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An examination of foodborne outbreaks of *Salmonella* Enteritidis in the United States, 1973-2008

Ashton Potter Wright ashtonpotterwright@gmail.com

AN EXAMINATION OF FOODBORNE OUTBREAKS OF SALMONELLA ENTERITIDIS IN THE UNITED STATES, 1973-2008

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ASHTON POTTER WRIGHT

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ABSTRACT

Ashton Potter Wright

An examination of foodborne outbreaks of *Salmonella* Enteritidis in the United States, 1973-2008

(Under the direction of Dr. Richard Rothenberg, faculty member)

Salmonella is a common enteric pathogen and is the most frequently reported bacterial infection in the United States. The two most commonly reported serotypes causing human illness in the United States are Salmonella serotype Typhimurium and Salmonella serotype Enteritidis (SE). The incidence and number of foodborne outbreaks of SE started to increase in the 1970s and by 1994, SE was the most common Salmonella serotype reported to the Centers for Disease Control and Prevention (CDC). SE has been most commonly associated with consumption of shell eggs. Outbreak reports were obtained from the Foodborne Disease Outbreak Surveillance System (FDOSS) and analyzed. The number of outbreaks of SE has declined by 67% since 1990, likely as a result of the combined effect of on-farm interventions, public health policies, and food safety education messages. In addition to the decline in SE outbreaks, study findings demonstrate that there have been changes in the geographical distribution of SE outbreaks in the US. "Simple egg" foods and retail food settings have been the most commonly and consistently associated vehicles and food consumption and preparation settings with SE outbreaks in the US from 1973 to 2008.

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Enteric Disease Epidemiology Branch (EDEB)

Finally, I would like to thank the state and local public health departments within the United States whose efforts contributed to the data available for this project.

LIST OF ACRONYMS & ABBREVIATIONS

SE	Salmonella enterica serotype Enteritidis
CDC	Centers for Disease Control and Prevention
USDA	United States Department of Agriculture
APHIS	Animal and Plant Health Inspection Service
FSIS	Food Safety Inspection Service
ST	Salmonella enterica serotype Typhimurium
FDA	Food and Drug Administration
PEQAP	Pennsylvania Egg Quality Assurance Program
EQAPs	Egg Quality Assurance Programs
FDOSS	Foodborne Disease Outbreak Surveillance System
FOST	FoodNet and Outbreak Surveillance Team
EDEB	Enteric Disease Epidemiology Branch
DFWED	Division of Foodborne, Waterborne, and Environmental Diseases
pFORS	paper-based Foodborne Outbreak Reporting System
eFORS	electronic Foodborne Outbreak Reporting System
CI	confidence interval

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CHAPTER I: INTRODUCTION

Background

Salmonella is a common foodborne pathogen that has caused sporadic illness and outbreaks for over 100 years.¹ While there are many different serotypes of Salmonella enterica, the two most common causing human illness in the United States are Salmonella serotype Typhimurium and Salmonella serotype Enteritidis (SE).¹ The incidence and number of foodborne outbreaks of SE started to increase in the 1970s and by 1994, SE was the most common serotype of Salmonella reported to the Centers for Disease Control and Prevention (CDC).² Although different serotypes of Salmonella have been associated with a variety of food vehicles, SE has been most commonly associated with consumption of shell eggs.² The emergence of shell eggs as a vehicle for human SE infection led to a series of interventions by public health professionals, regulatory agencies, and the egg industry during the 1990s.²

Study rational

It is hypothesized that SE was initially introduced into egg-laying flocks in the Northeastern region of the United States and subsequently spread to other parts of the country.² Although the egg industry responded through the implementation of egg quality assurance programs (EQAPs) and the public health community responded with educational campaigns and other interventions, causing an initial decline in infections of SE², the organism has and continues to cause outbreaks and cases of sporadic illness throughout the United States. It is known that shell eggs are a vehicle of primary importance for outbreaks of SE, and many interventions and policy measures have been implemented to control the proliferation of the SE epidemic.² There is evidence that adoption of state EQAPs reduced the incidence of SE

infections in humans in participating states.³ Mumma et al. reported that of the 41 states that submitted data, 15 reported that the egg industry in their respective state had adopted either a state-sponsored or industry-sponsored EQAP between 1989 and 1999.³ In addition, the results of this study indicate that increasing the number of eggs produced under EQAPs is correlated with reducing the incidence of SE.³ Despite these results, EQAPs have not completely addressed this food safety issue, as foodborne disease outbreaks associated with SE continue to be reported. Furthermore, as public health and regulatory interventions target the egg industry, it is uncertain if other food vehicles, such as broiler chickens, are emerging as important vehicles for outbreaks of SE.

Research Questions

Following an initial review of the literature the following research questions were formulated:

- 1) Have public health policies and industry interventions had an effect on the number of outbreak-related SE infections in the US?
- 2) Has the distribution of food vehicles associated with SE outbreaks changed over time in the US?
- 3) Has the geographic distribution of SE outbreaks changed over time in the US?

CHAPTER II: LITERATURE REVIEW

Public health significance of salmonellosis

Salmonella is a common enteric pathogen and is the most frequently reported bacterial infection in the United States.⁴ Approximately 95% of all cases of salmonellosis are attributable to foodborne sources ⁵. Symptoms of salmonellosis can range from mild to moderate and typically consist of diarrhea, abdominal cramps, and fever.⁴ Although symptoms are usually mild and patients recover relatively quickly, severe cases of Salmonella manifest in bloodstream infections that can potentially be fatal.⁴ It has been demonstrated that higher doses of Salmonella are usually correlated with a more severe gastrointestinal response including: earlier onset of diarrhea, increased likelihood of vomiting, and increased stool frequency.⁶ Infection with Salmonella is most severe in certain high risk groups such as infants (under 3 months of age), the elderly, and the immunocompromised. Salmonellosis not only results in morbidity and mortality; it has substantial economic implications as well.⁵ It has been estimated that the costs associated with premature death due to infection with Salmonella can range from \$2.2 million dollars to \$8.5 million dollars (1998 dollars).⁵ Additionally, the amount of potential earnings lost ranges from \$3.5 million dollars for females to \$4.1 million dollars for males and the medical costs and lost productivity associated with salmonellosis range from \$0.5 billion dollars to \$2.3 billion dollars.⁵

Estimated burden of salmonellosis in the United States

In the United States, *Salmonella* was designated as a notifiable disease in 1943.⁸ As a nationally notifiable disease, clinicians are expected to report all cases of salmonellosis to their local health department.⁸⁻⁹ Local health departments are then expected to collate cases and report them annually to the Centers for Disease Control and Prevention (CDC).⁸⁻⁹ Salmonellosis

has a long history of causing morbidity and mortality globally. Nontyphoidal salmonellosis was first identified as a pressing public health concern in the 1920s in Western Europe and in the 1950s and 1960s in North America. In the United States it has been estimated that approximately 1.3 million illnesses, 15,000 hospitalizations, and 500 deaths are attributable to foodborne salmonellosis each year. There have been steady increases in the incidence of *Salmonella* in the United States since 1943, when reporting for the infection began. CDC reported a 47% increase in cases of salmonellosis between the years 1972 and 1996. Although there are over 2,500 serotypes of *Salmonella*, 4 predominant serotypes constitute nearly half of all human isolates of salmonellosis in the United States—*Salmonella* Typhimurium (16.9%), Enteritidis (16.6%), Newport (8.3%), and Heidelberg (3.7%).

Estimated burden of Salmonella Enteritidis in the United States

Much of the increase in salmonellosis over the past decades has been driven by an increase in *Salmonella enterica* serotype Enteritidis (SE), a leading cause of foodborne salmonellosis. ^{4, 13} The incidence of SE increased dramatically in the Northeastern part of the United States beginning in the late 1970s and subsequently spread to other parts of the country in the 1980s and 1990s. ^{2, 13} In 1986, as a as a result of a large multi-state outbreak, SE truly commanded the attention of the public health community. ¹⁰ The outbreak sickened at least 3,300 people in 7 states and was eventually attributed to a commercial stuffed-pasta product that contained raw eggs. ¹⁰ Ten years later, it was estimated that between 200,000 and 1 million illnesses were attributable to SE each year in the United States. ⁴ In 2000, Schroeder and colleagues (2005) estimated that 182,060 illnesses, 2,000 hospitalizations, and 70 deaths were directly attributable to infection with egg-associated SE in the United States. ¹³ Rigorous epidemiologic

investigations initiated by the CDC in the late 1980s identified shell eggs as the primary vehicle of human exposure in the rapidly expanding epidemic.²

Although SE is prevalent in egg-laying flocks, it is estimated that only 1 in every 20,000 eggs produced in the United States is contaminated with SE, with a 90% certainty interval of 1 in 12,000 eggs to 1 in 30,000 eggs.^{2, 14} Although the chance of an egg being contaminated is relatively low, the proportion of eggs that are contaminated with SE will be higher in regions where SE is more prevalent in egg-laying flocks and just after the infection spreads.² Despite moderately low levels of contamination in table eggs in the United States, in the 1990s it was estimated that approximately 2.2 million eggs per year were contaminated with SE.²

Distribution of SE in the poultry industry, particularly among layer flocks

Like other serotypes of *Salmonella*, SE has a unique niche—the poultry industry.²

Poultry flocks are raised in three distinct tiers: primary flocks, also known as grandparent flocks or genetic stock, multiplier-breeder flocks, also known as parent flocks, and production or commercial flocks.¹⁵ Although SE has emerged as a problematic pathogen in all three levels of poultry production, it has historically presented the most concern for the shell egg industry.^{2, 15} Although SE does not typically cause overt disease in egg-laying hens, and SE infected eggs usually appear normal (making it hard to detect the problem on the farm), the pathogen poses a tremendous burden on human health.^{2, 10, 16} Near the beginning of the epidemic, it was well established that various types of *Salmonella* were present in the intestinal tracts of egg-laying hens.² Thus, it was reasonable to hypothesize that eggs could become infected with SE as they passed through hen's cloaca.² Additionally, it was hypothesized that the internal contents of an egg could become contaminated with SE through microscopic cracks on the surface of the egg shell once the egg had been laid.² Although control measures to ensure that eggs were cleaned,

