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Factors Contributing to Foodborne Disease Outbreaks Transmitted through Pork Products in the United States, 1998-2008

By

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Master of Public Health

Global Epidemiology

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By

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B.S., Gettysburg College, 2010

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Abstract

Factors Contributing to Foodborne Disease Outbreaks Transmitted through Pork Products in the United States, 1998-2008

By Amy Fothergill

Background: The average American eats 49 pounds of pork a year. Foodborne disease outbreaks associated with this commodity were reviewed. **Methods:** Data was obtained from the CDC's Foodborne Disease Outbreak Surveillance System for outbreaks during 1998-2008 in which pork was implicated as the single food commodity. Occurrence of improper preparation practices and food worker contamination events associated with outbreaks were analyzed. Poisson and negative binomial regressions were used to evaluate changes in the reporting of these events over time, and the relationships between these events and specific pathogens, food types, and food preparation locations of interest. **Results:** A total of 233 outbreaks were included in analyses, which resulted in 4346 illnesses, 255 hospitalizations and 1 death. A total of 73 worker contamination events and 319 improper preparation events were reported. There was no statistically significant change in rates of either worker contamination events or improper preparation events during the time period. Statistically significant lower rates of improper preparation practices were found for norovirus outbreaks compared to those for other pathogens (RR=0.217, 95% CI [0.10, 0.47]), and norovirus outbreaks involved slightly higher rates of worker contamination events (RR=1.64, 95 % CI [0.9, 2.99]) The rate of worker contamination events was significantly higher for *Staphylococcus* outbreaks (RR=2.366, 95% CI [1.44, 3.89] and significantly lower for *Clostridium* outbreaks compared to those for all other pathogens (RR=0.192, 95% CI [0.05, 0.79]). The rate of improper preparation events was significantly higher for *Salmonella* outbreaks compared to those for all other pathogens (RR=1.487, 95% CI [1.0, 2.2]). Statistically significant higher rates of worker contamination were noted for restaurants (RR=4.3, 95% CI [0.99, 18.7]) compared to those for grocery/convenience stores in *Staphylococcus* outbreaks. **Conclusions:** Despite an overall decline in the number of foodborne disease outbreaks due to pork over this time period, no significant change in rates of worker contamination events or improper preparation events was observed. Improvements in food handling and preparation do not appear to be occurring in pork products. The identification of relationships between certain pathogens and improper food preparation / worker contamination events is beneficial, and can possibly extend to other food commodities.

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Table of Contents:

Chapter I: Background/Literature review:

Foodborne disease is a preventable public health issue that affects an estimated 1 in 6 Americans each year (1, 2). There are many different types of pathogens that can contaminate food products, and more than 250 foodborne diseases have been described (3). Foodborne diseases are estimated to cause 48 million illnesses, 128,000 hospitalizations and 3,000 deaths each year in the United States (2). Over the course of time, the food commodities associated with disease transmission, pathogens causing infections, and the incidence of outbreaks has changed. Changes in food safety regulations have the potential to alter the course of foodborne diseases, and pork foodborne disease outbreaks are an important cause of illness in the United States. Between 1988 and 1992 pork outbreaks accounted for 10 out of 2,423 reported foodborne outbreaks (0.4%), and 691 illnesses (0.9%) (4). Between 1998 and 2008 there were 259 outbreaks attributed to pork (1.9% of all foodborne outbreaks), resulting in 5113 illnesses and 2 deaths.

The United States is the world's third largest pork producer, largest exporter, and second largest consumer of pork (5). On average, Americans eat 8 ounces of meat per day, and one-quarter of this is pork. Between 1986 and 2006, the average annual consumption of pork did not noticeably changed with an average consumption of 48.9 pounds per year in 2006 (5). Changes in pig farming in the United States over this time period in conjunction with changes in proportions of outbreaks and illnesses attributed to pork establish a need for a pork specific analysis of risk factors for disease outbreaks.

Changes to food supply systems, health and demographics, health system infrastructure, and the environment have all been suggested as potential ways for

foodborne disease occurrence and severity to increase(6). In the United States, pork production has shifted from the traditional method of raising pigs from birth to slaughter on the same farm, to modern farms with specialized operations for each distinct phase of the pig life cycle (5). While changes in pork production have been occurring, pork safety has improved over the last decades in the United States, as can be seen by the virtual elimination of parasitic pork infections (*Taenia solium*, *Trichinella spiralis*, and *Toxoplasmosis gondii*), all of which can be prevented and treated at the farm level. Pre-harvest control measures have been shown to be very effective in decreasing pig-born parasitic illnesses, but not enteric bacterial organisms (7).

Bacterial infections, due to bacteria initially residing in the pig's intestinal tract, have a more complex epidemiology and can result in contamination of meat at many points. Meat can become contaminated at the farm, during processing, or consumer level through cross-contamination, making bacterial control more challenging. Recent changes in pig farming, such as having larger herds, have been examined as possible factors for increasing transmission of enteric disease, but contradicting results have been found. There is no definitive evidence yet to suggest that increased intensive pork production has increased the risk of enteric bacterial pathogens (7).

In 1996, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) issued the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) (7). HACCP is a systematic approach to ensuring food safety by examining physical, chemical, and biological hazards throughout production as a means of prevention, rather than simply inspecting final products. It allows for the identification, evaluation and control of food safety hazards using seven principles: 1.

Conduct a hazard analysis 2. Determine Critical Control Points 3. Establish Critical Limits 4. Establish monitoring procedures 5. Establish Corrective Actions 6. Establish verification procedures and 7. Establish a record-keeping and documentation process. (8) The implementation of HACCP is not meant to replace current safety regulations in food processing, but rather to complement current methods, identify additional or more specific control measures needed, increase emphasis of good hygiene practices, foresee corrective measures, and give more training/responsibility to food workers(6). Additionally, HACCP places limits on the allowable levels of *Salmonella* in swine herds that were sent from farms to abattoirs. However, human disease caused by *Salmonella* has not decreased (7). Studies in Europe have suggested that changes in post-harvest conditions are more influential on illness reduction compared to on-farm changes (9). Over a ten year period of *Salmonella* incidence surveillance in Denmark, on-farm measures (monitoring and treating feed, identification of herds with *Salmonella*) were found to be less beneficial than post-harvest abattoir measures (wrapping colon and rectum in plastic bags before removing organs, hot-water decontamination of carcasses). Post-harvest abattoir measures implemented in Denmark are similar to HACCP measures suggested by the United States Food and Drug Administration (US FDA) (9).

The development and application of the Hazard Analysis and Critical Control Point (HACCP) system is currently making advances in food safety, and adherence to it is arguably the best method available to prevent foodborne disease outbreaks. HACCP has great potential to prevent large outbreaks, but it is essential that the measures are understood and correctly implemented. In addition to HACCP, good hygiene practices need to be conducted throughout the entire food chain: on the farm, processing,

manufacturing, transportation, distribution, and preparation for consumption (6). Even when efforts are made to implement safe food preparation practices, isolated incidents of non-adherence can result in outbreaks. For example, in a long-term care facility in Australia, an outbreak was linked epidemiologically to sweet-and-sour-pork served to a group of residents. Food preparation practices were observed in the facility after the outbreak, and were deemed to be of high standard, but temperatures for hot foods had not been recorded appropriately in the weeks before the outbreak (10).

Contamination of pork products with pathogens can occur at multiple stages along the food chain; production, processing, distributing, retail marketing, and handling/preparation (11). The introduction of HACCP and other quality control measures throughout pork production is necessary for improvements in food safety and reducing disease outbreaks. Improper food handling practices have been frequently documented in outbreaks transmitted through pork products, and sometimes multiple infractions are found to have occurred.

Past pork outbreaks attributed to improper preparation

Inadequate cooling in retail operations is a major safety problem. Safe lengths of time and safe temperatures for cooling pork products have been identified, and it is a critical control point that needs to be adhered to (12). Improper cooling of food is an important cause of foodborne illness, and half of all foodborne illness outbreaks are associated with restaurants (3). In a study to identify restaurant characteristics that increased improper food handling practices it was found that small, independently owned

restaurants where food safety certification for managers and workers did not receive food safety training were more likely to cool foods improperly (13). Interestingly, it was found in one outbreak where improper cooling/storage occurred that people who had reheated the pork in a conventional oven were found to have less illness compared to those who reheated the pork in a microwave. Microwaves heat food rapidly and unevenly, which could have resulted in inadequate killing of the pathogen. Given the increasing popularity of microwaves it would behoove public health officials to inform consumers of the risks of reheating meat in microwaves unless certain precautions are taken (14).

Inadequate food cooking practices have also been implicated in disease transmission. For example, an outbreak among church camp attendees found associations between consumption of pork, and the degree to which the pork was cooked with the occurrence of illness. Inadequate thawing, cooking, and length of time between cooking and consumption were considered likely to impact the pathogen presence in pork. The person responsible for food preparation in this outbreak had never purchased or prepared the type of pork (de-boned) implicated, and was not aware of proper cooking techniques (15).

