by NASA, which according to some is the future of food safety (Bryan 1999). Many countries are taking this approach, evident in they are already requiring many of their larger manufactures and suppliers to have such programs in place.

In summary, past studies have suggested that regulatory agencies need to periodically evaluate restaurant inspection practices to maintain their relevance (Cruz *et al.*2001). The identification of risk factors associated with BP-SFBI in commercial eateries using inspection records for is but one example of how such evaluations can be carried out. Despite the success of the current study to highlight such associations, work in this area is far from over. While the study successfully demonstrates how facilities at higher risk of causing foodborne illness can be identified from electronic health inspection records, it similarly illustrates that additional mitigation strategies targeting food establishments with poor records are required. This observation prescribes the development of new surveillance tools, risk-based inspection strategies (based on aforementioned profiles), and the re-assessment of local trends to evaluate the impact of intervention and surveillance initiatives. Since each of these is expected to provide opportunities for further epidemiological research, it is hoped that the present work represents the first of many studies conducted in this area by health agencies across Canada.

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Appendix I

Facility Types

Risk	Facility Type/Comments	Example
	RESTAURANTS	
001 (4) Class I	*Food Code 1* Pre-packaged non-potentially hazardous foods only. Limited preparation of non-potentially hazardous foods only.	Starbucks; Second Cup; Orange Julius; New York Fries , Cinnzeo; Baskin Robbins; Cinnamons
002 (5) Class II	*Food Code 2* Limited menu . Pre-packaged raw ingredients are cooked or prepared to order. Raw ingredients require minimal assembly. Most products are cooked/prepared and served immediately. Hot and cold holding of potentially hazardous foods is restricted to single meal service.	McDonalds; KFC; Burger King; Dairy Queen Taco Bell; Harvey's; Wendy's; Mr Sub; Subway; Quiznos: Pita Palace; Domino's; Pizza 73: Pizza Hut Express; Taco Time; Tim Hortons; Louie's Sub; Edo Japan, " Chinese " Food Food Fair Facilities
003 (6) Class III	*Food Code 3* Extensive handling of raw ingredients. Preparation process includes the cooking, cooling and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous food.	Lydo(non-Food -Fair take -out Chinese style restaurants) Smitty's; Alberts; Boston Pizza; Sawmill; Keegans; Joey's Only; Swiss Chalet; " Named " Steak & Pizza; Spagetti Factory; Tony Roma's; Red Lobster; Red Robin; The Keg; Earls; Red Tomato; Olive Garden; ABC Family Restaurant

004 (7) Class III or IV depends on # of categories in facility	*Food Code 4* Major hotels with separate banquet facilities; facilities with immuno-compromised clientele; buffet operations (daily lunch & supper) ; restaurant commissaries.	Buffet World, Royal Fork, Hotel MacDonald, Westin, Chateau Lacombe, Good Samaritan Lodges
061 (0)	*Temporary Food* Food facilities set up for less than 15 days.	Special Event Concessions; Charitable BBQ's; Church, Associations and School bake sales
062 (5) Class II	*Mobile Units* *(potentially hazardous)* A food vending cart or mobile unit that prepares and serves potentially hazardous food and operates more than 14 days a year.	Any mobile unit selling intermediate and high risk foods as defined in Capital Health's pamphlet- hamburgers, wraps etc.
070 (4) Class I	*Mobile Unit* *(non-potentially hazardous)*	Any Mobile Unit selling non-potentially hazardous - hot dogs, smokies, popcorn, pre-packaged confectionary items, prepackaged frozen foods, beverages, whole fruits & vegetables
FOOD DISTRIBUTOR		
021 (4) Class I or Class IV depending on # of categories in the facility	*Grocery* Stores which process fruits and vegetables and/or stock canned goods and/or sell bulk foods and/or sell prepackaged potentially hazardous & non-potentially hazardous foods. The bakery, meat, deli, restaurant or coffee shop are reported separately.	Safeway, IGA, Superstore, Costco, Save-on Foods, Chinese Superstore, Extra Foods etc. This category could include some smaller grocery stores which meet the definition

022 (4) Class I	*Food Store* Stores which sell prepackaged potentially hazardous and non-potentially foods but do not process any type of food. (repackaging of non-potentially foods is not considered processing)	M&M Meat Stores, Liquidation World, London Drugs, Zellers, Specialty Stores, Health Food Stores.
023 (4) Class I	*Convenience Stores - Low Hazard* Neighborhood stores which sell non-potentially hazardous foods. Hotdogs, nachos, popcorn, coffee, prepackaged foods	Bob's Corner Store, Shell Gas Stations, 7-11 Reddi- marts
024 (4) Class II	*Convenience Stores - Potentially Hazardous* Neighborhood stores which sell and prepare both potentially and non-potentially hazardous foods	Petro Canada / A&W, Esso/Pizza Hut
025 (4) Class I	*Confectionary* Limited operation in the sale of confectionary items such as packaged candies, chips and pop. (no potentially hazardous foods such as milk or sandwiches)	Smoke Shops, some Drug Stores
066 (6)	*Farmers Markets Vendors*	All Farmer's Market Vendors
401(?) Class III	*Farmers Markets*	Name of Market on Food Permit. This code is used to summarize violations for the Farmer's Market Managers.

