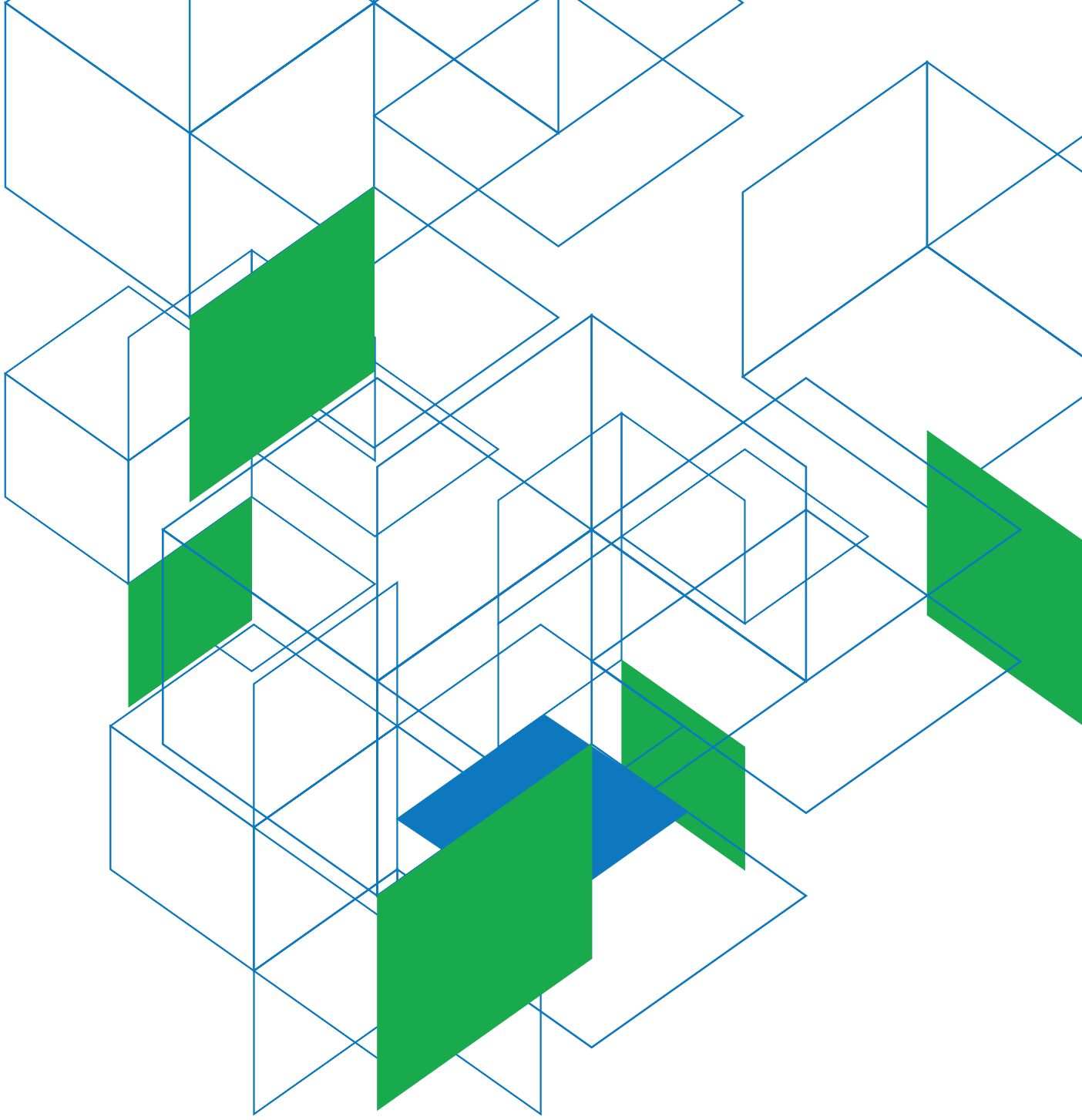

CIFOR GUIDELINES FOR FOODBORNE ILLNESS COMPLAINT SYSTEMS

CIFOR
Council to Improve Foodborne Outbreak Response

Detect • Investigate • Control • Prevent

Summary

This project was conducted under a contract with the Council of State and Territorial Epidemiologists (CSTE), on behalf of the Council to Improve Foodborne Outbreak Response (CIFOR), with funding through the Centers for Disease Control and Prevention's Food Safety Office.

This final project report summarizes the development of CIFOR Guidelines for Foodborne Illness Complaint Systems. These Guidelines were developed to address a gap in the Second Edition of the *CIFOR Guidelines for Foodborne Disease Outbreak Response* regarding the use of foodborne illness complaint systems to detect foodborne disease outbreaks, and are intended to be included for review and incorporation in the Third Edition of the *CIFOR Guidelines for Foodborne Disease Outbreak Response.*

This work was conducted in collaboration with the CIFOR Complaint Systems Work Group, a complaint systems work group established by the Integrated Food Safety Centers of Excellence, and key stakeholders representing local, state, and federal public health agencies responsible for managing and responding to foodborne illness complaints from consumers. A list of participants and reviewers who contributed to the development of these Guidelines is attached (Appendix 3). Input on the development of these Guidelines was obtained through a series of conference calls, feedback from reviews of preliminary drafts, and feedback from presentation at the CIFOR Steering Committee Meeting in March 2017.

