

Evaluating Environmental Health Agency-Level Interventions for Foodborne Illness Outbreak Prevention
and Surveillance

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Note: Previously published articles are included as indicated in the text. In the context of this dissertation, figures, headings, tables, and references have been renumbered from the original publication.

DEDICATION

To my niece, Ava Linh Kim. You can do all impossible things.

ABSTRACT

Protecting the safety of food is an integral public health function involving a continuous cycle of foodborne illness prevention, surveillance, and investigation. It is by conducting surveillance that public health can detect and investigate outbreaks. Investigation of these outbreaks enables public health to learn and adapt methods to better prevent illness. Environmental health (EH) professionals play critical roles in each of these stages beginning with their efforts in illness prevention through restaurant inspections. Chapter 2 illustrates the importance of the data collected by EH agencies, an underutilized data source for public health hazard surveillance. Efforts to standardize restaurant grading and disclosure practices have been hindered by the inability to compare their effects across multiple jurisdictions. Using national outbreak data and standard outcome metrics, Chapter 3 determines the effect of restaurant inspection agency practices in foodborne illness outbreak prevention by distinguishing inspection grading and disclosure practices that reduce foodborne outbreaks.

If foodborne illness is not prevented, detection of illness relies on public health surveillance methods. Complaint-based surveillance has traditionally been conducted via phone calls from the public to local EH agencies housed within health departments. This method, while effective, can be limited by hours of operations of EH agencies or discomfort of the public to place a call. Advancements in complaint-based surveillance by using online complaint forms managed by public health agencies can expand the reach of current surveillance efforts and improve timeliness of reporting. Chapter 4 investigates the impact of expanding complaint reception capability through online complaint forms as a means of enhancing complaint-based surveillance.

The robustness of a complaint-based surveillance system can be measured by its ability to detect foodborne outbreaks. However, while an increase in outbreak detection is beneficial for understanding risk factors involved in foodborne illness, it can also indicate deficient prevention measures upstream. Chapter 5 develops a novel framework that can be used to assess the interplay between the prevention interventions of grading and disclosure and surveillance system effectiveness.

Successful outbreak detection and investigation relies on combinations of policies and practices targeting illness prevention practices and surveillance systems in place to detect outbreaks (Chapter 6). By examining agency-level interventions that strengthen foodborne illness prevention efforts, and distinguish effective surveillance methods, the findings from this dissertation will be useful in influencing food safety policy standards that can reduce foodborne illness burden in the U.S.

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CHAPTER 1: INTRODUCTION TO FOODBORNE ILLNESS PREVENTION, SURVEILLANCE, AND INVESTIGATION

Of the 48 million foodborne illnesses (1) estimated to occur in the U.S. each year, only 9.4 million (2) of those are from 31 major known pathogens commonly associated with foodborne transmission. Economically, the burden of foodborne illnesses increased from \$15.5 billion in 2013 to \$17.6 billion in 2018 (3). Considering the cost of inflation of hospital care, wages, prescription, and over-the-counter drugs, which accounted for 7.8% of the rise in cost, the value of preventing foodborne illness increased by 5% over the price of inflation. Therefore, prevention of foodborne illness is economically valuable (3). Protecting the safety of food is an integral public health function involving a continuous cycle of foodborne illness prevention, surveillance, and investigation. Continual study and investment into public health food safety initiatives enables adaption of interventions to reduce the human and economic burden of foodborne illness.

Prevention of illness is the goal of an iterative public health action cycle (4). This cycle is driven by surveillance efforts to detect when prevention initiatives have failed, epidemiologic investigation to determine the reasons for the failure, and applied targeted research to develop and improve prevention measures (4). Because enteric foodborne illness is infectious and can cause acute illness, primary prevention (5) is the focus of public health food safety efforts. Primary prevention can occur at every stage of the farm to fork continuum, which spans from the source where food is produced to processing and, ultimately, to consumption (6).

Food consumption away from home, in settings such as restaurants, is becoming increasingly popular (7) in the U.S. making these settings particularly important for public health action (8). In 2021, one year after the identification of the COVID-19 pandemic, spending on foods eaten away from home was 10% higher than pre-pandemic levels (9). As it relates to foodborne illness in these settings, in 2017 alone, 841 foodborne illness outbreaks, 14,481 illnesses, 827 hospitalizations, and 20 deaths were reported (10). Though recognized foodborne outbreaks are responsible for only up to 10% of illnesses (11), restaurants have been identified as important settings for both outbreak-associated and sporadic foodborne illnesses (8). The proportion of outbreaks attributed to food prepared in restaurants increased from 41% (12) to 61% within a 48-year (1967-2015) time span (13). Prevention of illness in these settings is an essential public health function undertaken by environmental health (EH) agencies within public health departments. EH agencies food safety functions, including but not limited to facility inspections, are guided by a version of the U. S. Food and Drug Administration (FDA) Food Code, which provides a model set of uniform system provisions for adoption or adaption by local, state, and federal government EH agencies to ensure the safety and protection of food at retail and food service settings (14, 15). Focusing on restaurant outbreaks targets critical settings for food safety, complements the preventative purpose of inspections, and taps into the existing public health prevention framework that inspections provide.

The data that EH agencies generate and collect can provide useful sources of information to improve food safety practice (**Chapter 2**). Studies have shown a link between inspection practices, particularly grading and disclosure of inspection results, and improved public health outcomes (16–20). Efforts to standardize these grading and disclosure practices have been hindered by the inability to compare their effects across multiple jurisdictions. Because the FDA Food Code allows for flexibility of public disclosure of inspection results and does not contain guidance around grading methods, determination of grading and disclosure methodology is at the legislative and programmatic discretion of individual jurisdictions. This flexibility, while advantageous in some respects, has led to a diversity in practice that can be difficult to evaluate and can confuse consumers who may lose valuable food safety information by crossing jurisdictional boundaries. **Chapter 3** determines the role of restaurant inspection practices in foodborne illness outbreak prevention by distinguishing grading and disclosure practices that reduce foodborne outbreaks. By identifying and standardizing practices that demonstratively lead to better public health outcomes, public health can engage restaurant consumers in food safety awareness by ensuring access to inspection information that empowers them to make informed dining decisions regardless of where they choose to dine.

If foodborne illness is not prevented, detection of illness relies on public health surveillance methods. Foodborne illness surveillance routinely and systematically monitors disease incidence in a population and can trigger epidemiologic investigations when increases in incidence are detected (4). Identification of outbreaks, or two or more cases of similar illnesses associated with a common exposure, is the goal of foodborne illness surveillance (21). There are two primary methods by which surveillance is conducted by public health entities. Pathogen-specific surveillance involves reporting of individual cases of foodborne illness to public health agencies by healthcare providers and laboratorians. Complaint-based surveillance enables the public an avenue through which to report foodborne illness directly to public health agencies without the need to seek medical attention first (21).

Remarkable strides have been made in the past 30 years in foodborne illness surveillance (22–24). However, these strides have been predominantly made to improve pathogen-specific surveillance leaving innovations in complaint-based surveillance as an area for needed improvements. Complaint-based surveillance has traditionally been conducted via phone calls from the public to local or state EH agencies. This method, while effective, can be limited by hours of operations or differing communication preferences of the public. Advancements in complaint-based surveillance by using online complaint forms can expand the reach of current surveillance efforts and improve timeliness of reporting. **Chapter 4** investigates the impact of expansion of complaint reception capability through online complaint forms as a means of enhancing complaint-based surveillance.

The robustness of a complaint-based surveillance system can be measured by its ability to detect foodborne outbreaks. However, while an increase in outbreak detection is beneficial for understanding risk factors involved in foodborne illness, it can also indicate deficient prevention measures upstream. Public health interventions at restaurants, such as grading and disclosure of inspection results, have been associated with lower outbreak rates and can be effective intervention measures in preventing foodborne outbreaks (Chapter 3) (25, 26). **Chapter 5** develops a framework that

can be used to assess the interplay between the prevention interventions of grading and disclosure and complaint surveillance system effectiveness.

Protection of public health from foodborne illness relies on combinations of policies and practices targeting illness prevention practices and surveillance systems in place to detect outbreaks **(Chapter 6)**. The studies presented in this dissertation contribute to the larger body of literature in linking public health agency practice to important health outcomes while also identifying areas for future research. By examining agency-level interventions that strengthen foodborne illness prevention efforts and distinguish effective surveillance methods, the findings from this dissertation will influence food safety policy and standards that can reduce foodborne illness burden in the U.S.

CHAPTER 2: DATA-FORWARD ENVIRONMENTAL HEALTH FOOD SAFETY PRACTICE

Kim TN, Hedberg CW. 2022. Data-Forward Environmental Health Food Safety Practice. *Journal of Environmental Health* 85.

Editor's Note: The National Environmental Health Association (NEHA) strives to provide up-to-date and relevant information on environmental health and to build partnerships in the profession. In pursuit of these goals, NEHA features this column on environmental health services from the Centers for Disease Control and Prevention (CDC) in every issue of the *Journal*. In these columns, authors from CDC's Water, Food, and Environmental Health Services Branch, as well as guest authors, will share tools, resources, and guidance for environmental health practitioners. The conclusions in these columns are those of the author(s) and do not necessarily represent the official position of CDC. Thuy Kim is a PhD candidate at the University of Minnesota. Craig Hedberg is a professor at the University of Minnesota and codirector of the Minnesota Integrated Food Safety Center of Excellence.

Ensuring the safety of food served in restaurants and other licensed food service establishments requires actions that cut across the 10 Essential Environmental Public Health Services (27). To provide these services, environmental health agencies collect and maintain a wide variety of data that can inform foodborne illness prevention and surveillance practice.

Environmental Health Data Provide Important Context for Effective Prevention Measures

The most visible manifestation of food safety problems in a restaurant setting is the occurrence of an outbreak of foodborne illness among restaurant patrons. Approximately 64% of foodborne outbreaks in the U.S. are associated with restaurant settings (10). The primary goal of outbreak investigations is to interrupt the chain of illness transmission from consumption of contaminated food. Mitigation measures are generally focused on preventing contributing factors related to contamination, proliferation, and survival of pathogens in the implicated food item. Environmental health data generated outside of outbreak investigations, however, provide important context for translating investigation results into effective prevention measures. These environmental health data include restaurant practices, such as the presence of certified food safety managers and the routine documentation of risk factor inspection violations, and inspection agency practices, such as mandated grading of routine inspections and point-of-service disclosure of inspections results. Using a broad array of environmental health data can foster a more comprehensive understanding of the relationships between restaurant risk factors and foodborne illness.

Environmental Health Data Drive Outbreak Investigations

Although outbreaks of foodborne illness can be exceptional events, they provide critical learning opportunities to improve food safety practices. In 2014, the Centers for Disease Control and Prevention/National Center for Environmental Health launched the National Environmental Assessment Reporting System (NEARS) to capture environmental assessments conducted during identified restaurant-associated outbreaks (28). The NEARS platform provides a framework for the standardization of environmental health outbreak investigative activities to streamline communication of important environmental health findings across jurisdictions and disciplines. Lessons learned from NEARS data can be translated into regulatory actions and model practices to guide future investigative practices.

Environmental Health Data Drive Illness Prevention

Outbreaks represent only the tip of the iceberg of foodborne illnesses; therefore, there is significant value in analyzing routine restaurant inspection data. Risk factor violations cited during routine restaurant inspections have been associated with sporadic cases (29) and outbreaks of Salmonella (30). These findings validate concerns that poor inspection results might indicate failures in restaurant food safety management systems that, if uncorrected, can lead to foodborne illness (31). Because inspections are relatively common events, patterns of inspection results could be useful as food safety hazard surveillance.

Environmental Health Data Drive Inspection Practices

Just as important as the inspections themselves are the underlying drivers that maintain good retail practices at restaurants. These drivers can range from individual food handler and manager factors (32) to consumer perception of food safety factors that drive dining decision making. Many studies have focused on the impact of consumer perception to incentivize food safety practices. These studies found significant associations between disclosure of inspection results at the point-of-service and improved restaurant food safety (16, 33), fewer Salmonella cases(34), fewer hospitalizations (17), and fewer foodborne outbreaks (25, 26). These public health benefits of disclosure are practical examples of how data can identify effective inspection practices that improve public health in restaurants.

Investment in Information Systems Is Essential for the Progression of Data-Driven Public Health Practice

There is a need to advance public health surveillance systems that include restaurant inspection data (35). Integrating food safety hazards identified through routine inspections into other streams of foodborne illness surveillance can enhance outbreak detection and provide context to guide investigations and implement control measures. Unfortunately, current infrastructure limitations for environmental health restaurant inspection data collection and dissemination inhibit cross-jurisdictional collaboration and limit the use of the data to inform practice. These examples of how environmental health data can inform practice demonstrate the utility of environmental health data as a form of hazard surveillance and a catalyst for improving regulatory policies. Standards of data collection, analysis, and application of environmental health data to food safety practice strengthen public health prevention efforts and ultimately reduce the burden of foodborne illness in the U.S.

CHAPTER 3: PREVENTION OF ILLNESS THROUGH RETAIL FOOD ESTABLISHMENT INSPECTION GRADING AND DISCLOSURE

3.1 CHARACTERISTICS OF FOOD ESTABLISHMENT INSPECTION PROGRAMS ON FOODBORNE ILLNESS OUTCOMES

Kim TN, Firestone MJ, DeJarnett N, Dyjack DT, Edwards J, Stueven H, Hedberg CW. 2021. Disclosing Inspection Results at Point-of-Service: Affect of Characteristics of Food Establishment Inspection Programs on Foodborne Illness Outcomes. *Journal of Environmental Health* 83:8–13.

The significant proportion of foodborne illnesses attributed to restaurants highlights the importance of food establishment inspections. The objectives of this cross-sectional study were to characterize local inspection programs and evaluate the effects of programmatic characteristics, such as active public disclosure of inspection results, on select operational and foodborne illness outcomes. Between January 7 and April 6, 2020, an online 36-question survey was administered to 790 government-run food establishment inspection programs at state and local levels. Of 149 survey respondents, 127 (85%) were representing local food establishment inspection agencies. Agencies that disclosed at the point-of-service reported fewer mean numbers of re-inspections by 15%, foodborne illness complaints by 38%, outbreaks by 55% ($p = .03$), and Salmonella cases by 12% than agencies that disclosed online only. Agencies that used some type of grading method for inspection results reported fewer mean numbers of re-inspections by 37%, complaints by 22%, outbreaks by 61%, and Salmonella cases by 25% than agencies that did not grade inspections. Programmatic characteristics appear to be associated with foodborne illness outcomes. These results warrant future research to improve the effectiveness of food establishment inspection programs.

3.1.1 INTRODUCTION

Approximately 51% of each consumer dollar dedicated to food spending in 2019 was spent in the food service industry, specifically in restaurants, compared with just 25% in 1955 (36). Coincidentally, there is growing evidence that restaurants are an important source of sporadic and outbreak-associated foodborne disease in the U.S. (8). In 2017, there were 841 foodborne illness outbreaks resulting in 14,481 illnesses, 827 hospitalizations, 20 deaths, and 14 food recalls in the U.S., including Puerto Rico and Washington, D.C. (10).

Among the illnesses and outbreaks for which a single location was identified, 44% and 64%, respectively, were attributed to foods prepared in a restaurant setting (10). The rise in expenditure on foods eaten away from the home and the significant proportion of foodborne illnesses attributed to restaurants have highlighted the importance of food establishment inspections, as they could flag the existence of food safety hazards and mitigate their public health impact.

Public disclosure of inspection results from food establishments enables consumers to make informed decisions about where they choose to eat (37). Consumer priority of hygienic food preparation practices, in turn, incentivizes food establishments to improve hygiene practices—a proxy for better sanitary conditions—within their facility. Improved and maintained sanitary conditions, theoretically, lead to fewer foodborne illnesses. From a programmatic standpoint, however, disclosure of inspection results can create more work for the environmental health workforce tasked with putting the information into a presentable format. In a survey of the environmental health workforce, 76% of workers surveyed indicated working in food safety and protection programs; however, 17% of all respondents performed public health duties outside of environmental health, and of those, 37% spent >50% of their time working in nonenvironmental health programs (38).