In an outbreak in a small, privately owned, wine-house in Austria homemade jellied pork was found to be contaminated with *Listeria*, while none of the commercially purchased foods was found to be contaminated. Microbiological testing has shown that raw pork can support rapid growth of *Listeria*, particularly after it has undergone "temperature abuse" which is common at the retail level (16). Although no specific food handling or preparation practice was identified to have introduced the pathogen in this

outbreak, it has been shown that smaller restaurants such as this are more likely to practice unsafe food cooling practices (13), and since commercially produced foods were not found to be contaminated it is likely that the jellied pork became contaminated during preparation.

Carnitas, a pork dish typically prepared by Hispanic populations, was the most frequently implicated food vehicle of transmission for foodborne disease outbreaks in Chicago between 1995 and 2002. Unsafe food handling practices occurring after carnitas were cooked were identified as contributing to multiple outbreaks. Carnitas were held at improper temperatures after cooking, consumers were able to introduce contamination to a common source of carnitas through self-service, improperly sanitized utensils were used, cutting boards and personnel allowed for cross contamination, and carnitas were not refrigerated and/or heated to adequate temperatures between purchase and consumption. These outbreaks could have been prevented by proper food handling after cooking, and increased consumer knowledge on the safety of carnitas (17).

A *Salmonella* outbreak resulting in 22 illnesses was associated with eating roast pork that had been improperly thawed, cooked, and stored. The pig had been thawed at room temperature instead of refrigerator, was cooked for an inadequate length of time (subsequently no recorded temperatures were taken to verify it had been properly cooked), and was then left unrefrigerated for 17-20 hours after cooking (standard practice is no more than 2 hours). All of these factors could have led to *Salmonella* proliferation on the pig, resulting in human illness (14).

Sometimes, unsafe handling practices can result in disease among those who had not consumed the contaminated product. For example, chitterling preparation was found to be associated with yersiniosis among infants who had been present during food preparation but who had not eaten the final product. Parents whose children became ill acknowledge that unsafe practices had taken place during preparation: infants roaming freely in the room where chitterlings were being cleaned, juices from the chitterlings splashing on clean dishes/baby bottles, washing bottles in sinks used for chitterling preparation that had not been sufficiently cleaned, and feeding or handing objects to infants during chitterling preparation without washing hands (18) (19).

Where does Contamination Originate?

Proper food preparation and handling practices are particularly important because despite efforts made at the farm and abattoir levels, contaminated raw products are still being sent to retail stores. In a study conducted in the greater Washington, DC area it was found that 1.7% of pork samples were positive for *Campylobacter* and 16.3% were positive for *Escherichia coli*. There was a statistically significant difference in contamination levels between supermarket chains, even within the same brand-names, suggesting that processing done at the stores also contributes to contamination (11). (Note: in this report, the term significant refers to statistical significance.) In samples of pork collected from 24 stores in six cities in the United States, contamination with *Listeria, Yersinia, Salmonella,* and *Campylobacter* was found. A combination of store-packaged and pre-packaged samples was selected, as were different types of pork (whole-muscle, ground, sausage). The highest levels of contamination were found in store-ground pork, with the lowest in whole-muscle “enhanced” (marinated) and pre-packaged

pork. *Listeria* was detected in approximately 23% of all products sampled, and was present more frequently in ground products. *Yersinia* was detected most often in whole-muscle samples, and was in 19.8% of store packaged products and 11.5% of store-ground products (20).

Even when outbreaks are thoroughly investigated, it is often not possible to identify the point at which food became contaminated; investigations may fail to identify a single problem that led to the outbreak. Five major control factors for pathogen prevalence in food are personal hygiene, adequate cooking, avoiding cross contamination, keeping food at safe temperatures, and avoiding foods from unsafe sources. It has been recommended that "consumer food safety educators" educate on hand washing, avoiding cross-contamination, and adequate cooking (to eliminate pathogens that may have been introduced despite improved efforts), as poor personal hygiene is associated with pathogens that result in highest incidence and cost (21). Identifying particular control factors that are of importance in pork outbreaks would be beneficial in reducing morbidities due to contaminated products.

Chapter II: Manuscript

Title/Authors/Abstract:

Factors Contributing to Foodborne Outbreaks Transmitted through Pork Products in the United States, 1998-2008

BY: Amy Fothergill

Background: The average American eats 49 pounds of pork a year. Foodborne disease outbreaks associated with this commodity were reviewed. **Methods:** Data was obtained from the CDC's Foodborne Disease Outbreak Surveillance System for outbreaks during 1998-2008 in which pork was implicated as the single food commodity. Occurrence of improper preparation practices and food worker contamination events associated with outbreaks were analyzed. Poisson and negative binomial regressions were used to evaluate changes in the reporting of these events over time, and the relationships between these events and specific pathogens, food types, and food preparation locations of interest. **Results:** A total of 233 outbreaks were included in analyses, which resulted in 4346 illnesses, 255 hospitalizations and 1 death. A total of 73 worker contamination events and 319 improper preparation events were reported. There was no statistically significant change in rates of either worker contamination events or improper preparation events during the time period. Statistically significant lower rates of improper preparation practices were found for norovirus outbreaks compared to those for other pathogens (RR=0.217, 95% CI [0.10, 0.47]), and norovirus outbreaks involved slightly higher rates of worker contamination events (RR=1.64, 95 % CI [0.9, 2.99]) The rate of worker contamination events was significantly higher for *Staphylococcus* outbreaks (RR=2.366, 95% CI [1.44, 3.89] and significantly lower for *Clostridium* outbreaks compared to those for all other pathogens (RR=0.192, 95% CI [0.05, 0.79]). The rate of improper preparation events was significantly higher for *Salmonella* outbreaks compared to those for all other pathogens (RR=1.487, 95% CI [1.0, 2.2]). Statistically significant higher rates of worker contamination were noted for restaurants (RR=4.3, 95% CI [0.99, 18.7]) compared to those for grocery/convenience stores in *Staphylococcus* outbreaks. **Conclusions:** Despite an overall decline in the number of foodborne disease outbreaks due to pork over this time period, no significant change in rates of worker contamination events or improper preparation events was observed. Improvements in food handling and preparation do not appear to be occurring in pork products. The identification of relationships between certain pathogens and improper food preparation / worker contamination events is beneficial, and can possibly extend to other food commodities.

Introduction:

Foodborne disease outbreaks are an important cause of illness in the United States. (1) Causing an estimated 48 million illnesses each year, foodborne illness is thought to be more common than the flu and the common cold, and increasing centralization and globalization have the potential to increase incidence (22). Pork is commonly consumed in the United States and outbreaks transmitted through pork products are regularly identified but have not recently been summarized. Identifying risk factors for foodborne disease outbreaks in pork products is essential to reducing their morbidity.

During foodborne outbreak investigation the main goals are to identify the implicated food product and pathogen in order to remove the product from the market and reduce additional cases. The definitive identification of the causative pathogen is often not possible due to lack of left-over food products or collected stool samples. Despite the inability to definitively identify pathogens in outbreaks, the majority of analysis currently available focuses on pathogen or food product specific risks. Knowledge on risks associated with food commodities is needed so even though pathogens may not be identified or isolated, people will be aware of measures they can take to avoid foodborne illness.

The Centers for Disease Control and Prevention (CDC) conducts surveillance for foodborne disease outbreaks investigated by local and state health departments in the United States through the Foodborne Disease Outbreak Surveillance System. Reports of outbreaks are submitted to CDC on a voluntary basis and during the time period 1998-2008 was compiled into the electronic Foodborne Outbreak Reporting System (eFORS).

This dataset is the largest and most complete dataset on foodborne disease outbreaks available. The data shows that reported outbreaks associated with pork products have been declining, but the reason for this decline is unknown.

The driving factors behind the decline in outbreaks need to be identified in order to facilitate the continued decline and to increase the safety of pork products in the United States. When outbreaks are reported to the CDC, factors such as improper food preparation practices (improper cleaning of equipment, inadequate cooking/re-heating/cooling, poor food storage conditions, etc), inappropriate food worker health and hygiene (bare-hand contact with food, handling food by an infected person) or outside contamination factors (toxic substance in part of animal tissue, raw product/ingredient contaminated by pathogens from animal or environment) are reported if investigated. Changes in the occurrence of these factors may be affecting the apparent decrease in outbreaks.

Morbidity from foodborne illness has the potential to escalate beyond the typical gastrointestinal illness reported, particularly in vulnerable populations (children, elderly, and immunocompromised). Lack of education and safety trainings for consumers and food handlers has been identified as increasing unsafe food handling practices and foodborne disease (6). Demonstrating the importance of food preparation practice and food worker health and hygiene in the decline in outbreaks implicated in pork products will provide the public with ways to increase their safety when consuming food products.