The final draft for review and incorporation into the Third Edition of the *CIFOR Guidelines for Foodborne Disease Outbreak Response* includes the following sections:

A. A comprehensive review of current foodborne illness complaint systems,
B. Generalized CIFOR Guidelines for Implementing Foodborne Illness Complaint Systems
C. Guidelines adapted for multiple agency structures
D. A template for incorporation into third edition of the CIFOR Guidelines
E. Appendix 1. Foodborne Illness Complaint Form developed by EHSNET
F. Appendix 2: The One-Pager of Key Elements of Complaint System Operational Guidelines
G. Appendix 3. Complaint systems work group members, participants and reviewers

As a draft chapter to be incorporated into the Third Edition of the *CIFOR Guidelines for Foodborne Disease Outbreak Response,* it is anticipated that these Guidelines will undergo further editing and broad-based review along with the rest of the revised *CIFOR Guidelines for Foodborne Disease Outbreak Response.*

A. Comprehensive review of current foodborne illness complaint systems

Consumer complaint systems are an effective surveillance tool for detection of a variety of food-related incidents; in particular foodborne illnesses caused by various agents, including reportable pathogens. As noted in the *CIFOR Guidelines for Foodborne Disease Outbreak Response* (chapter 4.3) the purpose of foodborne illness complaint systems is to "receive, triage, and respond to reports from the community about possible foodborne disease events to conduct prevention and control activities. Programs range from ad hoc response to unsolicited phone reports to systematic solicitation and interview of and response to community reports."(1) The U.S. Food and Drug Administration (FDA)'s Voluntary National Retail Food Regulatory Program Standards (Standard 5) requires that programs have "an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination." (2) The standard requires that "the program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury, or intentional food contamination" (2). Similar provisions are required for FDA's Manufactured Food Regulatory Program Standards (3).

The second edition of the Guidelines was accompanied by target ranges for specific performance measures, including foodborne illness complaint reporting systems (4). For the metric: "Agency maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food related injury or intentional food contamination, and routinely reviews data to identify clusters of illnesses requiring investigation." The measurement methods include: "If an agency has any complaint system in place and it is used to review foodborne illness complaints, it will be considered acceptable. If an agency has an electronic database that can be systematically reviewed to link complaints, it will be considered preferable." Thus, the target ranges for this metric align with FDA's National Retail Food Regulatory Program Standard 5.

Because data on the CIFOR Metrics and Target Ranges has not been systematically collected, it is not possible at present to determine the prevalence of complaint systems by target range. FDA maintains a list of local and state agencies enrolled in the retail food programs standards and collects information from the agencies on their achievement of the standards, based on self-assessment and verification audit. However, since participation is voluntary, and Program Standard 5 includes more than the availability of the complaint system, measurement of the standard's achievement provides only a minimum estimate of the availability of complaint systems (https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm121796.htm). In order to address this data gap, CIFOR has developed C-MET, a tool that will allow officials from states and large cities/counties to anonymously enter their metrics data annually in order to measure progress over time, and to compare their data with aggregated data from other C-MET users for each of the metrics (http://metrics.cifor.us/). In collaboration with the Integrated Food Safety Centers of Excellence (CoE) Metrics Work Group, these aggregated data will be evaluated to identify needs for training and program development.

In 2010, a survey of local health departments (LHD) was conducted by Li and colleagues (5) from the University of Minnesota in conjunction with the National Association of County and City Health Officials (NACCHO). A random sample of 500 LHDs was stratified by the size of the population served (Table 1). Sampling weights based on the number of LHDs in each population stratum were determined and applied to the results to develop national estimates from the survey. A total of 307 LHDs responded to the survey (61% response rate). Overall, 81% of LHDs (95% confidence interval, 76%-86) reported having a "system that collected information from anyone suffering from foodborne illness that they attributed to a particular food establishment, food product, or event." These varied from 76% of LHDs serving populations <25,000 to 96% of LHDs serving populations of 500,000 – 999,999. Among LHDs that did not have a complaint system, 64% indicated that the state or another health department collected complaints for their jurisdiction. Lack of resources (28%) and lack of personnel (24%) were the other primary reasons for not having a complaint system.

Table 1. Percentage of local health departments with consumer complaint systems and reported outbreaks, by population of health department jurisdiction.

Table 1. Percentage of local health departments with consumer complaint systems and reported outbreaks, by population of health department jurisdiction.

POPULATION SERVED (1,000s)	% OF LHDS WITH COMPLAINT SYSTEM	MEDIAN NO. OF OUTBREAKS PER YEAR	MEDIAN NO. OF OUTBREAKS PER 1,000 COMPLAINTS	MEDIAN NO. OF COMPLAINTS PER 100,000 POPULATION
<25	76	0	0	46
25-49.9	83	0	0	26
50-99.9	84	0	0	32
100-249.9	82	0.5	4	26
250-499.9	86	1.5	18	25
500-999,9	96	2	20	9
>1,000	92	7	36	14
Total	81	0	7	21

Key information was collected from complainants by a high proportion of LHDs (Table 2). Almost all LHDs collected contact information from the complainant and information on the suspected establishment. At least 95% of LHDs collected information on symptoms and time of illness onset. Food histories were collected by 85% of LHDs.

Table 2. Percentage of local health departments collecting key information from complainants.

INFORMATION COLLECTED	% OF LHDS THAT COLLECT THE INFORMATION
Complainant's contact information	99
Suspected establishment/ product	99
Symptoms	97
Time of onset of illness	95
If complainant sought health care	93
Information on other ill individuals	92
No. of individuals ill in group	89
Food history	85
If complainant had a stool sample tested	82
No. exposed in group	81

A second survey was conducted among LHDs responding to the initial survey, to obtain details of the LHDs' practices and policies regarding their use of complaint systems. Of 190 LHDs surveyed, 89 responded (49% response rate). This survey collected information on how complaints are received, what information is collected, how information is managed, and who investigates complaints (Table 3).

