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_____ _____

Cassandra Harrison Date

Does Outbreak Size Matter?
An Analysis Comparing the Epidemiologic Characteristics of Small and Large Foodborne Disease Outbreaks.

By

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MSPH

Epidemiology

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Anne C. Spaulding, MD, MPH
Committee Chair

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By

Cassandra N. Harrison
B.A., University of Chicago, 2009

Thesis Committee Chair: Anne C. Spaulding, MD, MPH

An abstract of
A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Science in Public Health
in Epidemiology
2011

Abstract

Does Outbreak Size Matter?
An Analysis Comparing the Epidemiologic Characteristics of Small and Large Foodborne Disease Outbreaks.

By Cassandra Harrison

Background

Foodborne diseases are a substantial contributor to illness, hospitalizations, and deaths each year in the United States. Data provided from outbreak investigations can lead to a better understanding of the epidemiologic features of foodborne illnesses. The objectives of this study were to describe the epidemiologic factors associated with small and large foodborne disease outbreaks in the United States and to also determine differences between small and large outbreaks that might inform food safety policy.

Methods

Descriptive, bivariate, and logistic regression analyses were performed on foodborne disease outbreaks occurring between 1999-2008 that were voluntarily reported to the Centers for Disease Control and Prevention (CDC) Foodborne Disease Outbreak Surveillance System by September 1, 2010. Analyses focused on the demographic features, etiologic agents, settings, and commodities associated with small outbreaks (less than 10 illnesses) and large outbreaks (10 or more illnesses).

Results

During the ten-year period between 1999 and 2008, a total of 12,068 foodborne disease outbreaks were reported to the CDC. There were 6,704 small outbreaks (median outbreak size 4 illnesses) and 5,364 large outbreaks (median outbreak size 22 illnesses), comprising 56% and 44% of the dataset, respectively. Small outbreaks were less likely to be laboratory-confirmed or be caused by norovirus, but were more likely to be due to Ciguatoxin and Scombroid toxin from finfish. Results from the multivariable logistic model revealed that small outbreaks were most often associated with retail preparation settings, chemical toxin etiologies, and missing etiology data. On the other hand, large outbreaks were associated with institution and other settings, and viral etiologic agents.

Conclusions

Although small outbreaks do not often receive the same level of attention as large outbreaks in the mainstream media or scientific literature, small outbreaks are more common than large outbreaks and are commonly associated with retail preparation settings. Consequently, it is important to continue investigating and reporting these in order to understand the factors contributing to these outbreaks and prevent future illnesses.

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BACKGROUND

Each year in the United States, foodborne agents cause an estimated 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths (1, 2). In addition, foodborne illnesses have a significant economic impact due to lost work productivity and consumption of health resources (3, 4). Due to this burden, investigation and surveillance efforts are a regular part of public health activities in order to track foodborne illnesses, understand their risk factors, and prevent future cases. Even though the majority of foodborne illnesses are sporadic, the data provided from outbreak investigations can lead to a better understanding of the epidemiologic features of foodborne illnesses (5).

A foodborne disease outbreak is defined by the Centers for Disease Control and Prevention (CDC) as the occurrence of two or more similar illnesses resulting from ingestion of a common food (6). During the investigation of a foodborne disease outbreak, detailed information is collected to identify the causative agents, contaminated food vehicle, and contributing factors. Surveillance summaries published by CDC provide aggregate data from foodborne disease outbreaks occurring during a specific time period. These summaries describe the causes, implicated foods, and risk factors associated with foodborne disease outbreaks. Health care providers and public health professionals can use this information to identify common causes and sources of foodborne illness and to inform new policy and food safety measures to prevent future illnesses (7).

Many foodborne disease outbreaks occur each year, ranging in size from just a few cases to large, multistate outbreaks that sicken several hundred people. Media reports

tend to focus on large outbreaks that involve a food recall, as these have significant impact and interest to consumers. Even within the scientific community, a review in England and Wales found that the median size of foodborne disease outbreaks reported in the peer-reviewed literature was significantly larger than the median size of outbreaks in general (8). This suggests that our understanding of the epidemiologic features of foodborne disease outbreaks is based mostly on large outbreaks. As a result, policy and prevention efforts may be more focused on large outbreaks as well. However, small outbreaks also have a significant impact on public health and there is evidence to suggest that differences may exist between small and large outbreaks (9, 10).