Methods:

Hypothesis:

The decrease in foodborne disease outbreaks attributed to pork is a result of improved food preparation and food worker hygiene practices among consumers and at the retail level.

Study Design:

The Centers for Disease Control and Prevention (CDC) conducts surveillance for foodborne disease outbreaks investigated by local and state health departments in the United States through the Foodborne Disease Outbreak Surveillance System (http://www.cdc.gov/outbreaknet/surveillance_data.html). Data on foodborne disease outbreaks (two or more cases of a similar illness resulting from ingestion of a common food) in which the single contaminated ingredient or all ingredients were classified to the pork commodity by the CDC, during 1998-2008 were reviewed. (23) Geographic location of the outbreak was considered to be the reporting state, no multiple state outbreaks were in the dataset.

This study was determined exempt from IRB review due to it being a secondary analysis of non-human subjects research using de-identified data (Appendix C)

Study Variables:

Outbreaks with a single pathogen reported were included in that pathogen category regardless of whether the pathogen was defined as suspected or confirmed. (24)

Outbreaks with multiple pathogens listed were categorized bacterial toxin if one of the pathogens implicated was *Bacillus cereus*, *Staphylococcus aureus* or *Clostridium perfringens*, otherwise it was classified as mixed. One outbreak had a single etiology of "other bacterial toxin" and this outbreak was also included in the bacterial toxin category.

Implicated foods were categorized as follows: BBQ, Ham, processed (e.g. spam, sausage, bacon), pork entrée (eg chops, tenderloins, ribs), pork by-products/chitterlings, and other. These categories were determined using reported food products and if necessary, reported contaminated ingredients. If an outbreak had multiple food items implicated the contaminated ingredient was examined to determine food categorization. If the documented contaminated ingredient was unable to put the product in one of the predetermined categories or if there was no ingredient documented, the outbreak was classified as other. Outbreaks in the 'other' category are typically combination foods with pork as the probable contaminated ingredient, although not definitively identified. Although ham is typically considered a processed food, it was considered a separate category in this analysis due to the high number of outbreaks associated with ham and its association with *Staphylococcus*. The decision to separate ham from processed foods was considered acceptable when communicated to members of the Food Safety and Inspection Service (FSIS).

Settings of food preparation were categorized as follows: restaurant, private home, large gathering (wedding, banquet, caterer, church fair, and festival), grocery/convenience store, institutional (hospital, nursing home, school, work), unknown, other, and mixed. Two hundred twenty-eight outbreaks had one implicated preparation site. Of remaining

outbreaks, if the multiple locations listed fell into the same category, they were classified as that category, otherwise they were considered mixed.

Contributing factors originally categorized as contamination, proliferation/amplification, or survival factors were re-categorized as either improper food preparation within an establishment or worker contamination due to poor food worker hygiene. (Table 1)

Statistical Analysis:

Data analysis was performed using SAS 9.3 (SAS Institute, Cary NC).

Frequency distributions of outbreak characteristics were calculated. The relationship between reported improper preparation / worker contamination and predictor variables (pathogen, food type, and food preparation location) was tested by Chi-square analysis. A p-value of less than 0.05 was considered statistically significant. In this report, the term significant refers throughout to statistical significance. Univariate Chi-square test statistics and p-values are provided for the relationship between implicated pathogen, food type, and food preparation location and handling/worker infractions. For cells with counts less than five, the reported p-values are Fischer exact p-values. Outbreaks with an uncommon (occurring less than 15 times in the dataset) food type or food preparation location were not included in the analysis.

Poisson and negative binomial regressions were used for multivariate analyses. Counts of reported worker contamination and improper food preparation practices were modeled using Poisson and negative binomial regression respectively. Data was examined for presence of over and under dispersion using the mean deviance, Chi-square goodness of fit tests, and likelihood ratio tests. Reported improper preparation practices were found

to have significant over dispersion when evaluated with likelihood ratio tests, so negative binomial regression was used. No significant over or under dispersion was observed in reported food worker contamination events, so Poisson regression was used.

Variables and their interactions determined to be important were initially included in the model, resulting in the full model:

$$\text{Handling/Worker Count} = \alpha + \beta_1 (\text{year}) + \beta_2 (\text{pathogen}) + \beta_3 (\text{food type}) + \beta_4 (\text{prep location}) + \beta_5 (\text{year*pathogen}) + \beta_6 (\text{year*location}) + \beta_7 (\text{pathogen*food}) + \beta_8 (\text{food*location})$$

where the four pathogens were considered separately (*Clostridium*, *Salmonella*, *Staphylococcus*, and norovirus).

To assess the presence of interaction, chunk tests were performed to examine all possible subsets of interaction terms for each outcome of interest. The significance of the interaction terms and a goodness of fit test comparing the deviances of full and reduced models were used to assess the appropriateness of adjusted measures of occurrence rate. Interaction was assessed at the alpha = 0.05 level. If a covariate showed significant interaction, it was included in the final model.

To assess confounding, all possible subsets of confounders were explored. If a group of confounders resulted in a meaningfully different estimate compared to the full standard model it was eliminated from consideration. Meaningfully different was defined as a greater than 10 percent change.

Models that were not meaningfully different from the gold standard were evaluated based on precision. Final chosen models were also examined to see if they had good or better goodness of fit compared to the full model. For both Poisson and negative binomial regressions, this was done using the mean deviations as well as the Chi-square goodness of fit test.

Results:

Pork was reported as the implicated food commodity in 259 foodborne disease outbreaks, resulting in 5113 illnesses, 294 hospitalizations and 2 deaths. Thirty-eight states reported outbreaks attributed to pork during the study period, with half reporting fewer than five outbreaks, and only nine states reporting ten or more outbreaks. Two-hundred fifty three outbreaks had a single implicated food reported. In the remaining 6 outbreaks, multiple foods multiple foods were implicated, but pork was determined to be the contaminated ingredient. A single pathogen was reported for 180 (69.5%) outbreaks, 69 (26.6%) outbreaks had no pathogen reported, and 10 (3.9%) outbreaks had two pathogens reported. The four most commonly implicated pathogens in single pathogen outbreaks were norovirus (26, 10%), *Clostridium perfringens (*38, 14.7%*), Salmonella sp*. (43, 16.6%), and *Staphylococcus aureus (*56, 21.6%*).* The majority of outbreaks occurred in four food types, (pork entrée (113, 43.6%), ham (49, 18.9%), BBQ (63, 24.3%), and processed pork (17, 6.6%)), and food exposure most often occurred in one of 5 locations, (restaurant (119,45.9%), private home (45,17.4%), large gatherings (34, 13.1%), grocery/convenience stores (17,6.6%) or mixed (25, 9.7%)) (Table 1).

For further analysis, outbreaks were included if they had one of the four most commonly implicated pathogens or food types and exposure was in one of the five common locations. Of the original 259 outbreaks, 233 were included in analyses, which resulted in 4346 illnesses, 255 hospitalizations and 1 death. A total of 73 worker contamination events and 319 improper preparation events were reported.

In multivariate analysis, the presence of statistical interaction between independent variables and the primary exposure was explored. No interaction terms in any of the models were found to be significant using a chunk test ($p>0.05$). Chi-square tests examining the deviance/degrees of freedom for full and reduced models were also non-significant, and observed mean deviances for reduced models further supported the removal of all interaction terms. All interaction terms were removed.

Effect modification was evaluated by examining all combinations of independent variables and interactions between them. Combinations of confounders that did not result in meaningful changes (>10%) in the estimate of interest were considered for analysis. When choosing the group of independent variables a variation of the likelihood ratio test (model deviance = 2LogL) was used to determine the most appropriate group of confounders for analysis.