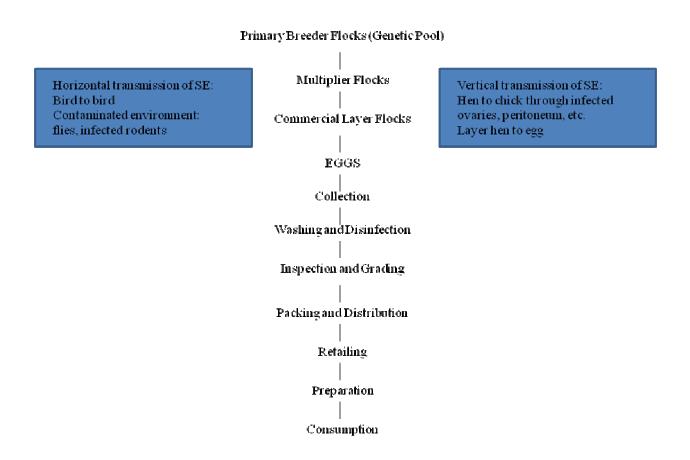
disinfected, and crack-free were put into place in the 1960s to address this concern of external contamination of shell eggs, SE continued to manifest itself on the farm, subsequently leading to human illness.² The continued presence of SE in the egg supply prompted further investigation into how eggs were getting contaminated.² Further studies elucidated the fact that eggs were likely being contaminated through the transovarian route (i.e., the contents of the egg were being contaminated with SE in the ovary of the hen before the shell was formed and before egg was laid).² After SE is deposited into the contents of the egg in the ovary of the hen, the pathogen is sealed in by the albumin and the shell and subsequently has an abundance of nutrients with which to sustain itself.¹⁷ The transovarian route of infection for SE was supported by earlier studies of Salmonella Gallinarium, a serotype of Salmonella that has historically caused illness in chickens but not in humans, which demonstrated that this serotype could be transmitted through the transovarian route and through studies that isolated SE from intact shell eggs and from the ovaries of egg-laying hens.^{2, 18-20} It is interesting to note that the decline of S. Gallinarium in hens is associated with the increase of SE in egg-laying hens, thus suggesting that SE took over the ecological niche that S. Gallinarium once dominated. 21-22 Although this evolutionary strategy proves extremely successful for the survival and proliferation of the pathogen, it has devastating consequences for public health because as SE proliferates in large quantities in the nutrients of the yolk, the potential for causing human illness is tremendous if the contaminated eggs are not fully cooked before consumption. 17

Several factors contribute to the proliferation of SE in egg-laying flocks. Egg-laying flocks that are exposed to large quantities of feces are more likely to produce eggs that are contaminated with SE. Similarly, egg-laying hens that are kept in houses that have large numbers of rodents are more likely to produce eggs that are contaminated with SE. Mice are

hypothesized to not only transmit SE but also to amplify SE in egg-laying hen houses.¹⁶ In addition, egg-laying hens that have been molted (i.e. have been deprived of food and water for periods of time) are more likely to test positive for SE than egg-laying hens of similar age that have not been molted.¹⁶

Attempts to decontaminate a farm by depopulating the SE-infected hens are often unsuccessful because even when a new flock is introduced, it often also becomes infected with SE.¹⁰ Failed attempts at elimination of the pathogen illustrate that transmission of SE occurs horizontally through the environment in addition to vertically through parent flocks.¹⁰ Figure 1 below illustrates how egg-laying hens can become infected with SE via both vertical and horizontal routes of transmission.²³

Figure 1. Salmonella Enteritidis in Eggs: From Chicken to Consumer (adapted from DHMH newsletter).²³



It has been suggested that the apparent increase in human illness associated with SE serves as a marker for the increase in egg-laying flocks in the United States.¹⁷ The issue of SE in egg-laying flocks is hypothesized to have originated in the Northeastern part of the United Sates and prevalence surveys on spent hens (hens who are no longer productive) conducted by the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) in the early 1990s demonstrated that 45% of egg-laying houses may be contaminated with SE in the Northern region of the United States, whereas only 17% of houses in the Central and Western regions and 3% of the houses in the Southeastern region may be contaminated.²⁴ The aforementioned regional distribution of SE is hypothesized to correlate with the distribution

of outbreaks of human illness and subsequent trace back investigations of SE-infected flocks. ²⁴⁻²⁵
In 1990, at approximately the same time the spent hen survey was conducted by APHIS, 81% of human cases of SE infection were reported from the Northern region, whereas 14% were reported from the Central and Western regions and 5% were reported from the Southeastern region. ²⁴ Similarly, of the 109 human cases of SE infection that were reported and subsequently traced back by USDA APHIS' *Salmonella* Task Force up until October of 1991, 81%, 10%, and 9% were reported from the Northern, Central and Western, and Southeastern regions respectively. ²⁴ A similar study conducted a couple of years later on the prevalence of SE in unpasteurized liquid egg products in the United States, found similar geographic differences which demonstrates that SE is likely not uniformly distributed among egg-laying flocks in all regions of the United States. ²⁶ Furthermore, it has been established that the epidemic of human SE infections is also expanding geographically across the United States. ²⁷

Shell eggs as a vehicle for SE infection in humans

It is estimated that over 46 billion shell eggs are distributed and consumed each year in the United States.²⁸ Enteritidis is the only serotype of *Salmonella* that has been consistently isolated from the internal contents of intact shell eggs²⁸, which supports the notion that SE in eggs is an on-going public health problem and a major food safety concern. Although shell eggs had been implicated as a plausible vehicle for SE in Europe²⁹, shell eggs were first epidemiologically linked to SE in the United States in 1988 when an in-depth review of SE outbreaks identified commercial Grade A shell eggs as the most important food vehicle for the transmission of SE to humans.³⁰ Not only is the egg a biologically efficient vehicle for transmission, the temperature at which eggs are stored and maintained plays a crucial role in the proliferation of SE.³¹ Whether or not eggs are refrigerated from the point of harvest on the farm,

refrigerated in transit during distribution, or their temperature is not properly maintained at the point of preparation or consumption (i.e., private home, retail food establishment, etc.) can have a direct impact on the growth and proliferation of SE.³¹ Numerous studies indicate that SE (and other types of *Salmonella*) thrives at warmer temperatures because the egg shell is more permeable (and therefore more susceptible to bacterial intrusion) and the bacteria are able to multiply with greater frequency under warmer conditions.³¹⁻³⁴

In addition to the shell egg's predilection for being a hospitable reservoir for SE, consumers and commercial food establishments play a substantial role in SE transmission and subsequent human illness.² Eggs and egg-containing foods are often consumed raw or undercooked in dishes such as Hollandaise sauce, mayonnaise, homemade ice cream, egg nog, or "over easy" eggs² in both private homes and in retail food establishments. Cooking eggs completely has been demonstrated to kill Salmonella, but consuming eggs that are runny or incompletely cooked places the consumer at increased risk for contracting salmonellosis.⁷ Additionally, if eggs contain large quantities of Salmonella, standard cooking procedures for common egg-containing foods (e.g., Hollandaise sauce, meringue, or soft-boiled eggs) may not be sufficient to kill the bacteria.⁷ Even when cooked, SE can survive in eggs if any part of the yolk is permitted to remain in a liquid state.²⁹ In addition to undercooking egg-containing dishes, restaurants and other commercial establishments are often associated with outbreaks of SE because of commonly practiced, hazardous methods of food preparation such as pooling eggs and inadequate holding temperatures for egg-containing foods, 2, 35 These unsafe food preparation practices permit SE to amplify, especially in raw or inadequately cooked eggs if held at room temperature for more than 2 hours. Restaurants and other commercial establishments can help to prevent outbreaks of SE by using pasteurized shell eggs or bulk-quantity pasteurized

egg products for recipes that call for pooling eggs and by following proper preparation and storage procedures.⁷

In addition to egg-laying hens, SE has also found a hospitable ecological niche in broiler chickens in the United States as well as in Europe. Although SE emerged concurrently in Europe in egg-laying hen flocks and in broiler chicken flocks, SE in the United States emerged first in the egg-laying flocks and has recently been observed in broiler chicken flocks. In 2006, USDA's Food Safety Inspection Service (FSIS) published data that indicated a significant increase in SE-positive rinses from broiler chickens from 2000-2005. This transition from layers to broilers, two distinct food production industries, in the United States is cause for concern since neither industry has been able to eradicate the pathogen and subsequently eliminate the occurrence of outbreaks of human illness associated with SE.

Epidemiology of Salmonella Enteritidis in the United States

Although outbreaks of *Salmonella* have occurred for decades, outbreaks of SE first emerged as a major public health concern in the 1980s.^{4, 38} Since the emergence and identification of SE in shell eggs in 1988, outbreaks of egg-associated SE infections have spread from the original foci in the Northeast to other parts of the country.³⁸ Outbreaks of SE have been linked to a variety of raw, partially cooked, or fully cooked egg or egg-containing foods including, but not limited to, cheesecake³⁹, hollandaise^{39,40}, chiles rellenos^{35, 39}, meringue⁴¹, egg rolls⁴², ice cream⁴³, bread pudding with vanilla sauce⁴⁰, Caesar salad⁴⁴, and tuna salad.⁴⁵ Large outbreaks of SE have also been attributed to ill food workers which highlights the need for improved food handler and food preparer exclusion policies in commercial food establishments.⁴⁶

Outbreak investigations and subsequent case-control studies have illuminated interesting details about the epidemiology of SE and have identified common food handling practices that contribute to the occurrence of SE outbreaks. In 1993 an outbreak of SE in Texas sickened 19 people, 2 of which were hospitalized.⁴² Epidemiologic investigation of the outbreak identified pooled shell eggs used to make egg roll batter as the vehicle of interest.⁴² Not only were large quantities of shell eggs pooled, the egg roll batter was permitted to sit at room temperature all day, thus providing a perfect environment for SE to grow and proliferate.⁴² A 1996 outbreak of SE in a Georgia restaurant resulted in 44 illnesses and 8 hospitalizations.³⁵ The epidemiologic investigation identified pooled shell eggs used to prepare chiles rellenos as the likely source of the outbreak, and the environmental investigation revealed numerous food handling violations which likely contributed to the amplification of the outbreak.³⁵ Outbreaks such as these could be prevented by replacing shell eggs with pasteurized eggs and ensuring that food handlers adhere to proper food preparation procedures.⁴²

Although pasteurized eggs have been demonstrated to be safer than non-pasteurized shell eggs, outbreaks linked to foods made with pasteurized eggs and egg products have occurred. The first outbreak of SE associated with a product made with pasteurized ingredients was reported in 1994. A nationally distributed brand of ice cream made with pasteurized ingredients resulted in 224,000 estimated illnesses of SE. Investigators determined that the tanker trailers used to transport the pasteurized ice cream premix previously transported SE-positive non-pasteurized liquid eggs, thus suggesting cross-contamination was responsible for the massive outbreak. This outbreak demonstrated to the food industry that improving methods to ensure the safety of all food products, even those made with pasteurized products, is imperative.