Recent MMWR reports and other studies have provided summaries of various risk factors of foodborne disease outbreaks including: etiologic agent, food vehicle, setting, and food handling procedures (5, 6, 11-13). However, these reports have not looked at the potential differences in these risk factors between small and large outbreaks. The objectives of this study were to determine the epidemiologic factors associated with small and large foodborne disease outbreaks in the United States and also to identify significant differences between small and large outbreaks.

METHODS

Data for this analysis were provided by CDC's Foodborne Disease Outbreak Surveillance System (FDOSS). The database, called the electronic Foodborne Outbreak Reporting System (eFORS), consists of foodborne disease outbreak reports that were submitted electronically by state, local, and territorial health departments to CDC using a standard form (CDC form 52.13, Investigation of a Foodborne Outbreak). For this analysis, the data were restricted to outbreaks occurring between January 1999 and December 2008 and reported to CDC by September 1, 2010. Introduced in 1998, it was not until 2001 when all states were submitting outbreak reports using eFORS. As a result, this database contains records from both paper-based and web-based form submissions. Variables of interest within the eFORS database included: year of outbreak, state where outbreak occurred, information related to the etiologic agent(s) implicated (including genus, species, and serotype), whether agent was laboratory-confirmed or suspected, preparation and consumption setting, total number of cases, number of cases per age group, and number of cases per gender. This analysis did not meet the definition of human subjects research and therefore no IRB review was required.

In addition to the variables provided in the eFORS database, a separate CDC database providing information on the commodity classification of implicated food vehicles was combined with the eFORS database. Outbreaks were assigned to one of 17 commodities by FDOSS based on information related to the ingredients of the implicated food vehicle of the outbreak. These 17 commodities include: finfish, crustaceans, mollusks, dairy, eggs, beef, game, pork, poultry, grains-beans, oils-sugars, fruits-nuts, fungi, leafy vegetables, root vegetables, sprouts, and vegetables from a vine or stalk (6).

Outbreaks that were due to a single contaminated food ingredient or a food vehicle that contained ingredients belonging to only one food commodity were assigned to that commodity. No commodity was assigned to outbreaks with food vehicles composed of ingredients belonging to multiple commodity groups, ingredients that did not belong to any of the 17 commodities, and outbreaks lacking sufficient food vehicle information for attribution. Those foods that were assigned to one of the 17 commodities were classified as simple; those that did not have enough information to classify the food into one of the 17 commodities (e.g., “meat”) or contained multiple foods were classified as complex.

Initial descriptive statistics were conducted to compare all small and large outbreaks over this ten year period. Small outbreaks were defined as having less than 10 cases and large outbreaks were defined as having 10 or more cases. Analyses run in this initial stage focused on number of outbreaks per year, total and median number of cases, median age group of cases, and gender distribution of cases. A chi-square test was performed to assess the significance of observed differences in gender distribution between small and large outbreaks. Due to the underlying differences in the investigation processes for multistate outbreaks and single state outbreaks, multistate outbreaks were excluded for all subsequent analyses.

Further bivariate analyses were conducted to examine the differences between small and large outbreaks for etiologic agents causing outbreaks, preparation setting, consumption setting, and commodity category. Outbreaks with more than one suspected agent were excluded from these analyses, since a subset of these outbreaks reflect situations where investigators suspected several possible causal agents based on available information on incubation period and symptoms. The top 10 etiologic agents and

proportion missing etiologies were determined for small and large outbreaks. Preparation and consumption settings were grouped into six main categories: retail food service, social, private home, institution, healthcare, commercial product, and other. For outbreaks with a preparation or consumption setting of "other," the remarks field was reviewed for additional information to make the correct determination on setting category. In addition, categories were created for outbreaks that had multiple settings and unknown settings. Commodities were grouped as described into three categories: simple, complex, or unknown. The proportions of small and large outbreaks associated with each of these categorical variables were calculated and chi-square tests were performed to assess significance. Significance was determined by $p<0.05$.

Variables that were significant in the bivariate analyses were then included in multivariable modeling. Due to the high correlation between preparation setting and consumption setting, only preparation setting was included in the multivariable model. Furthermore, the preparation setting was re-categorized into one of four groups: retail (commercial product and retail food service), private home, institution (healthcare and institution), and other (social and other). Outbreaks associated with unknown or multiple preparation settings were not included in the multivariable analysis. In addition, etiologic agents were categorized into one of four groups: viral, bacterial, chemical, and missing.