Table 3. Summary of LHD use of consumer complaint systems.

CHARACTERISTIC	% OF LHDS WITH CHARACTERISTIC
How LHD receives complaints	
• Staff member takes complaint by telephone	98
• E-mail	75
• In person	72
• Voicemail	69
• Web-based reporting form	40
Standard set of questions asked of each complainant	88
Food history taken	87
• < 3 day food history	13
• 3 day food history	80
• >3 day food history	7
Information stored in electronic database	43
Who investigates complaints	99
• Environmental health specialist inspects establishment	88

Continued on following page

• Health official/epidemiologist contacts caller	84
Table 3. Summary of LHD use of consumer complaint systems. continued	
Stool samples collected from callers	
• Never	20
• Sometimes	79
• Always	1
Information shared with state health department	69
Information shared with other LHDs	55

Adapted from Li, 2010 (5).

Results of the surveys demonstrate that the vast majority of LHDs maintain a system to collect foodborne illness complaints from consumers. Most LHDs collect sufficient information to assess the likelihood that the complaint represents a foodborne illness and have established procedures for following up with complaints. The CDC National Center for Environmental Health's Environmental Health Specialists Network (EHS-Net) developed a standardized Foodborne Illness Complaint Form that captures all these data elements (6). This form was designed to "help determine whether a consumer foodborne illness complaint should be investigated as potentially linked to a foodborne illness outbreak" (6).

The usefulness of complaint systems to detect foodborne outbreaks is demonstrated by the observation that 69% of foodborne outbreaks reported by these LHDs were detected by the complaint system (5). Furthermore, LHDs with an electronic complaint database were more likely to have a mechanism to identify common exposures among complaints (83% compared to 57%) and had higher rates of reported outbreaks per 1,000 complaints across all populations categories (15-58/1,000 complaints compared to 0-28/1,000 complaints)(5).

In an evaluation of the Minnesota foodborne illness complaint system, Li and colleagues attempted to identify factors that would predict which characteristics of a complaint were more likely to identify the occurrence of a foodborne outbreak (7). For outbreak-associated complaints, the median number of illnesses in the party was 3 (compared to 1 for non-outbreak complaints) and the median incubation period was 27 hours (compared to 6 hours for non-outbreak complaints). There were statistically significant differences in age, % of ill persons with diarrhea, and % of ill persons with fever. However, the differences were small and not discriminatory for individual complaints. Only 7% of complaints were associated with outbreaks, although these accounted for 79% of foodborne outbreaks reported during this time frame (7).

In a follow-up study to determine the proportion of complaints due to norovirus infection, Saupe and colleagues collected stool samples from 25% of callers to the MN foodborne illness hotline from October 2011-January 2013 (8). Eighty percent of callers associated with outbreaks and 49% of non-outbreak callers tested positive for norovirus infection. Norovirus was detected throughout the year, but was more common during the typical norovirus season, a pattern that was typical of the complaints themselves. Results of this study and others confirm that consumer complaints generally reflect the occurrence of gastrointestinal illness in the community and function as limited syndromic surveillance.

The usefulness of consumer complaint systems to identify outbreaks is based either on 1) the ability of groups with a common exposure to self-identify illness and link it to the exposure, or 2) the ability of the complaint system to independently link multiple independent complaints to a common source. The proliferation of on-line complaint reporting systems operated by LHDs and independent organizations offers considerable promise to increase the identification of foodborne outbreaks. However, most on-line complaint systems focus on identifying the source of exposure suspected by the complainant. For example, a private on-line system called

"Iwaspoisoned.com" promotes the use of crowd-sourcing to detect foodborne outbreaks. The website posts recent complaints and solicits on-line submissions that capture the date and location of the exposure, the occurrence of diarrhea, vomiting, nausea and fever, an email address for follow-up and an open text field for additional information. The website operators have started forwarding complaints to state and local agencies. However, the scant information provided has not proved to be very useful to the regulatory agencies. The website operators have also started to follow-up with selected reports to collect additional details captured on standard foodborne illness complaint forms, including a 72 hour food history. In theory, this information with complainant contact information could be a useful supplement to existing local complaint systems. An alternative approach, the Healthmap Foodborne Dashboard adopted by the Florida Center of Excellence uses geolocation to identify and respond to foodborne illness complaints via Twitter. These approaches are being actively evaluated to determine their potential usefulness in routine practice.

While many on-line complaint systems provide opportunities to report 3-day food histories, most complainants do not fill out these supplementary histories. Thus, critical exposures that could be linked to identify outbreaks are rarely reported, and few outbreaks are identified. If a system of web-based reporting could be coupled with incentives to complete 72 -hour food histories, or followed up with interviews to ascertain food history details from complainants, the usefulness of web-based reporting would be greatly enhanced. However, many data systems operated by local agencies were developed as management systems rather than searchable databases. Thus, even if a 72-hour food history is obtained, only the primary establishment may be captured and linked to the complaint. Furthermore, many of these systems will not support a search function to link multiple complaints.

The vast majority of LHDs maintain foodborne illness complaint systems and would at least be in the acceptable range for this CIFOR performance measure. However, only 43% reported maintaining data in an electronic database that place them in the preferable range (5). Cost was the leading reason cited for not having an electronic system and 60% of such agencies stated they would use an electronic complaint database if one was made available at no charge. To address this gap, the Colorado Integrated Food Safety Center of Excellence has developed and is distributing electronic versions of a standard Foodborne Illness Complaint Form with an accompanying database and instructions for use: http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/foodsafety/Pages/Tools.aspx. The CO-COE complaint form is based on the EHSNET complaint form (Appendix 1) and is formatted to facilitate data entry. The Florida COE also has an electronic complaint form version, will share the code for free and help support the implementation of an electronic system for another state/region/county health department.