The value of actively disclosing inspection results to the public has been demonstrated in several settings throughout the U.S. The debate about the best mode to convey inspection results to the public, however, is still ongoing. A study of people at the Minnesota State Fair found increased interest in public access to inspection results. Furthermore, fairgoers expressed interest in disclosure methods of posting online and at the point-of-service, that is, at a food establishment (34). For local inspection agencies that disclose inspection results, the most common method is through online disclosure only, typically accessed via departmental websites. Drawbacks of this method include difficulty in navigating these websites and lengthy reports that are confusing to the general public. Moreover, this method might not be accessible to those who are most vulnerable to foodborne illness, such as older adults (39).

Disclosure at the point-of-service eliminates a barrier to using inspection data in the decision-making process, as this approach does not require a person to have online access to check a website for inspection results. With the introduction of public disclosure by means of a color-coded inspection sticker placed at or near restaurant entrances, Columbus Public Health (Ohio), saw inspection scores improve by 1.14 points out of a possible 100 points (16). In New York City, New York, implementation of public disclosure at the point-of-service in the form of letter grades was associated with improvements in sanitary conditions (19) and a 5.3% decrease in Salmonella cases per year (18). Furthermore, in Los

Angeles County, California, public disclosure of letter grades at the establishment led to a 13% decline in hospitalizations due to foodborne illness (17).

While the act of disclosure is important, what information is disclosed and how the public interprets it is also important. Familiarity with the symbols used to represent inspection results lends to easier interpretation by the general public. Grading practices can include letter grading and/or numerical grading, similar to most grading methods in a school system (e.g., A, B, C grades or 100%, 90%, 80%) or other ordinal methods (e.g., stoplight colors, emoticons).

During inspections, a labeling system is used to classify different types of violations and convey severity of the violations. These violation schemes often correlate with the version of the Food and Drug Administration (FDA) Food Code an agency has adopted and can be used in combination at the agency's discretion. For example, in Food Code versions before 2009, violations that were more likely "to contribute to food contamination, illness, or environmental health hazard" were classified as critical. In 2009, FDA revised the Food Code to distinguish critical items as priority if the item includes a quantifiable measure to show control (e.g., cooking), or priority foundation if the item requires the purposeful incorporation of specific actions (e.g., training) (Food and Drug Administration [FDA], 2015). The categorization of risk factor or good retail practices corresponds to the organization of the FDA Food Establishment Inspection Report.

Current inspection practices and methods of disclosure vary widely across jurisdictions in the U.S. and present unique challenges to evaluating program effectiveness. The objectives of this cross-sectional study were to 1) characterize local inspection programs and 2) evaluate the effects of programmatic characteristics, such as active public disclosure methods, on select operational and foodborne illness outcomes.

3.1.2 METHODS

An online 36-question survey was administered via Qualtrics to 790 government-run food establishment inspection programs at state, county, city, district, and territorial levels. Recipients were chosen based on availability of program inspection data online or participation in FDA's Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The Retail Program Standards provide recommendations aimed at facilitating inspections that are more effective and implementing foodborne illness prevention strategies. Enrollees in this program intend to actively use these standards as a tool to assess and improve their regulatory programs (FDA, 2019).

We administered the survey in two rounds. The first round consisted of 151 recipients whose inspection data were publicly available online, resulting in a 40% response rate ($n = 60$ respondents). The second round included 639 recipients who participated in the Retail Program Standards, resulting in a response rate of 19% ($n = 122$ respondents). Via the survey, we obtained information on general program characteristics such as size of population served; number of routine inspections conducted; number of licensed establishments within the inspection jurisdiction; and operational characteristics such as public disclosure method, grading method, and FDA *Food Code* version in use.

The time period for the survey was chosen to match the availability of inspection data from the agencies. Three geographically diverse local inspection agencies piloted the survey to ensure appropriateness and relevancy of questions and answer choices. The data collection period was January 7–April 6, 2020. We paused data collection in April due to the COVID-19 pandemic response taking precedent at state and local health departments.

We categorized inspection agencies into two main types, state and local. A state agency was defined as an inspection program that oversees the inspection of food establishments at the state government level, including U.S. territories and Washington, DC. A local agency differs in that the oversight of the inspection programs is at the county, city, city–county, or district government level. One survey respondent represented a university and thus was excluded from this analysis, as there could be significant policy differences between government agencies and universities. Local agencies were the primary focus of this analysis, as most food establishment inspection programs are operated at the local government level.

Four operational and foodborne illness outcomes were calculated as rates from a combination of variables obtained from the survey and expressed as an average number of:

1. Re-inspections/establishment/year, calculated as the quotient of average number of re-inspections and number of licensed food establishments within the jurisdiction of the agency.
2. Foodborne illness complaints/1,000 licensed food establishments/year (2016–2018; most recent years included in data set).
3. Foodborne outbreaks/1,000 licensed food establishments/year (2016–2018).
4. Salmonella cases reported/100,000 population served/year (2016–2018).

In addition to the survey data, we were able to obtain some *Salmonella* case counts using departmental websites for jurisdictions that reported these data online.

For the purposes of this study, active disclosure was defined as agencies that voluntarily and preemptively publicize some or all inspection data to the public. Inspection violation scheme was not included in the survey, but was determined by searching online for inspection data from the responding agencies.

Predictors were classified into three categories:

1. Disclosure method consisting of online, point-of-service, no disclosure, and other disclosure methods.
2. Grading method consisting of numerical score, letter grade, no grading, and other grading methods.
3. Inspection violation scheme used for routine inspections consisting of subcategories Priority-Priority Foundations-Core; Critical/Noncritical; Risk Factor-Good Retail Practices; and other schemes.

The Risk Factor-Good Retail Practices subcategory relates to the inspection report form and therefore can be used in combination with other violation schemes. The mean and median values of outcomes for each combination of schemes were assessed in addition to the non-mutually exclusive scheme categories previously stated. One respondent used a combination of three schemes: Risk Factor-Good Retail Practices, Critical/Noncritical, and Red/Blue. Of note, Red/Blue is similar and is sometimes used in reference to Critical/Noncritical; therefore, this respondent's jurisdiction was included in the Risk Factor-Good Retail Practices and Critical/Noncritical scheme combination.

Mean and median values were calculated to identify trends in outcomes based on each subcategory. The means were compared using *t*-tests; *p*-values were reported assuming unequal variance. The analysis was conducted using SAS 9.4m6 University Edition. Linear regression was used to determine associations between the outcome variables reported by the local responding agencies. The level of statistical significance was set at $\alpha = .05$.

3.1.3 RESULTS

Of the 149 survey respondents, 127 (85%) represented a local food establishment inspection agency. More than one half of agencies (66%) actively disclosed inspection scores to the public and most (91%) did so by posting online; only some (30%) posted at the point-of-service. Approximately 43% of the agencies used numerical scores as a grading method, 24% used no grading method, and 16% used letter grades (Table 3.1). Frequently used inspection violation schemes included Priority-Priority Foundations-Core (32%) and Critical/Noncritical (28%). The scheme Risk Factor-Good Retail Practices (31%) was used in combination with other violation schemes. Of the 23 agencies that used Risk Factor-Good Retail Practices with another scheme, 43% used Priority-Priority Foundations-Core, 22% used Critical/Noncritical, and 13% used Major/Minor schemes. Violation schemes for 53 respondents could not be determined using online searching.

Agencies disclosing at the point-of-service had lower mean values for all outcome measures than did agencies disclosing online (Table 3.2). Of the 24 agencies disclosing inspection results at the point-of-service, however, 21 (88%) also disclosed inspection results online (Table 3.1). Due to this overlap, we made further comparisons of agencies disclosing at the point-of-service and agencies disclosing online only (Table 3.3). Agencies that disclosed inspection results at the point-of-service reported fewer mean number of re-inspections by 15%, complaints by 38%, outbreaks by 55% ($p = .03$), and *Salmonella* cases by 12% than did agencies that disclosed online only.

Agencies that used some type of grading method for inspection results reported fewer mean numbers of re-inspections by 37%, complaints by 22%, outbreaks by 61%, and *Salmonella* cases by 25% than did agencies that did not grade inspection results. Agencies using letter grades had lower mean values for complaints by 14% and outbreaks by 43% than agencies using numerical scores, but 5% more *Salmonella* cases (Table 3.2). Almost one third of agencies, however, using numerical scores also used letter grades (Table 3.1).

Agencies that used a Critical/Noncritical violation scheme reported 3% more mean complaints but 3% fewer mean re-inspections, 27% fewer outbreaks, and 19% fewer *Salmonella* cases than those

using Priority-Priority Foundations-Core schemes. Agencies that used Risk Factor-Good Retail Practices schemes tended to have fewer re-inspections and complaints, but more outbreaks and *Salmonella* cases than did agencies not using these schemes (Table 3.2). Although most of these findings are not statistically different from each other, the overall pattern of results is noteworthy.

Regarding associations between outcome measures, we observed an almost statistically significant relationship between reported number of complaints/1,000 establishments/year and number of *Salmonella* cases/100,000 population/year. Every unit of increase in reported *Salmonella* cases/100,000 population/year was associated with an increase in 1.03 complaints/1,000 establishments ($p = .051$) (Table 3.4).

3.1.4 DISCUSSION

The trends observed in this study complement the existing literature that supports the value of transparency in the disclosure of food establishment inspection data. Disclosure at the point-of-service was associated with fewer mean numbers of re-inspections, complaints, outbreaks, and *Salmonella* cases than disclosure online only, with a significant difference ($p = 0.03$) in the number of outbreaks between the two disclosure methods. These findings are consistent with previous studies in New York City and Los Angeles that demonstrated benefits to disclosure at the point-of-service. In this study, disclosure at the point-of-service included posting of inspection results inside and outside of the food establishment. It was not the goal of this study to parse the outcomes resulting from disclosures of inspection results posted inside or outside of food establishments. Future studies might be warranted to evaluate the effectiveness of the nuance of disclosure location at food establishments.

Letter grading methods were associated with fewer complaints and outbreaks than numerical scoring methods, but both methods had better outcomes than for inspections in the absence of a grading system. The Critical/Noncritical inspection violation scheme was associated with fewer outbreaks and *Salmonella* cases than Priority-Priority Foundations-Core or Risk Factor-Good Retail Practices schemes. These results suggest that how local agencies conduct and score food establishment inspections and disclose results to the public likely affect the success of the programs to control and prevent foodborne illnesses and food safety hazards.

A strength of this study is that use of the Retail Program Standards listserv allowed for direct contact and survey dissemination to managers or primary contacts of food establishment inspection programs. The use of this listserv also enabled access to a wide geographic range of potential respondents, as this program included agencies from all 50 states and Washington, DC, as well as five U.S. territories: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. Additionally, given the variations in inspection practices, many survey questions included an open-text option for "Other" answers that were not listed as potential answer choices. This allowed for the capture of unique or less common practices.

There are several limitations to this study. First, the presence of selection bias cannot be understated given the use of a convenience sample of survey recipients and online recruitment. This limits the representativeness of the results to those who participated in the FDA Retail Food Program¹²

Second, *Salmonella* cases were self-reported. Many inspection agencies do not track the number of *Salmonella* cases, as that is typically the duty of epidemiology divisions. As such, the number of cases reported by survey respondents might not reflect true case counts. Third, missing data and an abbreviated collection period weakened the survey data analysis; the data collection period was truncated by local and state health departments needing to focus on the COVID-19 pandemic response. This necessity limited the ability to obtain missing data points and limited the ability of agencies to respond. Fourth, the survey did not collect information about the number and types of triggers for re-inspection of an establishment, which vary across agencies. A potential confounder might be the size of the inspection agency or the number of inspectors, as agencies with more inspectors or more aggressive practices could potentially be able to conduct more re-inspections or to detect more violations, illnesses, and outbreaks than smaller agencies. Fifth, the survey did not allow for capture of programmatic changes that occurred between 2016 and 2018 (e.g., if a jurisdiction updated its food code during this time).

Although most findings were not statistically significant on an individual basis due to limitations in sample size, the overall pattern of results supports and enhances the existing literature on the performance of food establishment inspection programs. For example, for every unit increase in complaints, there was a corresponding increase in the number of re-inspections. There was a similar relationship with reported foodborne outbreaks. Future research should include a larger number of agencies by a factor of 2 or 3 to clarify several of these relationships.

3.1.5 CONCLUSION

Overall, characteristics of food establishment inspection programs appear to be associated with foodborne illness and outcomes. These results warrant future research efforts to improve the effectiveness of these programs. This study suggests that agencies that disclose at the point-of-service reported 55% fewer average number of outbreaks compared with those using online disclosure only. Similarly, applying a grading scheme as a summary measure of inspection results was associated with improved foodborne illness outcomes. Policy makers should consider these findings when evaluating program effectiveness measures and when considering changes to existing food inspection programs.

3.1.6 TABLES AND FIGURES

Table 3.1 Summary Statistics for Local Agency Respondents (N = 124)

	# (%)
Active disclosure	82 (66)
Active disclosure methods	
Online	75 (91)
Point-of-service	24 (29)
Other	4 (5)
No active disclosure	42 (27)
Grading methods	
Numerical score	53 (43)
Letter grade	20 (16)
Other	34 (27)
No grading	30 (24)
Inspection violation schemes (n =75)	
P-PF-C	24 (32)
C/NC	21 (28)
RF-GRP*	23 (31)
P-PF-C	10 (43)
C/NC	4 (17)
Major/minor	3 (13)
Other	7 (9)

P-PF-C = Priority-Priority Foundations-Core; C/NC = Critical/Noncritical; RF-GRP = Risk Factor-Good Retail Practices.

*Of the 23 agencies that indicated using RF-GRP, 6 agencies used RF-GRP only. The other 17 agencies used RF-GRP in combination with the other schemes listed below.

Table 3.2. Mean, Standard Deviation, and Median Estimates for Outcomes by Disclosure Methods, Grading Methods, and Inspection Violation Schemes

	Average # of Re-Inspections/Establishment/Year (n = 109)		Average # of Complaints/1,000 Establishments/Year (n = 100)		Average # of Outbreaks/1,000 Establishments/Year (n = 101)		Average # of <i>Salmonella</i> Cases/100,000 Population Served/Year (n = 48)	
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median
Disclosure								
Online	0.40 (0.55)	0.24	44.2 (49.6)	27.3	1.7 (2.4)	0.84	14.4 (7.2)	14.0
Point-of-service	0.35 (0.46)	0.17	30.3 (45.3)	22.2	0.9 (1.4)	0.25	12.9 (6.5)	14.0
None	0.53 (0.46)	0.50	31.3 (36.0)	18.5	7.0 (24)	0.00	9.9 (9.9)	6.7
Other*	0.36 (0.43)	0.17	74.5 (86.4)	42.7	3.7 (4.7)	2.39	–	–
Grading methods								
Numerical score	0.32 (0.37)	0.17	40.6 (54.6)	22.2	3.0 (10.7)	0.35	12.4 (6.8)	13.6
Letter grade	0.31 (0.48)	0.13	34.9 (41.7)	24.6	1.3 (1.6)	0.71	13.0 (7.0)	14.2
None	0.59 (0.64)	0.50	49.1 (49.2)	29.2	6.5 (25.0)	0.82	15.9 (12.2)	13.1
Other	0.46 (0.57)	0.27	36.4 (35.0)	27.6	1.9 (2.7)	0.95	12.0 (5.2)	12.7
Inspection violation schemes								
P-PF-C	0.39 (0.45)	0.18	47.2 (53.3)	29.0	1.5 (1.7)	0.95	15.7 (7.4)	16.4
C/NC	0.38 (0.49)	0.25	48.7 (45.2)	42.7	1.1 (1.4)	0.85	12.7 (8.8)	13.1
RF-GRP	0.32 (0.39)	0.17	38.1 (51.1)	22.8	2.4 (2.2)	1.97	16.8 (8.1)	17.1
Other	0.29 (0.37)	0.19	57.9 (73.9)*	11.8*	0.77 (0.78)*	0.62*	10.9 (7.8)*	11.7*

P-PF-C = Priority-Priority Foundations-Core; C/NC = Critical/Noncritical; RF-GRP = Risk Factor-Good Retail Practices.