Before performing the multivariable analysis, the possibility of interaction was assessed between commodity category and the preparation setting and also between the etiologic agent and the preparation setting. After finding no evidence of interaction, a multivariable logistic regression was performed. The dependent variable for this model was category of outbreak size, with small outbreaks serving as the outcome and large

outbreaks as the referent group. Statistically significant variables ($p<0.05$) were retained in the final multivariable model.

RESULTS

During the ten-year period between 1999 and 2008, a total of 12,068 foodborne disease outbreaks were reported to the CDC. This consisted of 6,704 small outbreaks and 5,364 large outbreaks, comprising 56% and 44% of the dataset, respectively. The number of small and large outbreaks per year is displayed in Figure 1. For the 54 states and territories reporting foodborne disease outbreaks to CDC, the median proportion of a state's total reported outbreaks that were small was 49% (range: 8%-100%). Among all outbreaks, the median number of cases per outbreak was 8 (range: 2-1644); the median number of cases was 4 (range: 2-9) for small outbreaks and 22 (range: 10-1644) for large outbreaks. In total, small outbreaks accounted for 28,229 illnesses and large outbreaks accounted for 217,628 illnesses. The median age group was 20-49 years old for both small and large outbreaks. Large outbreaks had a statistically significant larger proportion of male cases than small outbreaks, 72% and 62% respectively ($p<0.001$). During this time period, 118 multistate outbreaks were reported, and 92% of these were large outbreaks. In addition to these differences, small and large outbreaks also differed in several other areas of interest including: consumption and preparation setting, commodity category, etiologic agent responsible, and confirmation of agent.

Both small and large outbreaks were most often associated with the retail food service and private home settings (Table 1). However, significant differences were found between small and large outbreaks for all preparation setting categories except commercial product and other. The retail food service preparation setting made up a significantly larger proportion of small outbreaks than large outbreaks (78% vs. 55%, $p<0.001$). On the other hand, the following categories made up a significantly larger

proportion of large outbreaks than small outbreaks: institution (9% vs. 1%, p<0.001), social (8% vs. 1%, p<0.001), unknown (8% vs. 4%, P<0.001), multiple (4% vs. 1%, p<0.001), healthcare (2% vs. 0.5%, p<0.001), and private home (11% vs. 10%, p<0.01).

For consumption setting, small outbreaks were most often in the retail food service and private home settings and large outbreaks were most often in the retail food service and social settings (Table 2). Significant differences were found between small and large outbreaks for all consumption setting categories except commercial product. Retail food service (61% vs. 33%, p<0.001) and private home (21% vs. 11%, p<0.001) made up a significantly larger proportion of small outbreaks than large outbreaks. Conversely, the social (26% vs. 7%, p<0.001), institution (13% vs. 2%, p<0.001), unknown (8% vs. 5%, p<0.001), multiple (4% vs. 1%, p<0.001), healthcare (3% vs. 0.8%, p<0.001), and other (1% vs. 0.8%, p<0.001) consumption setting categories made up a significantly larger proportion of large outbreaks than small outbreaks.

The proportion of small and large outbreaks associated with each of the commodity groups are displayed in Figure 2. Results from chi-square tests on the broader commodity categories revealed that there were significant differences between small and large outbreaks for the proportion of outbreaks due to simple (27% vs. 21%, p<0.001) and unknown (45% vs. 50%, p<0.001) commodity categories, but not complex (28% vs. 29%, p=0.21).

There were significant differences between small and large outbreaks for confirmed vs. suspected etiology and also for the proportions caused by each of the top ten agents. Among outbreaks due to a single etiologic agent, investigators had confirmed the agent responsible in only 54% of small outbreaks. Alternatively, 68% of large

outbreaks were confirmed. This difference was found to be statistically significant, with a p-value <0.001. Results related to the proportion of small and large outbreaks due to each top agent are presented in Figure 3. An etiologic agent was not reported for 47% of small outbreaks and only 23% of large outbreaks (p<0.001). In addition, scombroid toxin (4% vs. 0.3%, p<0.001), ciguatoxin (2% vs. 0.1%, p<0.001), *Staphyloccocus* (5% vs. 3%, p<0.001) and *Bacillus* (3% vs. 0.8%, p<0.001) made up a significantly larger portion of small outbreaks than large outbreaks. On the other hand, norovirus (46% vs. 16%, p<0.001), *Clostridium* (6% vs. 3%, p<0.001), and *Salmonella* (12% vs. 9%, p<0.001) comprised a significantly larger portion of large outbreaks than small outbreaks. There were no statistically significant differences between the proportion of small and large outbreaks associated with *Campylobacter*, *E. coli*, and *Shigella*.