Public health policies pertaining to contamination of shell eggs with Salmonella Enteritidis

Outbreaks of SE can be prevented at multiple levels on the farm to table continuum—at the egg production level, at the retail food and food service establishment level, and at the consumer level.⁴⁵ It has been suggested that implementation of routine microbiologic testing as a part of farm-based control programs by all egg producers nationwide would significantly contribute to reducing the number of human infections with this pathogen.⁴⁵ In addition, it is recommended that only pasteurized egg products or pasteurized in-shell eggs be used for recipes that call for pooled, raw, or undercooked eggs in retail and food service establishments, especially in hospitals, nursing homes, or other institutional settings that serve high risk groups. 45, 47 Similarly, institutional food service establishments should only purchase or accept eggs from distributors that certify that egg and egg products are stored at temperatures below 45 degrees Fahrenheit at all times. 45, 47 Additionally, the CDC has recommended that consumers not eat raw or undercooked eggs, especially those at high risk, such as children, the elderly, and the immunocompromised. 45, 47 Likewise, consumers should wash and disinfect hands, cooking utensils, and anything else that may have come into contact with raw eggs during food preparation. 45,47 Finally, consumers should not purchase eggs from a retail food establishment or distributor that does not continually refrigerate eggs and egg products at temperatures less than 45 degrees Fahrenheit. 45,47 If observed and followed properly, these recommendations should reasonably prevent most outbreaks of SE.

In addition to the aforementioned preventions strategies, pasteurization of shell eggs is a potentially viable method for reducing the number of outbreaks of SE infections.⁴⁸ Several different methods for shell egg pasteurization have been explored, but studies conducted by Stadelman et al. suggest that water bath heating to 55 or 56 degrees Celsius (131 or 132 degrees

Fahrenheit) for approximately 15 minutes is the most efficient way to kill the most bacteria while still retaining the protein components of the egg in the shell.⁴⁹ Although only 0.05% of shell eggs are pasteurized in the United States each year, the pasteurization process typically results in a 5-log₁₀ reduction in *Salmonella*.⁴⁸ A risk assessment model developed by the Food Safety Inspection Service (FSIS) estimated that if pasteurization of all shell eggs in the United States was initiated to achieve such a reduction, SE-associated human illnesses would drop to less than 20,000 per year.⁴⁸ A recognized limitation of this model is the factor of cost—the authors of the risk assessment acknowledge that they cannot comment on the economic feasibility of requiring all shell eggs to be pasteurized.⁴⁸ Even though the economic cost of shell egg pasteurization has not been determined, is hypothesized that if it were achieved, SE infection could potentially be eliminated as a public health concern in United States.¹⁷

Several European countries have demonstrated that implementation of effective policies and targeted interventions can help curtail outbreaks and human illnesses associated with SE.

Beginning in 1998, the French Ministry of Agriculture and Fishing initiated a SE control program that implemented systematic testing at specific intervals for SE and ST (*Salmonella* Typhimurium) in breeding flocks and in layer flocks.⁵⁰ An evaluation of this initiative in France demonstrated that the control program was responsible for a decline in the two serotypes of interest.⁵⁰ The Netherlands initiated a similar "top-down" approach to ensure that new egglaying chicks are SE-free and to ensure that all poultry houses are properly disinfected before introducing new chicks.⁵¹ This SE control program has been effective in containing human SE infections in the Netherlands.⁵¹ Additionally, Gillespie et al. suggest that vaccination of poultry flocks has contributed to the decline in SE outbreaks in the United Kingdom.⁵² Lack of adoption of the aforementioned strategies for prevention and continued outbreaks of SE

associated with shell eggs and egg-containing foods highlight the importance of refining existing control measures and developing new prevention strategies from farm to fork through public health policy and communication in the United States.

Federal regulations for egg safety dates back to the 1960s when legislation was passed requiring that all shell eggs be maintained at temperatures below 60 degrees Fahrenheit.⁵³

Although this marks one of the first attempts at temperature regulation of shell eggs, in hindsight this regulation was not stringent enough, because even temperatures below 60 degrees Fahrenheit are conducive to the growth and proliferation of SE.¹⁵

In response to the 1988 study that identified Grade A shell eggs as a principal vehicle for SE in the United States, several Federal agencies initiated discussions about how to remedy the problem and eventually proposed a mandatory testing program for SE in all egg-laying flocks nationwide. This proposed program would mandate testing all flocks and would divert any eggs from SE-positive flocks to egg pasteurization plants. This initial proposal was met with opposition, on the grounds that the proposed testing program would be too expensive to implement and was potentially premature given the lack of prevalence data for SE in egg-laying flocks and the lack of technical knowledge about SE in egg-laying flocks at the time. An alternative SE control program was proposed and implemented by the United States Department of Agriculture (USDA) in February of 1990 that sought to follow-up outbreaks of human SE that were attributed to eggs in order to trace back the infections to specific egg-laying flocks. Once the implicated egg-laying flocks were identified through trace back investigation, the flocks would be tested for SE, and if found to be positive, all eggs from the implicated flock would be diverted to plants for pasteurization. Funding for the USDA SE testing and trace back program

expired on October 1, 1995 and the Food and Drug Administration (FDA), which has regulatory authority over shell eggs in commerce, took over this important initiative.⁴⁴

Although seemingly a cost-effective solution to reducing outbreaks of SE, the SE outbreak trace back program initiated by USDA's APHIS in 1990 arguably lacked the ability to lower rates of SE infection in humans quickly enough, so in 1992 a voluntary SE Pilot Project was launched in Pennsylvania.²⁵ The Pilot Project in Pennsylvania was launched in collaboration with egg producers and State and Federal agencies and sought to test hen houses for SE. 25 Once SE-positive houses were identified, the eggs produced from those houses were tested for SE and if positive, were diverted to pasteurization plants.²⁵ In conjunction with the testing program, a suite of on-farm control measures such as utilizing "SE-free feed, SE-free pullets, biosecurity, rodent control, cleaning and disinfection, and use of an SE vaccine" were implemented and evaluated for effectiveness in preventing, controlling, and eliminating SE in egg-laying flocks in Pennsylvania.²⁵ In his review of the SE Pilot Project, Mason comments on the paradigm shift within the industry and the Government to test eggs instead of egg-laying hens to assess the prevalence of SE contamination.²⁵ He notes that while egg-laying hens could be positive for SE, their eggs could potentially by SE-free if tested and handled appropriately, so it was arguably inefficient to divert all eggs from SE-contaminated flocks to pasteurization without first testing the actual eggs.²⁵ This pilot program eventually evolved into the Pennsylvania Egg Quality Assurance Program (PEQAP) in 1994 and was supervised by USDA until 1996 when oversight was transferred to the Pennsylvania Department of Agriculture and the egg industry in Pennsylvania.⁴⁴ The PEQAP soon served as a model for other states, and as of 2000, 13 states were voluntarily participating in Quality Assurance Programs (QAPs). 39,54

In 1990, the same year the SE trace back program was initiated by the USDA, the FDA added eggs to the list of potentially hazardous foods in the Model Retail Food Safety Code. ⁵⁵
Also in 1990, the USDA enacted a regulation that required all offspring (hatching eggs and newly-hatched chicks) of egg-laying breeding flocks originate from grandparent flocks that are certified to be free of SE. ⁵⁶ Soon after, in 1991, additional food safety legislation was enacted that required refrigeration of all shell eggs while in interstate commerce. ⁵⁷ Nearly a decade later, the President's Council on Food Safety published the Egg Safety Action Plan in late 1999 to attempt to curtail risky egg-preparation practices, in order to reduce outbreaks and illnesses associated with SE. ⁵⁸ Calling for a 50% reduction in egg-associated SE illnesses by 2005, the Plan's specific objectives include: "reducing consumer exposure to SE-containing foods; expanding and upgrading surveillance systems for human and poultry SE infection; improving communication among federal, state, and local agencies to accelerate SE outbreak detection and initiation of investigations; conducting research; and educating persons using science-based materials". ^{39, 58}

Although a variety of policies and interventions have been implemented since the recognition of SE as a pathogen of concern in shell eggs over two decades ago, outbreaks of SE continue to occur and cause unnecessary illnesses, hospitalizations, and deaths. Enhanced interagency and multidisciplinary collaboration, in addition to the implementation of rigorous farm-to-table interventions, are needed to combat the ongoing SE epidemic in the United States.

CHAPTER III: METHODS

Institutional Review Board Application

The protocol title "An examination of the changing geographical distribution of egg-associated outbreaks of *Salmonella* Enteritidis in the United States, 1973-2008" was approved by the Georgia State University Institutional Review Board on July 8, 2010. The corresponding protocol number is H11007.

Description of Datasets

Surveillance for foodborne disease outbreaks in the United States

The Foodborne Disease Outbreak Surveillance System (FDOSS) is maintained at the CDC.⁵⁹ Standardized reports of foodborne disease outbreaks are submitted voluntarily from state, local, and territorial health departments to CDC.⁵⁹ For reporting purposes, "a foodborne disease outbreak is defined as the occurrence of two or more similar illnesses resulting from ingestion of a common food".⁵⁹ In addition, since 1998 the outbreak surveillance database is dynamic in that state, local, and territorial health departments can submit new reports and can update or delete previously reported outbreaks at any time.⁵⁹

pFORS and eFORS Datasets

Data were obtained from two data sources maintained by the Foodborne Disease

Outbreak Surveillance System (FDOSS), within the FoodNet and Outbreak Surveillance Team

(FOST), within the Enteric Diseases Epidemiology Branch (EDEB) of the Division of

Foodborne, Waterborne, and Environmental Diseases (DFWED), at the Centers for Disease

Control and Prevention (CDC): the paper-based Foodborne Outbreak Reporting System

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(pFORS) and the electronic Foodborne Outbreak Reporting System (eFORS). The pFORS dataset contains reports of outbreaks of foodborne illness reported to CDC by state and local health departments from 1973 through 1997. The eFORS dataset contains reports occurring from 1998 through 2008. eFORS is an open dataset which means that data can be added and/or modified by state and local health departments at any time. Variables that were common to both datasets were used for analysis. These common variables included: the year outbreak was reported; reporting state; number of estimated illnesses associated with each outbreak; number of hospitalizations associated with each outbreak; number of deaths associated with each outbreak; etiologic agent (genus, species, and serotype) responsible for the outbreak; implicated food(s) associated with the outbreak; where the implicated food was consumed; and where the implicated food was prepared. Additional variables were created from the existing set of variables for analysis. For the purposes of this analysis, only foodborne outbreaks were included. Outbreaks involving person-person transmission were excluded from the analysis.

Census Dataset

Census data were obtained from the United States Census Bureau's website (http://www.census.gov/popest/archives/). Specifically, annual state population estimates were obtained in order to calculate the annual rate of outbreak reporting per population.