*Contains data from ≤5 respondents.

Table 3.3. Mean, Standard Deviation, and Median Estimates for Outcomes by Point-of-Service (POS) Disclosure Versus Online (no POS) Disclosure

	Average # of Re-Inspections/Establishment/Year (<i>n</i> = 71)	Average # of Complaints/1,000 Establishments/Year (<i>n</i> = 62)	Average # of Outbreaks/1,000 Establishments/Year (<i>n</i> = 63)	Average # of <i>Salmonella</i> Cases/100,000 Population Served/Year (<i>n</i> = 31)
<i>p</i> -value	.65	.16	.03	.44
POS disclosure				
Mean (<i>SD</i>)	0.35 (0.46)	30.3 (45.3)	0.92 (1.4)	11.7 (6.6)
Median	0.17	22.17	0.25	12.5
Online (no POS) disclosure				
Mean (<i>SD</i>)	0.41 (0.57)	48.6 (50.0)	2.04 (2.69)	13.3 (8.5)
Median	0.24	29.0	0.95	12.7

Table 3.4. Linear Regression Comparisons of Outcomes

	Average # of Re-Inspections/Establishment / Year			Average # of Complaints/1,000 Establishments/Year			Average # of Outbreaks/1,000 Establishments/Year			Average # of <i>Salmonella</i> Cases/100,000 Population Served/Year		
	Parameter Estimate (SE)	p-Value	#	Parameter Estimate (SE)	p-Value	#	Parameter Estimate (SE)	p-Value	#	Parameter Estimate (SE)	p-Value	#
Average # of Re-Inspections/Establishment /Year	-			11.49 (11.16)	.306	91	0.943 (3.44)	.784	92	-0.18 (3.21)	.956	44
Average # of Complaints/1,000 Establishments/Year	0.001 (0.000995)	.306	91	-			0.058 (0.033)	.079	93	0.06 (0.031)	.051	48
Average # of Outbreaks/1,000 Establishments/Year	0.00089 (0.00323)	.78	92	0.579 (0.326)	.079	93	-			0.40 (0.50)	.43	47
Average # of <i>Salmonella</i> Cases/100,000 Population Served/Year	-0.00042 (0.0074)	.96	44	1.305 (0.652)	.051	48	0.035 (0.044)	.43	47	-		

3.2 EVALUATION OF GRADING AND DISCLOSURE PRACTICES USING NATIONAL FOODBORNE OUTBREAK SURVEILLANCE DATA

Kim TN, Wildey L, Gleason B, Bleser J, Firestone MJ, Bare G, Bliss J, Dewey-Mattia D, Stueven H, Brown L, Dyjack D, Hedberg CW. 2022. Foodborne Outbreak Rates Associated with Restaurant Inspection Grading and Posting at the Point of Service: Evaluation Using National Foodborne Outbreak Surveillance Data. *Journal of Food Protection* 85:1000–1007.

A previously conducted national survey of restaurant inspection programs associated the practice of disclosing inspection results to consumers at the restaurant point-of-service (POS) with fewer foodborne outbreaks. We used data from the national Foodborne Disease Outbreak Surveillance System (FDOSS) to assess the reproducibility of the survey results. Programs that participated in the survey accounted for approximately 23% of the single state, foodborne illness outbreaks in restaurant settings reported to FDOSS during 2016 – 2018. Agencies that disclosed inspection results at the POS reported fewer outbreaks (mean = 0.29 outbreaks per 1,000 establishments) than those that disclosed results online (0.7) or not at all (1.0). Having any grading method for inspections was associated with fewer reported outbreaks than having no grading method. Agencies that used letter grades had the lowest numbers of outbreaks per 1,000 establishments. There was a positive association (correlation coefficient, $r = 0.54$) between the mean number of foodborne illness complaints per 1,000 establishments, per the survey, and the mean number of restaurant outbreaks reported to FDOSS ($R^2 = 0.29$). This association was stronger for bacterial toxin-mediated outbreaks ($R^2 = 0.35$) than for norovirus ($R^2 = 0.10$) or Salmonella ($R^2 = 0.01$) outbreaks. Our cross-sectional study findings are consistent with previous observations that linked the practice of posting graded inspection results at the POS with reduced occurrence of foodborne illnesses and outbreaks associated with restaurants. Support for foodborne illness surveillance programs and food regulatory activities at local health agencies is foundational for food safety systems coordinated at state and federal levels.

3.2.1 INTRODUCTION

It is estimated that known foodborne pathogens are responsible for 9.4 million illnesses annually in the U.S. (2, 10). Depending on the pathogen, <1% to 10% of cases are known to be associated with a recognized outbreak (11). Nevertheless, outbreak investigations provide key information on the food, pathogens, and settings associated with foodborne illness. An outbreak is defined by the Centers for Disease Control and Prevention (CDC) as an incident in which two or more people become ill from the same contaminated food or drink (40); sporadic cases are illnesses that have not been identified to be part of an outbreak. Restaurants are an important setting for both outbreak-associated and sporadic (non-outbreak-associated) foodborne illness in the U.S. (8, 10). The percentage of foodborne illness outbreaks attributed to restaurant settings increased from a mean of 41% for the period of 1967–1997 (12) to a mean of 61% for the period of 2009–2015 (13).

Recognizing the important role that restaurants play in foodborne illness and outbreak prevention, studies to identify model practices for agencies that inspect restaurants for compliance with food safety regulations suggest that disclosing inspection results at the point-of-service (POS) (i.e., at the establishment) using some form of grading (letter grade, color, numerical score, emoji, etc.) is associated with improved public health outcomes (16–19). The evidence gathered by these efforts suggests that such disclosure yielded improved inspection scores (16), improved sanitary conditions (19), decreased incidence of *Salmonella* infection (18), and decreased hospitalizations due to foodborne illness (17). The results of these previous studies strongly suggest that the actions of restaurant inspection programs play an important role in reducing foodborne illness transmitted in restaurant settings.

In 2021, a national survey of restaurant inspection programs found that disclosure at the POS was associated with fewer foodborne illness outbreaks reported per 1,000 licensed food establishments. Survey methods were previously described (25). Briefly, the survey was disseminated to a total of 790 restaurant inspection agencies at two times: January 7, 2020 and March 3, 2020 (25). A third dissemination of the same survey occurred on November 2, 2020. Although not included in the original study results, these data were included in the analysis for this study. The net total number of agencies responding to the survey was 165. Of these, 140 respondents represented local agencies while the remainder represented state or territorial agencies (25).

This survey captured various restaurant inspection agency characteristics across the U.S., including estimates of complaints received and use of methods of grading, inspection results disclosure, and inspection violation schemes. It also captured counts of foodborne illness outbreaks, sporadic illness cases, and foodborne illness complaints. Survey recipients represented inspection agencies that disclosed inspection results online and those enrolled in the Food and Drug Administration (FDA) Voluntary National Retail Food Regulatory Program Standards program (Retail Program Standards). This program helps food regulatory programs meet the widely recognized Voluntary National Retail Food Regulatory Program Standards (41). The FDA *Food Code* is a model set of science-based, comprehensive food safety guidelines that provides the technical and legal basis for local, state, tribal, and federal food codes that regulate retail food service in the U.S. (14).

A limitation of the survey-reported data was the lack of important details on the etiologic agent (e.g., bacterial or viral pathogen) and setting of these outbreaks (25). We sought to address these gaps by using data routinely reported by state public health agencies to the CDC through the Foodborne Disease Outbreak Surveillance System (FDOSS). FDOSS is a national, passive surveillance system that collects information on enteric and non-enteric foodborne outbreaks including information on the number of cases, case outcomes, dates of illness onset, implicated foods, and locations of food preparation (40). The objective of our present study was to use FDOSS outbreak data to compare the number of outbreaks per 1,000 licensed restaurants by restaurant inspection grading and disclosure practices conducted by agencies responding to the initial survey (25).

3.2.2 METHODS

We used results from the previously conducted national survey of regulatory restaurant inspection agencies at state, county, city, district, and territorial levels as a baseline for this study (25). We limited analyses to local agencies representing city, county, or district jurisdictions (n=140), hereafter referred to as “agencies.” The decision to focus on local agencies is supported by the tendency of restaurant inspection programs to operate at the local government level (25). The agencies were drawn from 34 states representing all regions of the country (median = 3 agencies per state, range = 1-14). This current study used the following data from the original survey: jurisdiction of the survey respondents, number of licensed restaurants, number of complaints received from 2016-2018, method of inspection grading, and method of public disclosure of inspection results.

Like inspection practices, inspection terminology can vary by agency. We defined public disclosure as the act of voluntarily and preemptively publicizing some or all inspection data to the public (e.g., posting at the restaurant or online). This study also defined grading method as the act of applying an ordinal ranking system to inspection results (e.g., numerical scores or letter grades). Disclosure at the POS is inclusive of any type of display of inspection results on the restaurant premises, regardless of font size or location. Complaints are reports to public health of possible foodborne illness from the public, including individuals or groups of individuals (21).

We obtained foodborne outbreak data for our analysis from FDOSS, which also contained associated details about etiology and food preparation location. We applied the following inclusion criteria to the FDOSS data extracted on November 18, 2019: the primary mode of transmission was foodborne; the outbreak report was finalized; date of first illness was between January 1, 2016 and December 31, 2018; the number of estimated primary illnesses was greater than one; the exposure location was within the jurisdiction of an agency that participated in our survey; and the location where food was prepared was a restaurant setting— including sit-down dining, buffet, fast food, or other or unknown restaurant type.

We linked the FDOSS data to the survey data by jurisdiction, identified by the reporting agency. An outbreak was attributed to a regulatory agency if the agency’s jurisdiction was listed in FDOSS as the location in which the exposure occurred. Outbreaks in which exposure occurred in multiple counties were assigned to agencies based on the listed exposure locations. If a multicounty outbreak had exposure locations in jurisdictions for multiple agencies, each outbreak was counted once for each 20

agency. Multistate outbreaks were excluded from analysis. Some counties contain city agencies that conduct inspections independently of the county agency. These incidences were identified by comparing the survey-reported population served by the county agency with the U.S. Census Bureau estimates of population for the jurisdiction. Using this method, city-level exposure data were used to identify and assign outbreak counts to the appropriate agency for four outbreaks. Outbreaks for which multiple pathogens were identified were counted only once in the outbreak total but were counted for each pathogen for pathogen-specific analyses.

We grouped FDOSS restaurant outbreaks by etiology. Outbreaks in FDOSS with the suspected etiology of “other-bacterium” were reviewed; most were attributed to an unspecified bacterial toxin based on details provided by the reporting agency. These counts were then combined with *Bacillus cereus*, *Clostridium perfringens*, and *Staphylococcus aureus* and collectively referred to as “bacterial toxin-mediated.” The proportion of outbreaks by etiology were compared between agencies that participated in the restaurant grading project survey (Survey Group) and all other agencies reporting to FDOSS. This comparison between the two groups enumerated the contributions of the Survey Group in the context of the overall national outbreak surveillance data for the study period.

We calculated mean and median values for rates to identify trends in outcomes based on each category of grading method, disclosure method, and inspection violation scheme. Mean rates for the Survey Group and all other agencies were compared using t-tests and p-values were reported based on unequal variance assumptions. The level of significance was set at $\alpha=0.05$. Analysis was conducted using SAS 9.4 (SAS Institute, Cary, NC). Scatterplots, correlation coefficients, and R^2 values were obtained using Microsoft Excel to assess the relationship between the mean number of complaints reported and the mean number of outbreaks by etiology.

3.2.3 RESULTS

There were 2,608 single-state foodborne outbreaks reported to FDOSS during 2016–2018 with 1,638 attributed to food prepared in a restaurant setting. Of these, outbreaks in the Survey Group jurisdictions accounted for 23% (n=381) and all other jurisdictions accounted for the remaining 77% (n=1,257).

Outbreak numbers and etiology by group. The proportion of outbreaks in restaurant settings was significantly higher among agencies in the Survey Group compared with all other agencies (Relative risk [RR] = 1.10, 95% confidence interval [CI] = 1.03, 1.17). The most common etiologies reported to FDOSS in restaurant settings from the Survey Group were norovirus (177 [46%] outbreaks), *Salmonella* (48 [13%] outbreaks), *Vibrio spp.* (39 [10%] outbreaks) and bacterial toxin-mediated (36 [9%] outbreaks) (Table 1). The etiology was unknown for 47 outbreaks (12%) (Table 1). The proportions of restaurant setting outbreaks attributed to norovirus (RR = 1.14; 95% CI = 1.01, 1.29) and *Vibrio spp.* (RR = 2.94; 95% CI = 1.99, 4.35) were significantly higher among the Survey Group, while the proportion of unknown outbreaks was significantly lower (RR = 0.48; 95% CI = 0.36, 0.64) among the Survey Group compared with all other agencies.

Outbreak rates by inspection disclosure and grading methods. There was a pattern of lower mean annual number of outbreaks per 1,000 establishments for agencies in the Survey Group that disclosed inspection results at the POS compared with agencies that either disclosed online (OL) or did not disclose (ND) (means: 0.29 POS vs. 0.70 OL, 1.0 ND) (Table 2). A similar pattern was also seen for inspection grading methods; agencies with any (letter grade (LG) or numerical score (NS)) grading method had a lower mean annual number of outbreaks per 1,000 establishments than agencies with no grading method (NG) (means: 0.57 LG, 0.69 NS vs. 0.96 NG).

Comparison of POS and online disclosure methods. Inspection disclosure methods varied across agencies within states. For example, in ten states that had six or more agencies included in the survey, only two had all of the agencies in the state use the same practices for disclosing inspection results. Of the 28 agencies that disclosed at the POS according to the survey, 24 (86%) also disclosed online. However, there were fewer outbreaks reported by agencies that disclosed at the POS, compared with agencies that disclosed online without POS disclosure (0.3 POS vs 0.8 OL, $p=0.002$) (Table 3).

Complaint rates by restaurant outbreak etiologies reported to FDOSS. There was a positive association (correlation coefficient, $r=0.54$) between the mean number of complaints per 1,000 establishments per year reported to FDOSS and the mean number of restaurant outbreaks per year reported to FDOSS ($R^2=0.29$, Figure 1). When reported restaurant outbreaks were stratified by etiology, there was a positive association between the mean number of complaints and the mean number of norovirus outbreaks in restaurants reported to FDOSS ($R^2=0.10$, Figure 2), and a positive association for bacterial toxin-mediated restaurant outbreaks ($R^2=0.35$, Figure 3). Conversely, there was no meaningful trend for *Salmonella* ($R^2=0.01$, Figure 4), suggesting that *Salmonella* outbreaks are not associated with foodborne illness complaints.

3.2.4 DISCUSSION

Relevance to practice. Our findings were consistent with previous survey (15) results showing the disclosure of graded inspection results at the POS was associated with fewer outbreaks reported to FDOSS. These results provide further support for recommendations (15) to post graded restaurant inspection results at the POS by demonstrating that agencies that used some grading system had lower mean numbers of FDOSS restaurant outbreaks per 1,000 establishments than did agencies that did not post graded inspection results. Agencies that used letter grades had the lowest mean and median numbers of FDOSS restaurant outbreaks per 1,000 establishments, although the study had limited power to distinguish between the grading methods.

Restaurant inspections are a measure of how well a restaurant adheres to food safety guidelines that prevent foodborne illness. The finding that graded inspection results posted at the POS was associated with fewer outbreaks occurring in restaurants based on FDOSS data is consistent with hypotheses that consumers use this information to guide their dining decisions (10, 11, 23). Because having this information is important to consumers, a favorable score may attract more consumers, while a less favorable score may provide food operators with additional incentive to improve their food safety performance. Disclosing inspection results at the POS allows this measure of food safety performance to be readily available and interpretable to consumers at a location where many dining decisions are made.