In addition to consumer complaint systems operated by local and state health departments, both the FDA and the USDA's Food Safety Inspection Service (FSIS) maintain consumer complaint reporting systems. FDA Consumer Complaint Coordinators collect reports of problems with FDA-regulated products (https://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm), and FSIS maintains the USDA Meat and Poultry Hotline, 1-888-MPHotline (1-888-674-6854), for consumers to call in and solicits reports on-line using an Electronic Consumer Complaint Reporting Form (https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/report-a-problem-with-food). Poison Control Centers also distribute information about food related poisonings and receive calls regarding potential foodborne illnesses (http://www.aapcc.org/prevention/food-mushroom-poisoning//). However, an evaluation of Poison Control System data identified significant limitations to using foodborne illness exposures reported to Poison Control Centers as a source for surveillance of large national outbreaks (9). It was suggested that improved data collection and coordination with public health agencies could improve the potential to identify local foodborne outbreaks.

B. Generalized CIFOR Guidelines for implementing foodborne illness complaint systems

The CIFOR Guidelines included "Keys to Success" within each section to highlight activities, relationships, and resources that are critical to the successful performance of the function. These keys to success also form the basis for the CIFOR Guidelines Toolkit and worksheets developed to allow state and local health departments to conduct self-assessments of their outbreak detection and investigation procedures, and to implement appropriate recommendations (http://www.cifor.us/toolkit.cfm). The Keys to Success for Complaint systems are highlighted in Table 4, along with implementation strategies from the CIFOR Toolkit and recommendations from the MN COE Key Points for Creating a Successful Foodborne Illness Complaint System.

The keys to success for complaint systems, with implementation recommendations from the Toolkit and lessons learned from well-documented complaint systems provide the basis for operational guidelines that could be implemented by a variety of LHD structures (Table 5, Template for incorporation into a future edition of the CIFOR Guidelines).

An important principle is that foodborne illness outbreaks are usually detected through one of three ways: pathogen-specific surveillance of reportable diseases, reports of illnesses by healthcare providers or institutions, or consumer complaints of suspected foodborne illness. Thus, a successful complaint system should be linkable with pathogen-specific surveillance, and other reports of illness from healthcare providers or institutions.

All complaints require some level of follow-up. If a call is received by telephone, the complainant should be given some expectation for what follow-up is likely. If the complaint is received by text, email, or on-line reporting system, the complainant should receive notification that the complaint was received.

Complaints received by telephone should be documented with a standard intake form to record complainant information. For example, a model foodborne illness complaint form was developed by the EHSNET program (Appendix 1: https://www.cdc.gov/nceh/ehs/ehsnet/docs/ehs-net_foodborne_illness_complaint_form.pdf). Complaints received through other formats warrant follow-up to fully document the complaint. Questions should cover identifying information for the caller, detailed illness information (including exact time of symptom onset and recovery), suspected food product or establishment, names and contact information for the complainant and other members of the dining party (if applicable), and all potentially relevant non-foodborne exposures (See Appendix 1. Foodborne Illness Complaint Form).

When illness is limited to a single person or members of a single household, a 3-day food history should be obtained, focused on meals eaten outside of the home. Only 1 in 5 complaints with a known etiology is caused by an agent with an incubation period <24 hours, and people often identify an incorrect exposure as the cause of their illness (e.g., last thing they ate). When illness is reported among members of multiple households, information should be taken only for meals in common to members of the different households. Staff should attempt to contact and interview ill meal companions reported by the original caller about symptoms and food consumption. All information collected should be entered into the complaint database.

If the complaint is taken by the environmental health staff responsible for inspecting the food establishments that the caller mentions, they should evaluate the complaint considering the likelihood of a foodborne illness or outbreak, review the inspection history of the establishment, contact the establishment's manager, and determine the value of conducting an environmental assessment. If the complaint is received by communicable disease surveillance staff, the complaint information should be immediately (via fax or electronically) shared with the responsible environmental health staff.

Complaints involving multiple households, instances of multiple independent complaints about the same food establishment, reports of clusters of illness, and complaints involving multiple people in the same household that suggest an exposure outside the home, should be reported to and evaluated by supervisory staff as the complaints are received. The supervisor, or outbreak response team should evaluate the need to initiate an outbreak investigation based on the number of reported ill persons, reported symptoms and incubations from exposures of interest, whether or not illness was reported in multiple households, the presence/absence of other shared exposures, and whether other independent complaints were received.

To complement the review of individual complaints and patterns of complaints detected through the foodborne illness complaint system, communicable disease surveillance staff should conduct standard interviews for foodborne illness cases detected through pathogen-specific surveillance (e.g., Salmonella and Shiga toxin–producing E. coli). All food establishments that affected persons reported eating at within the 7 days prior to illness onset should be entered into the complaint database. As new information is added, the complaint system supervisor should examine a list of restaurants or other food establishments from both foodborne illness complaint and pathogen-specific surveillance streams to search for common establishments.