Description of variables

The variables describing the implicated food vehicles in pFORS and eFORS varied slightly so the implicated food(s) for each outbreak were reclassified into a new categorical variable. Foods were classified as either "simple egg", "complex egg", "at least one food contains egg", "simple chicken", "complex chicken", "at least one food contains chicken",

"both", "other", and "missing/unknown". In pFORS a food was considered "simple egg" if the food consisted of only egg (e.g., scrambled eggs or boiled eggs) or if "made with raw egg" or "(any dish) with egg" was specifically listed in the implicated food field. This assumption was made in order to make the data from pFORS resemble the data from eFORS, because in eFORS, states have an option to choose from a menu of "contaminated ingredients" (e.g., beef, pork, eggs) in addition to listing implicated food items. For pFORS, it was assumed that if there had been a field "contaminated ingredient" as there is in eFORS, states would have selected "eggs" as the contaminated ingredient for implicated foods where eggs were specifically indicated such as "made with raw egg" or "(any dish) with egg" and thus would have been classified as a "simple egg" since all foods in eFORS with a contaminated ingredient specified are considered "simple" foods (e.g., if a state lists "béarnaise sauce" as the implicated food item and selects "eggs" as the contaminated ingredient, then the food falls into the "simple egg" category). If more than one implicated food was listed and all foods listed contain eggs as a primary ingredient (e.g., "French toast and scrambled eggs") then the food was classified into the "simple egg" category. In addition, in eFORS if states filled in the "egg tab" (i.e., if they provided information about how eggs were prepared or mishandled) and the implicated food was not already classified as "simple egg" then the implicated food was assumed to be eggs and was subsequently classified as "simple egg".

In pFORS and eFORS the implicated food was designated as "complex egg" if the food is known to contain eggs (e.g., béarnaise, hollandaise, egg nog), but no explicit mention of eggs was made (either in the implicated food field—pFORS or in the contaminated ingredient field—eFORS) or if the recipe for the food was found to contain eggs, using the Painter method of recipe acquisition using Google searches.⁶⁰ To employ this method, the name of the implicated

food and the word "recipe" was entered into the Google search bar and the first three recipe results returned by Google were examined. If "egg" was listed as an ingredient in at least two of the three recipes for the implicated food then the implicated food was classified as "complex egg" or "at least one food contains egg" (if more than one implicated food was listed). The same method was used for implicated foods that contained chicken (i.e., foods that were known to contain chicken or were found to have chicken in the recipe using the Painter method were classified as "complex chicken" or "at least one food contains chicken").

In pFORS and eFORS a food was classified as "both" if the implicated food(s) listed contained both egg and chicken (e.g., "scrambled eggs and chicken salad" or "chicken salad and egg salad"). In addition, in pFORS and eFORS if the implicated food(s) listed did not contain egg or chicken (e.g., "shrimp salad", "ground beef", "salsa") the food was classified as "other". Finally, in pFORS and eFORS if nothing was reported in the implicated food field, then the outbreak was classified as "missing/unknown".

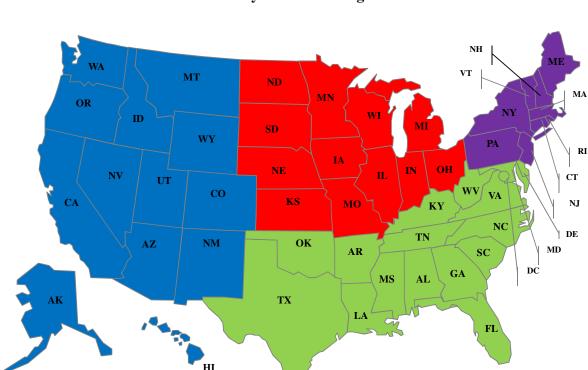
Both the pFORS and eFORS datasets contained the variable "where prepared" which provides information about where the food that was implicated in the outbreak was prepared. Although this variable was similar between both datasets, standardized data fields changed when surveillance transitioned from pFORS to eFORS, and there was an opportunity in both systems to provide information in an open text-field. Consequently, responses varied substantially and needed to be categorized. The new categorical variable grouped the location of preparation into the following categories: "healthcare", "institutional", "social", "retail food", "private home", "multiple locations", "other", and "missing/unknown". Similarly, both the pFORS and eFORS datasets contained the variable "where eaten" which provides information about where the implicated food was consumed. Although this variable was similar between both datasets, it also

was captured in the same way as the "where prepared" field. A new categorical variable was created that divided the location of consumption into the following categories: "healthcare", "institutional", "social", "retail food", "private home", "multiple locations", "other", and "missing/unknown". Examples of "healthcare" settings include, but are not limited to: "hospital", "nursing home", or "drug rehab facility". Examples of "institutional" settings include, but are not limited to: "college", "university", "daycare", or "county jail". Examples of "social" settings include, but are not limited to: "hotel", "wedding", "country club", or "office party". Examples of "retail" food settings include, but are not limited to: "restaurant", "mobile food vendor", "deli", or "caterer". Examples of "private home" settings include, but are not limited to: "private home" or "party, home". Examples of "multiple locations" include, but are not limited to: "church, home", "private home, work", or "school, private home". Settings were classified as "other" if the state listed "other" in the "where eaten" or "where prepared" fields but did not list a specific location. Similarly, food consumption and food preparation settings were classified as "missing/unknown" if the "where eaten" or "where prepared" fields were blank or contained "unknown".

United States census regions were used to separate reporting states into four categories for analysis as demonstrated in Figure 2. The four census regions were defined as: Northeast—Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; Midwest—Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; South—Alabama, Arkansas, Delaware, the District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; West—Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New

Mexico, Oregon, Utah, Washington, and Wyoming. The total US population in 1973 was 211,360,233 and the total US population in 2008 was 304,059,724. The average annual population for each census region over the 36 year period was: Northeast 51,524,391; Midwest 61,312,397; South 88,504,711; West 53,736,779. There were 20 outbreaks that were not classified into one of the four census regions. Ten of these were multi-state outbreaks and were not attributed to the various states involved in order to prevent duplicating outbreaks. These outbreaks were classified as "multi-state" in the analysis. In addition, 7 outbreaks were reported from Puerto Rico, 2 outbreaks were reported from cruise ships, and 1 outbreak was reported from an air force base that is no longer in operation and thus could not be classified as a particular state or census region.

Figure 2.



States by US Census Region

Data Analysis

Data were analyzed in SPSS Statistics version 17.0. Some data manipulation and the generation of all figures and tables were performed using Microsoft Excel. Exploratory data analysis was conducted to elucidate the number of SE outbreaks by year (1973-2008); the number of SE outbreaks per US census region; the average annual rate of SE outbreaks per 100,000 population per US census region; the number of illness, hospitalizations, and deaths associated with the total number SE outbreaks per year (1973-2008); the distribution of food

categories associated with outbreaks of SE; the distribution of categories of location of implicated food consumption associated with outbreaks of SE; and the distribution of categories of location of implicated food preparation associated with outbreaks of SE. Poisson Regression was performed to obtain risk ratios for the different food categories, using the "simple egg" category as the referent. Cross tabulations were performed to obtain risk ratios and 95% confidence intervals (CI) for each year (1973-2008) comparing outbreaks associated with all other food categories combined together to the "simple egg" food category (referent). Risk ratios were utilized because in the Poisson equation the dependent variable of outbreak counts were a function of the annual population estimates, thus generating an annual population-based probability (or risk ratio) of an outbreak occurring for each additional independent variable included in the model.

CHAPTER IV: RESULTS

Descriptive analysis

Descriptive data of foodborne disease outbreaks due to *Salmonella* are provided in Table 1. Between 1973 and 1997 there were a total of 1,913 outbreaks of *Salmonella* reported to pFORS. Of these, 8 were person-to-person and 1,905 were foodborne. Of the 1,905 outbreaks of foodborne salmonellosis, 858 were outbreaks due to SE—8 of which were person to person and 850 of which were foodborne. Between 1998 and 2008 there were a total of 1,552 outbreaks of *Salmonella* reported to eFORS. Of the 1,552, 60 were person to person and 1,492 were foodborne. Of the 1,492 outbreaks of foodborne salmonellosis, there were 450 outbreaks of SE—12 of which were person-to-person and 438 of which were foodborne. All person to person outbreaks were excluded from the analysis. Overall, there were 3,397 outbreaks of *Salmonella* reported to the CDC from 1973-2008, of which 1,288 (38%) were outbreaks of SE.

Table 1. Outbreaks reported to pFORS and eFORS

Outbreaks reported to pFORS (1973-1997)	n	%
Salmonella (all serotypes)	1913	100
Foodborne	1905	99.6
Person-person (excluded)	8	0.4
Salmonella enterica serotype Enteritidis (SE)	858	44.9
Foodborne	850	44.4
Person-person (excluded from analysis)*	8	0.4
Outbreaks reported to eFORS (1998-2008)		
Salmonella (all serotypes)	1552	100
Foodborne	1492	96
Person-person (excluded)	60	4
Salmonella enterica serotype Enteritidis (SE)	450	29
Foodborne	438	28
Person-person (excluded from analysis)	12	0.8
Total foodborne outbreaks of Salmonella (all serotypes)**	3397	
Total foodborne outbreaks of Salmonella enterica serotype Enteritidis (SE)***	1288	38

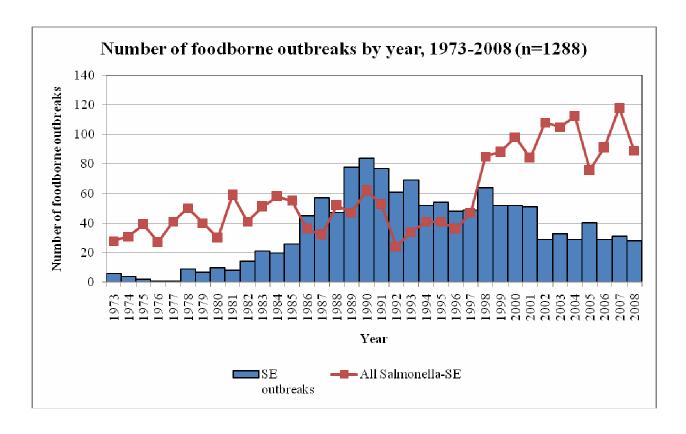
^{*}All (n=8) person-person outbreaks reported to pFORS were outbreaks of SE

^{**}Outbreaks used in analysis (n=3397)

^{***}Outbreaks used in analysis (n=1288)

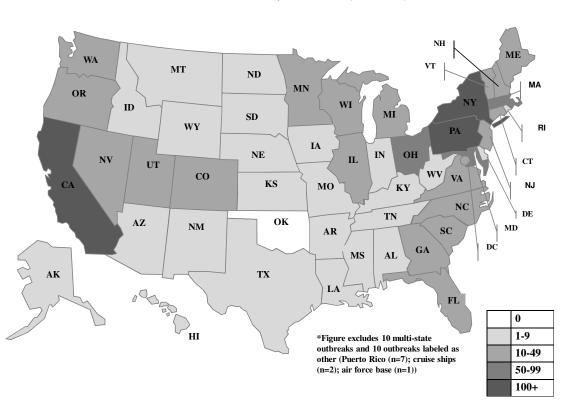
Figures 3 illustrates the distribution over time of reported SE outbreaks and all other reported outbreaks of *Salmonella* excluding SE. Outbreaks of SE began to increase in the 1980s at an average annual rate of 32% and reached a peak in 1990 (n=84). After 1990, outbreaks of SE generally decreased—from 1990 to 1997 the average annual rate of decline was 5% and from 1998 to 2008 the average annual rate of decline was 2%. In contrast, the number of reported outbreaks due to other *Salmonella* serotypes was highly variable, with no trend in the average annual number reported until 1996. From 1996 to 2008, the average annual rate of increase in reported *Salmonella* outbreaks due to serotypes other than SE was 10%.