Distribution of outbreaks. The higher proportion of outbreaks reported by the Survey Group suggests that these agencies were more likely to report restaurant-associated outbreaks and were more likely to report outbreaks due to norovirus, but less likely to report outbreaks of unknown etiology than all other agencies. This suggests that agencies in the Survey Group were better at determining the outbreak setting and etiology of the outbreaks they investigated. The relative effectiveness of agencies in the Survey Group to detect and investigate outbreaks adds further support for the credibility of findings within this group regarding differences in outbreak reporting based on inspection grading and disclosure practices.

Usefulness of consumer complaints. In addition to our findings regarding inspection reporting, the results of this study support the importance of agencies having a mechanism to receive foodborne illness complaints. Our finding of a positive correlation between the number of complaints received per 1,000 establishments and the number of restaurant outbreaks reported to FDOSS means that the ability to receive and investigate foodborne illness complaints may be an important predictor of the ability of the agency to detect foodborne outbreaks. In particular, the positive associations between complaints and restaurant outbreaks of bacterial toxin-mediated and norovirus outbreaks reflects the reliance on complaint-based surveillance to detect these outbreaks with short incubation periods. It is primarily through complaint-based surveillance systems that these types of outbreaks, and others with short incubation periods, are detected by public health agencies, thereby underscoring the need for continued complaint-based surveillance systems (6). In contrast, *Salmonella*-associated outbreaks are detected primarily through pathogen-specific surveillance; thus, supporting the finding of no effect between the occurrence of complaints and outbreaks of *Salmonella*, which has a longer incubation period than toxin-mediated pathogens (4, 17).

Complaint-based surveillance is one of the two main methods of foodborne outbreak detection in the U.S. (6) While this study does not assume that having the ability to receive complaints is indicative of the existence of a complaint system, it is notable that 81% of local health departments have a complaint-based surveillance system (16) and approximately 75% of all foodborne outbreaks are detected through complaint systems (7). The usefulness of complaints to detect outbreaks has been demonstrated by multiple studies (12, 16, 17, 18, 25). A survey of local health departments identified a positive correlation between outbreak and complaint rates per population served; agencies that received more complaints detected more outbreaks (16). An analysis of the Florida Department of Health's complaint and outbreak reporting system found that 56% of foodborne outbreaks were identified through complaints (18). Likewise, complaints led to detection of 80% of foodborne outbreaks in Rhode Island (25) and 79% of confirmed foodborne outbreaks in Minnesota (17). Not only can complaints be used to detect outbreaks, but they can also help identify specific indicators of risk. For example, a study of consumer complaints in Washington, D.C. found that complaints were significantly correlated with cited inspection violations of improper holding temperatures and contaminated equipment (12). These studies highlight the usefulness of consumer complaints and underscore the need for complaint-based surveillance in foodborne outbreak detection for pathogens with short incubation periods.

Strengths and limitations. Strengths of this study include the use of national data (FDOSS) through a well-established outbreak surveillance system to validate outbreak counts reported via survey. The surveyed agencies accounted for nearly one-quarter of restaurant setting outbreaks reported to FDOSS. This study did not adjust for potential confounders such as jurisdiction size, geographic region, state-level food program inspection and reporting requirements, funding, and staffing of the inspection agency. These factors may have affected an agency's ability to investigate consumer complaints, detect outbreaks, and subsequently report them to FDOSS. However, there did not appear to be an association between jurisdiction size and reported outbreak rate ($R^2 < 0.01$). In most states there was considerable variation between agencies with respect to restaurant grading and disclosure practices. As noted above, the higher proportion of outbreaks attributable to norovirus and lower proportion of outbreaks with unknown etiology among the surveyed agencies may reflect a better capacity to investigate foodborne illness outbreaks than agencies that did not respond to the survey.

There are inherent limitations to the use of FDOSS data. First, because the FDOSS database is dynamic, agencies are permitted to submit, update, or delete reports at any time. Data used in the analysis for this study were pulled at one point in time, therefore, previous and future analyses using FDOSS data extracted in a similar fashion may produce slightly different results. Second, outbreak counts are reflective of those that were able to be detected. Not all outbreaks are identified by public health agencies and as noted previously, the majority of foodborne illnesses are not a part of recognized outbreaks. It is unknown how well the etiologies and locations implicated in outbreaks reflect those of sporadic foodborne illnesses, i.e., illnesses not associated with outbreaks.

Limitations related to using the survey methods described include the use of a convenience sample of agencies that were enrolled in the Retail Program Standards program, which limited the representativeness of these results to enrollees. Agencies that enroll in this voluntary program may differ from those that choose not to enroll; however, since most (98%) of the agencies participating in the study were participants in the Retail Program Standards program, participation in the Retail Program Standards program is unlikely to bias the findings with respect to the main effect measures. Due to the inquiry of data from multiple time points (survey results during 2019–2020 and outbreak data during 2016–2018), survey responses may not be truly reflective of practices during the time the outbreaks occurred.

A consumer's propensity to file a foodborne illness complaint involving a restaurant is influenced by a variety of factors including poverty status. Unpublished work studying the association of foodborne illness and inspection report data in Hennepin County, MN found that census blocks with high poverty levels were associated with fewer foodborne illness complaints (OR= 0.31; 95%CI: 0.13-0.73) (24). Nevertheless, underlying poverty status in the Survey Group was not deemed an important confounder in our analysis. Because the ability to detect outbreaks in restaurants heavily relies on complaint-based surveillance, any biasing effect poverty status may have on their propensity to file a complaint would also be reflected in the number of outbreaks. There are also different kinds of complaints that can be received about a restaurant: relating specifically to foodborne illness and relating to specific good retail practice violations. While our study did not differentiate between the two types, it

is plausible that the occurrence of violations may be an indicator of food safety practices that could lead to foodborne illness in the future.

Although this was a cross-sectional study that cannot control for the effects of policy changes within inspection programs, our associations are consistent with the studies in Los Angeles County (20) and New York City (9) that demonstrated reductions in the occurrence of foodborne illnesses after implementing posting of inspection grades at the POS. This study assessed the impact of the presence of disclosure at the POS, rather than the specific manners (e.g., location, font size) by which it occurred. If additional evidence were needed to encourage local food regulatory agencies to adopt a practice of grading and posting inspection results at the POS, then a randomized community-control trial could be considered as a next step.

Policy implications. Surveys of public health agencies that are validated by national surveillance data can be powerful tools to identify model practices that contribute to prevention of foodborne outbreaks and illnesses. Particularly, our cross-sectional study findings are consistent with previous observations that linked the practice of posting graded inspection results at the POS with reduced occurrence of foodborne illnesses and outbreaks associated with restaurants. Other food regulatory practices, such as maintaining a robust foodborne illness complaint system, may improve foodborne illness surveillance, outbreak detection, and response. Improving foodborne illness and outbreak surveillance is a prerequisite for improving and measuring the effectiveness of our food safety systems. Support for foodborne illness surveillance programs and food regulatory activities at local health agencies is foundational for food safety systems coordinated at state and federal levels.

3.2.5 TABLES AND FIGURES

Table 3.5. Etiological distribution of outbreaks in restaurant settings reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) for agencies participating in the restaurant grading project survey compared with all other jurisdictions, 2016–2018.

	Restaurant outbreaks for survey group agencies, n=381 (%)	Restaurant outbreaks in all other jurisdictions, n=1,257 (%)
Bacterial toxin	36 (9)	109 (9)
<i>Bacillus</i>	11	23
<i>Clostridium</i>	10	44
<i>Staphylococcus</i>	6	37
Unspecified	9	5
<i>Campylobacter</i>	10 (3)	30 (2)
Ciguatoxin	0 (0)	3 (0.2)
<i>Cryptosporidium</i>	1 (0.3)	2 (0.2)
<i>Cyclospora</i>	4 (1)	23 (2)
<i>Escherichia</i>	6 (2)	18 (1)
<i>Hepatitis</i>	1 (0.3)	9 (0.7)
Norovirus	177 ^a (46)	489 (39)
<i>Salmonella</i>	48 (13)	125 (10)
<i>Sapovirus</i>	2 (0.5)	5 (0.4)
<i>Scombroid toxin</i>	4 (1)	27 (2)
<i>Shigella</i>	0 (0)	5 (0.4)
<i>Vibrio</i>	39 ^a (10)	18 (1)
Multiple Etiologies	6 (2)	22 (2)
Unknown Etiology	47 ^a (12)	372 (30)

^a Proportion of outbreaks significantly different between survey group and all other jurisdictions.

Norovirus (RR = 1.14; 95% CI = 1.01, 1.29) and *Vibrio* (RR = 2.94; 95% CI = 1.99, 4.35) were more frequently reported by agencies in the Survey Group, while unknown etiologies (RR = 0.48; 95% CI = 0.36, 0.66) were less frequently reported.

Table 3.6. Number and mean annual rate of outbreaks in restaurant settings reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) by disclosure methods and grading methods for agencies participating in the restaurant grading project survey, 2016–2018.

	Number of agencies	Number of outbreaks in restaurants	Outbreaks per 1,000 restaurants	
	n	n	Mean (SD)	Median
Disclosure Methods				
Point of Service	8	24	0.29 (0.2)	0.3
Online	36	226	0.70 (0.7)	0.4
None	11	72	1.0 (1.0)	0.5
Grading Methods				
Letter grade	42	310	0.57 (0.7)	0.3
Numerical score	19	148	0.69 (0.7)	0.4
None	12	89	0.96 (0.9)	0.7
Other	16	138	0.76 (0.8)	0.4

Table 3.7. Mean annual rate of outbreaks in restaurant settings reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) by point of service disclosure versus online without POS disclosure for agencies participating in the restaurant grading project survey, 2016–2018.

Disclosure method	Outbreaks per 1,000 restaurants, n=202		
	Mean (SD)	Median	p-value ^a
Point of Service	0.3 (0.2)	0.3	.002
Online without Point of Service	0.8 (0.7)	0.5	

^a p-value for comparison of means

Figure 3.1: Mean annual number of outbreaks in restaurant settings per 1,000 restaurants reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) and the mean number of survey-reported complaints per 1,000 restaurants per year for agencies (●) participating in the restaurant grading project survey, 2016–2018.

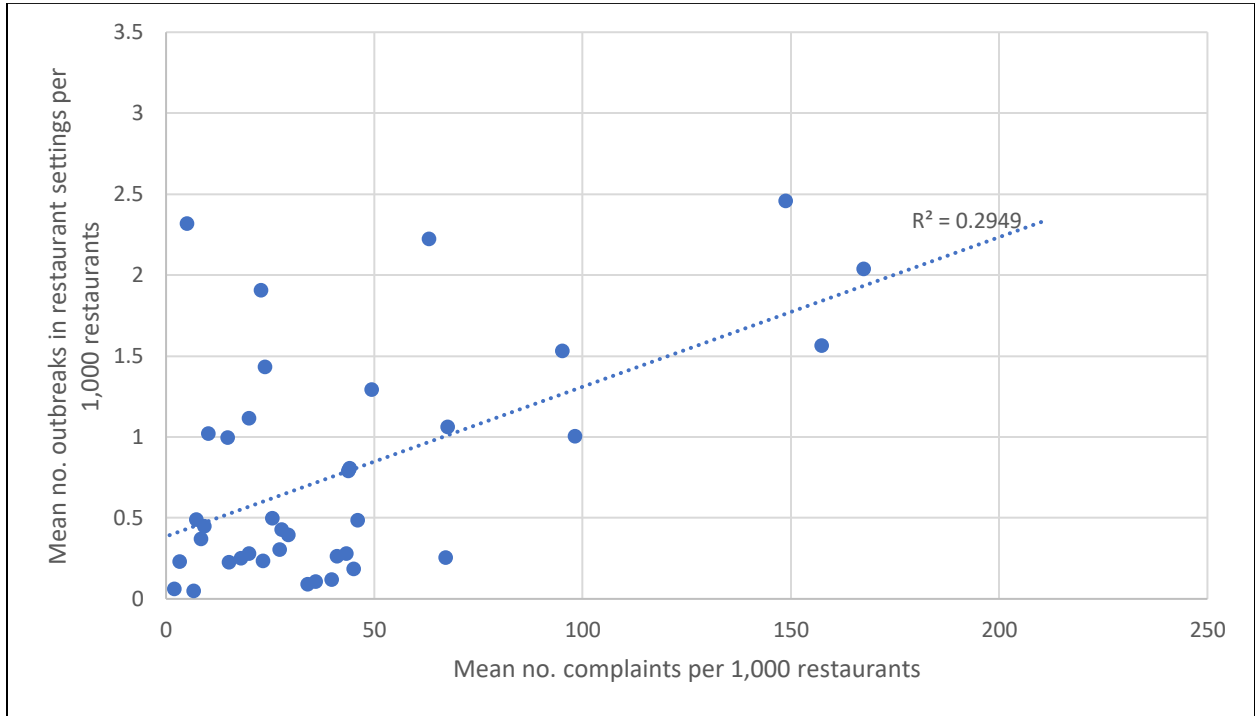


Figure 3.2. Mean annual number of norovirus outbreaks in restaurant settings per 1,000 restaurants reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) and the mean number of survey-reported complaints per 1,000 restaurants per year for agencies (●) participating in the restaurant grading project survey, 2016–2018.

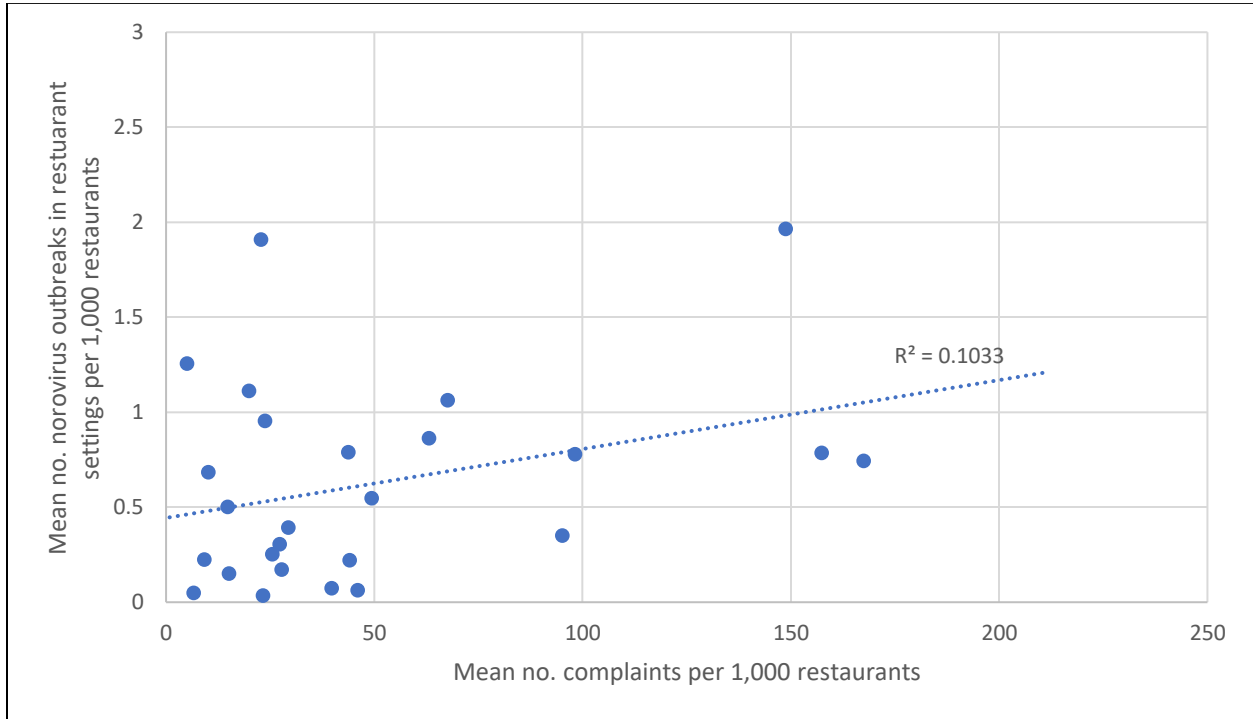


Figure 3.3. Mean annual number of bacterial toxin-mediated outbreaks in restaurant settings per 1,000 restaurants reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) and the mean number of survey-reported complaints per 1,000 restaurants per year for agencies (●) participating in the restaurant grading project survey, 2016–2018.