In the univariate analysis, the characteristics of outbreaks with one or more improper preparation incident or worker contamination event reported were compared (Table 3, Table 4). Occurrences of outbreaks with at least one improper preparation event was found to be significantly different among types of food ($p=0.0019$), and ham was found to have significantly lower rates of improper preparation events (RR=0.473, 95% CI

[0.29, 0.76]). Processed pork products had significantly higher rates of worker contamination compared to pork entrées (RR=2.718, 95% CI [1.31, 5.64]). Grocery/convenience stores had significantly lower rates of improper preparation events compared to restaurants (RR 0.478, 95% CI [0.23, 0.99]). The rate of improper preparation events was not found to change significantly over the time period (RR=1.03, 95% CI [0.98, 1.09]), nor was the rate of worker contamination events (RR=1.03, 95% CI [0.98, 1.09]). (Table 3 & 4)

Staphylococcus

In the univariate analysis, *Staphylococcus* outbreaks were significantly more likely to have at least one worker contamination event reported and had significantly higher rates of worker contamination events compared to all other pathogens (p=0.0072, RR= 2.24, 95% CI [1.4, 3.57]). (Table 3 & 4) In multivariate analysis, ham products were found to be less often associated with improper preparation events in *Staphylococcus* outbreaks (RR= 0.414, 95% CI [0.25, 0.69]). (Table 5)

The final Poisson regression models for rates of worker contamination events (Table 6) showed that Staphylococcus outbreaks had significantly higher rates of worker contamination compared to all other pathogens, (RR=2.366, 95% CI [1.44, 3.89]) and food type was significantly associated with the rate of worker contamination events in *Staphylococcus* outbreaks, and processed foods had a significantly higher rate compared to pork entrées (RR=3.259, 95% CI [1.51, 7.02]). (Table 6) Restaurants had significantly higher rates of worker contamination (RR=4.3, 95% CI [0.99, 18.7]) compared to grocery/convenience stores in *Staphylococcus* outbreaks. (Table 7)

Clostridium

In univariate analysis, *Clostridium perfringens* was significantly more likely to have no worker contamination events reported and had significantly lower rates of worker contamination events compared to other pathogens (p=0.007, RR=0.174, 95 % CI [0.04, 0.71]). Outbreaks with *Clostridium perfringens* as the implicated pathogen were significantly more likely to have at least one reported improper preparation event (p-value = <0.001). (Table 3 & 4) In multivariate analysis, ham products were identified as having significantly lower rates of improper preparation events in *Clostridium perfringens* outbreaks (RR= 0.518, 95% CI [0.32, 0.84]). (Table 5) Processed pork products was more likely to have higher rates of worker contamination compared to pork entrées (RR=2.46, 95% CI [1.18, 5.16]). *Clostridium perfringens* outbreaks had significantly lower rates of worker contamination events compared to all other pathogens (RR=0.192, 95% CI [0.05, 0.79]). (Table 6)

Norovirus

Although not significant, the rate of worker contamination events was found to be slightly higher for norovirus outbreaks compared to all other pathogens in univariate analysis (RR=1.64, 95 % CI [0.9, 2.99]). Outbreaks with norovirus as the implicated pathogen were significantly more likely to have at least one reported improper preparation event, however the rate of improper preparation events was found to be significantly lower compared to all other pathogens (p-value = 0.0102, RR=0.195, 95% CI [0.09, 0.42]). Norovirus outbreaks were more likely to have a reported improper preparation event, but the average number per outbreak (measured by the rate) was lower

compared to other pathogens. (Table 3 &4) In multivariate analysis, rates of improper preparation events were significantly lower for norovirus compared to other pathogens (RR=0.217, 95% CI [0.10, 0.47]). (Table 5) Although not significant, restaurants were also found to have higher rates of worker contamination compared to grocery/convenience store in norovirus outbreaks (RR = 3.6, 95% CI [0.85, 15.3]). (Table 6)

Salmonella

In univariate analysis the rate of improper preparation events was significantly higher for *Salmonella* outbreaks compared to all other pathogens (RR=1.63 95% CI [1.11, 2.39]). (Table 3 &4) In multivariate analysis, rates of improper preparation events for *Salmonella* were significantly higher (RR=1.487, 95% CI [1.0, 2.2]). Ham products were identified as having significantly lower rates of improper preparation events in *Salmonella* outbreaks, (RR= 0.539 95%CI [0.34, 0.87]). (Table 5) Although not significant, restaurants were also found to have higher rates of worker contamination compared to grocery/convenience store in *Salmonella* outbreaks (RR = 3.51, 95% CI [0.82, 15.05]). (Table 7)

The rates of improper preparation events for restaurants and private homes were nearly equal across all pathogen types. Although not significant, food products were more likely to be improperly prepared in restaurants compared to grocery/convenient stores across all pathogen types. The exposure of interest, year, was not found to significantly

affect the rate of improper preparation or worker contamination events in any of the models. (Table 5 & 6 & 7)

Discussion:

Prevention is the key to avoiding foodborne illness outbreaks. Proper preparation practices and eliminating contact between infected food workers and food products are important in outbreak prevention. This analysis was unable to identify significant changes in reported rates of improper food handling practices or worker contamination events over time through crude or adjusted analyses. Depending on the level of investigation conducted for an outbreak, information on point of contamination may not have been identified. Factors such as location of the outbreak, number of ill persons involved, severity of illness caused, and presence of adequate numbers of public health workers on the case, may all influence the rigor with which an outbreak was investigated. The lack of significant changes in improper food handling practices and worker contamination events during the studied time period suggests that despite increased knowledge or preventative practices, widespread improvements are not being made in pork production in the United States.

Staphylococcus outbreaks have decreased over this time period, yet they were associated with statistically significant higher rates of worker contamination and slightly higher, though not statistically significant, rates of improper food preparation compared to other pathogens. *Staphylococci* exist in the environment (air, dust, on surfaces) as well as in humans and animals (25). This allows them to be introduced into foods in a variety of ways and unless heat processes are properly applied *staphylococci* are expected to exist

in all food products that are handled directly by humans or are of animal origin. The toxins produced by *Staphylococci* are highly heat stable, so even if heat treatment is applied after toxin formation the product will still be infectious (25). Given the likelihood of s*taphylococcal* presence and its ability to cause illness, improvements in food preparation practices and decreased worker contamination events should facilitate the continued decline of *Staphylococcus* outbreaks.

Clostridium outbreak occurrence did not change with any noticeable trend over the time period. The significantly lower rates of worker contamination events in *Clostridium* implicated outbreaks is expected since *Clostridium* food poisoning is usually caused by improper preparation practices (25). Although not statistically significant, *Clostridium* outbreaks were associated with slightly higher rates of improper preparation practices compared to all other pathogens.

Norovirus outbreaks increased slightly over the time period. Significantly lower rates of improper preparation practices were found for norovirus outbreaks compared to those due to other pathogens, and norovirus episodes were associated with slightly higher rates of worker contamination events. Although this increased rate was not significant, it is expected because norovirus does not have a natural reservoir in food products, and typically is introduced by infected food workers.

Salmonella outbreaks slightly increased (although not significantly) over the time period. The significantly higher rates of reported improper preparation events for *Salmonella* outbreaks compared to those for other pathogens suggests that lack of improvement in food preparation practices could be affecting *Salmonella* outbreak occurrence.

Salmonella is found in the intestinal tracts of vertebrates and can exist in the environment (pond-water sediment) (25). The bacteria can survive on low-moisture foods and cross contamination, due to improper preparation practices, is known to occur frequently.

There was no significant change in rates of either worker contamination events or improper preparation events observed during the time period suggesting, despite increased knowledge on food safety, improvements in food handling and preparation practices are not being made. Many of the above mentioned rates of worker contamination and improper preparation events with regard to individual pathogens demonstrate patterns and trends that are biologically plausible and suggest that with more data significant relationships may be observed.

In a study conducted from 2002-03, it was found that 65% of foodborne illness outbreaks involved an infected restaurant employee (26). Although no outbreaks included in this literature review specifically identified an infected employee as the pathogen source, the source was not determined in a few outbreaks and it is possible that an infected employee was responsible. Of the 2,423 foodborne outbreaks reported between 1992 and 1998, 1,435 were associated with at least one contributing factor (improper holding temperature, inadequate cooking, contaminated equipment, poor personal hygiene) documented. The majority of factors documented were improper holding temperatures and poor personal hygiene in outbreaks due to either bacterial or unknown pathogens (4). In the data reported here, contributing factors considered were grouped into worker contamination and improper preparation categories. (Appendix A) Of the 223 pork outbreaks between 1998 and 2008, 57 reported at least one worker contamination event, and 133 reported at least one improper preparation event. The high proportion of pork

related outbreaks with contributing factors documented supports the importance of post-harvest practices and the need for post-harvest changes.

Study Strengths / Weaknesses

This is the first study examining foodborne disease outbreaks due to pork over this time period. Compared to other commodities causing foodborne disease outbreaks, less has been published about outbreaks due to pork. The information generated through this analysis can be useful as a baseline for studies specific to the pork commodity. The dataset used for this analysis was taken from the most complete and largest database collected for this type of information. Surveillance tools used to collect data did not change during the time period, lessening some reporting biases. However, since the length of data collection extended over eleven years it is possible that personnel responsible for conducting surveillance may have changed, resulting in reporting changes.

The tool used for data collection is well designed, but there are several areas where interpretation of entered data could result in different conclusions. When classifying foods and food exposure locations into categories a number of assumptions were made that may have resulted in groupings that may not be comparable to other research studies. It is also impossible to tell what level of rigor was used when conducting each outbreak investigation. Outbreaks in which certain data fields were empty could be due to that variable not being present, or it may have not been examined during investigation. These variations in reporting stringency can vary between states, and also within states over the time period.