As noted by the MDH COE, "Consumer complaint systems are an effective surveillance tool for detection of foodborne illnesses caused by various agents, including reportable pathogens. Complaint systems can be used to enhance pathogen-specific surveillance and provide the primary means of outbreak detection for non-reportable and emerging pathogens for which clinical laboratory diagnosis is not available. The use of a complaint based surveillance system can also speed up investigations; investigators do not have to wait for cases to be reported through pathogen-specific surveillance. When complaint systems are in place, the lag time between illness and reporting to the health department is decreased, which can lead to more timely investigations and follow-up by health departments." (http://mnfoodsafetycoe.umn.edu/foodborne-illness-complaint-system/)

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Table 4. Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Soliciting and receiving reports		
• Agency/jurisdiction has an established process for receiving reports about possible foodborne illness(es) from the public.	• Establish a formal system for receiving reports about possible foodborne illness from the public. • To increase reporting from the public, make the reporting process as simple as possible.	
• Public knows how to report possible foodborne illnesses to the agency/jurisdiction.	• Use one 24/7 toll-free telephone number or one website address that easily can be remembered or found in the telephone directory or by using an internet search engine. • Promote awareness of reporting system through agency website, social media outlets.	
• Agency/jurisdiction solicits reports of possible foodborne illness from other agencies and organizations likely to receive these reports (e.g., poison control center, industry) inside and outside the jurisdiction.	• Identify and regularly communicate with agencies, organizations, businesses and health care facilities that receive possible foodborne illness complaints and ensure that they have current contact information for reporting complaints. • Establish memos of understanding (MOU) to describe* methods for sharing information with other agencies or organizations that receive possible foodborne illness complaints such as a shared database that public health agencies can access and review. • Train food managers and workers about the importance of reporting potential foodborne illnesses among workers or customers and food code requirements for disease reporting. (http://cifor.us/documents/CIFOR%20Industry%20Guidelines/CIFOR-Industry-Guidelines.pdf) *MOUs were recommended to formalize interagency reporting processes.	Get stakeholder buy in: • Clearly describe how the complaint system will work – engage stakeholders to define roles for state and local health departments, and epidemiology and environmental health components of each. • Ensure that complaint information is made available to everybody who needs it. For example, in Minnesota, MDH epidemiology staff collect complaint information for the whole state and then send it to the environmental health jurisdiction (state or local, public health or agriculture) for each food establishment mentioned in a complaint, independent of whether an outbreak investigation is initiated at a particular establishment. Environmental health staff follow-up with complaints following their agency's standard procedures.

Table 4. *continued* Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Soliciting and receiving reports		
• Agency/jurisdiction works with the local media to solicit reports of possible foodborne illness from the public.	• Routinely distribute press releases about food safety that include the telephone number or website address for reporting to encourage reporting by the public.	
Detection of clusters/outbreaks		
• Staff collects specific information about each possible foodborne illness report and records the information in an electronic data system.	• Use a standard process to collect information from individuals reporting a possible foodborne illness, including use of a standard interview form that solicits information on both food and nonfood exposures (See Appendix 1. Foodborne Illness Complaint Form). • Collect as much information as possible during the initial report. Food histories and other exposures are critical to detecting clusters. • Compile interview data in a log or database to facilitate examination of reports for exposure clustering, trends, or commonalities. A database with templates for rapid data entry and analysis will streamline the data management process and improve cluster and outbreak identification.	• Collect appropriate information from complainants. Do not limit the complaint system to information only about the restaurant that the complainant suspects. Only 1 in 5 complaints with a known etiology was caused by an agent with an incubation period <24 hours, and people often identify an incorrect exposure as the cause of their illness (e.g., last thing they ate). • Get details about symptoms, onset date and time, and recovery date and time. These are needed to determine the likely etiology and determine which establishment (if any) was the most likely source of illness. • Enter complaint information into an electronic database, immediately or within the same day.* • Develop a shared/centralized complaint system so that all agencies can evaluate all illness complaints. Experience gained by staff that review and evaluate complaints on a routine basis facilitates efficient, effective outbreak detection and investigation. *Timeliness of data entry was identified as a barrier to quickly identifying trends.

Table 4. *continued* Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Soliciting and receiving reports		

• Staff regularly review reports of foodborne illness to identify cases with common characteristics or suspicious exposures that might represent a common source outbreak.	• Set up the reporting process so all reports go through one person or one person routinely reviews all reports to increase the likelihood that patterns among individual complaints will be detected.
	• As new complaints are received, review previous complaints to recognize multiple persons with a similar illness or a common exposure.*
	• Compare exposure information collected through the complaint system with data from pathogen-specific surveillance, when feasible**, to reveal potential connections between cases and increase the likelihood of detecting an outbreak.
	• Alert the appropriate regulatory authority when a commercially distributed food item is suspected. This will allow the agency to check complaint information against their databases (e.g., USDA/FSIS Consumer Complaint Monitoring System) to identify cases with similar characteristics or exposures. To alert the FSIS complaint management team directly, an email can be sent to ccms@fsis.usda.gov.
	*To standardize the review process, it was recommended that reviewing previous complaints should occur as new complaints are received, rather than the less well defined process of regularly (daily).
	**It was noted that complaint systems and pathogen-specific surveillance data are maintained by separate surveillance groups in many LHDs, and that the feasibility of routine comparisons of this type will have to be determined for each agency.
		• Review and respond systematically to complaints.
		• Centralization allows all complaints to be reviewed by the same epidemiology staff to determine the need for further investigation and facilitate a consistent response for the same types of complaints. It allows complaints to be cross-referenced to identify multiple independent complaints about a restaurant or event. City- or county-specific complaint systems are more likely to fail to recognize independent complaints that name the same restaurant, if the complaints are made to different city/county health departments.
		• Cross-reference restaurants named on complaints with those mentioned on pathogen-specific surveillance interviews:
		  • Allows detection of more Salmonella, and STEC outbreaks.
		  • Allows detection of Salmonella, and STEC outbreaks more quickly than is possible by pathogen specific surveillance alone.
		This is much easier to accomplish if complaint systems are centralized at the same level as pathogen-specific disease surveillance.