The results of the multivariable logistic regression analysis focusing on the relationships between preparation setting, commodity type, etiologic agent and outbreak size are reported in Table 3. Both preparation setting and etiologic agent categories were significantly associated with outbreak size, but there was no significant association between commodity type and outbreak size. With the private home preparation setting as the referent group, retail preparation settings had nearly two times greater odds of being associated with small outbreaks (OR=1.89, p<0.001). Conversely, the institution setting had lower odds of being associated with small outbreaks, about one-fifth as likely (OR=0.19, p<0.001). Other preparation settings were about one-quarter as likely to be associated with small outbreaks when compared to the private home preparation setting (OR=0.28, p<0.001). With bacterial agents as the referent group, missing etiologic agents had nearly two times greater odds of being associated with small outbreaks (OR=1.98,

p<0.001), and chemical agents were almost eleven times more likely (OR=10.57, p<0.001). On the other hand, viral agents had about one-third lower odds of being associated with small outbreaks (OR=0.34, p<0.001).

DISCUSSION

While surveillance summaries describing the results of reported foodborne disease outbreaks are produced regularly, there has not been a study to compare the epidemiologic features of reported small and large outbreaks. Due to media influence, publication bias, and prioritization of resources, focus is usually placed more heavily on large outbreaks than small outbreaks. As a result, much of our understanding of foodborne disease outbreaks derives from the epidemiology of large outbreaks. Determining the significant epidemiologic differences between small and large outbreaks in terms of risk factors and causes will help develop more comprehensive control and prevention policies.

This analysis used 10 years of outbreak data from CDC's eFORS, which is a passive surveillance system that relies on voluntary reporting. Small outbreaks comprised 56% of the dataset, however the total number of small outbreaks reported was most likely an underestimate. An underlying obstacle to detecting small outbreaks and obtaining complete data from these outbreak investigations is that there are fewer cases to seek care, get tested, and receive a diagnosis of foodborne illness. As a result, small outbreaks often go undetected if people do not report their symptoms. Even if illnesses are reported to a health agency, small outbreaks may not be prioritized when there are limited resources. Furthermore, it is often difficult to link cases and compile enough data to implicate a food or etiologic agent in small outbreaks. The results of the logistic regression model demonstrated this limitation, as the "missing" category for etiologic agent was significantly associated with small outbreaks.

The difficulty of detecting and obtaining data in small outbreaks combined with the fact that large outbreaks are often very resource intensive and time consuming may have a negative impact on the local capacity to investigate small outbreaks. This prioritization of resources may be a driver of the observed decreased reporting of small outbreaks over the study period. Nonetheless, despite the problems associated with investigation and data quality, small outbreaks contribute to a larger proportion of total outbreaks reported and also cause a substantial number of illnesses as well. As a result, it is important to consider the causes and risk factors of small outbreaks as well as large outbreaks when informing actions to prevent future illness.

Preparation setting was a major focus of this analysis, as it may be a source of contamination. However, it is important to note that the preparation setting was not necessarily the source of contamination, as there was a possibility it could have occurred before or after preparation. Nonetheless, retail food settings were more commonly associated with small outbreaks, suggesting that investigation of these outbreaks represents an important opportunity to identify contributing factors and to assist with foodborne illness prevention in these settings—even if no etiologic agent is confirmed. Social and institutional settings were more likely to be associated with large outbreaks. It is not unexpected that large outbreaks may be strongly associated with social events and institutions due to the large, connected network of people that are associated with these settings. Guests from the same social event may discuss their illness afterwards and realize they were all impacted and then report the outbreak, and persons sickened in institutional settings are also connected and more likely to recognize a common link in their symptoms than in other situations. Nonetheless, these findings demonstrate that

prevention strategies targeting the food handling practices in these settings could significantly reduce the burden of foodborne illness, as these settings are particularly vulnerable to improper food handling—such as improper holding times, and temperature abuse—as large amounts of food are prepared in advance and served over a longer period of time.