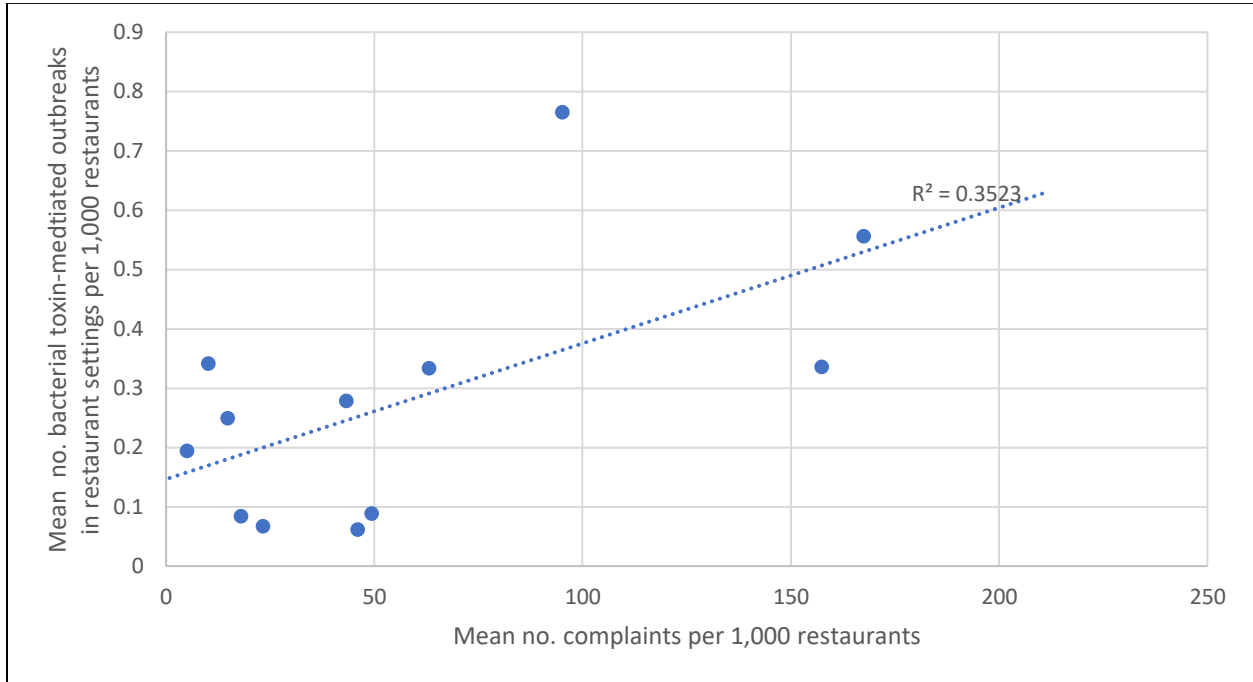
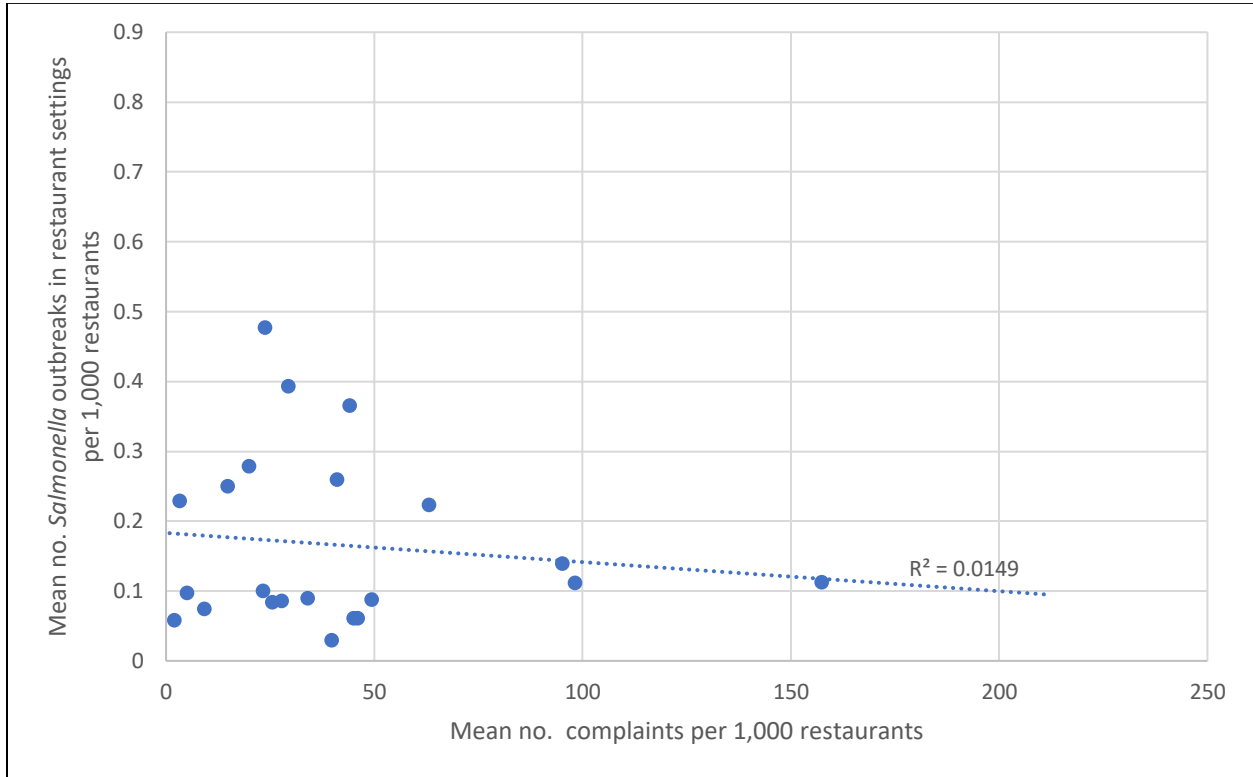


Figure 3.4. Mean annual number of *Salmonella* outbreaks in restaurant settings per 1,000 restaurants reported to the Foodborne Disease Outbreak Surveillance System (FDOSS) and the mean number of survey-reported complaints per 1,000 restaurants per year for agencies (●) participating in the restaurant grading project survey, 2016–2018.



CHAPTER 4: ENHANCING COMPLAINT SYSTEM SURVEILLANCE THROUGH ONLINE COMPLAINT FORMS

Kim TN, Decuir M, Smith K, Medus C, Hedberg CW. 2023. Use of Online Consumer Complaint Forms to Enhance Complaint-Based Surveillance for Foodborne Illness Outbreaks in Minnesota. *Journal of Food Protection* 86:100095.

Foodborne illness complaint systems that collect consumer reports of illness following exposure at a food establishment or event are a primary tool for detecting outbreaks of foodborne illness. Approximately 75% of outbreaks reported to the national Foodborne Disease Outbreak Surveillance System are detected through foodborne illness complaints. The Minnesota Department of Health added an online complaint form to their existing statewide foodborne illness complaint system in 2017. During 2018-2021, online complainants tended to be younger than those who used traditional telephone hotlines (mean age 39 vs 46 years; p-value <0.0001), reported illnesses sooner following onset of symptoms (mean interval 2.9 vs 4.2 days; p-value = 0.003), and were more likely to still be ill at the time of the complaint (69% vs 44%; p-value <0.0001). However, online complainants were less likely to have called the suspected establishment to report their illness than those who used traditional telephone hotlines (18% vs 48%; p-value <0.0001).

Of the 99 outbreaks identified by the complaint system, 67 (68%) were identified through telephone complaints alone, 20 (20%) through online complaints alone, 11 (11%) using a combination of both, and 1 (1%) through email alone. Norovirus was the most common outbreak etiology identified by both complaint system methods, accounting for 66% of outbreaks identified only via telephone complaints and 80% of outbreaks identified only via online complaints. Due to the COVID-19 pandemic in 2020, there was a 59% reduction in telephone complaint volume compared to 2019. In contrast, online complaints experienced a 25% reduction in volume. In 2021, the online method became the most popular complaint method. Although most outbreaks detected by complaints were reported by telephone complaints alone, adding an online form for complaint reporting increased the number of outbreaks detected.

4.1 INTRODUCTION

Current foodborne illness surveillance in the United States occurs primarily through two systems: pathogen-specific surveillance and complaint-based surveillance. Complaint-based surveillance is characterized by its rapidity in detecting outbreaks and ability to detect outbreaks caused by any type of hazard (21). Approximately 81% of local health departments have some form of a complaint system (42). Complaint-based surveillance is responsible for detecting approximately 75% of foodborne outbreaks reported to the Centers for Disease Control and Prevention (CDC) Foodborne Disease Outbreak Surveillance System (FDOSS) (43). However, the proportions of outbreak detection through complaint surveillance range from 56% in Florida (44) to as high as 79% and 80% in Minnesota (45) and Rhode Island (46), respectively. Federal food safety agencies including the Food and Drug Administration (FDA) (47) and the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) (48) operate complaint systems with online reporting specific to the food commodities they regulate. Poison Control Centers field some complaints related to foodborne illness from consumers (49), but these and other third-party complaint systems (50) require additional steps to get actionable information to the health jurisdictions responsible for investigating and controlling foodborne illness outbreaks (51).

In contrast to pathogen-specific surveillance, by which cluster detection can take 2-3 weeks, complaint surveillance does not rely on an ill individual to seek medical attention or undergo laboratory testing. This allows complaint-based surveillance to detect outbreaks within days of onset. It also allows detection of outbreaks caused by agents that are not reportable to public health, i.e., for which there is no routine clinical laboratory-based detection and reporting. Timely outbreak detection translates to improved ability to obtain more accurate exposure information by interviewing ill individuals closer to the time of exposure. Many complainants are focused on the last meal they, the complainants, ate. However, most foodborne illnesses have incubation periods that encompass multiple meals. Thus, complaint systems need to be able to collect food histories that span at least 2-3 days. The ability to compare multiple food exposures across multiple complaints increases the ability to detect an outbreak (26, 42).

The Minnesota Department of Health (MDH) established a statewide foodborne illness complaint surveillance system in 1998. Initially, this system provided the public with a central, statewide telephone number to report foodborne illness (45). As the technology became more accessible, email through the MDH website was added as a complaint reporting method, and, in 2017, a new online complaint form was added to the MDH website using Research Electronic Data Capture (REDCap) software. REDCap, developed in 2004, is a web application used to build and manage online surveys and databases that meet Health Insurance Portability and Accountability Act (HIPAA) compliance standards (52). Complaints initially received by local health agencies in Minnesota are forwarded to the central system. Questions on the MDH foodborne illness complaint intake forms were developed based on the CIFOR Guidelines recommendations and common exposures identified by foodborne outbreak investigation experience. Regardless of the complaint-receiving agency or method, ill individuals are interviewed with a standard reporting form and are prompted to enter demographic, symptom, and food history information that is collected and stored in a central database. Incomplete complaints

received online or by email are followed up by a telephone call from MDH staff. For complaints involving ill individuals from more than one household, MDH focuses on common meals shared by the households. For single individual or household complaints, a 4-day food history is obtained.

MDH defines a confirmed foodborne disease outbreak as an incident in which two or more persons experienced a similar illness after ingestion of a common food or meal, and epidemiologic evaluation implicated the meal or food as the source of illness. A probable foodborne outbreak is an incident in which there are two or more persons experienced a similar illness after ingestion of a common food or meal and a specific food or meal was suspected, but person-to-person transmission or other exposures could not be ruled out.

Approximately 88.5% of households in Minnesota have broadband Internet access and current grant funding initiatives by the state legislature look to expand access to unserved or underserved areas (53, 54). With increased access to the Internet (55) and general comfort of the public in using online information sources and in sharing information on social platforms, online tools provide an accessible and useful avenue for dissemination of food safety information to the public (56). A study using focus groups of U.S. consumers found that barriers to reporting foodborne illness included not knowing who to contact and believing that reporting would not be beneficial (57). Thus, there is a need for more easily identifiable procedures to contact and report foodborne illness to public health. Public health agencies could potentially meet this need by providing online spaces on their agencies' websites and/or social media accounts to capture reports of suspected foodborne illness.

The objective of this study was to investigate how addition of an online complaint reporting form (herein referred to as "online") to established telephone and email reporting methods influenced a public health agency's ability to improve detection of foodborne illness outbreaks.

4.2 METHODS

We queried the MDH complaint database for complaint records that met the following inclusion criteria: submitted from 1/1/2018 through 12/31/2021 and received by the MDH complaint-based surveillance system. Data were extracted from the MDH complaint database on December 5, 2022. Records received in 2017, the year the online form launched, were excluded as use of the online form during this time may reflect increased public awareness campaigns rather than actual use. Records were excluded if they contained no location information, did not involve a foodborne illness or illness-related issue (e.g., foreign objects in food, rodents/pests, COVID-19-related), or did not contain enough illness information to determine if a foodborne illness occurred (e.g., no illness onset date, no symptoms reported). A purpose of complaint-based systems is to enact control measures at points of exposure for foodborne illness. Complaint records without location information were excluded because they provided no opportunity for public health action. Grocery stores are regulated by the Minnesota Department of Agriculture, but may contain retail components, such as restaurants within the store or delis in which service is more akin to restaurants compared to retail food packed offsite, that are regulated by the Minnesota Department of Health. Unfortunately, the MDH complaint system cannot

differentiate which component is most relevant to the complaint; therefore, grocery store complaints were included in this analysis.

Each complaint record included method of complaint reporting (telephone, online, email, or other). Because only a small proportion of complaints were received by email or other methods, our study focused on differences in telephone and online methods as the dichotomous outcome variable. Outbreaks can be detected using a combination of telephone and online methods, which we classified as “combination telephone and online” when discussing outbreaks. However, we counted each complaint independently towards the respective method complainants chose to properly represent reporting method preference. We assessed the following variables: age of complainant, whether the complainant also contacted the suspected food establishment, reporting timeliness defined as the difference in days between illness onset and complaint report date, past and present symptomology at the time of reporting, if medical care was sought by the complainant prior to complaint, and whether a complaint led to an outbreak investigation as determined by MDH assessment of complaint information.

Race and ethnicity information was not routinely captured from telephone complainants and was therefore excluded from this study. Age, measured in years, is captured by both telephone and online complaint reporting methods. The instances in which a complaint is a self-report or a surrogate report (i.e., parent reporting for a sick child) are indistinguishable in this age variable. We decided on a cutoff age of 16 years, the legal driving age in Minnesota. Those at this age and older are presumed to be freer to travel independently and, therefore, have exposures that can only be reliably reported by themselves. Because it can be reasonably assumed that self-reports can be received from persons aged 16 years and older, age comparisons between reporting methods excluded reports (n= 1,945) from or about persons less than 16 years of age. Mean and median ages were compared using T-tests and Wilcoxon-Mann-Whitney tests, respectively.

Reporting timeliness was calculated as the difference in days between illness onset date and complaint receipt date. Despite a REDCap data validation-initiated pop-up text warning indicating to the complainant if an illness onset date precedes the complaint report date, 11 complainants reported negative incubation periods. An illness onset date preceding a complaint date would mean anticipated foodborne illness, which is illogical. However, since this may be due to entry error (perhaps due to poor use experience design of REDCap’s date/time fields) and not assumed to be a malicious or false complaint, these records were only excluded from summaries and comparisons of timeliness. Mean and median times were compared using T-tests and Wilcoxon-Mann-Whitney tests, respectively.

Comparisons were made between complaint reporting methods and associated predictor variables using Chi-square tests, odd ratios, and risk ratios, where appropriate. The level of significance was set at $\alpha=0.05$. Analysis was conducted using SAS 9.4 (SAS Institute, Cary, NC) and Microsoft Excel.