Table 4. *continued* Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Responding to complaints		
• Staff review, evaluate and respond to complaints based on the likelihood of an outbreak and the risk posed to public health.	For individual complaints: • Collect a detailed exposure history for the 3* days before onset of illness. If clinical or laboratory evidence is available to suggest a specific agent with a longer incubation period, collect food history for the incubation period corresponding to the agent. • Train staff to give appropriate instructions to persons reporting a possible foodborne illness about prevention of secondary spread and seeking health care. • Guide staff on how to respond to and communicate with upset members of the public and dealing with death. • Decide whether to routinely collect clinical specimens from independent complaints or encourage patients to seek health care. When serious illness (e.g., bloody diarrhea) or a likely outbreak is identified, clinical specimens should be aggressively pursued. • Prioritize the investigation of establishments identified in individual complaints based on whether the complainant's illness is consistent with foods eaten at the establishment, whether a food preparation or serving problem was reported, and the number of persons (with no other shared food history) implicating the establishment. Past inspection history of priority and priority foundation violations may also prove informative.	If only one person was ill or all ill persons live in the same household: • Collect 3* days of food history. Outbreaks are frequently detected at food establishments or food sources identified 2 or 3 days back in the food history, and not at the food establishment that the complainant suspects. *Recommendation was made to collect a 3-day food history, to comply with the use of standard complete intake forms that include a 3-day food history template. In addition, most foodborne illness complaints are associated with agents that have incubation periods of less than 3 days. Incorporated into the recommendation is the guidance that If clinical or laboratory evidence is available to suggest a specific agent, collect food history for period corresponding to incubation period for the agent.

Table 4. *continued* Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Responding to complaints		
• Staff review, evaluate and respond to complaints based on the likelihood of an outbreak and the risk posed to public health.	Responding to group complaints: • Investigate more aggressively reports of illness among groups who ate together than complaints involving only one ill individual or ill individuals all from the same household. • Investigate cases of serious illness (e.g., bloody diarrhea, neurological symptoms) more aggressively than cases of mild illness. • Focus interviews associated with group complaints on the event shared by members of the group. Be sure to determine whether the group might have had other exposures in common. • Obtain and test clinical specimens from several members of the ill group. Identifying an etiology will help investigators understand the outbreak, link it to other outbreaks or sporadic cases, and allow actions to be implemented to stop the outbreak and prevent additional illnesses or spread to the community. • While awaiting confirmation of the etiologic agent, use predominant signs and symptoms, incubation period, illness duration, and suspect food item to provide clues about the possible agent and better focus investigation activities. • If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. Test only after epidemiologic or environmental investigations implicate the food. Contact the laboratory that will be conducting the testing for guidance on collecting, labeling, storing and transporting food specimens.	If a complaint reports ill persons from multiple households" • Collect info only on common meals or other environmental exposures (i.e., water). • Collect names and contact information for other ill people reported by the complainant; if they are reluctant to provide this information, ask them to give your telephone # to the ill people to call (and stress the importance of them doing so). Illness information from other ill people is critical in determining if an outbreak actually occurred, the likely etiology, and on which restaurant(s) an investigation should be focused. Respond systematically to complaints. • Complaints should be evaluated to determine if an environmental investigation is conducted. • Individual jurisdictions respond to complaints as they deem appropriate if the complaint doesn't clearly signal a potential outbreak; responses can vary from no action to a call to the establishment to an inspection.

Table 4. *continued* Keys to success for complaint systems and suggested implementation strategies modified from Toolkit and the MN Integrated Center of Excellence Key Points for Creating a Successful Foodborne Illness Complaint System.

ACTIVITY	TOOLKIT IMPLEMENTATION STRATEGY	MN-COE KEY POINTS RECOMMENDATIONS
Responding to complaints		

• Staff review, evaluate and respond to complaints based on the likelihood of an outbreak and the risk posed to public health.	Responding to group complaints:
	• Store food specimens as appropriate to the sample. Refrigerate perishable food samples but keep foods that are frozen when collected frozen until examined. In general, if perishable food samples cannot be analyzed within 48 hours after receipt, freeze them (–40 to –80o C).
	• Collect and test foods for outbreaks suspected to involve preformed toxins (e.g., enterotoxins of Staphylococcus aureus or Bacillus cereus), because detection of toxin or toxin-producing organisms in clinical specimens can be problematic.
		If a complaint reports ill persons from multiple households"
		• If a complaint warrants the initiation of an outbreak investigation, the appropriate epidemiology and environmental health jurisdictions should be notified, and a conversation between appropriate agencies should take place to plan and initiate the investigation.
		• The clinical profile of reported illnesses (distribution of incubation periods, symptoms, and durations) is often suggestive of a particular etiology and should guide the EH assessment.
		  • E.g., short incubation, little or no fever - suggestive of foodborne intoxication, focus on time temperature abuse.
		  • E.g., norovirus profile, focus on food worker illness, handwashing, and bare-hand contact with ready-to-eat foods.

Making changes		
• Agency/jurisdiction has performance indicators related to complaint systems and routinely evaluates its performance in this Focus Area.		

C. Guidelines adapted for multiple agency structures

Most foodborne illness complaint systems are managed by the Environmental Health staff at LHDs that also license and inspect restaurants and other food service establishments. This has the immediate benefit of linking the complaint to the official most likely to be aware of conditions at the establishment that may require additional assessment or intervention. However, this structure may not be the most effective approach for foodborne illness complaint systems to serve as surveillance to identify outbreaks in a larger community setting.