Figure 3.



Since the prevalence of SE in egg-laying flocks was highest in the Northeastern United States, the regional distribution of reported SE outbreaks from 1973 to 2008 was examined to determine if outbreaks in humans reflected the distribution of SE in the poultry reservoir. Figure 4 illustrates the distribution of SE outbreaks from 1973 to 2008 throughout the United States by categories of numbers of outbreaks (0; 1-9; 10-49; 50-99; 100+).

Figure 4.



Number of SE Outbreaks,1973-2008 (n=1268*)

Detection and reporting of outbreaks is likely related to the size of the population under surveillance, so the regional distribution of reported SE outbreaks was also examined after adjusting the outbreak number by the state's population. Figures 5 and 6 depict the annual rate

of reporting per 100,000 population and the total number of outbreaks of SE before and after 1990—the year that the intensive SE trace back program was initiated by the USDA and the year that the FDA added eggs to the list of risky foods in the Retail Food Code.

Figure 5.

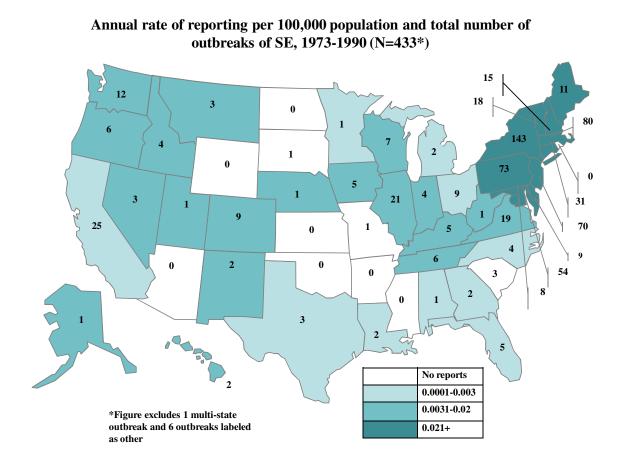
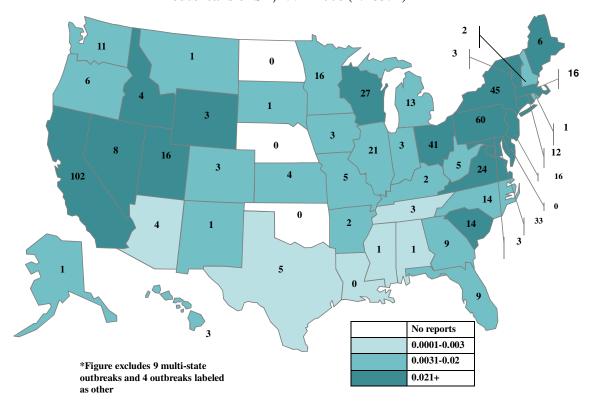


Figure 6.

Annual rate of reporting per 100,000 population and total number of outbreaks of SE, 1991-2008 (N=835*)



States were divided into US census regions because eggs produced in a few states on farms contaminated with SE are more likely to be distributed to nearby states; thus, the differences between states within a census region may be greater than differences between individual states. Table 2 indicates the distribution of SE outbreaks by United States census region from 1973 to 2008.

Table 2. SE Outbreaks by US Census Region

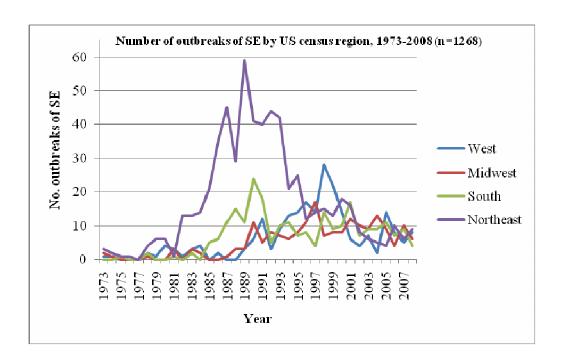
Census Region	No. (%) SE Outbreaks
Northeast	602 (47)
South	247 (19)
West	231 (18)
Midwest	188 (15)
Multistate	10 (0.8)
Other	10 (0.8)
Total	1288 (100*)

^{*}percentage totals to more than 100 due to rounding

It is apparent from Table 2 that the Northeast has historically reported more outbreaks of SE than any other region, but it was hypothesized that there was some variation among census regions over time due to the spread of the SE epidemic in egg-laying flocks and as a result of the timing of different interventions to control SE. Figure 7 illustrates the differences in the number of outbreaks of SE by US census region. This figure excludes 20 outbreaks—10 multi-state outbreaks and 10 outbreaks categorized as other (Puerto Rico n=7; cruise ship n=2; air force base n=1). As a comparison, Figure 8 illustrates the differences in the number of outbreaks of all serotypes of *Salmonella* excluding SE by United States census region.

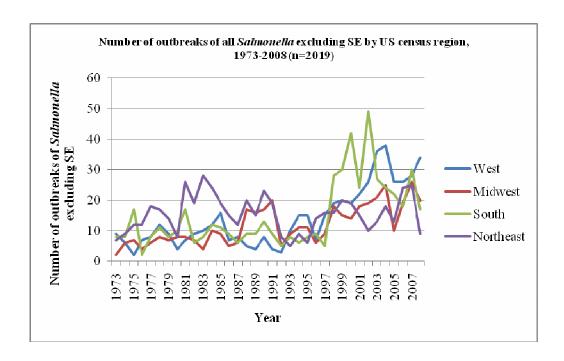
^{*10} outbreaks were excluded: 7 reported outbreaks from Puerto Rico, 2 reported outbreaks from cruise ships, and 1 reported outbreak from an air force base that has been closed

Figure 7.



^{*10} outbreaks were excluded: 7 reported outbreaks from Puerto Rico, 2 reported outbreaks from cruise ships, and 1 reported outbreak from an air force base that has been closed

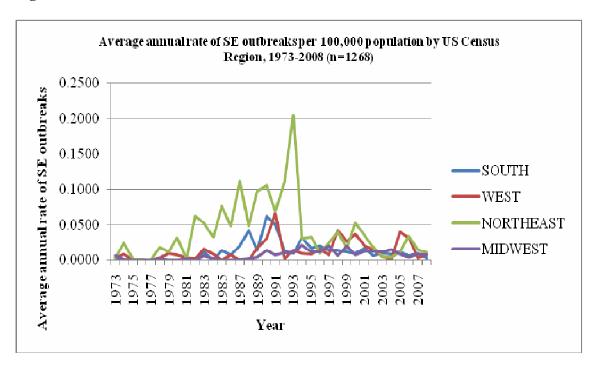
Figure 8.



^{*100} outbreaks were excluded: 76 multi-state outbreaks and 14 outbreaks categorized as "other"

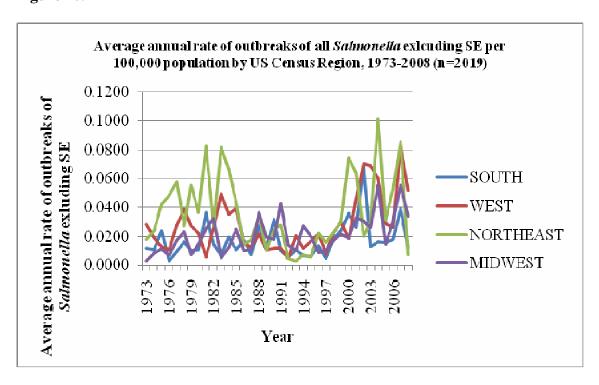
As mentioned previously, detection and reporting of outbreaks is likely related to the size of the population under surveillance, so the regional distribution of reported outbreaks was also examined by US census region after adjusting the outbreak number by the state's population within each region. Figure 9 illustrates the average annual rate of SE outbreaks per 100,000 population by United States census region. The average annual rate of SE outbreaks per 100,000 population peaked first in the South region and the West region and then peaked several years later in the Northeast region. The average annual rate of SE outbreaks per 100,000 in the Midwest region remains relatively constant from 1973 to 2008. Figure 10 illustrates the average annual rate of all outbreaks of *Salmonella* excluding outbreaks of SE per 100,000 population by United States census region. It is interesting to note the sizable peak in the average annual rate of SE outbreaks per 100,000 population in the Northeast. A similar peak is not observed in the average annual rate of all outbreaks of *Salmonella* excluding SE; however, Figure 10 illustrates that the average annual rate of all outbreaks of *Salmonella* excluding SE has two sizable peaks—one in the late 1970s to early 1980s and a second in the 2000s.

Figure 9.



^{*10} outbreaks were excluded: 7 reported outbreaks from Puerto Rico, 2 reported outbreaks from cruise ships, and 1 reported outbreak from an air force base that has been closed

Figure 10.



^{*100} outbreaks were excluded: 76 multi-state outbreaks and 14 outbreaks categorized as "other"

Table 3 depicts the annual number of outbreaks, the number of ill persons, the median number of cases, the number of hospitalizations, and the number of deaths associated with SE outbreaks from 1973 to 2008. Overall from 1973 to 2008 there were a total of 1,288 foodborne outbreaks of SE which resulted in at least 40,963 illnesses, 4,333 hospitalizations, and 102 deaths.