4.3 RESULTS

MDH’s complaint-based surveillance system received 3,768 complaints through telephone, online, email, and other methods of reporting from 2018 through 2021 (Table 1). More complainants preferred to report via telephone (n= 2,151, 62%) and online form (n= 1,284, 37%) than via email (n=36

307, 8%) or other methods (n= 26, 1%). In 2018, 1 year after the online form was made available, 34% of the total complaints to MDH were received via the online form (Figure 1). During the COVID-19 pandemic in 2020, telephone complaints decreased 59% compared to 2019. Online complaints were less impacted by the pandemic, with just a 25% reduction in volume. In 2021, online reporting became the most popular complaint method (Table 1).

Complainant Demographics. People who identified as female made up the majority of complainants for both reporting methods (online = 63%, telephone = 59%) (Table 1). Online complainants had higher odds of being female-identifying than telephone complainants (OR = 1.18, p = 0.029) (Table 2). For complainants 16 years of age and older, online complainants were younger than telephone complainants (mean = 39 vs 46 years, p<0.0001) (Table 1).

Foodborne Illness Outbreaks. A lower proportion of online complaints resulted in an outbreak investigation compared to telephone complaints, but the difference was not statistically significant (OR = 0.73, p = 0.077) (Table 2). MDH investigated 194 confirmed and probable foodborne outbreaks during 2018-2021. Of these, 99 (51%) were identified through complaint surveillance, either by a single complaint to a local public health agency (which was then forwarded to MDH), single complaint to MDH, or multiple complaints (Table 3). For outbreaks identified by the complaint system, 67 (68%) were identified by telephone complaints alone, 20 (20%) through online complaints alone, 11 (11%) using a combination of both, and 1 (1%) through email alone. Norovirus (telephone alone= 66%, online alone= 80%, combination telephone and online= 82%) was the most common outbreak etiology confirmed or suspected across all complaint methods (Table 3). The MDH complaint system detected 51% of foodborne illness outbreaks in Minnesota during 2018-2021.

Timeliness and Healthcare Seeking. The odds of still being sick at the time of reporting were higher for online complainants than telephone complainants (OR = 2.74, p<0.0001) (Table 2). Relatedly, online complainants reported their illness to MDH significantly more quickly than telephone reporters (2.9 days vs 4.2 days, p<0.0001) (Table 1). Conversely, online complainants were less likely to call the suspected complaint location to report their illness (OR = 0.24, p<0.0001) and less likely to have sought medical care at the time of report than telephone complainants (OR = 0.68, p = 0.0025) (Table 2). There were no notable differences in symptoms or hospitalizations between online and telephone complainants (Appendix 1).

4.4 DISCUSSION

For detecting outbreaks from foodborne illness complaints, the first step is the collection of exposure and illness information, such as food history, symptoms, and illness onset times through interviewing. Interviews conducted to gather this information are typically done via telephone by public health agencies, most often during traditional business hours (8am – 5pm) when many individuals are at work or are otherwise unavailable. This time constraint can delay collection of exposure information and may present issues of recall bias or incomplete information. We observed a significantly shorter time between the dates of illness onset and complaint reporting with the online reporting method compared to the telephone reporting method. Online complaint reporting forms, accessible through public health

agency websites at any time, can alleviate the frequency or severity of these biases by allowing complainants to report information at their convenience. Complainants using the online reporting method were more likely to still be sick at the time of reporting. The immediacy of their illness may increase complainants' motivation to cooperate with public health agencies gathering exposure information. As illness wanes, interest in identifying the source may also.

In contrast to a study by Green and colleagues (58) that found complainants were three times more likely to report a complaint to the suspected complaint location than the health department, complainants to MDH using the online form were less likely to have called the suspected complaint location to report their illness than telephone complainants. This could be due to their general preference for online communication methods, which may not be used by or provide direct access to some complaint locations or the disinclination of the younger population to talk on the phone (59). A smaller proportion of online complainants sought medical care than telephone complainants, 13% compared to 18%. It is plausible that, given the severity of their illness to warrant medical care in the first place, complainants may perceive that calling may result in a more immediate response from public health. Alternatively, because online complainants are reporting sooner after illness onset, they may not have had time to seek medical care before reporting. Assumptions cannot be made about future medical care seeking activities (i.e., whether they choose to seek medical care after reporting a complaint to MDH).

Limitations. Minnesota benefits from a statewide complaint system in which consumer complaints are primarily received and reviewed by centralized staff. Implementing online complaint forms at the local agency level without a means to continuously communicate across local jurisdictions might not provide the wide lens of surveillance available at the state level. Differences in funding resources may also limit implementation of online complaint reporting at the local level. Most state agencies receive federal funding, while local agencies receive very little, if any, federal funding and rely heavily on fees and fines associated with inspection duties (60). Our analysis considered each complaint as a separate record, though complainants may report a complaint multiple times using multiple methods during our study period. Though the impact would be low considering our robust sample size, if there are complainants who reported multiple complaints, they would be over-represented in our analysis. The odds ratios presented in Table 2 are unadjusted and, therefore, may be confounded by age, gender, and other factors.

Challenges to implementation of an online complaint form. Hosting an online form on a website requires resource investments in information technology personnel and maintenance, which may be limited given the finite budget with which local agencies operate. Even within local agency websites, competing information may obscure food safety information and illness complaint forms, making them more difficult to find and use (61). Smaller public health agencies may not have a dedicated website or webpage or may not have information technology assistance to set up and maintain an online reporting system. Future studies may benefit from economic analysis of implementing online complaint surveillance methods whether hosted by the public health agency itself or through other internet platforms.

Complainants who indicated an age of 15 years or younger were excluded from age-related analyses. While young persons may report illness, it is more likely that complaints associated with this younger age group were made by proxy (e.g., a caretaker reporting the illness of a child). Exclusion of complainants aged 15 years and younger may provide an inaccurate picture of the reporters themselves. However, no determination could be made from our data between self-reporting and proxy-reporting. This age cutoff was chosen based on assumptions of complainant maturity and information reliability. However, it is possible that younger populations may feel more comfortable self-reporting their illness than we anticipated, and that the exposure information provided by younger complainants may be no less reliable than that of older complainants. In general, age demographic identification of populations using online reporting tools can inform public health information and resource promotion and dissemination. While not collecting race and ethnicity identification information means we cannot evaluate the racial and ethnic representativeness of these data, no justification can be made for prioritizing collection of this data as they have no bearing on identifying and responding to outbreaks.

Reduction in foodborne illness and complaint volume during COVID-19 pandemic. The MDH foodborne illness complaint volume decreased in the years following recognition of the COVID-19 pandemic compared with prior years. This trend likely reflects a true reduction in foodborne illness incidence in Minnesota associated with statewide temporary suspension of dine-in service at retail food establishments, changes in healthcare-seeking behaviors, decreased travel, and changes in social gathering willingness. Nationally, effects of the pandemic resulted in a single-year 26% decrease in illnesses commonly associated with foodborne transmission (62). The lower proportion of outbreaks detected by the MDH complaint system during our study period (51%), compared with the previous estimate of 80% (45), could be attributed to effects of the COVID-19 pandemic on reducing food consumption outside the home. Complaint systems often capture outbreaks linked to restaurants or single-occurrence exposure events, such as social gatherings. Because the pandemic restricted restaurant operations and reduced social gathering willingness, outbreaks associated with such establishments and events were also reduced. Nevertheless, with over half of all foodborne outbreaks detected by the MDH complaint system, complaint-based surveillance remains a primary source for outbreak detection.

In 2021, the online reporting method became more popular than the telephone. A by-product of the COVID-19 pandemic was the increase in online presence of restaurants as they began using online platforms to sustain business - whether through third party delivery apps or to manage incoming take-out orders with limited staff capacity. This increased online presence may drive more consumers to use online resources to not only order food but to also report illness. This differential effect in online reporting following the reopening of restaurants and public gathering spaces may also reflect the demographics of those who might be more willing to risk COVID-19 by eating out. Younger people, who may be more apt to use online reporting, may have been more ready to go out to eat than older people (63).

Enhancement, not replacement. While comfort with online reporting of foodborne illness has increased, online reporting alone may not yet be a sufficient reporting method to capture most outbreaks occurring within a population. As evidenced by the number and wider range of etiologies of

outbreaks reported by telephone alone and the greater odds of a telephone complaint resulting in an outbreak investigation compared with the online form alone, there is still substantial value in operating a telephone-based complaint system. Therefore, adding an online form for complaint reporting can enhance telephone-based surveillance efforts, but cannot replace them. A variety of online crowdsourcing platforms, such as iwaspoisoned.com, collect foodborne illness information from consumers. However, consumers should be made aware that only reporting avenues provided by official public health agencies can trigger appropriate investigation and regulatory corrections. Further, while datamining of consumer review platforms such as Yelp (64) and Twitter (65) have been suggested as complementary methods of surveillance to traditional surveillance systems, it remains to be seen whether these efforts are worth the intensive public health resource investments they require.

As of January 2023, MDH added an online form in three additional languages- Hmong, Somali, and Spanish. Evaluations of public health systems, like this study, will allow MDH to identify populations that are not captured and develop methods to remedy the disparity. Overall, use of the online form was a success as it increased the number of outbreaks MDH was able to detect. Rapid reporting and detection of foodborne illness outbreaks, a defining feature of complaint-based surveillance, enables public health to obtain exposure information closer to the time of exposure than pathogen-specific surveillance. Capitalizing on this asset of speed, online reporting tools that provide additional avenues of illness reporting to public health agencies at the convenience of ill persons will likely be important technological advancements to adapt current complaint-based surveillance systems to be timelier, more user-friendly, and more inclusive of the populations at risk.

4.5 TABLES AND FIGURES

Table 4.1. Minnesota Department of Health foodborne illness complaint-based surveillance system complainant demographic and follow-up information compared using Chi-square tests for independence, 2018-2021.

	N	Telephone, n (%)	Online, n (%)	p-value
Total Complaints ^{a,b}	3,435	2,151	1,284	
2018		809 (66)	415 (34)	
2019		731 (70)	312 (30)	
2020		302 (56)	233 (44)	
2021		309 (49)	324 (51)	
Gender	3,312			
Female		1,268 (59)	805 (63)	
Male		803 (37)	421 (33)	
Trans/non-binary		--	4 (<1)	
Prefer not to say		--	8 (<1)	
Missing		80 (4)	43 (3)	
Age, years	2,485	1,295	1,190	
Mean (SD)		46 (17)	39 (13)	<0.0001 ^c
Median		46	35	
Range		16-93	16-84	
Missing		856	94	
Illness onset to report time, days	3,308	2,027	1,281	
Mean (SD)		4.2 (11)	2.9 (13)	<0.0001 ^c
Median		2	1	
Range		0 – 221	0 – 366	
Seek Medical Care	2,579	1,870	709	0.003
No		1,529 (82)	618 (87)	
Yes		331 (18)	91 (13)	
Still Sick	3,206	1,979	1,227	<0.0001
No		1,100 (56)	385 (32)	
Yes		879 (44)	842 (69)	
Complainant called establishment		1,342	822	<0.0001
No		701 (5)	673 (82)	
Yes		641 (48)	149 (18)	
Follow-up Type		884	459	0.08
No outbreak investigation		755 (85)	408 (89)	
Outbreak investigation		129 (15)	51 (11)	

^a total complaints received by hotline and online methods; total for all complaint methods= 3,768

^b row percentages

^c Wilcoxon-Mann-Whitney test p-value

Table 4.2. Adjusted odds ratios for complainant demographic and follow-up information comparing online complainants to telephone complainants received by the Minnesota Department of Health, 2018-2021.

	Odds Ratio (95%CI)	p-value
Gender (Female/Non-Female)	1.18 (1.02 – 1.36)	0.029
Seek Medical Care (Yes/No)	0.68 (0.53 – 0.87)	0.0025
Hospitalized (Yes/No)	1.22 (0.66 – 2.26)	0.52
Still Sick (Yes/No)	2.74 (2.36 – 3.18)	<0.0001
Complainant Called Establishment (Yes/No)	0.24 (0.20 – 0.30)	<0.0001
Follow-up Type (Outbreak investigation/ No Outbreak Investigation)	0.73 (0.52 – 1.03)	0.077

Table 4.3. Number of complaint system-identified^a Minnesota Department of Health outbreak investigations by etiology, 2018-2021 (N=99^b).

	Telephone alone ^c	Online alone	Telephone + Online combination
Norovirus	44	16	9
Bacterial intoxication- unknown pathogen	9	1	1
Scombroid toxin	3	--	--
<i>Staphylococcus aureus</i>	1	--	--
<i>Clostridium perfringens</i>	1	--	--
<i>Salmonella</i>	3	1	--
<i>Vibrio</i>	3	--	--
<i>Campylobacter</i>	--	1	--
<i>Cyclospora</i>	2	--	--
Unknown	1	1	1
Total	67	20	11

^a identified by a single complaint to a local public health agency, single complaint to MDH, or multiple complaints.

^b includes one outbreak identified by Email only

^c includes three norovirus outbreaks identified by Telephone and Email in combination, but not by Online form.

Appendix 4.1. Minnesota Department of Health foodborne illness complaint-based surveillance system complainant hospitalization and symptom information compared using Chi-square test for independence, 2018-2021.

	N	Telephone, n (%)	Online, n (%)	p-value
Provider requested stool specimen		295	95	0.45
No		189 (61)	59 (67)	
Yes		120 (39)	31 (34)	
Hospitalized	360	278	82	0.52
No		229 (82)	65 (79)	
Yes		49 (18)	17 (21)	
Symptoms ^a				
Vomiting	2146	1298 (60)	848 (40)	
Diarrhea	2775	1730 (62)	1045 (38)	
Cramps	2791	1658 (59)	1133 (41)	
Fever	819	421 (51)	398 (49)	
Bloody stool	150	81 (54)	69 (46)	
Nausea	541	406 (75)	135 (25)	
Other	1075	617 (57)	458 (43)	
Symptoms of still ill complainants ^a				
Still Vomiting	394	141 (36)	253 (64)	
Still Diarrhea	1253	643 (51)	610 (49)	

^a row percentage

Figure 4.1. Minnesota Department of Health Foodborne Illness Complaint Trends by Complaint Method and Year, 2018-2021.

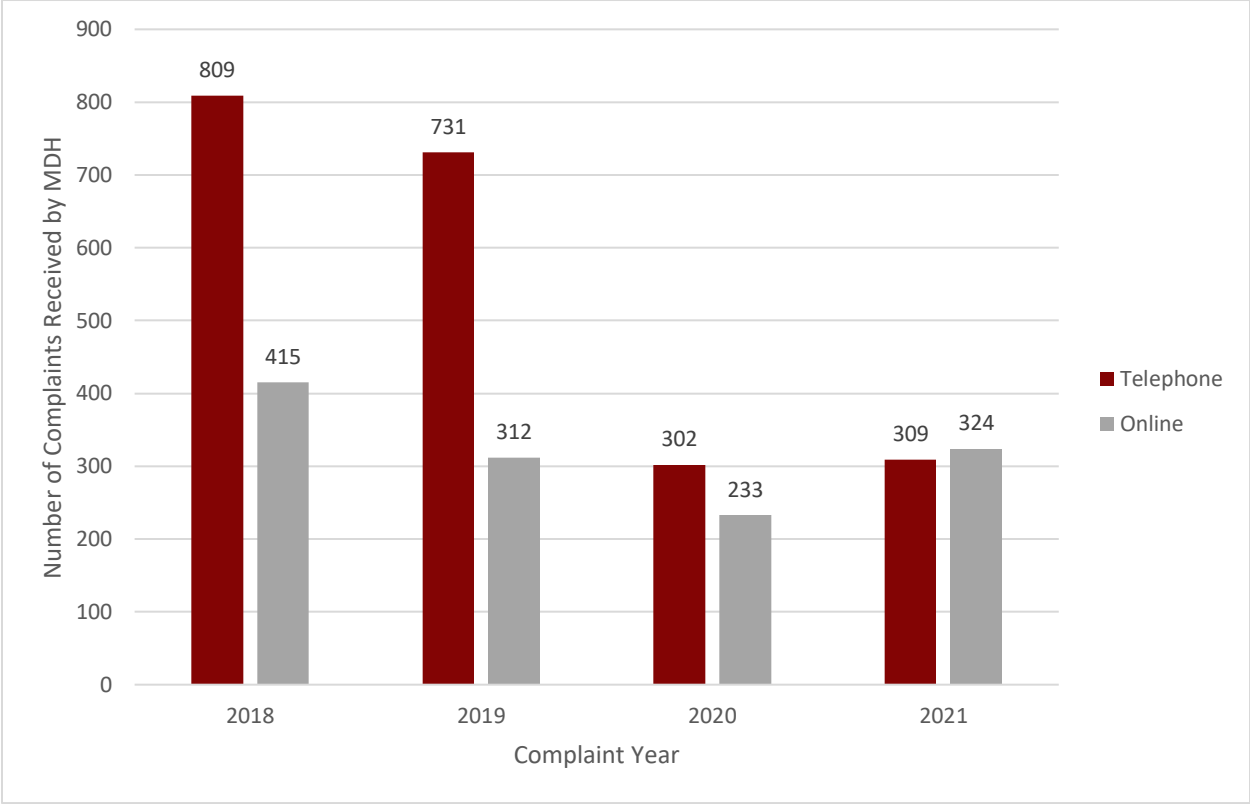


Figure 4.2. Minnesota Department of Health Foodborne Illness REDCap Online Complaint Form, 2022.