The differences between small and large outbreaks in terms of etiologic agent have implications for control and prevention of future outbreaks as well. Viruses were most commonly associated with large outbreaks, driven mostly by norovirus. This is expected since this organism has a low dose for infection, and is highly contagious leading to person-to-person spread. In addition, the short incubation period of norovirus facilitates the linkage of illnesses to a specific meal (14, 15). On the other hand, chemical toxins were most often associated with small outbreaks. Chemical toxins (such as scombroid toxin and ciguatoxin), which are often attributed to finfish consumption, can cause gastrointestinal illness as well as other more severe symptoms, but are self-limiting and do not spread from person-to-person (16-19). Due to the severity of the illness, a high proportion of cases likely seek healthcare and receive a diagnosis. As a result, the high proportion of small outbreaks due to chemical toxins may be due to the higher sensitivity of detection because of their severe symptoms; scombroid toxin and ciguatoxin are the 4th and 7th most common etiologic agents (respectively) among all small outbreaks. Meanwhile, illness due to non-chemical etiologic agents may be less detected simply due to their milder presentation and therefore make up a lower proportion of small outbreaks. As reported in other studies, agents with less severe symptoms would be harder to detect

in a small outbreak due to the fact that fewer cases seek health care, thus reducing the number of stool samples available for testing and confirmation (9, 10, 20).

There were several limitations to this study. As mentioned previously, the number of small outbreaks reported in this surveillance system was most likely an underestimate of the true occurrence of small outbreaks, and many of the small outbreaks had missing or unconfirmed etiology. Furthermore, the inconsistent reporting of small outbreaks (particularly those of 2-3 cases) among reporting agencies has been cited in the literature and is most likely due to differences in the interpretation of a reportable foodborne disease outbreak, public health resources and priorities across the reporting health agencies (10). Among both small and large outbreaks, nearly half had an unknown food commodity. Outbreaks with missing data on these various epidemiologic characteristics provide insight into the challenges associated with outbreak surveillance.

In conclusion, there were significant differences between small and large outbreaks. Small outbreaks were most often associated with the retail preparation setting, chemical toxins, and missing etiology data. These risk factors and causes are important to consider when determining how to control and prevent outbreaks, as different methods are employed depending on the type of agent and type of setting, and overemphasis on the results of large outbreak investigations may lead to an incomplete understanding of the contributing factors to foodborne illness (e.g. food handling in retail settings). As a result, the significant differences between small and large outbreaks reveal that it is important to continue investigating and reporting all outbreaks, regardless of size, in order to not only understand the causes and risk factors, but also to inform prevention and control measures.

TABLES

Table 1. Preparation setting for small and large outbreaks.

	Small Outbreaks <10 Cases		Large Outbreaks >=10 Cases	
	Frequency	Percent	Frequency	Percent
Retail Food Service*	5113	77.74	2722	54.51
Social*	82	1.25	376	7.53
Private Home*	647	9.84	574	11.49
Institution*	79	1.2	447	8.95
Healthcare*	30	0.46	124	2.48
Commercial Product	224	3.41	176	3.52
Other	20	0.30	11	0.22
Multiple*	88	1.34	176	3.52
Unknown*	294	4.47	388	7.77
Total	**6577**		**4994**	

*Statistically significant differences between small and large outbreaks at the 0.01 level

Percentage sums may not total 100 due to rounding

Table 2. Consumption setting for small and large outbreaks.

	Small Outbreaks <10 Cases		Large Outbreaks >=10 Cases	
	Frequency	Percent	Frequency	Percent
Retail Food Service*	4013	61.02	1667	33.38
Social*	468	7.12	1276	25.55
Private Home*	1413	21.48	574	11.49
Institution*	135	2.05	644	12.90
Healthcare*	54	0.82	168	3.36
Commercial Product	21	0.32	8	0.16
Other*	50	0.76	72	1.44
Multiple*	88	1.34	182	3.64
Unknown*	335	5.09	403	8.07
Total	**6577**		**4994**	

*Statistically significant differences between small and large outbreaks at the 0.01 level

Percentage sums may not total 100 due to rounding

Table 3. Results of multivariable logistic regression analysis of independent variables on small outbreak size.