Data on foodborne disease outbreaks due to contaminated pork may be underestimated due to underreporting and incomplete food vehicle information; for example, outbreaks in which implicated food products could not definitively be defined as pork (sausage, hot dogs, etc) were not included in analysis. The points of contamination are unknown for some outbreaks and, as this was the outcome of interest, the lack of data for these outbreaks may influence finding of non-significant results.

Only a small proportion of foodborne illness reported each year are identified as part of an outbreaks and agencies can submit new reports and change/delete previous reports as more information becomes available. Due to this potential variability in data values, past and future studies using the same dataset may produce different results. Many outbreak investigations were unable to identify the pathogen, and conclusions drawn from outbreaks with identified pathogens may not be applicable to outbreaks with unknown pathogens.

This study did not examine changes in rates of reported outside contamination events. These events (raw product/ingredient contaminated by pathogens from animal or environment, ingestion of contaminated raw products, obtaining foods from polluted sources, etc) may have a significant relationship with outbreaks analyzed, particularly *Salmonella*. In order to fully understand some of the important changes in food contamination and resulting outbreaks over time the role of outside contamination needs to be evaluated further.

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Tables:

Table 1. Characteristics of all outbreaks and those included in analysis*.

	Total (n=259)	**Included in Analysis (n=223)**
	n (%)	n (%)
Outbreaks	259	223
Illnesses	5113	4346
Hospitalizations	294	255
Deaths	2	`
Pathogen		
Norovirus	26 (10%)	26 (11.2%)
Clostridium	38 (14.7%)	31 (13.3%)
Salmonella	43 (16.6%)	39 (16.7%)
Staphylococcus	56 (21.6%)	53 (22.7%)
All Other	96 (37%)	74 (33.2%)
Food Type		
BBQ	63 (24.3%)	58 (26%)
Ham	49 (18.9%)	44 (19.7%)
Processed	17 (6.6%)	15 (6.7%)
Pork Entree	113 (43.6%)	106 (47.5%)
Preparation Location		
Restaurant	119 (45.9%)	111 (49.8%)
Private Home	45 (17.4%)	37 (16.6%)
Large Gathering	35 (13.5%)	35 (15.7%)
Grocery/Convenience Store	17 (6.6%)	17 (7.6%)
*Mixed***	25 (9.7%)	23 (10.3%)

*Outbreaks included in the analysis were those that occurred in a common food type or food preparation location (at least 15 times in the dataset), and in one of the four most common pathogens.

**Outbreaks classified as “mixed” had multiple preparation locations implicated that were not similar enough to be placed into another category.

Table 2. General characteristics of outbreaks included in analysis that have at least one reported worker contamination or improper preparation event. (n=233)

	Outbreaks with at least 1 Reported Improper Food Preparation	Outbreaks with at least 1 Reported Worker Contamination	Total Outbreaks*
Year			
1998	15 (75%)	3 (15%)	20
1999	6 (30%)	4 (20%)	20
2000	15 (60%)	10 (40%)	25
2001	15 (62.5%)	7 (29.2%)	24
2002	17 (70.1%)	4 (16.7%)	24
2003	13 (72.2%)	5 (27.8%)	18
2004	6 (40%)	2 (13.3%)	15
2005	17 (77.3%)	5 (22.7%)	22
2006	9 (45%)	6 (30%)	20
2007	10 (50%)	6 (30%)	20
2008	10 (66.7%)	5 (33.3%)	15
Pathogen			
Norovirus	5 (19.2%)	10 (38.5%)	26
Clostridium	25 (80.6%)	2 (6.5%)	31
Salmonella	28 (71.8%)	7 (17.9%)	39
Staphylococcus	37 (69.8%)	21 (39.6%)	53
Other	38 (51.4%)	17 (22.9%)	74
Food Type			
BBQ	40 (68.9%)	16 (27.6%)	58
Ham	16 (36.4%)	11 (25%)	44
Processed	7 (46.7%)	8 (53.3%)	15
Pork Entree	70 (66%)	22 (20.8%)	106
Preparation Location			
Restaurant	73 (65.8%)	34 (30.6%)	111
Private Home	21 (56.8%)	8 (21.6%)	37
Large Gathering	18 (51.4%)	7 (20%)	35
Grocery/Convenience Store	7 (41.2%)	2 (11.8%)	17
Mixed	14 (60.9%)	6 (26.1%)	23
Total	133 (59.6%)	57 (25.6%)	223

*"Total outbreaks" is the total number of outbreaks for that variable included in analysis. It is possible for an outbreak to have reported a worker contamination event and an improper preparation event, allowing the number outbreaks for a given variable to add up to more than the total for that variable. If an outbreak reported neither a worker contamination event nor an improper preparation event, then it is not included in this table, allowing for the number of outbreaks for a given variable to sum to less than the total.

Table 3. Worker contamination & improper preparation by pathogen, food type, and preparation location. (n=223 **)

	Outbreaks with at least 1 reported Improper Preparation n (%)	No Improper Preparation n (%)		Outbreaks with at least 1 reported Worker Contamination n (%)	No Worker Contamination n (%)		Total
Pathogen			**P-value***			**P-value***	
Staphylococcus	37 (69.81)	16 (30.19)	0.0839	21 (39.62)	32 (60.38)	0.0072	53
Norovirus	5 (19.23)	21 (80.77)	<0.001	10 (38.46)	16 (61.54)	0.1086	26
Salmonella	28 (71.79)	11 (28.21)	0.0886	7 (17.95)	32 (82.05)	0.2303	39
Clostridium	25 (80.65)	6 (19.35)	0.0102	2 (6.45)	29 (93.55)	0.0071	31
Other	38 (51.35)	36 (48.65)	0.075	17 (22.97)	57 (77.03)	0.532	74
Preparation Location							
Restaurant	73 (65.77)	38 (34.23)	0.2616	34 (30.63)	77 (69.37)	0.4432	111
Private Home	21 (56.76)	16 (43.24)		8 (21.62)	29 (78.38)		37
Large Gathering	18 (51.43)	17 (48.57)		7 (20.0)	28 (80.0)		35
Grocery/Convenience Store	7 (41.18)	10 (58.82)		2 (11.76)	15 (88.24)		17
Mixed	14 (60.87)	9 (39.13)		6 (26.09)	17 (73.91)		23
Food Type							
Pork Entrée	70 (66.04)	36 (33.96)	0.0019	22 (20.75)	84 (79.25)	0.0576	106
Processed	7 (46.67)	8 (53.33)		8 (53.33)	7 (46.67)		15
Ham	16 (36.36)	28 (63.64)		11 (25.0)	33 (75.0)		44
BBQ	40 (68.97)	18 (31.03)		16 (27.59)	42 (72.41)		58

*P-values for pathogens compare each listed pathogen to all other pathogens.

**Outbreaks included are those with a food type and food preparation location implicated in at least 15 outbreaks.

Table 4. Crude Risk Ratios for outbreaks with and without reported worker contamination and improper preparation.

	Improper Preparation		**Worker Contamination**	
	Rate Ratio	95% CI	Rate Ratio	95% CI
Year	1.03	(0.981, 1.089)	1.013	(0.941, 1.091)
Pathogen				
Staphylococcus	1.11	(0.768, 1.604)	2.238*	(1.404, 3.567)
Norovirus	0.195*	(0.09, 0.421)	1.64	(0.901, 2.99)
Salmonella	1.63*	(1.112, 2.396)	0.581	(0.279, 1.21)
Clostridium	1.464	(0.954, 2.248)	0.174*	(0.043, 0.711)
Preparation Location				
Restaurant	-	-	-	-
Private Home	0.969	(0.624, 1.506)	0.732	(0.367, 1.461)
Large Gathering	0.870	(0.549, 1.378)	0.774	(0.387, 1.544)
Grocery/Convenience Store	0.478*	(0.231, 0.988)	0.319	(0.077, 1.317)
Mixed	1.324	(0.8016, 2.188)	1.177	(0.589, 2.349)
Food Type				
Pork Entrée	-	-	-	-
Processed	0.547	(0.269, 1.11)	2.718*	(1.31, 5.636)
Ham	0.4732*	(0.297, 0.755)	1.389	(0.736, 2.624)
BBQ	1.142	(0.802, 1.626)	1.546	(0.876, 2.728)

* Significant at $\alpha = 0.05$

Table 5. Final Negative Binomial Models (Improper Preparation)