068 (4) Class I	*Liquor Outlets - Confectionary* Includes the sale of beverages used as mix.	Sale of mix including pop, juice, egg nog, water and ice etc
073 (4)	*Food Transport Vehicle* Independent vehicles that transport food. Not in association with a permitted facility.	

FOOD PROCESSORS

041 (5) Class II	*Bakery (potentially hazardous)* Bakery with limited seating is still a bakery. Sale of potentially hazardous products only.	Canada West, Artisan
042 (4) Class III	*Secondary Meat* Meat Facilities which are licensed as secondary meat facilities by Alberta Agriculture or Agriculture Canada	
043 (4) Class III	*Meat/Butcher*	All independent butcher shops & butcher shops located in Grocery stores
044 (7) Class III	*Food Manufacturers* *Potentially hazardous foods processed and not licensed by CFIA or Alberta Agriculture.* Wholesale food manufacturers (cabbage rolls, sausage rolls, pasta, noodles) commercial fish processors, and bottled water and/or ice facilities.	Royal Foods, Mr. Snack, Checkers Foods, Konpar Processing, Gourmet Delight, Troika Foods, Billingsgate Fish Co.

045 (7) Class III	*Caterers* Stand-alone primary purpose companies. If operating under a restaurant's permit, will not be permitted separately. If using community hall, the hall will have a permit, not the caterer.	Gourmet Goodies, A Cappella Catering, Dandy Fine Foods
046 (5) Class Iii	*Deli* Sale and processing of specialty meat. Must have separate deli area with all facilites (meat shop with deli cooler does not qualify).	
047 (4) Class II	*Retail Fish* Independent operation separate from other food prep. Area.	
049 (4) Class II	*Food Manufacturer (non- potentially hazardous)*	Large water bottling plants
050 (4) Class I	*Bakery (non- potentially hazardous)* Sale of non- potentially hazardous products only.	
065 (0)	*Community Halls (non-permitted)* Facilities with kitchens that are not permitted.	
067 (4) Class II	*Home Craft Operation (potentially hazardous)*	

Appendix II

Description of Violation	#	Crit
Floors, Walls & Ceilings (Sanitation)	322	0
Non-Food Contact Surfaces Unsanitary	227	0
Floors, Walls & Ceilings (Structural)	203	0
Food Equipment Unsanitary	197	0
Cold Storage of Food	169	1
Handwashing Supplies	165	1
Thermometer Missing	158	1
Mechanical Procedures	114	0
Food Held at Room Temperature	92	1
Food Equipment in Disrepair	86	0
Test Equipment - Temp/Chem (Machine)	71	0
Refrigeration Storage	67	1
Pests/Vermin	66	1
Unacceptable Containers	62	1
Thawing of Food	52	1
Shelving	49	0
Separate Storage Space	47	0
Plumbing Maintenance	47	0
Food Transportation (Unclean/Unsanitary)	42	0
Handwashing	40	1
Cleaning Cloths	38	1
Washroom Sanitation	37	0
Manual Procedures	36	0
Screen Doors / Weather Stripping	36	0
Machine Disrepair (Dishwasher)	34	0
Wash Basin (missing or inaccessible)	33	1
Test Equipment - Temp/Chem (Manual)	32	0
Dishes/Utensils Storage	31	0
Improper Food Handling	30	1
Food Manager Certification	29	0
Hot Holding of Food	27	1
Unacceptable Packaging	27	1
Washroom Maintenance (Structural)	27	0
Food Contact Surfaces	25	1
Dishes/Utensils Unclean	24	0
Cold Display of Food	23	1
Chilling of Food	22	1
Freezer Temperature	17	1
Poison Use	16	1
Ventilation System	16	0
Poison Storage	14	1
Adequate Storage Space / Shelving	14	0
Refuse Storage	13	0
Food Worker Clothing	12	0
Unrelated Tasks	9	1
Dipper Well	9	0
Customer Contamination	8	1