Variable	OR (95% CI)
Preparation Setting	
Private Home	1.00 (Ref)
Retail	1.89 (1.65, 2.16)*
Institution	0.19 (0.15, 0.25)*
Other	0.28 (0.21, 0.37)*
Etiologic Agent	
Bacterial	1.00 (Ref)
Viral	0.34 (0.30, 0.37)*
Chemical	10.57 (7.65, 14.60)*
Missing	1.98 (1.78, 2.21)*

*P<0.001

FIGURES

Figure 1. Number of small and large outbreaks per year. 1999-2008.

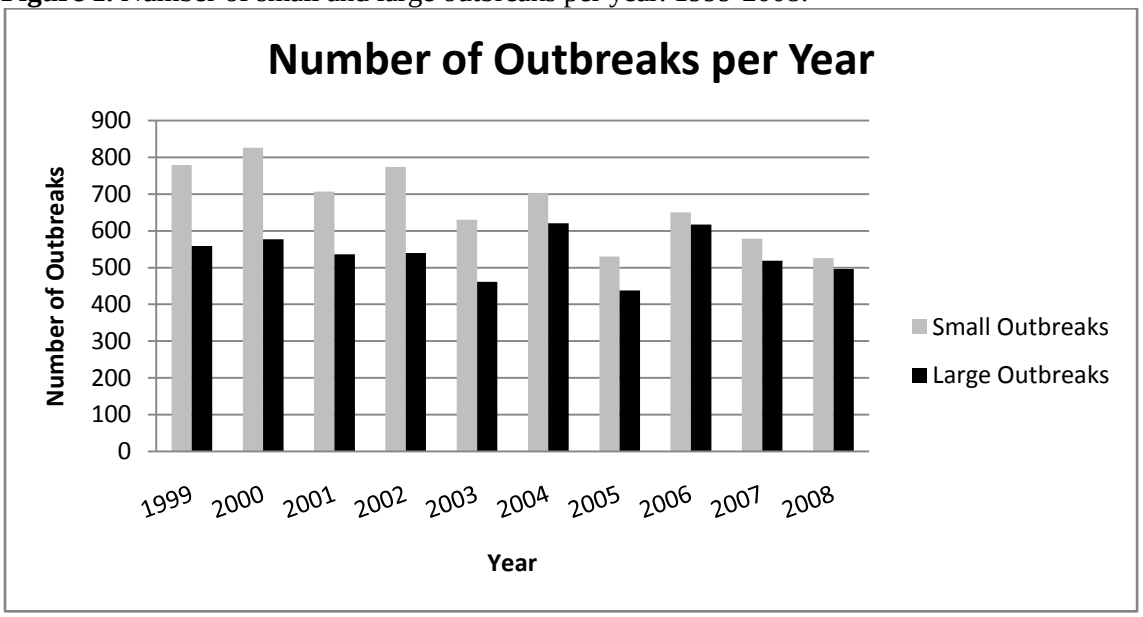
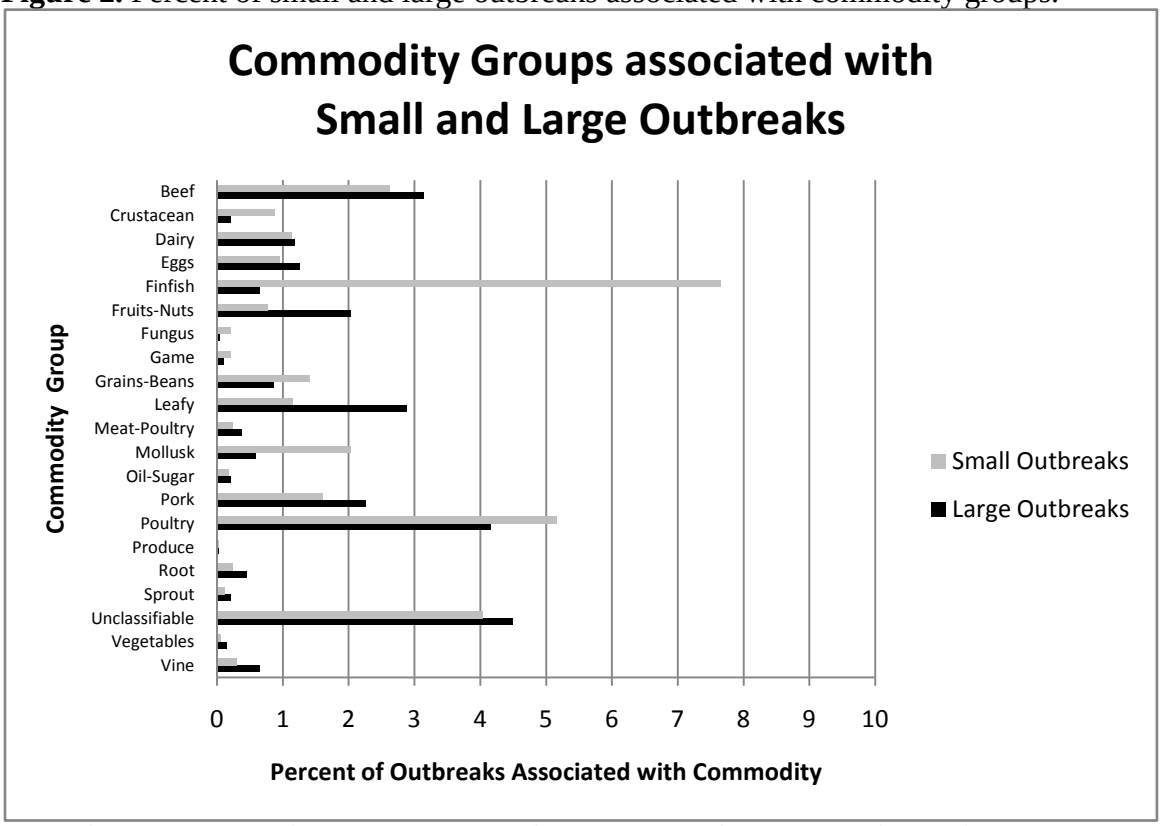
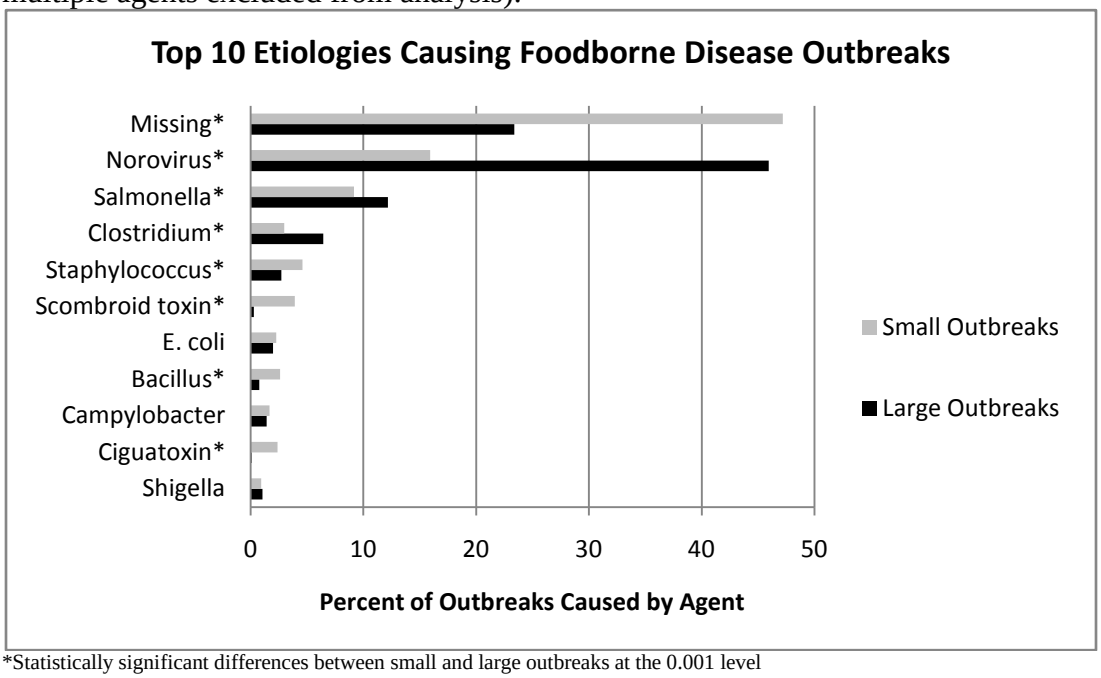


Figure 2. Percent of small and large outbreaks associated with commodity groups.



Multiple foods comprised 28% of small outbreaks and 29% of large outbreaks. No food was reported for 41% of small outbreaks and 45% of large outbreaks.