What is the name of the restaurant/establishment?	<input type="text"/>
Where is [food_establishment] located?	<input type="text"/>
	Expand
What date and time was your meal at [food_establishment]?	<p>Please provide the address or cross-streets and city</p> <input type="text"/> <input type="button" value="Now"/> M-D-Y H:M <small>If you ate there multiple times, please fill out multiple forms</small>
Incubation	<input type="text"/> View equation
You have entered a meal date and time after when you said your illness started ([onset])	
What did you eat and drink at [food_establishment]?	<input type="text"/>
	Expand
Did you eat here with other people?	<input type="radio"/> Yes <input type="radio"/> No
	reset
How many people were in your dining party at [food_establishment]?	<input type="text"/>
	<small>Include yourself in this number</small>
How many people who ate with you at [food_establishment] became ill?	<input type="text"/>
	<small>Include yourself in this number</small>
You have indicated that more people are ill than attended this meal	
How many different households have ill people who ate at [food_establishment]?	<input type="text"/>
	<small>Include your household in this number</small>
You have indicated that more households have ill people than the number of ill people you reported	
Have you contacted [food_establishment] to let them know about your illness?	<input type="radio"/> Yes <input type="radio"/> No
	reset

CHAPTER 5: BALANCING PREVENTION AND SURVEILLANCE OUTCOMES

Kim TN, Edmundson AR, Hedberg CW. Framework for balancing the effects of environmental health prevention and epidemiologic surveillance activities in restaurant-associated foodborne illness outbreaks, 2016-2018.

Restaurants have long been recognized as important settings for foodborne illness outbreaks. The impact that the COVID-19 pandemic-initiated restaurant restrictions had on the reduction of outbreaks further illustrates the close relationship between interventions implemented in restaurants and foodborne illness. A lack of detail on how restaurant inspection agencies conducted surveillance for consumer complaints precluded a more comprehensive evaluation of the relationships between potential prevention effects of grading and disclosure practices and the effectiveness of outbreak detection through consumer complaint surveillance. Using data from two surveys and CDC's national outbreak database, this study evaluated the association between the number of foodborne illness outbreaks in restaurant settings reported to the CDC and the complaint system methods of restaurant inspection agencies while adjusting for the effects of restaurant grading and disclosure as prevention measures. Agencies using numerical score grading reported 292% more (IRR= 2.92 95% CI= 1.33 – 6.38, p-value= 0.007) restaurant outbreaks per 1,000 restaurants compared with those that do not use numerical scores, while those using letter grading reported 93% fewer (IRR= 0.074 95% CI= 0.186 – 0.295, p-value= <0.001) restaurant outbreaks per 1,000 restaurants compared with those that do not use letter grades after adjusting for surveillance measures. Those with a centralized complaint database system reported 203% more (IRR= 2.03 95% CI= 1.06 – 3.91, p-value= 0.033) restaurant outbreaks per 1,000 restaurants than those without a centralized system. For every one complaint received by surveyed agencies in the 3-year study period, there was a 0.1% increase in restaurant outbreaks per 1,000 restaurants detected (IRR= 1.001 95% CI= 1.0006 – 1.002, p-value= <0.001), adjusting for prevention measures. The novel framework introduced in this study will be a powerful tool for future evaluations of complaint-based surveillance systems that account for any biases introduced by effective prevention measures.

5.1 INTRODUCTION

Advances in laboratory diagnostics (22, 23) and epidemiologic methods (66, 67) have improved the ability of public health agencies to detect, investigate, and prevent foodborne illness (68). Restaurants are important settings for foodborne illness transmission. Of the 841 foodborne illness outbreaks reported to CDC in 2017, 489 were attributed to foods prepared in restaurant settings with 366 (48%) specifically from sit-down dining restaurants (6). While interventions implemented to control the COVID-19 pandemic led to 10-41% declines in pathogens transmitted commonly through food in 2020 compared to the preceding 3 years, the number of restaurant-associated outbreaks declined by 70% (62, 69). This occurred in the context of a 15% drop in expenditure for food consumed outside the home (70). The impact that pandemic-initiated restaurant restrictions had on the reduction of outbreaks further illustrates the close relationship between interventions implemented in restaurants and foodborne illness.

There are two primary sources of surveillance for detecting outbreaks of foodborne illness: pathogen-specific and complaint-based (21). Pathogen-specific surveillance is primarily responsible for detecting multistate outbreaks caused by agents such as *Salmonella* and Shiga toxin-producing *E. coli*, that are detected through clinical laboratory testing. Restaurants are frequently identified as settings for sub-clusters of cases in outbreaks associated with distribution of contaminated food commodities. However, most outbreaks in restaurants are detected through surveillance of complaints from consumers of the establishment. Thus, the effectiveness of consumer complaint surveillance by local health agencies may determine the number of foodborne outbreaks the agency is likely to detect.

A survey of restaurant inspection agencies (n= 140) conducted in 2020 found that agencies that conducted grading of restaurant inspections and routinely disclosed the results to the public reported fewer foodborne illness outbreaks than did agencies that did not grade or disclose inspection results (25, 26). These findings suggested a potential protective effect of these practices on foodborne illness. However, there was also a positive association between the number of foodborne illness complaints received by agencies in the study and the number of outbreaks detected. A lack of detail on how agencies conducted surveillance for consumer complaints precluded a more comprehensive evaluation of the relationships between potential prevention effects of grading and disclosure practices and the effectiveness of outbreak detection through consumer complaint surveillance.

The objectives of this study were to: 1) identify methods that restaurant inspection agencies use to conduct surveillance for consumer complaints of foodborne illness and to 2) link them to inspection grading and disclosure practices to 3) evaluate the association between the number of foodborne illness outbreaks in restaurant settings reported to the Centers for Disease Control and Prevention (CDC) Foodborne Disease Outbreak Surveillance System (FDOSS) (40) and the complaint system methods of restaurant inspection agencies while adjusting for the effects of restaurant grading and disclosure as prevention measures.

5.2 METHODS

Respondents to a previous Restaurant Grading Survey were contacted via email and phone to obtain information about how they conducted surveillance for consumer complaints of foodborne illness linked to food service establishments in their jurisdiction. This new survey (Complaint System Survey) was launched on March 11, 2022 and closed on January 2, 2023. We linked respondent agencies by jurisdiction to the exposure locations for restaurant-associated outbreaks reported to the national foodborne disease outbreak surveillance system (FDOSS) (40), as previously described (26). Briefly, these

FDOSS data, extracted on November 18, 2019, included foodborne outbreaks where food was prepared in a restaurant setting within the jurisdiction of the agency and where the first illness occurred between January 1, 2016 and December 31, 2018.

From the Restaurant Grading Survey, we used the variables of number of restaurants, cumulative average number of complaints (2016-2018), average number of routine inspections performed per year, disclosure practices (online, point of service, none), and grading practices (numerical score, letter grading, none). From the Complaint System Survey, we examined the variables of having a complaint system, operating a centralized complaint system, and collection of food history for complainants at initial complaint intake. Analysis for this study used the subset of agencies that had a complaint system as those without a system represented only 9% of respondents and, of those, fewer reported outbreak outcomes. We obtained the number of restaurant outbreaks and the pathogens attributed to these outbreaks from FDOSS.

The primary outcome for this study was the cumulative count of restaurant outbreaks where the exposure occurred within the jurisdiction of the responding agencies for the 3-year study period of 2016-2018. The secondary outcome examined in this study was the number of restaurant outbreaks per 1,000 restaurants per year, which was further divided by pathogen (norovirus, *Salmonella*, and toxin-mediated) for comparison of medians.

Predictors included in the model were either agency-level restaurant grading and disclosure practices, or operational characteristics of consumer complaint surveillance. The prevention predictors included: disclosure (routinely disclosed restaurant inspection results to the public = 1, did not disclose = 0), grading (used summary grades to categorize restaurant inspection results = 1, did not grade = 0), numerical score (used a numerical score for grading restaurant inspection results = 1, did not use = 0), letter grade (used a letter grade for grading restaurant inspection results = 1, did not use = 0) and the average annual number of routine restaurant inspections performed by the agency. The surveillance predictors included collection of a food history of 3 days or more from consumers complaining about a possible foodborne illness (collected any food history = 1, no food history collected = 0), operated a centralized complaint system to allow for detection of clusters of complaints associated with food service establishments (used a centralized complaint system = 1, did not use = 0), and the 3-year cumulative average number of complaints received by the agency. We also included as a model offset, the number of food establishments to account for differences for jurisdiction size. For binary variables such as centralized complaint system or collection of any food history, we compared medians using Wilcoxon-Mann-Whitney tests.

There were 29 states represented among the 77 respondents. No clustering by state was found between responding agencies. No overdispersion was evident in the final model as indicated by the likelihood ratio test of alpha, which was not significant, and an overdispersion parameter, which was less than zero.

Our overarching theoretical assumption was that foodborne outbreaks occur annually in every jurisdiction whether they are detected and reported or not. As such, we did not allow a count of zero outbreaks for any agency. We compared Akaike information criterion (AIC) and Bayesian information criterion (BIC) values (71, 72) for general and zero-truncated Poisson and negative binomial regression models to determine goodness of fit. Based on comparison of these goodness of fit values between models, and a statistically significant Likelihood Ratio Test (LRT) based on a chi-square distribution, we chose a zero-truncated negative binomial regression model (73) to calculate adjusted incidence rate

ratios (IRR). The level of significance was set at $\alpha=0.05$. Analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC) and Stata/BE version 17.0 (StataCorp LLC, College Station, TX).

5.3 RESULTS

Of the 140 agencies that were contacted for this follow to the Restaurant Grading Survey, a total of 77 local inspection agencies responded (55% response rate). Most responding agencies represented county government-level agencies followed by city and city-county combination agencies (Table 1). Most respondents (91%) reported having a consumer complaint surveillance system that allows the public to report suspected foodborne illnesses that may have been caused by a restaurant. Those that did not have a system ($n=7$, 9%) cited that complaints were taken by the state health department or other state agency ($n=3$), lacked resources ($n=3$) or personnel ($n=2$) to operate a system, or had too few complaints to warrant a system ($n=1$). We limited further analysis to those agencies with a complaint system.

Of the 70 agencies that had some system for collecting consumer complaints, 47 (67%) had a centralized system in which data were collected into one database that could be analyzed to look for clusters. Those who chose "Other" ($n=7$) explained that they were in the process of developing a system and were therefore recategorized as not having a centralized system. These responses were combined with those who answered that they did not have a centralized complaint system (total $n=23$). Although recommended by the Council to Improve Foodborne Outbreak Response (21), only 53 (74%) agencies routinely collected any food history from complainants. Forty-three agencies collected 3-day food history while nine agencies collected 5 or more days of food history (Table 1).

Although no statistically significant differences in the median number of restaurant outbreaks per 1,000 restaurants were detected among complaint system characteristics or disclosure and grading methods, the trends shown in Table 2 indicate that the effects of these characteristics may differ by pathogen. Additionally, no statistically significant differences in the number of complaints per 1,000 restaurants or restaurant outbreaks per 1,000 restaurants were detected in these characteristics (Appendix 1). In contrast, the zero-truncated negative binomial regression model with the two continuous variables of average number of complaints (p -value= 0.005) and average annual number of routine inspections (p -value= 0.013) performed were statistically significant predictors of the number of restaurant outbreaks per 1,000 restaurants for the 3-year study period. Overall, the model had a statistically significant goodness of fit as measured by the Likelihood Ratio Test (LRT) (LRT p -value= 0.025) (Table 3). After adjusting for the surveillance predictors of any food history collected and centralized complaint system, the cumulative average number of complaints (p -value= 0.190) was no longer statistically significant in predicting the number of restaurant outbreaks per 1,000 restaurants (LRT p -value= 0.09).

The zero-truncated negative binomial regression model with the prevention factors as predictors of the number of restaurant outbreaks per 1,000 restaurants showed only one statistically significant predictor (letter grade) but the overall model did not have a statistically significant goodness of fit (LRT p -value= 0.206) (Table 5). In this model, the average number of routine inspections performed per year was no longer significant as it was in Table 3.

When controlling for surveillance and other prevention factors, in a fully adjusted model (LRT p -value= 0.0015), the number of restaurant outbreaks per 1,000 restaurants reported by agencies that disclosed inspection results to the public via an online platform for the 3-year study period was 24% (IRR= 0.76, 95% CI= 0.303 – 1.93, p -value= 0.569) lower than for those that did not disclose online (Table 5).

6). Agencies disclosing at the point of service (POS) reported 20% more outbreaks than those not disclosing at the POS (IRR= 1.20, 95% CI= 0.502 – 2.86, p-value= 0.683). The two most frequently used grading methods were included in the model. Agencies using numerical score grading reported 292% more (IRR= 2.92 95% CI= 1.33 – 6.38, p-value= 0.007) outbreaks compared with those that do not use numerical scores, while those using letter grading reported 93% fewer (IRR= 0.074 95% CI= 0.186 – 0.295, p-value= <0.001) outbreaks compared with those that do not use letter grades.

Compared with agencies that do not collect food history, those that collect this data reported 250% more (IRR= 2.50 95% CI= 0.43 – 14.7, p-value= 0.309) detection of outbreaks than those that did not collect a food history (Table 6). Those with a centralized complaint database system reported 203% more (IRR= 2.03 95% CI= 1.06 – 3.91, p-value= 0.033) outbreaks than those without a centralized system. Complaints provide signals for outbreak detection. For every one complaint received by surveyed agencies in the 3-year study period, there was a 0.1% increase in outbreaks detected (IRR= 1.001 95% CI= 1.0006 – 1.002, p-value= <0.001). For every routine inspection performed every year by surveyed agencies, there was a 0.1% decrease in outbreaks detected (IRR= 0.99995 95% CI= 0.99990 – 0.999998, p-value= 0.039).

5.4 DISCUSSION

Routine restaurant inspection and inspection grading and disclosure provide some understanding of prevention effectiveness. Disclosure and grading practices are intended to motivate restaurant operators to prioritize food safety within their establishments. After adjusting for surveillance factors, grading using a letter grade significantly prevented outbreaks in restaurant settings. However, the method used to disclose these grades to the public warrant further investigation as disclosure factors were not statistically significant in the prevention-specific and fully adjusted models. Despite this, the trends seen in the median average number of restaurant outbreaks per 1,000 restaurants suggest pathogen-specific effects for both prevention and surveillance factors. Due to the low number of respondents in our Complaint System Survey, our analysis was underpowered to detect statistically significant differences in outbreak outcomes among prevention and surveillance factors. Future studies with sufficient sample size on the pathogen-stratified effects of prevention and surveillance measures may be useful. Our findings also showed the importance of routine restaurant inspections as a prevention measure, even after adjusting for differences in surveillance methods that could hinder detection and reporting.