Food/Storage Area Incursions	6	0
Bulk Food Non-Perishable	6	0
Food unfit for human consumption	5	1
Nuisance	5	0
Personal Hygiene	4	1
Reheating of Food	3	1
Food Storage in Washroom	3	0
Utensils/Dishware Damaged	3	0
Water Supply	3	0
Single Service Utensils Reused	2	0
Food Labelling	1	1
Food Worker Hair Control	1	0
Inadequate Cooking of Food	0	1
Improper Food Transportation (Temperatures)	0	1
Bulk Ice Cream Temperature	0	1
Infection Control	0	1
Non-potable Water	0	1
Expired Foods	0	1
Unapproved Foods	0	1
Un-inspected Meat	0	1
Re-served Foods	0	1
Live Animal in Food Establishment	0	1
Metal Containers	0	1
Sewage	0	1
Food Transportation (inadequate protection)	0	0
Quick Freeze Facilities	0	0
Wood Dishes / Utensils	0	0
Required Sinks	0	0
Unapproved Dishwashing Equipment	0	0
TOTAL:	2957	
Bulk Liquid Containers	not	included
Bulk Food Dispensers	not	included
Moist Bulk Food	not	included
Bulk Food - Maintenance	not	included
Bulk Food - Perishable	not	included
Bilk Food - Ingredient List	not	included
Permit Not Displayed	not	included
Violation of Permit Restrictions	not	included
No Permit	not	included
Lighting Levels	not	included
Protective Light Covers	not	included
Market Stall Unclean / Unsanitary	not	included

Violations with limited field applications or implausible biological credibility / relevance to suspected food poisonings were not analyzed. In some instances, insufficient data existed. The "#" column represents the number of food establishments that had the violation cited. "Crit" indicated whether the violation code was critical (1) or non-critical (0). Critical violations are believed to be of greatest relevance to food safety.

Appendix III

Suspected Foodborne Illness
Case-Control Study, Capital Health (2003)

Complaint Date: ____________:__________:__________. S.F.B.I.#________________

Class:_______

PERSON #___

Suspected food/beverage: ____

____

____

Date food eaten:__________:__________:__________ Time:__________am/pm 1st Symptom________________

Date of 1st symptom:____________:__________:__________ Time:__________am/pm

Predominant Symptoms

( ) Nausea ( ) Cramps ( ) Headache ( ) Chills ( )______________

( ) Vomiting ( ) Diarrhea ( ) Fever ( ) Bloody Diarrhea ( )______________

Duration of illness: ____________(HOURS / DAYS) ( ) Still ill at time of report

++

PERSON #___

Suspected food/beverage: ____

____

____

Date food eaten:__________:__________:__________ Time:__________am/pm 1st Symptom________________

Date of 1st symptom:____________:__________:__________ Time:__________am/pm

Predominant Symptoms

( ) Nausea ( ) Cramps ( ) Headache ( ) Chills ( )______________

( ) Vomiting ( ) Diarrhea ( ) Fever ( ) Bloody Diarrhea ( )______________

Duration of illness: ____________(HOURS / DAYS) ( ) Still ill at time of report

++

PERSON #___

Suspected food/beverage: ____

____

____

Date food eaten:__________:__________:__________ Time:__________am/pm 1st Symptom________________

Date of 1st symptom:____________:__________:__________ Time:__________am/pm

Predominant Symptoms

( ) Nausea ( ) Cramps ( ) Headache ( ) Chills ( )______________

( ) Vomiting ( ) Diarrhea ( ) Fever ( ) Bloody Diarrhea ( )______________

Duration of illness: ____________(HOURS / DAYS) ( ) Still ill at time of report

Doctor or Hospital contacted by anyone? ( ) Yes ( ) No

Clinical samples taken (stool / vomitus)? ( ) Yes ( ) No
if "*yes*", results:______________________

Leftover food submitted? ( ) Yes ( ) No
if "*yes*", results:______________________

Comments: ____

Date: _______:_______:_______

Transcribed by:________________
Checked by:___________________

Reviewer Section

I have reviewed the attached summary, and by checking "YES" agree that the suspected foodborne illness is biologically plausible in accordance with the parameters set for the study. By checking "NO" I am stating that the implicated meal is an unlikely source for the illness described.