Figure 3. Percent of small and large outbreaks due single agents or missing agent information (analysis includes both confirmed and suspected agents; outbreaks due to multiple agents excluded from analysis).



*Statistically significant differences between small and large outbreaks at the 0.001 level

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APPENDIX

IRB Determination

EMORY UNIVERSITY | Institutional Review Board

April 4, 2010

Cassandra Harrison
Epidemiology Department
Rollins School of Public Health
Emory University

RE: **Determination: No IRB Review Required**
FDOSS/eFORS Data Access
PI: Cassandra Harrison

Dear Ms. Harrison:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition of research involving "human subjects" or the definition of "clinical investigation" as set forth in Emory policies and procedures and federal rules.

Specifically, in this project, you will be accessing a CDC maintained database on foodborne disease outbreaks. As the data you will receive will not have any attached identifiers or links to any identifiable data, there is no interaction with "human subjects" as defined in 45 CFR 46.102(f). As such, this project does not fall under the purview of the IRB.

This determination could be affected by substantive changes in the study design or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Sean Kiskel
Research Protocol Analyst
Emory University IRB

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CDC form 52.13, Investigation of a Foodborne Outbreak

Electronic
Foodborne
Outbreak
Reporting
System

Investigation of a Foodborne Outbreak

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 as possible of Part 1 and Park 2 as you can.

CDC Use Only

State Use Only

Part 1: Required Information

1. Location of Exposure

State: ___ ___
Multi-state exposure
Other State:

Country: _____
Multi-county exposure
Other Countries:

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

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

Name of Food	Main Ingredients	Contaminated Ingredient(s)	Reason(s) Suspected (see below)	Method of Preparation (see list on page 2)
e.g. lasagna	*pasta, sauce, eggs, beef*	*eggs*	*4*	*M1*
1.)				
2.)				
3.)				

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 it likely source

8. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include serotype and other characteristics such as phage type, virulence factors, molecular fingerprinting, antibiogram, metabolic profile.) Confirmation criteria available at http://www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol 49/SS-1/Appendix B

Etiology		Serotype (if available)	Other characteristics (if available)
1.)	Confirmed Suspected		
2.)	Confirmed Suspected		
3.)	Confirmed Suspected		

Etiology undetermined

Isolated / Identified from: (Check all that apply:)

Patient specimen(s)
Food specimen(s)
Environment specimen(s)
Food Worker specimen(s)

This questionnaire is authorized by law (Public Health Act, 42 USC §241). Although response to the questions asked is voluntary, cooperation of the patient is necessary to the study and control of disease. Public reporting burden for this collection of information is estimated to average 15 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to PHS Reports Clearance Officer; Rm 721-H, Humphrey Bg; 20 Independence Ave, SW; Washington, DC 20201; ATTN: PRA, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

9. Contributing Factors:** (See list on page 3, check all that apply)

Contributing factors unknown

Contamination Factor:

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):

P1 P2 P3 P4 P5 P6 P7 P8 P9

P10 P11 P12 (describe in Comments) N/A

Survival Factor (microbial outbreaks only):

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 evidence)

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

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		
Fever		
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, cough, coma, descending paralysis, diplopia, flushing, headache, hemolytic uremic syndrome (HUS), hypotension, itching, jaundice, lethargy, myalgia, paresthesia, septicemia, sore throat, tachycardia, thromobocytopenia, temperature reversal, urticaria, wheezing

14. If Cohort Investigation Conducted:

Event-specific Attack Rate = _____ / _____ x 100 = _____%

(# ill total / # of persons for whom you have illness info.)

15. 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 services
Contaminated food imported into U.S.
Commercial product, served without further preparation
Other (please describe)
_____

16. 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, temporary/ mobile service
Other (please describe)
_____

17. Other Available Info:

Unpublished agency report (please attach)

Epi-Aid

Publication (please reference)

_____

Not available

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

_____

_____

_____

_____

_____

State Health Departments: If you have not entered this information into EFORS (Electronic Foodborne Outbreak Reporting System), please send this document to the Foodborne and Diarrheal Disease Branch, Centers for Disease Control and Prevention, 1600 Clifton Road Mailstop A-38, Atlanta, GA 30333, Phone: 404-639-2206, Fax: 404-639-2205

****Contributing factor definitions:**

Contamination Factors:

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 spp., Salmonella spp., 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*)

Proliferation Factors:

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*)

Survival Factors:

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*)