Larger community settings may require linking the foodborne illness complaint data to communicable disease surveillance data maintained by other staff at the same LHD. Linkage between complaint data and results of pathogen-specific surveillance are much easier to accomplish if complaint systems are centralized at the same jurisdictional level as pathogen-specific disease surveillance. This may occur at the level of the LHD, or between individual City-based Environmental Health staff and County-based communicable disease program, or at the state level. Such a shared/centralized system should enhance the ability of agencies to detect and respond to possible foodborne outbreaks, but should not prevent any participating jurisdiction from fulfilling whatever role is required by law or is determined to be necessary to protect health in the jurisdiction's area.

When multiple LHDs serve a larger metropolitan area, they should aggregate data to allow complaints to be cross-referenced across agencies to identify a common food establishment, food source or event. City- or county-specific complaint systems are more likely to fail to recognize independent complaints that name the same food source, if the complaints are made to different city/county health departments.

All jurisdictions should have a process to ensure that complaints not under their jurisdiction are forwarded to the proper authority. This includes forwarding complaints between LHDs, from LHDs to state Departments of Agriculture or Health, and from LHDs and state agencies to FSIS for meat, poultry and egg product-related complaints or to FDA for complaints related to other food items in interstate commerce.

D. Template for incorporation into third edition of the CIFOR Guidelines

Table 5. Template for incorporation into third edition of the CIFOR Guidelines.

ACTIVITY	OPERATIONAL GUIDELINES
Soliciting and receiving reports	

• Agency/jurisdiction has an established process for receiving reports about possible foodborne illness(es) from the public.	• Identify how the complaint system links with other surveillance programs (i.e., pathogen-based, poison control, school-based, syndromic surveillance).
	• Develop written policies to clearly describe how the system will work:
	  • Complaints received by telephone should be documented with a standard intake form to record complainant information (See Appendix 1). Complaints received through other formats warrant follow-up to fully document the complaint.
	  • All information collected should be entered into the complaint database.
	  • If a call is received by telephone, the complainant should be given some expectation for what follow-up is likely. If the complaint is received by text, email, or on-line reporting system, the complainant should receive notification that the complaint was received.
	  • The agency should refer complaints to other jurisdictions (local, state, or federal) as needed.

• Public knows how to report possible foodborne illnesses to the agency/ jurisdiction.	• Use one 24/7 toll-free telephone number and one website address that can be easily remembered or found in the telephone directory or by using an internet search engine. • Advertise toll-free number on agency website, through social media outlets and through distribution of brochures at a variety of venues, including community events, health fairs, and health care provider conferences. Mail larger poster versions to emergency rooms and family practice and pediatric clinics within jurisdiction.
• Agency/jurisdiction solicits reports of possible foodborne illness from other agencies and organizations likely to receive these reports (e.g., poison control center, industry) inside and outside the jurisdiction.	• Agency/jurisdiction Food Safety programs should enroll in FDA Retail Program Standards and achieve Standard 5. • Define roles for state and local health departments, and epidemiology and environmental health components of each. Ensure that complaint information is made available to all participating agencies. • Identify agencies, organizations, businesses and health care facilities that receive possible foodborne illness complaints, ensure that they have current contact information for reporting complaints, and that the program has contact information of relevant staff at these partner agencies. • Communicate with agencies as needed to respond to foodborne illness complaints and at least distribute annual complaint summaries to them. • Train food managers and workers about the importance of reporting illnesses among workers or customers and food code requirements for disease reporting.

Table 5. Template for incorporation into third edition of the CIFOR Guidelines.

ACTIVITY	OPERATIONAL GUIDELINES
Soliciting and receiving reports	
• Agency/jurisdiction works with the local media to solicit reports of possible foodborne illness from the public.	• Routinely distribute press releases about food safety that include the telephone number or website address for reporting to encourage reporting by the public. • Respond to inquiries from news media regarding foodborne illness events and provide reminders about the importance of foodborne illness reporting.
Detection of clusters/outbreaks	
• Staff collects specific information about each possible foodborne illness report and records the information in an electronic data system.	• Use a standard process to collect information from individuals reporting a possible foodborne illness, including use of a standard interview form that solicits information on both food and nonfood exposures (See Appendix 1. Foodborne Illness Complaint Form). • Collect as much information as possible during the initial report. Get details about symptoms, onset date and time, and recovery date and time. These are needed to determine the likely etiology and determine which food establishment (if any) was the most likely source of illness. Food histories and other exposures are critical to detecting clusters. • Enter complaint information into an electronic database to facilitate examination of reports for exposure clustering, trends, or commonalities. A database with templates for rapid data entry and analysis will streamline the data management process and improve cluster and outbreak identification. • Develop a system for sharing complaint information so all participating agencies can review and evaluate complaints. Experience gained by staff that review and evaluate complaints on a routine basis facilitates efficient, effective outbreak detection and investigation.
• Staff regularly review reports of foodborne illness to identify cases with common characteristics or suspicious exposures that might represent a common source outbreak.	• Set up the reporting process so all reports go through one person or one person routinely reviews all reports to increase the likelihood that patterns among individual complaints will be detected. • As new complaints are received, review previous complaints to recognize multiple persons with a similar illness or a common exposure. • Compare exposure information collected through the complaint system with data from pathogen-specific surveillance, as feasible, to reveal potential connections between cases and increase the likelihood of detecting an outbreak. • When possible, centralize the complaint system at the same level as pathogen-specific disease surveillance to allow all complaints to be reviewed by the same staff to determine the need for further investigation and facilitate a consistent response for the same types of complaints. Cross-reference complaints to identify multiple independent complaints about a food establishment or event. Stand-alone city- or county-specific complaint systems are less likely to recognize independent complaints that name the same food establishment, if the complaints are made to different city/county health departments.