 $Table\ 3.\ Illnesses,\ hospitalizations,\ and\ deaths\ associated\ with\ SE\ outbreaks,\ 1973-2008$

Median No. No. no. No. No.							
Year	outbreaks	ill	no. cases	hosp.	%	deaths	%
1973	6	321	17	17	5	0	0
1974	4	92	16.5	10	11	0	0
1975	2	38	19	1	3	0	0
1976	1	15	15	1	7	0	0
1977	1	44	44	0	ó	0	0
1978	9	512	30	10	2	0	0
1979	7	355	23	39	11	0	0
1980	10	550	46	33	6	0	0
1981	8	220	13.5	28	13	7	3.2
1982	14	1160	40.5	168	14	3	0.3
1983	21	901	16	42	5	2	0.2
1984	20	954	23.5	102	11	3	0.3
1985	26	1362	24	141	10	1	0.1
1986	45	1294	15	97	7	6	0.5
1987	57	2670	18	541	20	15	0.6
1988	47	1311	17	167	13	10	0.8
1989	78	2650	24	241	9	17	0.6
1990	84	2613	18	387	15	1	0
1991	77	2630	14	262	10	5	0.2
1992	61	2315	14	234	10	4	0.2
1993	69	2283	15	228	10	6	0.3
1994	52	2270	15	208	9	0	0
1995	54	1110	12.5	110	10	7	0.6
1996	48	1443	14	130	9	1	0.1
1997	49	1124	13	129	11	0	0
1998	64	861	7	102	12	3	0.3
1999	52	1413	13	69	5	0	0
2000	52	1110	11.5	109	10	2	0.2
2001	51	1839	12	111	6	0	0
2002	29	1645	15	106	6	0	0
2003	33	636	9	78	12	1	0.2
2004	29	371	7	64	17	5	1.3
2005	40	1311	19	158	12	2	0.2
2006	29	441	9	66	15	1	0.2
2007	31	576	8	77	13	0	0
2008	28	523	13.5	67	13	0	0
Total	1288	40963	15	4333	11	102	0.2

Another objective of this study was to characterize the different food categories that have been associated with SE outbreaks to see if targeted interventions at a single commodity resulted in a relative decrease in the proportion of outbreaks due to eggs and egg-containing foods. If so, this evidence would highlight the need to target other food commodities in order to successfully control the SE epidemic. Table 4 summarizes the number of outbreaks per food category from 1973 to 2008. The food category most commonly associated with outbreaks of SE was the "simple egg" category (after excluding the food category "missing/unknown"). The next largest food category most commonly associated with SE was the "complex egg" category.

Table 4. SE outbreaks by food category

Food category	No. Outbreaks	%
Simple egg	246	19.1
Complex egg	193	15.0
At least one food contains egg	55	4.3
Simple chicken	33	2.6
Complex chicken	17	1.3
At least one food contains chicken	18	1.4
Contains egg and chicken	19	1.5
Other	171	13.3
Missing/unknown	536	41.6
Total	1288	100

The distribution of food categories associated with outbreaks of SE over time was also a point of interest in this study in order to determine if a decline in one food commodity resulted in the rise of another food commodity with respect to their association with outbreaks of SE. Since eggs and egg-containing foods are commonly associated with outbreaks of SE, the decline in SE outbreaks since the 1990s would suggest a similar decline in egg and egg-containing food categories. Figure 11 illustrates the distribution of all nine food categories over time from 1973

to 2008. Figure 12 isolates the "simple egg" category, the "complex egg" category, the "simple chicken" category, the "complex chicken" category, and the "other" category. It is interesting to note that the "simple egg" food category peaked from 1988 to 1992 and then again in 2000 and the "complex egg" food category peaked between these two peaks in 1994 and 1998. Figure 13 illustrates the original food categories collapsed into more broad food categories. The "egg-containing" category includes the "simple egg" category, the "complex egg" category, and the "at least one food contains egg" category. The "chicken-containing" category contains the "simple chicken" category, the "complex chicken" category, and the "at least one food contains chicken" category. The "egg-containing" category and the "chicken-containing" category are plotted with the "both" category (i.e., the implicated food(s) contained egg and chicken) and the "other" category (i.e., the implicated food(s) contained neither egg nor chicken). Figure 13 further highlights the importance of egg-containing foods as sources of SE outbreaks.

Figure 11.

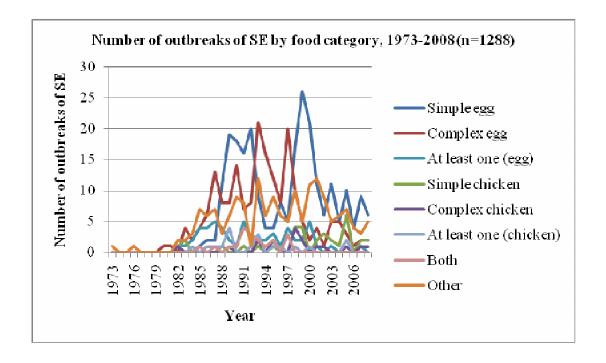


Figure 12.

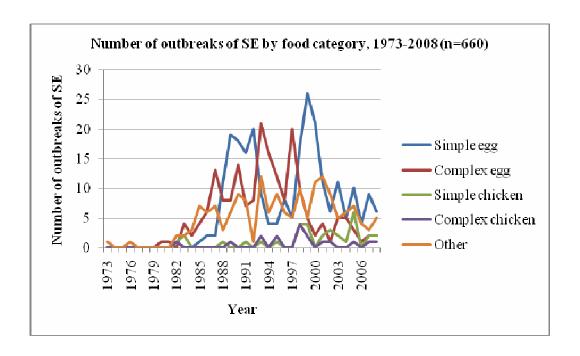
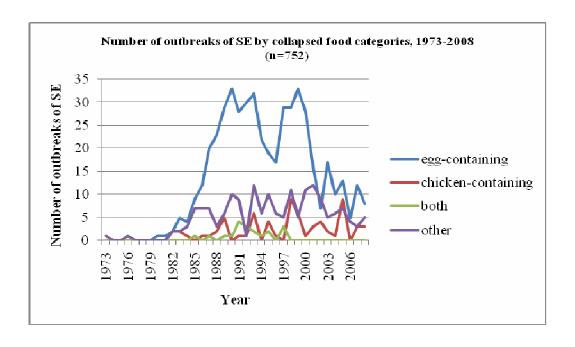


Figure 13.



In addition to food categories associated with SE outbreaks, an objective of the study was to examine the distribution of locations of consumption of implicated food(s) associated with SE outbreaks over time in order to determine if there is evidence that interventions targeting specific food consumption settings (e.g., changes to the Food Code) had an impact on the relative proportion of SE outbreaks associated with these regulated settings. Table 5 categorizes all of the SE outbreaks from 1973 to 2008 by location of consumption of the implicated food(s). The location of consumption of the implicated food(s) most commonly associated with outbreaks of SE was the retail food setting. The second largest category for location of consumption of the implicated food(s) most commonly associated with outbreaks of SE was private home.

Table 5. SE outbreaks by location of implicated food consumption

Location of consumption	No. Outbreaks	%
Healthcare	110	8.5
Institutional	129	10.0
Social	151	11.7
Retail food	555	43.1
Private home	211	16.4
Multiple locations	73	5.7
Other	5	0.4
Missing/unknown	54	4.2
Total	1288	100

Figure 14 illustrates the distribution of all food consumption settings over time from 1973 to 2008. Figure 15 depicts the distribution of the five most common food consumption settings from 1973 to 2008—retail food, private home, social, institutional, and healthcare. It is apparent from both figures that the retail food setting has consistently been the food consumption setting most commonly associated with outbreaks of SE since about 1982; although the number of SE

outbreaks associated with the retail food setting appears to have dropped back down to be relatively equivalent with all other food categories in 2008.

Figure 14.

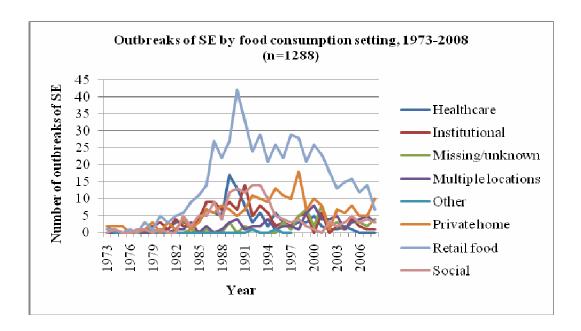
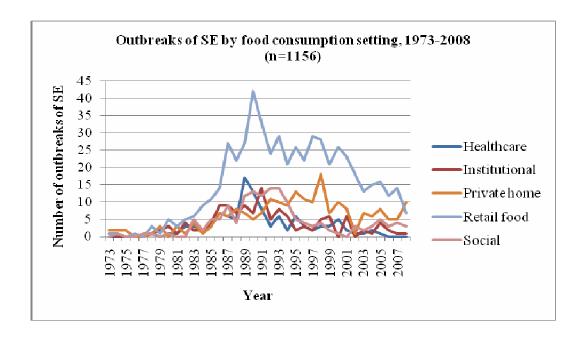


Figure 15.



Although location of food consumption and location of food preparation were often the same, locations of implicated food(s) preparation associated with SE outbreaks were explored in order to determine if there is evidence that interventions targeting specific food preparation settings (e.g., changes to the Food Code) had an effect on the relative proportion of SE outbreaks associated with these regulated settings. Table 6 categorizes all SE outbreaks by location of preparation of the implicated food(s) from 1973 to 2008. The location of preparation of the implicated food(s) most commonly associated with outbreaks of SE was the retail food setting. The second largest category for location of preparation of the implicated food(s) most commonly associated with outbreaks of SE was the private home category. This finding confirms that the two most common locations of implicated food consumption and implicated food preparation associated with outbreaks of SE from 1973 to 2008 were the same.

Table 6. SE outbreaks by location of implicated food preparation

Location of preparation	No. Outbreaks	%
Healthcare	105	8.2
Institutional	135	10.5
Social	81	6.3
Retail Food	699	54.3
Private home	189	14.7
Multiple locations	19	1.5
Other	5	0.4
Missing/unknown	55	4.3
Total	1288	100

Although the two most common locations associated with food consumption and food preparation were found to be the same (retail food and private home), food preparation settings were examined over time (1973-2008) to see if any differences emerged and to see if the number

of reported outbreaks associated with retail food establishments and private homes mirrored the trend in the total number of reported outbreaks of SE (increasing during the 1980s and 1990s and then declining). Figure 16 illustrates the distribution of all locations of preparation of implicated food(s) over time from 1973 to 2008. Figure 17 shows the distribution of the five most common locations of preparation from 1973 to 2008—retail food, private home, institutional, healthcare, and social.

Figure 16.