	Staphylococcus		***Norovirus***		***Salmonella***		***Clostridium***	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Year	1.021	(0.971, 1.075)	1.03	(0.983, 1.084)	1.018	(0.968, 1.07)	1.023	(0.973, 1.077)
Pathogen				**		**		
Staphylococcus	1.421	(0.969, 2.08)						
Norovirus			0.217*	(0.101, 0.468)				
Salmonella					1.487*	(1.006, 2.2)		
Clostridium							1.305	(0.858, 1.986)
Preparation Location								
Restaurant	-	-	-	-	-	-	-	-
Private Home	1.03	(0.661, 1.618)	1.034	(0.671, 1.596)	0.96	(0.611, 1.509)	1.083	(0.693, 1.6936)
Large Gathering	0.907	(0.576, 1.426)	0.931	(0.601, 1.439)	0.902	(0.576, 1.411)	0.907	(0.577,1.426)
Grocery/Convenience Store	0.597	(0.286, 1.245)	0.533	(0.262, 1.086)	0.498	(0.235, 1.054)	0.616	(0.296, 1.282)
Mixed	1.464	(0.898, 2.388)	1.409	(0.882, 2.25)	1.44	(0.891, 2.328)	1.468	(0.903, 2.387)
Food Type		**		**		**		**
Pork Entrée	-	-	-	-	-	-	-	-
Processed	0.584	(0.283, 1.205)	0.671	(0.332, 1.355)	0.687	(0.335, 0.869)	0.640	(0.311, 1.317)
Ham	0.414*	(0.249, 0.686)	0.591	(0.37, 0.943)	0.539*	(0.335, 0.869)	0.518*	(0.321, 0.837)
BBQ	1.078	(0.746, 1558)	1.134	(0.802, 1.609)	1.094	(0.762, 1.569)	1.172	(0.815, 1.687)
Test Statistics								
Mean deviance	1.14		1.14		1.16		1.16	
Chi-Square GOF	0.0753		0.08		0.0423		0.059	

*Significant at $\alpha = 0.05$

**Type 3 analysis for entire variable is significant at $\alpha = 0.05$

Table 6. Final Poisson Models (Worker Contamination)

	Staphylococcus		***Norovirus***		***Salmonella***		***Clostridium***	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Year	1.054	(0.973, 1.14)	1.038	(0.959, 1.124)	1.047	(0.968, 1.133)	1.021	(0.945, 1.10)
Pathogen	**						**	
Staphylococcus	*2.366	(1.439, 3.89)						
Norovirus			1.457	(0.773, 2.745)				
Salmonella					0.712	(0.327, 1.548)		
Clostridium							0.192*	(0.047, 0.793)
Preparation Location								
Restaurant	-	-	-	-	-	-	-	-
Private Home	.739	(0.357, 1.529)	0.718	(0.346, 1.488)	0.779	(0.372, 1.633)		
Large Gathering	0.777	(0.386, 1.566)	0.826	(0.408, 1.67)	0.838	(0.413, 1.699)		
Grocery/Convenience Store	0.232*	(0.053, 1.00)	0.277	(0.065, 1.178)	0.285	(0.759, 2.91)		
Mixed	1.161	(0.577, 2.333)	1.094	(0.539, 2.22)	1.129	(0.829, 2.707)		
Food Type	**							
Pork Entrée	-	-	-	-	-	-	-	-
Processed	3.259*	(1.514, 7.017)	2.988	(1.401, 6.370)	2.954	(0.759, 2.91)	2.46*	(1.175, 5.157)
Ham	1.171	(0.587, 2.333)	1.44	(0.728, 2.849)	1.487	(0.759, 2.91)	1.199	(0.624, 2.30)
BBQ	1.274	(1.439, 1.142)	1.458	(0.809, 2.626)	1.498	(0.829, 2.707)	1.478	(0.833, 2.623),
Test Statistics								
Mean deviance	0.865		0.911		0.913		0.888	
Chi-Square GOF	0.923		0.821		0.815		0.934	

*Significant at $\alpha = 0.05$

**Type 3 analysis for entire variable is significant at $\alpha = 0.05$

Table 7†. Final Poisson Models (Worker Contamination) with Alternate Reference Group for Preparation Location

	Staphylococcus		***Norovirus***		***Salmonella***		***Clostridium***	
	RR	95% CI	RR	95%CI	RR	95% CI	RR	95% CI
Year	1.054	(0.973, 1.14)	1.038	(0.959, 1.124)	1.047	(0.968, 1.133)	1.021	(0.945, 1.10)
Pathogen	**							
Staphylococcus	*2.366	(1.439, 3.89)						
Norovirus			1.457	(0.773, 2.745)				
Salmonella					0.712	(0.327, 1.548)	0.192*	(0.047, 0.793)
Clostridium								
Preparation Location								
Restaurant	4.315*	(0.99,18.7)	3.604	(0.849,15.304)	3.51	(0.82,15.04)		
Private Home	3.19	(0.68,15.06)	2.588	(0.559,11.972)	2.74	(0.59,12.66)		
Large Gathering	3.35	(0.69, 16.09)	2.976	(0.640,13.835)	2.95	(0.63,13.75)		
Grocery/Convenience Store	-	-	-	-	-	-		
Mixed	5.0*	(1.06, 23.69)	3.942	(0.854, 18.196)	3.97	(0.86,18.36)		
Food Type	**							
Pork Entrée	-	-	-	-	-	-	-	-
Processed	3.259*	(1.514, 7.017)	2.988	(1.401, 6.370)	2.954	(0.759, 2.91)	2.46*	(1.175, 5.157)
Ham	1.171	(0.587, 2.333)	1.44	(0.728, 2.849)	1.487	(0.759, 2.91)	1.199	(0.624, 2.30)
BBQ	1.274	(1.439, 1.142)	1.458	(0.809, 2.626)	1.498	(0.829, 2.707)	1.478	(0.833, 2.623),
Test Statistics								
Mean deviance	0.865		0.911		0.913		0.888	
Chi-Square GOF	0.923		0.821		0.815		0.934	

† The numbers in this table for the restaurant variable can also be generated using the tables in table 6. For RR and confidence intervals the following equation can be used to convert table 6 numbers into the numbers shown above: $e^{-(\ln(X))}$, where 'X' is the value in table 6.

*Significant at $\alpha = 0.05$

**Type 3 analysis for entire variable is significant at $\alpha = 0.05$

Chapter III: Summary, Public Health Implications, Possible Future Directions

Summary / Implications:

In 1998, 2002 and 2008 the U.S. FDA measured the occurrence of food preparation practices and employee behaviors that were observed most commonly by the CDC as contributing factors in foodborne disease outbreaks. (27) They found that more effective strategies to improve food safety practices in "retail and foodservice establishments" are necessary to reduce foodborne disease outbreaks. In similar studies by the FDA in 2000 and 2004, they found that the same risk factors identified in the 1998 study were still in need of improvement. These risk factors include improper holding/time and temperature, poor personal hygiene and contaminated equipment/prevention of contamination. (27) Although these studies by the FDA encompassed all types of food commodities, these factors have been identified in pork specific analyses.

Although this study was unable to identify a significant change in reported rates of improper food preparation practices or worker contamination events over time it is possible that a relationship still exists. This analysis specifically involved outbreaks through contaminated pork, and it is possible that when all food commodities are considered the relationship is more defined.

The identification of relationships between certain pathogens and improper food preparation / worker contamination events is beneficial, particularly with regards to *Salmonella*, and can possibly extend to other food commodities as well. *Salmonella* is commonly identified as a pathogen responsible for high percentages of hospitalizations and deaths, and of the 294 hospitalizations documented in this dataset, 125 (42.5%) were due to *Salmonella*. *Salmonella*

was found to have significantly higher rates of improper food preparation practices compared to other pathogens, suggesting that improving preparation practices should result in fewer *Salmonella* outbreaks and decreased illness.

Future Studies:

This study exclusively examined food outbreaks transmitted through the pork commodity. This analysis was unable to identify a significant change in improper food preparation or worker contamination events in pork outbreaks; however it is possible that a relationship exists for food outbreaks in general. A future study looking at all food products with respect to improper food preparation and worker contamination would be beneficial for identifying broad improvements that need to be made in food safety.

Further examination into practices specific to restaurants would also be beneficial, as the majority of foodborne outbreaks have their origins in restaurants. Extending on the study done by the CDC that identified relationships between restaurant type and occurrence of improper preparation techniques, expansions could made to attempt to identify relationships between certain restaurant types/improper practices and outbreaks. Identifying a link between restaurant type and outbreak occurrence may help in targeted safety improvement measures.

Although no current standard exists for outbreak size, it would be beneficial to look at different improper preparation practices associated with size of outbreaks. Identifying certain preparation locations or certain practices that are more likely to result in larger outbreaks would allow for targeted interventions and generate the most public health benefit.

Finally, this study identified relationships between *Salmonella* outbreaks and improper preparation events and worker contamination events that could be further explored. *Salmonella* is a very important pathogen in foodborne illness and explorations into the numbers of outbreaks with outside contamination reported and how these events have changed over time and with respect to food preparation locations and food types would be beneficial.