Reviewer #1: **{ } YES** **{ } NO** **Signed:**________________

Reviewer #2: **{ } YES** **{ } NO** **Signed:**________________

Reviewer #3: **{ } YES** **{ } NO** **Signed:**________________

Appendix IV

Recognized restaurant "chains" with HACCP-style food safety programs

A & W
Arbys
Boston Pizza
Burger King
Chili's
Coast Hotels
Costco
Dairy Queen
Denny's
GMCC
Harveys
KFC
McDonald's
Olive Garden
Outback
Red Lobster
Red Robin
Safeway
Save-On Foods
Sobey's
Subway
Swiss Chalet
Taco Bell
The Keg
Tim Horton's
Wendys
White Spot

Each of the food establishments on the above list were considered to have a food safety program (FSP) in place for the purposes of the study. It does not necessarily represent all facilities having such a program inside or outside the Capital Health region. Facilities were selected on the basis that they were national or international chains, that written records of temperatures, cleaning and sanitation programs, and incident reports were taken and retained as part of day-to-day activities. While not reflective of all food establishments with a FSP, it is felt that the decision to exclude individual restaurants from consideration serves to reduce misclassification and selection bias for the FSP group. Moreover, as the selection criteria are restrictive, the potential to have individual facilities with a FSP in the "no FSP" is increased. It is felt that this will move results of analysis towards the null – strengthening any observed associations found.

Appendix V

Descriptive data for inspection frequency

Class II and Class III food establishments were studied independently because program expectations are different for the respective facility types (see Chapter One). Inspection frequency data for Class II food establishments are summarized in Table V-1. The same data for Class III food establishments are summarized in Table V-2.

Table V-1. Inspection frequency data in case and control groups for Class II food establishments

			Group Allocation		
			Control	Case	Total
Number of Inspections	1	Count	32	1	33
		% within Group Allocation	28.1%	2.6%	21.7%
	2	Count	29	9	38
		% within Group Allocation	25.4%	23.7%	25.0%
	3	Count	15	6	21
		% within Group Allocation	13.2%	15.8%	13.8%
	4	Count	13	7	20
		% within Group Allocation	11.4%	18.4%	13.2%
	5	Count	10	3	13
		% within Group Allocation	8.8%	7.9%	8.6%
	6	Count	6	5	11
		% within Group Allocation	5.3%	13.2%	7.2%
	7	Count	4	0	4
		% within Group Allocation	3.5%	.0%	2.6%
	8	Count	1	1	2
		% within Group Allocation	.9%	2.6%	1.3%
	9	Count	2	5	7
		% within Group Allocation	1.8%	13.2%	4.6%
	10	Count	1	0	1
		% within Group Allocation	.9%	.0%	.7%
	12	Count	1	1	2
		% within Group Allocation	.9%	2.6%	1.3%
Total		Count	114	38	152
		% within Group Allocation	100.0%	100.0%	100.0%

Table V-2. Inspection frequency data in case and control groups for Class III food establishments

			Group Allocation		
			Control	Case	Total
Number of Inspections	1	Count	7	0	7
		% within Group Allocation	3.5%	.0%	2.6%
	2	Count	33	1	34
		% within Group Allocation	16.4%	1.5%	12.7%
	3	Count	44	7	51
		% within Group Allocation	21.9%	10.4%	19.0%
	4	Count	31	9	40
		% within Group Allocation	15.4%	13.4%	14.9%
	5	Count	23	7	30
		% within Group Allocation	11.4%	10.4%	11.2%
	6	Count	25	10	35
		% within Group Allocation	12.4%	14.9%	13.1%
	7	Count	15	8	23
		% within Group Allocation	7.5%	11.9%	8.6%
	8	Count	12	6	18
		% within Group Allocation	6.0%	9.0%	6.7%
	9	Count	4	4	8
		% within Group Allocation	2.0%	6.0%	3.0%
	10	Count	1	4	5
		% within Group Allocation	.5%	6.0%	1.9%
	11	Count	4	6	10
		% within Group Allocation	2.0%	9.0%	3.7%
	12	Count	2	2	4
		% within Group Allocation	1.0%	3.0%	1.5%
	14	Count	0	2	2
		% within Group Allocation	.0%	3.0%	.7%
	21	Count	0	1	1
		% within Group Allocation	.0%	1.5%	.4%
Total		Count	201	67	268
		% within Group Allocation	100.0%	100.0%	100.0%

Differences in inspection frequency were observed between the respective facility classifications, and between case and control groups. Five hundred twenty-four inspections were conducted in Class II food establishments (n=152), with a mean of 3.45 (±2.42) inspections per year and a range of one to 12 inspections within the critical period reviewed. Class III eateries (n=268) received 1,382 inspections, with a mean of 5.16 (±2.85) inspections per year and a range of one to 21 inspections within the study period. Controls generally had fewer inspections than cases. Those with the greatest number of inspections were more likely to be a Class III food establishment and/or a facility with a BP-SFBI.