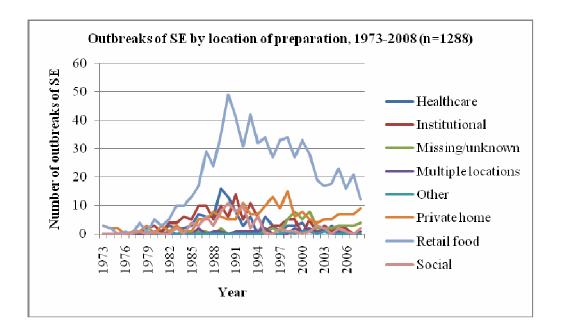
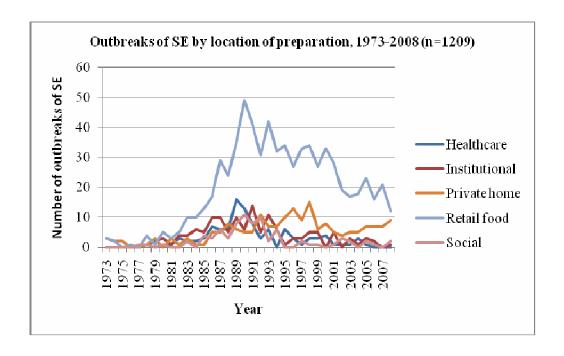


Figure 17.



Poisson regression

Exploratory data analysis revealed that the "simple egg" food category was the food category most commonly associated with outbreaks of SE from 1973 to 2008. A Poisson regression was performed in order to statistically determine which food categories were most associated with outbreaks of SE over the time period of study, accounting for reporting variability between states. Table 7 displays the variables that were included in the model, the associated risk ratios, and the 95% confidence intervals (CI) obtained from the Poisson regression. The dependent or outcome variable was the number of outbreaks per food category by state by year. Other variables included in the model were: year the outbreak occurred, annual state population estimates, state, and all food categories except for "simple egg". The "simple egg" category was used as the referent food category. All food categories, with the exception of "missing/unknown" were found to be less likely to be associated with outbreaks of SE than the

"simple egg" category. Although the "complex egg" category was found to be less likely to be associated with outbreaks of SE than the "simple egg" category, this result is not statistically significant. State and year were included in the model because they are mathematically important sources of variability; however, the epidemiologic interpretation of the risk ratios associated with each is difficult. These results indicate that outbreaks associated with the "simple egg" food category are more likely to be associated with outbreaks of SE than all other food categories.

Table 7. Risk ratios associated with food categories, state, and year

Variable	RR	95% CI	
Simple egg	referent		
Complex egg	0.866	(0.742, 1.01)	
At least one food contains egg	0.615	(0.532, 0.712)	
Simple chicken	0.650	(0.557, 0.758)	
Complex chicken	0.624	(0.499, 0.780)	
At least one food contains chicken	0.534	(0.453, 0.630)	
Both	0.682	(0.568, 0.819)	
Other	0.795	(0.692, 0.914)	
Missing/unknown	1.18	(1.01, 1.36)	
State	1.01	(1.00, 1.01)	
Year	0.986	(0.981, 0.992)	

A similar Poisson regression was performed using census regions in place of states to see if one particular census region was statistically more commonly associated with outbreaks of SE. Table 8 illustrates the risk ratios and 95% confidence intervals (CI) obtained from the second Poisson regression that was conducted. The dependent or outcome variable was number of outbreaks per food category by state by year. Other variables included in the model were: year the outbreak occurred, annual state population estimates, all census regions except for "Northeast", and all food categories except for "simple egg". The "Northeast" census region was used as the referent census region category and the "simple egg" category was used as the

referent food category. All food categories, with the exception of "missing/unknown" were found to be less likely to be associated with an outbreak of SE than the "simple egg" category. Although the "complex egg" category was found to be less likely to be associated with an outbreak of SE than the "simple egg" category, this result is not statistically significant. In addition, year was found to be mildly important in the model and all other census regions were less likely to have outbreaks of SE than the Northeast census region. Year was included as an important source of variability in the model, but the epidemiologic interpretation of the risk ratio is difficult. These results indicate that outbreaks associated with the "simple egg" food category are more likely to be associated with outbreaks of SE than with all other food categories and all other census regions are less likely to be associated with an outbreak of SE compared to the Northeast region.

Table 8. Risk ratios associated with food categories, census region, and year

Variable	RR	95% CI	
Simple egg	referent		
Complex egg	0.874	(0.750, 1.02)	
At least one (egg)	0.620	0.536, 0.717)	
Simple chicken	0.643	(0.546, 0.757)	
Complex chicken	0.643	(0.506, 0.819)	
At least one (chicken)	0.510	(0.432, 0.603)	
Both	0.691	(0.562, 0.851)	
Other	0.785	(0.682, 0.903)	
Missing/unknown	1.19	(1.03, 1.38)	
Northeast	referent		
South	0.734	(0.676, 0.841)	
Midwest	0.735	(0.651, 0.830)	
West	0.683	(0.599, 0.778)	
Year	0.993	(0.987, 0.998)	

Additional risk estimates

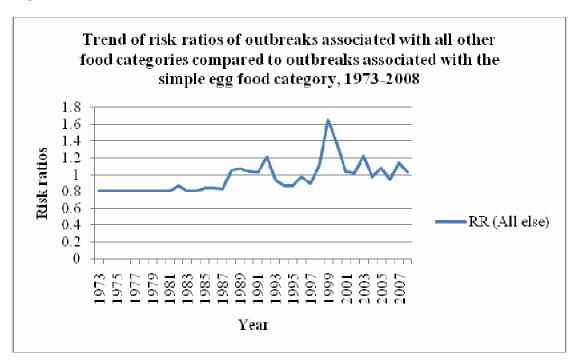
Year the outbreak occurred was found to be significant in the model so cross tabulations by year were performed comparing all other food categories to the "simple egg" food category. Table 9 displays the risk ratios and 95% confidence intervals associated with all other food categories combined, per year compared to the simple egg food category. The years with statistically significant results (i.e., 95% confidence interval does not include 1) are highlighted in yellow.

Table 9. Risk ratios between all other food categories combined compared to the "simple egg" category

Year	RR (All else)	95% CI (All else)
1973	0.808	(0.787, 0.830)
1974	0.808	(0.787, 0.830)
1975	0.809	(0.787, 0.830)
1976	0.809	(.0788, 0.831)
1977	0.809	(.0788, 0.831)
1978	0.808	(0.786, 0.830)
1979	0.809	(0.787, 0.830)
1980	0.808	(0.786, 0.829)
1981	0.808	(0.787, 0.830)
1982	0.870	(0.750, 1.008)
1983	<mark>0.806</mark>	(.0784, 0.828)
1984	0.806	(.0785, 0.828)
1985	0.838	(0.772, 0.909)
1986	0.841	(0.785, 0.901)
1987	0.831	(0.785, 0.879)
1988	1.058	(0.902, 1.242)
1989	1.074	(0.944, 1.222)
1990	1.032	(0.920, 1.157)
1991	1.023	(0.909, 1.150)
1992	1.214	(1.017, 1.449)
1993	0.926	(0.842, 1.019)
1994	<mark>0.871</mark>	(0.802, 0.947)
1995	<mark>0.868</mark>	(0.801, 0.941)
1996	0.970	(0.852, 1.104)
1997	0.897	(0.813, 0.990)
1998	1.107	(0.953, 1.286)
1999	1.644	(1.251, 2.160)
2000	1.372	(1.095, 1.719)
2001	1.033	(0.892, 1.196)
2002	1.021	(0.846, 1.231)
2003	1.219	(0.956, 1.554)
2004	0.977	(0.826, 1.156)
2005	1.081	(0.902, 1.296)
2006	0.937	(0.808, 1.087)
2007	1.143	(0.911, 1.434)
2008	1.03	(0.848, 1.252)

Figure 18 demonstrates the trend in risk ratios for outbreaks of SE associated with all other food categories combined compared to outbreaks of SE associated with the "simple egg" food category over time (1973-2008). This figure demonstrates that all other food categories combined were less likely to be associated with outbreaks of SE than the "simple egg" food category until about 1989. From 1989 to 1991, there was no substantial difference between the likelihood of an outbreak of SE being associated with all other food categories combined and being associated with the "simple egg" food category. It appears that around 1992 all other food categories combined were more likely to be associated with an outbreak of SE than the "simple egg" category. From 1993 to 1997 all other food categories combined were less likely to be associated with an outbreak of SE than the simple egg food category. For the period between 1998 and 2003 all other food categories combined were more likely to be associated with an outbreak of SE than the "simple egg" food category. Since 2004, all other food categories combined and the "simple egg" food category have been relatively equally likely to be associated with an outbreak of SE; although in 2007 all other food categories combined were more likely to be associated with outbreak of SE than the "simple egg" food category.

Figure 18.



CHAPTER V: DISCUSSION AND CONCLUSIONS

Study Significance

The findings of this study are significant in that this is the first study that examines the number of reported SE outbreaks in the context of the regulatory and public health interventions that have been implemented over time. The objectives of this study were to explore the following research questions:

- 1) Have public health policies and industry interventions had an effect on the number of outbreak-related SE infections in the US?
- 2) Has the distribution of food vehicles associated with SE outbreaks changed over time in the US?
- 3) Has the geographic distribution of SE outbreaks changed over time in the US?

Although it is difficult to causally link specific public health policies and industry interventions to a marked reduction in the number of outbreak-related SE infections in the United States, it is apparent that the collective result of such policies and interventions have had an effect on the number of outbreak-associated SE infections, as demonstrated by the decline in number of reported outbreaks of SE since the early 1990s (Figure 3). This study also demonstrates that there have been changes in the distribution of food categories of implicated foods over time (1973-2008) (Figures 11 and 12). More specifically when all egg-containing food categories were combined for the 1973-2008 time period, egg-containing foods were the most commonly implicated food category, especially during the period from 1985 to 2000 (Figure 13). In addition, this study demonstrates that the geographic distribution of SE outbreaks has changed over time. More specifically, although more stringent trace backs, microbiological testing, and

on-farm interventions were implemented beginning in 1990, the SE epidemic expanded from its origin in the Northeast to other parts of the country (Figures 5 and 6). Although the cause of the expansion of the epidemic is unclear, it could be related to the fact that many of the initial interventions and policies were targeted toward the Northeastern states, because they were the original foci of the epidemic, and states in other regions had not yet adopted EQAPs, had not implemented the changes to the Food Code, or had not yet recognized the importance of SE as a public health concern.