Appendices:

A. Categorizations of reported events into either "worker contamination" or "improper preparation".

Factor	Classification
Contamination Factors	
C9- Cross-contamination from raw ingredient of animal origin	Improper Preparation
C10- Bare-handed contact by handler/worker/preparer	Worker Contamination
C11- Glove-handed contact by handler/worker/preparer	Worker Contamination
C12- Handling by an infected person or carrier of pathogen	Worker Contamination
C13- Inadequate cleaning of processing/preparation equipment/utensil	Improper Preparation
C14- Storage in contaminated environment	Improper Preparation
Proliferation Factors	
P1 - Allowing foods to remain at room or warm outdoor temperature for several hours	Improper Preparation
P2 - Slow cooling	Improper Preparation
P3- Inadequate cold-holding temperatures	Improper Preparation
P4- Preparing foods a half day or more before serving	Improper Preparation
P5- Prolonged cold storage for several weeks	Improper Preparation
P6- Insufficient time and/or temperature during hot holding	Improper Preparation
P7- Insufficient acidification	Improper Preparation
P9- Inadequate thawing of frozen products	Improper Preparation
Survival Factors	
S1- Insufficient time and/or temperature during cooking/heat processing	Improper Preparation
S2- Insufficient time and/or temperature during reheating	Improper Preparation
S4- Insufficient thawing, followed by insufficient cooking	Improper Preparation

B. Electronic Foodborne Outbreak Reporting Form

Retrieve Data | Reset Radio Buttons | Reset Form

FORM APPROVED
OMB NO.0920-0004

CDC USE ONLY

STATE USE ONLY

INVESTIGATION OF A FOODBORNE OUTBREAK

CDC — Centers for Disease Control and Prevention

This form is used to report foodborne disease outbreak investigations to CDC. A foodborne outbreak is defined as the occurrence of **two or more cases** of a similar illness resulting from the ingestion of a common food in the United States. This form has **two** parts: Part 1 asks for the minimum data needed and Part 2 asks for additional information. For this investigation to be counted in the CDC annual summary, Part 1 must be completed. **We encourage you to complete as much of Part 1 and Part 2 as you can.**

Part 1: Required Information

1. Location of Exposure:
State: ____
☐ Multi-state exposure
County: ____
☐ Multi-county exposure
List other states/counties in Comments, bottom of this page

2. Dates:
Date first case became ill: ____ Month/Day/Year
Date of first known exposure: ____ Month/Day/Year
Date of last known exposure: ____ Month/Day/Year

3. Numbers of Cases Exposed:
Lab-confirmed cases: ____ *(A)*
Probable cases: ____ *(B)*
Estimated total ill: ____
(If greater than sum of A+B)

4. Approximate Percentage of Total Cases in Each Age Group:
<1 year: ____% 20-49 yrs: ____%
1-4 yrs: ____% ≥ 50 yrs: ____%
5-19 yrs: ____%

5. Sex: (Estimated percent of total cases)
Male: ____ %
Female: ____ %

6. Investigation Methods: (Check all that apply)
☐ Interviews of cases only
☐ Case-control study*
☐ Cohort study*
☐ Food preparation review
☐ Food product traceback
☐ Investigation at factory or production plant
☐ Investigation at original source (farm, marine estuary, etc.)
☐ Environment / food sample cultures
* Please provide OR/RR and P value for each food item.

7. Implicated Food(s): (based on Reasons listed in Item 15 on page 3) Pg 3
☐ Could not be determined

8. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include details such as phage type, virulence factors, molecular fingerprinting, antibiogram, metabolic profile.

Etiology	**Serotype** (if avail.)	**Other Characteristics** (if avail.)

☐ Confirmed*
☐ Suspected
☐ Unknown etiology
☐ Multiple etiologies

Isolated/identified from (check all that apply)
☐ Patient specimen(s)
☐ Food specimen(s)
☐ Environment specimen(s)
☐ Food Worker specimen(s)

* See criteria at http://www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol 49/SS-1/Appendix B.

9. Contributing Factors: (See list on page 2, check all that apply) Pg 2
☐ Contributing factors unknown

Contamination Factor: List of Contamination Factors
☐ C1 ☐ C2 ☐ C3 ☐ C4 ☐ C5 ☐ C6 ☐ C7 ☐ C8 ☐ C9
☐ C10 ☐ C11 ☐ C12 ☐ C13 ☐ C14 ☐ C15 *(describe in Comments)* ☐ N/A

Proliferation/Amplification Factor (bacterial outbreaks only) List of Proliferation/Amplification Factors
☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ P5 ☐ P6 ☐ P7 ☐ P8 ☐ P9
☐ P10 ☐ P11 ☐ P12 *(describe in Comments)* ☐ N/A

Survival Factor (microbial outbreaks only): List of Survival Factors
☐ S1 ☐ S2 ☐ S3 ☐ S4 ☐ S5 *(describe in Comments)* ☐ N/A

Was food-worker implicated as the source of contamination? ☐ Yes ☐ No
If yes, please check ***only one*** of following:
laboratory *and* epidemiologic evidence
epidemiologic evidence (w/o lab confirmation)
lab evidence (w/o epidemiologic confirmation)
prior experience makes this the likely source *(please explain in Comments)*

10. Agency reporting this outbreak:

Contact Person:
NAME: ____
TITLE: ____
PHONE NO: ____
FAX NO: ____
E-MAIL: ____

Date of completion of this form:
____ Month/Day/Year

☐ **Initial Report**
☐ **Updated Report**
☐ **Final Report**
☐ **Additional data suggests this is not a foodborne outbreak**

Comments:

Save Data | Print | Email Form | Page 2 (Code Desc) | Page 3 (Part 2)

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Previous Page

The following codes are to be used to fill out Part 1 (question 9) and Part 2 (question 15).

Contamination Factors:[1]

- ☐ C1 - Toxic substance part of tissue (e.g., ciguatera)
- ☐ C2 - Poisonous substance intentionally added (e.g., cyanide or phenolphthalein added to cause illness)
- ☐ C3 - Poisonous or physical substance accidentally/incidentally added (e.g., sanitizer or cleaning compound)
- ☐ C4 - Addition of excessive quantities of ingredients that are toxic under these situations (e.g., niacin poisoning in bread)
- ☐ C5 - Toxic container or pipelines (e.g., galvanized containers with acid food, copper pipe with carbonated beverages)
- ☐ C6 - Raw product/ingredient contaminated by pathogens from animal or environment (e.g., *Salmonella enteriditis* in egg, Norwalk in shellfish, *E. coli* in sprouts)
- ☐ C7 - Ingestion of contaminated raw products (e.g., raw shellfish, produce, eggs)
- ☐ C8 - Obtaining foods from polluted sources (e.g., shellfish)
- ☐ C9 - Cross-contamination from raw ingredient of animal origin (e.g., raw poultry on the cutting board)
- ☐ C10 - Bare-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
- ☐ C11 - Glove-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
- ☐ C12 - Handling by an infected person or carrier of pathogen (e.g., *Staphylococcus*, *Salmonella*, Norwalk agent)
- ☐ C13 - Inadequate cleaning of processing/preparation equipment/utensils – leads to contamination of vehicle (e.g., cutting boards)
- ☐ C14 - Storage in contaminated environment – leads to contamination of vehicle (e.g., store room, refrigerator)
- ☐ C15 - Other source of contamination (*please describe in Comments*) Return to Pg 1

Proliferation/Amplification Factors:[1]

- ☐ P1 - Allowing foods to remain at room or warm outdoor temperature for several hours (e.g., during preparation or holding for service)
- ☐ P2 - Slow cooling (e.g., deep containers or large roasts)
- ☐ P3 - Inadequate cold-holding temperatures (e.g., refrigerator inadequate/not working, iced holding inadequate)
- ☐ P4 - Preparing foods a half day or more before serving (e.g., banquet preparation a day in advance)
- ☐ P5 - Prolonged cold storage for several weeks (e.g., permits slow growth of psychrophilic pathogens)
- ☐ P6 - Insufficient time and/or temperature during hot holding (e.g., malfunctioning equipment, too large a mass of food)
- ☐ P7 - Insufficient acidification (e.g., home canned foods)
- ☐ P8 - Insufficiently low water activity (e.g., smoked/salted fish)
- ☐ P9 - Inadequate thawing of frozen products (e.g., room thawing)
- ☐ P10 - Anaerobic packaging/Modified atmosphere (e.g., vacuum packed fish, salad in gas flushed bag)
- ☐ P11 - Inadequate fermentation (e.g., processed meat, cheese)
- ☐ P12 - Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*) Return to Pg 1

Survival Factors:[1]

- ☐ S1 - Insufficient time and/or temperature during initial cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization)
- ☐ S2 - Insufficient time and/or temperature during reheating (e.g., sauces, roasts)
- ☐ S3 - Inadequate acidification (e.g., mayonnaise, tomatoes canned)
- ☐ S4 - Insufficient thawing, followed by insufficient cooking (e.g., frozen turkey)
- ☐ S5 - Other process failures that permit the agent to survive (*please describe in Comments*) Return to Pg 1