Centralized surveillance database systems are useful in detecting outbreaks. Centralized systems allow for the detection of outbreak signals that occur over time. This is essential for pathogens with longer incubation periods such as *Salmonella* and *E. coli* (74). For respondents to our survey, public health outcomes for those without a complaint system were limited, which could be an indication of limited ability to detect outbreaks. Toxin-mediated outbreaks are often related to single-occurrence events and, therefore, may be detected by a single complaint report. Outbreak detection from a single complaint report may not reflect the full utilization of a centralized system. Consistent with a previous study documenting the improved ability of centralized database to detect outbreaks (42), we concluded that having a centralized system to manage consumer complaints is useful for detecting more outbreaks than not having a centralized system.

Increasing complaints can enhance opportunity to detect more outbreaks. The association with increased complaint reception and increased ability to detect outbreaks found in this study is consistent with previous findings (26). Complaint quality should also be considered by agencies looking to increase their complaint intake volume. Collecting food history lessens the chance for last meal bias in

reporting and management of these complaint data in a central location allows for analysis to detect outbreak signals. Although not statistically significant, our results suggest that collecting food history of 3 days or more was a practice that may detect more outbreaks than not collecting this information.

Limitations. It has been estimated that 22% of small agencies with jurisdictions less than 250,000 people do not have capacity to record and respond to foodborne illness complaints (60). While it is possible that unmeasured agency-specific reporting rules and capacity factors such as staffing characteristics, such as levels and training, can affect complaint system management and outbreak investigation and reporting. Because the study sample is a subset of respondents to a previously conducted survey, it is worth noting that a more ample sample size may have produced more significant and robust associations.

Application to practice. Studies on the effects of public health practice often examine the effects of prevention and surveillance measures separately, though these measures work simultaneously in practice. When we examined these factors separately, the results were unstable in predicting the effects they had on the number of outbreaks. However, when combined in a fully adjusted model, the prevention and surveillance factors predicted the outcome in a cohesive and significant manner. The novel framework introduced in this study will be a powerful tool for future evaluations of complaint-based surveillance systems that account for any biases introduced by effective prevention measures. Improving consumer complaint system structure and management can bolster outbreak detection and maximize limited public health resources while increasing the efficiency of complaint-based surveillance.

5.5 TABLES AND FIGURES

Table 5.1. Summary statistics of local agency respondents to the Follow-up Restaurant Grading Survey Focused on Complaint Systems, 2016-2018 (N=77)

	n (%)
Agency Type	
County	50 (65)
City	10 (14)
City-County Combination	9 (12)
District	5 (6)
Other, specify:	3 (4)
Regional Collaborative	1
Town	1
5 County Public Health Agency	1
Does your agency have a consumer complaint surveillance system that allows the public to report foodborne illnesses they suspect were caused by particular products, events, or food establishments?	
No	7 (9)
Complaints are taken by the state health department or other state agency	3 (43)
Too few complaints received to warrant a complaint system	1 (14)
Lack of personnel	2 (29)
Lack of resources	3 (43)
Complaint surveillance is not effective in detecting foodborne illness outbreaks	1 (14)
Yes^a	70 (91)
Statewide phone number	14 (20)
Local phone number	68 (97)
Email	59 (84)
Online complaint form	47 (67)
Our agency monitors social media (e.g., health department Twitter)	18 (26)
Privately managed reporting site reports to our agency (e.g., iwaspoisoned.com)	16 (23)
Other, specify:	4
In person (face to face)	2
311 system	1
State Department of Health website	1
Do you have a complaint system in which data are collected into one database that can be analyzed to look for clusters of complaints or repeated complaints regarding the same facility?	70
Yes	47 (67)
No	16 (23)
Other	7 (10)
How do complaints get recorded by your agency?	
Informally on an available sheet of paper	4 (6)
Email inbox	8 (11)
Paper log	12 (17)
Computer log: local hard drive	17 (24)

Computer log: non-cloud-based database accessible by multiple computers	19 (27)
Computer log: cloud-based database	40 (57)
Other	2 (3)
Upon initial intake of a complaint, what information is recorded by your agency?	70
Contact information of the caller	70 (100)
Foods eaten by complainant at complaint location	64 (91)
Illness symptoms	67 (96)
Location/establishment of complaint	69 (99)
Medical diagnosis if healthcare was sought	56 (80)
Number of ill persons who ate food from complaint location	59 (84)
Suspected food product and product packaging information (if applicable)	58 (83)
Stool specimen was obtained by healthcare provider	30 (43)
Willing to give a stool specimen to public health	23 (33)
Food history	52 (74)
3-day food history	43
5-day food history	4
>5-day food history	5
Date of illness onset	61 (87)
Time of illness onset	60 (86)
Date of illness recovery	50 (71)
Time of illness recovery	44 (63)
Other potentially relevant non-food exposures	43 (61)
Other	4 (6)

^aNo state clustering was evident for these factors

Table 5.2. Average Annual Estimates of Restaurant Outbreaks by etiology (Norovirus, Salmonella, and Toxin-Mediated) by Disclosure Methods and Grading Methods, and Complaint System Characteristics, 2016-2018 for Agencies with a Consumer Complaint System (N=70)^a

	Outbreaks in Restaurant Settings per 1,000 Restaurants		Norovirus Outbreaks in Restaurant Settings per 1,000 Restaurants		Salmonella Outbreaks in Restaurant Settings per 1,000 Restaurants		Toxin-mediated Outbreaks in Restaurant Settings per 1,000 Restaurants	
	n	Median	n	Median	n	Median	n	Median
Complaint System Characteristics								
Has complaint system	35	0.37	24	0.57	20	0.11	10	0.24
Centralized system	23	0.50	17	0.78	14	0.18	7	0.19
No centralized system	12	0.33	7	0.30	6	0.08	3	0.28
Any food history	29	0.39	19	0.78	18	0.13	8	0.26
No food history	6	0.29	5	0.25	2	0.09	2	0.17
Disclosure Methods								
Online	28	0.33	19	0.74	16	0.13	8	0.26
POS	6	0.28	4	0.26	4	0.15	2	0.21
None	6	0.38	4	1.1	3	0.06	2	0.17
Grading Methods								
Numerical score	11	0.28	6	0.52	5	0.10	5	0.18
Letter grade	5	0.25	2	1.0	3	0.09	1	0.08
None	8	0.74	6	0.78	5	0.11	3	0.28
Other	14	0.42	10	0.37	9	0.22	2	0.55

^a Wilcoxon-Mann-Whitney p-values for dichotomous variables were not statistically significant

Table 5.3. Zero-truncated negative binomial regression analysis of restaurant outbreaks complaint and inspection rates

	IRR	Standard Error	95% Confidence Interval	p-value
Avg. no. complaints	1.001	0.0005	1.0004 – 1.002	0.005
Avg. no. routine inspections	0.99994	0.00002	0.9999 – 0.99999	0.013
Intercept	0.0012	0.0005	0.0006 – 0.0026	<0.001

Likelihood Ratio Test p-value= 0.025

Table 5.4. Zero-truncated negative binomial regression analysis of restaurant outbreaks by surveillance factors and average number of complaints received

	IRR	Standard Error	95% Confidence Interval	p-value
Any food history	3.35	2.68	0.697 – 16.10	0.131
Centralized system	1.89	1.09	0.615 – 5.82	0.266
Avg. no. complaints	1.0006	0.0005	0.9997 – 1.002	0.190
Intercept	0.0002	0.0002	0.00003 – 0.0016	<0.001

Likelihood Ratio Test p-value= 0.09

Table 5.5. Zero-truncated negative binomial regression analysis of restaurant outbreaks by prevention factors

	IRR	Standard Error	95% Confidence Interval	p-value
Online	0.436	0.343	0.093 – 2.04	0.291
POS	2.11	1.97	0.34 – 13.14	0.423
Numerical score	1.39	0.928	0.38 – 5.14	0.617
Letter grade	0.056	0.065	0.006 – 0.55	0.013
Avg. no. routine inspections	1.000	0.00003	0.9999 – 1.00	0.872
Intercept	0.0028	0.0019	0.00075 – 0.010	<0.001

Likelihood Ratio Test p-value= 0.206

Table 5.6. Fully adjusted zero-truncated negative binomial regression analysis of restaurant outbreaks, 2016-2018

	IRR	Standard Error	95% Confidence Interval	p-value
Online	0.76	0.361	0.303 – 1.93	0.569
POS	1.20	0.532	0.502 – 2.86	0.683
Numerical score	2.92	1.16	1.33 – 6.38	0.007
Letter grade	0.074	0.052	0.186 – 0.295	<0.001
Any food history	2.50	2.26	0.43 – 14.7	0.309
Centralized system	2.03	0.68	1.06 – 3.91	0.033
Avg. no. complaints	1.001	0.0004	1.0006 – 1.002	<0.001
Avg. no. routine inspections	0.99995	0.00002	0.99990 – 0.999998	0.039
Intercept	0.0004	0.0003	0.0001 – 0.0016	<0.001

Likelihood Ratio Test p-value= 0.0015

Appendix 5.1. Complaint outcomes by grading, disclosure, and complaint system characteristics, 2016-2018 for Agencies with a Consumer Complaint System

	Complaints per 1,000 Establishments		Outbreaks in Restaurant Settings per 1,000 Complaints	
	n	Median	n	Median
Complaint system characteristics ^a				
Centralized database	40	23.6	18	5.04
No centralized database	16	35.0	10	3.61
Any Food History	41	30.7	23	4.63
No Food History	15	23.4	5	3.70
Disclosure methods				
Online	40	27.9	23	4.44
POS	12	22.17	6	4.17
None	14	22.17	4	4.18
Grading methods				
Numerical Score	21	21.5	9	4.05
Letter Grade	11	25.4	5	2.10
None	14	44.7	5	3.39
Other	17	29.4	12	5.42

^a Wilcoxon-Mann-Whitney p-values for complaint system characteristics variables were not statistically significant

CHAPTER 6: SUMMARY AND FUTURE DIRECTIONS

This dissertation created a novel framework for examining environmental health (EH) agency-level interventions to 1) strengthen foodborne illness prevention efforts in restaurants, 2) distinguish effective surveillance methods that can reveal a more comprehensive picture of foodborne illness, and 3) assess consumer complaint surveillance system effectiveness while accounting for the prevention measures of grading and disclosure of inspection results. Complaint-based surveillance is an essential part of public health foodborne illness surveillance responsible for detecting most outbreaks. Innovations to complaint surveillance methods are needed to adapt to the changing needs of the U.S. population and advancements in technology that make faster outbreak detection more attainable. This work is useful for redefining the role of environmental health data in foodborne illness prevention and surveillance.

Federal support for public health surveillance through epidemiology and laboratory capacity building grants have been positively correlated with higher rates of foodborne illness outbreak detection (75). While grant funding is limited due to its competitive nature and reliance upon congressional discretion, it is not the only avenue through which surveillance can be strengthened. Identification of effective methods of surveillance can provide sustainable and, in the long term, cost-effective actions by modifying currently ongoing efforts. For example, it is widely accepted that the effectiveness of foodborne illness surveillance can be measured by its ability to detect outbreaks of foodborne illness (21). Higher rates of outbreak detection have been associated with an agency's use of an electronic database to manage the complaints (42) and ability to receive more foodborne illness complaints (26). However, less than 40% of local and state agencies surveyed in 2013 reported regularly reviewing complaint data to identify trends and 25% of smaller local agencies and 50% of state agencies did not have a procedure to manage final resolution of complaints (60).

Chapter 2 provided an overview of the demonstrated utility of EH data in foodborne illness prevention, surveillance, and investigation. Routinely collected EH data, specifically restaurant inspection results, can provide important context for developing and refining effective prevention measures. With the recognized importance of this source of information, comes a renewed call for needed investments into public health data information systems that can facilitate EH data collection and management. Data-driven food safety practice is public health advancement.

Previous literature examined public health outcomes within specific EH agency jurisdictions comparing outcomes using a pre- and post-implementation approach. In **Chapter 3**, we demonstrated that the public health benefit of illness burden reduction through increased transparency in restaurant grading and disclosure practices was present across a sample of local EH agencies in the U.S. This ability to compare the impact of these practices across multiple EH agencies and their jurisdictions for a cross section of time using, first, survey data (25) and, second, national surveillance data (26) to validate the findings from agency-reported data was an innovative approach to furthering the literature on restaurant food safety. The geographic and administrative diversity of the study sample provided a more

representative picture of the influences of practices across the U.S. making the results more generalizable to a larger population than other studies that have assessed the impact of grading and disclosure practices. These studies concluded that agencies assigning a summative score, or grade, to restaurant inspections reported fewer outbreaks than those that did not grade. Agencies that disclosed inspections results to the public also reported fewer outbreaks. Further, those that disclosed at the point of service (POS) reported fewer outbreaks than those disclosing online only. The results of these two studies, while noteworthy alone and in the context of existing literature, were remarkable in their consistency with each other, though two sources were used to obtain the outcome data of outbreaks per 1,000 restaurants. Surveys of public health agencies that are validated by national surveillance data can be powerful tools to identify model practices that contribute to prevention of foodborne illnesses and outbreaks.

In Chapter 3.2, we found a positive association between the number of complaints received by an agency and the number of outbreaks reported by the agency (26). From this, we concluded that having a mechanism to receive complaints can lead to increased detection and reporting of outbreaks. The study presented in **Chapter 4** was the first to assess the utility of the Minnesota Department of Health's (MDH) online foodborne illness complaint reporting form comparing factors of reporting timeliness, population reach, and outbreak detection that relate to reporting online as opposed to via telephone (76). We found those who used the online complaint form were more likely to be younger, still ill, and call the suspected restaurant. Those reporting online also reported their illness to public health closer to the time of illness than those reporting by telephone, which may reduce food history recall bias and allow for faster mitigation of illness spread. However, there were a significant number of outbreaks, and of a broader array of etiologies, detected through telephone complaints alone. We concluded that online complaint forms, while advantageous for their ability to increase complaint volume and expedite reporting to MDH, should be seen as an enhancement rather than a replacement of traditional telephone-based methods for complaint-based surveillance.

This dissertation culminates in **Chapter 5** in which we introduce a framework to analyze the interplay between surveillance effectiveness measures and prevention interventions to strengthen environmental health strategies in restaurant settings. This novel approach to complaint surveillance evaluation adjusted for prevention interventions can be readily translated into practice. Targeted transparency in the form of restaurant inspection results disclosure is one way to help alleviate public concerns of foodborne illness risks in restaurants while also compelling restaurant operators to prioritize foodborne illness prevention efforts. Opportunity to identify potential outbreaks through consumer complaints can be enhanced by using multiple avenues for complaint reporting, especially when these avenues are inclusive of consumer communication preferences (76). In this regard, increased counts of outbreaks reported by a public health agency is an indication of a well-functioning complaint-based surveillance system. Outbreaks that are not prevented using grading and disclosure practices must be detected through surveillance. Thus, the rate of reported foodborne illness outbreaks can serve both a measure of surveillance effectiveness and a measure of public health prevention. Because interventions at the agency level may reduce the risk of outbreak occurrence, controlling for prevention measures is needed to improve the evaluation of complaint systems.

FUTURE DIRECTIONS

Small sample sizes of surveyed agencies precluded determination of statistically significant effects of prevention and surveillance predictors of interest on the number of outbreaks detected. More data are needed to further test the new model for evaluating complaint systems developed in this dissertation. In late 2022, the Minnesota and Colorado Integrated Food Safety Centers of Excellence, in collaboration with the South Carolina Department of Health and Environment, re-established the National Workgroup on Foodborne Illness Complaint Systems. This workgroup will assess national ability to detect foodborne illness outbreaks, identify model complaint system characteristics, and make recommendations to improve outbreak detection through complaint systems. One of the first actions of this workgroup is to survey state and local health departments to gather data on current complaint-based surveillance systems in use across the U.S. Once this data is collected, it can be used in this predictive model to evaluate the effectiveness of these systems and to identify model practices that can be promoted to all agencies collecting consumer complaint data.

Prevention and surveillance activities, though often studied separately, are complementary and operate concurrently. This dissertation demonstrated their intersectionality and the ability to combine these strategies into a predictive model that can inform public health practice and ultimately reduce the burden of foodborne illness.

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