Outbreaks of SE continue to be an important public health problem in the United States. Despite the persistence of outbreaks of SE, the incidence of SE²¹ and the number of outbreaks of SE have declined by 67% since 1990. Although this analysis could not provide a single explanation for this decrease, it is hypothesized that a combination of on-farm interventions such as the implementation of biosecurity, vaccination campaigns, and the uptake of egg quality assurance programs (EQAPs) in egg-laying flocks combined with changes to the Retail Food Code⁶¹ and consumer education efforts have contributed to the decline in SE infections²¹ as well as the decline in outbreaks of SE. Although recent studies indicate that the implementation of EQAPs in many states beginning in the 1990s are responsible for a decline in human illness associated with SE², as of 1999 less than half of all shell eggs produced in the United States were included under an EQAP.³ Since most EQAPs are voluntary programs that certain egg-laying producers chose to opt into, it is reasonable to assume that further reductions in outbreaks of SE would ensue if more producers were to implement and adhere to EQAPs.³

Although outbreaks of "simple egg" food vehicles have consistently been the most commonly implicated food category in SE outbreaks over time, it appears that the trend of outbreaks associated with this category has declined, likely as a result of the targeted

interventions and public health messages associated with shell eggs. Despite this decline, novel public health interventions and stronger regulatory policies are still needed to address the persistence of egg-associated SE outbreaks. A recent outbreak of SE that was traced back to egg-laying farms in Iowa further highlights the need to re-evaluate existing policies related to controlling SE on the farm and to develop new intervention methods and communication strategies to prevent human illness associated with SE. This summer's outbreak of SE caused over 1,800 illnesses and resulted in the recall of over half a billion shell eggs. Although data from this year are not included in this analysis, it will be interesting to examine if this large multi-state outbreak has an effect on the overall trend of SE outbreaks.

Important Study Findings

From 1973 to 2008 there were 1,288 foodborne outbreaks of SE reported to the CDC that resulted in at least 40,963 illnesses, 4,333 hospitalizations, and 102 deaths. At least 38% of the 1,288 reported outbreaks of SE were attributed to egg-containing foods. In 2004, Patrick et al. reported that between 1985 and 1999, 80% of the 371 outbreaks where a food vehicle was identified that were reported to the CDC were egg-associated. In the present study, a food vehicle was identified in 58% of all reported foodborne outbreaks of SE from 1973 to 2008. When a food vehicle was identified, 66% of the outbreaks were attributed to egg-containing foods. This is less than that the 80% of outbreaks attributed to egg-containing foods in the Patrick et al. study only examined data from 1985-1999—the peak of the SE epidemic in the United States. If this present study is limited to the aforementioned peak of the SE epidemic (1985-1999) the proportion of outbreaks, where a food vehicle was identified, attributable to egg-containing foods is 70%. Different methods of assigning implicated foods to food categories could also explain

the slight difference in the proportion of outbreaks attributable to egg-containing foods between the two studies.

The majority (43%) of implicated food(s) in SE outbreaks was consumed outside the home in retail food establishments, whereas only 16% was consumed inside of the home. These findings may reflect surveillance bias, in that outbreaks associated with retail food establishments are more likely to be detected, investigated, and reported by public health departments than outbreaks associated with other venues. In addition, these findings are supported by a previously published study that reported an increase in consumption of food prepared outside the home was associated with increased outbreaks of salmonellosis.⁸ This trend of consuming more food outside of the home highlights the need to develop new communication strategies for retail food establishments in order to enhance their understanding of how SE is transmitted and to aid them in preventing future outbreaks of SE. In addition to increased communication strategies targeted at retail food establishments, compliance with the FDA's Food Code should be mandatory in all states and territories in the United States. As of June 2005, 48 of the 56 states and territories reported adoption of one of the five versions of the Food Code (1993 edition, 1997 edition, 1999 edition, 2001 edition, and 2005 edition).⁶¹ A revised Food Code was published in 2009.⁶¹ This Code should be adopted by all states and territories in order to help prevent outbreaks of SE from occurring in retail food establishments.

The Northeast region of the United States had the highest proportion of all SE outbreaks (47%) followed by the South region (19%), the West region (18%), and the Midwest region (15%). This observation correlates with studies in poultry that showed the highest prevalence of SE in Northeastern flocks.²⁴ Likewise, the greatest rate of decline in reported SE foodborne disease outbreaks occurred in the Northeast in the early 1990s—soon after the USDA

implemented the SE testing and trace back program and soon after the first egg quality assurance program was initiated in Pennsylvania. This finding demonstrates that although the number of SE outbreaks has declined in the Northeast since the early 1990s, historically, the Northeast region of the United States experienced the greatest rate of increase in reporting of SE foodborne disease outbreaks from the early 1980s to the early 1990s. From 1981 to 1991, the decade preceding the peak of the epidemic, the Northeast experienced a 2.3 fold higher increase in the number of reported SE foodborne disease outbreaks than the South, a 13 fold higher increase than the West, and a 59 fold higher increase than the Midwest. Since about 1995 all regions have experienced roughly the same number of reported SE foodborne disease outbreaks. Although once confined almost exclusively to the Northeast, SE outbreaks spread throughout most of the United States, thus demanding the nationwide implementation of rigorous prevention and control measures to mitigate the illnesses, hospitalizations, and deaths associated with such outbreaks.

Although the "simple egg" food category was found to be more commonly associated with outbreaks of SE during the study period than all other food categories combined, there is evidence that the decline in foodborne disease outbreaks associated with the "simple egg" category are likely attributable to a suite of on-farm interventions and policies initiated in response to the dramatic increase in outbreaks of SE beginning in the late 1980s. Following initial recognition of shell eggs as the primary food source of infection in 1988, there was an increase in the risk ratio associated with other food sources of infection relative to the "simple egg" category, reaching statistical significance in 1992. In spite of changes made to the Food Code, the "simple egg" category of food was at least or more common than other food sources of infection for the next five years, not significantly dropping again until the President's Council on

Food Safety published the Egg Safety Action Plan in 1999. It is not clear whether the relative increase in the number of outbreaks due to the "simple egg" food vehicles from 1993-1997 reflected the increasing geographic range of the pathogen in US poultry flocks, incomplete adoption of the Food Code and EQAPs among states, or a time lag between the provision of guidance and the widespread implementation of interventions; but since 1999 "simple egg" food vehicles have not been as commonly implicated as the source of reported outbreaks as they were during the years 1973-1987.

Study Limitations

The method used to classify foods into the nine different food categories may be a limitation of this study. The Painter Google method is somewhat limited in that it is unclear as to whether the most commonly used recipes are those that can be readily retrieved from the internet. Thus, the food categories are subject to some misclassification bias (e.g., a recipe that was found to contain eggs using the Painter method may not have been the recipe used to prepare the implicated food in the particular outbreak or eggs were used in the recipe for the implicated food in the outbreak but the recipe was not found to contain eggs using the Painter method). In addition, it is unknown how recipes may change over time such that those obtained from Google at the time of this study many not reflect those used in the 1970s or 1980s, etc.

The large number of implicated foods that were classified as "missing" or "unknown" is another limitation of the study. There are many reasons why a specific food vehicle may not be implicated in an outbreak investigation³⁸, and it is likely that many of the implicated foods that were assigned to the "missing/unknown" category in this analysis could have contained eggs but were not categorized as such, thus the number of egg-associated outbreaks of SE is likely underestimated. In addition, by the time an outbreak has been identified and interviews are

conducted, case-patients may have trouble recalling all of the specific foods items that they may have eaten prior to their illness.³⁸ Additionally, even if case-patients can accurately articulate a complete list of foods consumed prior to illness onset, a strong statistical association may not be apparent once the case-patient data is analyzed, thus failing to implicate a specific food vehicle.³⁸

Outbreak investigation bias is also a potential limitation of the study. For example, in an outbreak situation where SE has been identified as the pathogen of interest, investigators may assume that an egg-containing food is the culprit before confirming the specific cause of the outbreak. This may bias reporting of egg-associated SE outbreaks by states and territories to CDC. In addition, laboratory bias may be a potential limitation of this study. It is reasonable to hypothesize that certain states do not report as many SE outbreaks as others because some states might not have the laboratory capacity to serotype all Salmonella isolates. It is also reasonable to hypothesize that certain regions, such as the Northeast, may tend to report more outbreaks of SE than other regions because the states in the Northeast have increased awareness of the SE epidemic, due to their extensive experience with the pathogen. Finally, SE outbreaks associated with food preparation originating in retail food establishments, such as restaurants, are more likely to be investigated and reported than SE outbreaks associated with food preparation originating at private homes. Although outbreaks associated with retail food establishments are more likely to be reported, this does not necessarily mean that food handling practices are worse in retail food establishments than in private homes.

Future Studies and Recommendations

Further study is needed to examine the effectiveness of a recently launched public health initiative to reduce the number of illnesses, hospitalizations, and deaths associated with SE outbreaks. On July 9, 2010, the FDA enacted the Egg Rule intended to prevent 79,000 SE-

associated illnesses and 30 SE-associated deaths annually.⁶⁴ The Egg Rule is a comprehensive SE control policy that requires routine microbiologic testing for SE for producers who maintain more than 50,000 egg-laying hens^{62,65} in addition to many other interventions. It will be interesting to examine the trends in SE outbreak data following complete implementation and adoption of this newly proposed rule to see if it has a significant impact on the number of SE-associated outbreaks in the United States in the future.

In addition, the promulgation of innovative interventions is needed to reduce the number of egg-associated outbreaks of SE in the United States. Eggs and egg-containing foods continue to be important vehicles for outbreaks of SE and the persistent occurrence of such outbreaks demands that public health officials, policy makers, and industry representatives collaborate more effectively to develop strategies to reduce the prevalence of this problematic pathogen.

More effective, targeted polices and interventions are also needed in specific locations of food preparation and food consumption, especially in retail food settings such as restaurants, delis, and mobile food vendors. Retail food personnel and food preparers should be routinely educated on proper egg handling techniques and should use pasteurized egg products whenever possible 45 in order to reduce the number of SE-associated outbreaks in retail food settings.

Although it first emerged as a public health threat in the 1980s, SE continues to be a formidable pathogen that causes unnecessary outbreaks, illnesses, hospitalizations, and deaths each year. Although the collective effect of public health policies and industry interventions have likely contributed to the decline of SE outbreaks, no single policy or intervention has succeeded in completely quelling this epidemic, as evidenced by the continued occurrence of SE outbreaks. Efforts surrounding the prevention and control of SE should be synergized and public health professionals, policy makers, and egg-industry farmers should seek to collaborate to find

an effective, multi-pronged approach to reduce the prevalence of SE in egg-laying flocks and shell eggs and to educate the public about safe egg preparation and egg consumption practices. In revising existing prevention strategies and implementing new control measures, the United States should take note of the SE-control models implemented in Europe. Interventions including rigorous flock testing and vaccination campaigns have been demonstrated to be successful in reducing outbreaks and infections associated with SE. Only through effective collaboration and swift regulatory action can this pressing public health problem be controlled.

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