Method of Preparation:[2]

- ☐ M1 - Foods eaten raw or lightly cooked (e.g., hard shell clams, sunny side up eggs)
- ☐ M2 - Solid masses of potentially hazardous foods (e.g., casseroles, lasagna, stuffing)
- ☐ M3 - Multiple foods (e.g., smorgasbord, buffet)
- ☐ M4 - Cook/serve foods (e.g., steak, fish fillet)
- ☐ M5 - Natural toxicant (e.g., poisonous mushrooms, paralytic shellfish poisoning)
- ☐ M6 - Roasted meat/poultry (e.g., roast beef, roast turkey)
- ☐ M7 - Salads prepared with one or more cooked ingredients (e.g., macaroni, potato, tuna)
- ☐ M8 - Liquid or semi-solid mixtures of potentially hazardous foods (e.g., gravy, chili, sauce)
- ☐ M9 - Chemical contamination (e.g., heavy metal, pesticide)
- ☐ M10 - Baked goods (e.g., pies, eclairs)
- ☐ M11 - Commercially processed foods (e.g., canned fruits and vegetables, ice cream)
- ☐ M12 - Sandwiches (e.g., hot dog, hamburger, Monte Cristo)
- ☐ M13 - Beverages (e.g., carbonated and non-carbonated, milk)
- ☐ M14 - Salads with raw ingredients (e.g., green salad, fruit salad)
- ☐ M15 - Other, does not fit into above categories *(please describe in Comments)*
- ☐ M16 - Unknown, vehicle was not identified Return to Pg 3

[1] Frank L. Bryan, John J. Guzewich, and Ewen C. D. Todd. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitations. Journal of Food Protection, 60; 6:701-714, 1997.
[2] Weingold, S. E., Guzewich JJ, and Fudala JK. Use of foodborne disease data for HACCP risk assessment. Journal of Food Protection, 57; 9:820-830, 1994.

Next Page

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Previous Page Page 1 (Part 1)

Part 2: Additional Information (Please complete as much as possible)

11. Numbers of:

OUTCOME / SYMPTOM	Cases with Outcome / Symptom	Total cases for whom you have information available
Healthcare Provider Visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Feverish		
Abdominal cramps		
*		
*		
*		
*		

12. Incubation Period:

(circle appropriate units)

Shortest: ____ (Hours, days)
Longest: ____ (Hours, days)
Median: ____ (Hours, days)

☐ Unknown

13. Duration of Acute Illness Among Those Who Recovered:

(circle appropriate units)

Shortest: ____ (Hours, days)
Longest: ____ (Hours, days)
Median: ____ (Hours, days)

☐ Unknown

* Use the following terms, if appropriate, to describe other common characteristics of cases:

anaphylaxis, arthralgia, bradycardia, bullous skin lesions, bradycardia, cough, coma, diplopia, descending paralysis, flushing, headache, hemolytic uremic syndrome (HUS), hypotension, itching, jaundice, lethargy, myalgia, paresthesia, septicemia, sore throat, tachycardia, thrombocytopenia, temperature reversal, urticaria, wheezing

14. If Cohort Investigation Conducted:

Event-specific Attack Rate = ____ (# ill) / ____ (total # of persons for whom you have illness info.) x 100 = ____ %

List of Preparation Methods

15. Implicated Food(s): (Please provide known information.)

Name of Food	Main Ingredients	Contaminated Ingredient	Reason(s) Suspected (see below)	Method of Preparation (see list on page 2)
e.g., lasagna	*pasta, sauce, eggs, beef*	*eggs*	*4*	*M1*

☐ Food vehicle could not be determined

Reason Suspected (choose all that apply):
1 - Statistical evidence from epidemiological investigation**
2 - Laboratory evidence (e.g., identification of agent in food)
3 - Compelling supportive information
4 - Other data (e.g., same phage type found on farm that supplied eggs)
5 - Specific evidence lacking but prior experience makes this likely source
** If the reason suspected is #1, please attach the statistical evidence.

Return to Pg 1

16. Where was Food Prepared? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Caterer
☐ Grocery store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, other temporary/mobile service
☐ Contaminated food imported into U.S.
☐ Commercial product, served without further preparation
☐ Other (please describe)

17. Where was Food Eaten? (Check all that apply)

☐ Restaurant or deli
☐ Day care center
☐ School
☐ Church, temple, etc.
☐ Camp
☐ Grocery Store
☐ Hospital
☐ Workplace cafeteria
☐ Nursing home
☐ Prison, jail
☐ Private home
☐ Picnic
☐ Fair, festival, or mobile location
☐ Other (please describe)

18. Other Available Info:

☐ Unpublished agency report (please attach)
☐ Epi-Aid
☐ Publication (please reference)
☐ Not available

19. Remarks: Briefly describe important aspects of the outbreak not covered above (e.g., restaurant closure, product recall, immunoglobulin administration, economic impact, etc.)

State Health Departments: Please FAX this document to Foodborne and Diarrheal Diseases, DBMD, CDC, at (404) 639-2205.

CDC 52.13 (E), Rev. 10/2000, CDC Adobe Acrobat 5.0 Electronic Version, 7/2003

Save Data Print Email Form

C. IRB Approval

EMORY UNIVERSITY | Institutional Review Board

TO: Amy Fothergill
Principal Investigator

DATE: February 23, 2012

RE: Notification of Submission Determination: No IRB Review Required
Decline in foodborne disease outbreaks due to pork

The above-referenced study has been vetted by the Institutional Review Board (IRB), and it was determined that it does not require IRB review because it does not meet the definition of "Research involving Human Subjects" under applicable federal regulations. Based on the information submitted by the PI, the aim of the secondary data analysis is to identify factors that are contributing to the occurrence of foodborne disease outbreaks transmitted through pork products. She will receive de-identified data from the CDC Foodborne Disease Outbreak Surveillance System (FDOSSS) to conduct the secondary data analysis. The PI will not have access to identifiers or access to coded-links to identifiers now or in the future. Accordingly, IRB review is not required.

45 CFR Section 46.102(f)(2) defines "Research involving Human Subjects" as follows:

> Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:
>
> (1) data through intervention or interaction with the individual, or
> (2) identifiable private information
>
> Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Please note that any changes to the protocol could conceivably alter the status of this research under the federal regulations cited above. Accordingly, any substantive changes in the protocol should be presented to the IRB for consideration prior to their implementation in the research.

Sincerely,

Carol Corkran, MPH, CIP
Senior Research Protocol Analyst
This letter has been digitally signed

D. Permission for Use of Data

Dear Amy,

Thank you for your request for data from the CDC Foodborne Disease Outbreak Surveillance System (FDOSS). We have completed extraction of the data on Pork-assoicated outbreaks, 1998-2008 that you requested on 6/13/2011.

The CDC foodborne outbreak reporting system in place since 1998 is a dynamic surveillance system. Most outbreaks are reported by the state, local, territorial, or tribal health department that conducted the outbreak investigation. Outbreak reporting is voluntary. Multistate outbreaks are generally reported by CDC. The contents of the database change frequently as reporting agencies enter new records and modify or delete old ones. Reporting agencies can modify or delete past outbreak reports at any time, even months or years after an outbreak. The data you requested were downloaded on 6/15/2011. The attached dataset accurately represents the data present in the system on that date. The data provided were extracted using the following methodology: mode of transmission as foodborne, outbreak report has been finalized, onset year between 1998 and 2008, # ill > 1, and commodity=pork.

The data you requested are attached, along with a data dictionary and a snap-shot of the database's relationships. In analyzing a relational database, it is important to understand that multiple values are allowed for a single variable. For example, if two etiologies were reported for a single outbreak, these etiologies would be captured as two records within the Etiology Table rather than as two variables, as would be seen within a flat database. The Access table (table named *'PorkMain'*) should be used as a guide when determining the true number of outbreaks reported. This table is flat, so it does not allow multiple values for a single record. Therefore, the number of records in this table represents the number of outbreak reports contained within the entire database; this is the only flat table within the database. Another complexity of the database is that the implicated food variable (in the Implicated Foods table) is a free-text field. This characteristic means that similar or identical foods may be entered in different ways. For example “ground beef” could be entered as “beef”, “hamburger”, “taco meat” or “lasagna”, to name just a few of the possibilities. Therefore, we suggest using broad keyword searches to search the Implicated Foods table to ensure that foods of interest are not accidentally overlooked.

Thank you again for your request. Please feel free to contact me with any questions.

Kind regards,
Kelly Walsh
Data Request Manager

_____

Kelly A. Walsh, MPH
Surveillance Epidemiologist, NORS-Foodborne
Outbreak Surveillance and Analytic Team
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