Table 5. Template for incorporation into third edition of the CIFOR Guidelines.

ACTIVITY	OPERATIONAL GUIDELINES
Responding to complaints	
• Staff review, evaluate and respond to complaints based on the likelihood of an outbreak and the risk posed to public health.	If only one person was ill or all ill persons live in the same household: • Collect 3-day food history. Outbreaks are frequently associated with food consumed 2 or 3 days back in the food history, and not at the source that the complainant suspects. If clinical or laboratory evidence is available to suggest a specific agent with a longer incubation period, collect food history for incubation period corresponding to the agent. (https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html)
	If a complaint reports ill persons from multiple households: • Collect info only on common meals or environmental exposures (i.e., water). • Collect names and contact information for other ill people reported by the complainant; if they are reluctant to provide this information, ask them to give your telephone # to the ill people to call (and stress the importance of them doing so). Illness information from other ill people is critical in determining if an outbreak actually occurred, the likely etiology, and on which food source an investigation should be focused.

	Complaint assessment and follow-up:
	• Evaluate the clinical profile of reported illnesses (incubation periods, symptoms, and durations). If symptoms and likely incubation period are consistent with known foodborne illness, and a suspect food source is identified, an environmental assessment should be conducted by a trained environmental health specialist.
	• If the complaint provides evidence of multiple illnesses that warrant the initiation of an outbreak investigation, the appropriate epidemiology and environmental health jurisdictions should be notified, and a conversation between appropriate agencies should take place to plan and initiate the investigation.
	• If an etiology has been confirmed, that information should guide the EH assessment. If the etiology is not confirmed, use the clinical profile of reported illnesses (distribution of incubation periods, symptoms, and durations) to guide the EH assessment.
	  • E.g., short incubation, little or no fever - suggestive of foodborne intoxication, focus on time-temperature abuse.
	  • E.g., norovirus profile, focus on food worker illness, handwashing, and bare-hand contact with ready-to-eat foods.
	• In an outbreak investigation, obtain and test clinical specimens from several members of the ill group. This may identify links to other outbreaks or sporadic cases.
	• If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. Test only after epidemiologic or environmental investigations implicate the food.
	• Store food specimens as appropriate to the sample. Refrigerate perishable food samples but keep foods that are frozen when collected frozen until examined. In general, if perishable food samples cannot be analyzed within 48 hours after receipt, freeze them (–40 to –80o C).

Table 5. Template for incorporation into third edition of the CIFOR Guidelines.

ACTIVITY	OPERATIONAL GUIDELINES
Making changes	
• Agency/jurisdiction has performance indicators related to complaint systems and routinely evaluates its performance in this Focus Area.	• Write an outbreak investigation report summarizing key investigation steps, timeline, and findings for every investigation conducted, and share with all collaborators and relevant stakeholders. • Compile information to measure performance against CIFOR target ranges and enter metric data into C-MET.

E. Appendix 1: Foodborne illness complaint form developed by EHSNET

FOODBORNE ILLNESS COMPLAINT FORM

The Environmental Health Specialists Network (EHS-Net) designed this form for state and local environmental health specialists working in food safety programs to use to capture information from consumers about their foodborne illness complaints. The information collected with this form can be used to help determine whether a consumer foodborne illness complaint should be investigated as potentially linked to a foodborne illness outbreak.

Incident No._____ Contact No. _____

ORIGIN OF COMPLAINT

Date Received_____ **Receiving Agency**_____ **Call Received By** _____

COMPLAINANT DATA

Name: _____ **DOB:**_____ **Gender** M F

Phone: (Work)_____ (Home)_____ (Cell)_____ (Email)_____

Occupation(s)_____ **Previous Illness or Chronic Condition:** Y N **Exisiting Medications:** Y N

Comments:_____

ILLNESS DATA

Illness Onset: Date:_____ Time:_____ AM/PM **Illness Stopped:** Date:_____ Time:_____ AM/PM
❑ **Illness Ongoing**

Signs and Symptoms

❑ Diarrhea ___Watery ___Bloody
❑ Vomiting
❑ Nausea
❑ Abdominal Pain
❑ Fever _____˚F
❑ Chills
❑ Headache
❑ Myalgia (muscle ache)
❑ Dizziness
❑ Double Vision
❑ Jaundice
❑ Weakness
❑ Itching (location)_____
❑ Numbness (location)_____
❑ Tingling (location)_____
❑ Edema (location)_____
❑ Rash
❑ Other _____

Diarrhea Onset: Date:_____ Time:_____AM/PM **Diarrhea Stopped:** Date:_____ Time:_____AM/PM
❑ **Illness Ongoing**

Vomitting Onset: Date:_____ Time:_____AM/PM **Vomitting Stopped:** Date:_____ Time:_____AM/PM
❑ **Illness Ongoing**

CLINICAL DATA

Was a doctor or other healthcare provider visited? Y N

Date Visited:_____ **Time**_____ AM/PM **Admitted:** Y N **Length of Stay:**_____(hrs)

Healthcare Facility:_____ **Physician Name:**_____ **Phone:**_____

Were clinical specimens taken? Y N ❑ Blood ❑ Stool **Diagnosis**_____

Would you be willing to provide a stool sample? Y N N/A Samples no longer available

SUSPECT MEAL DATA

Date:_____ **Location:**_____ **Suspect Meal:**_____

Time:_____AM/PM _____ _____

_____ _____

_____ _____

Number of people in party:_____ **Number of people reportedly ill:**_____

Group Contact:_____ **Phone:**_____

List anything unusual about the meal (temperature, taste, color, etc.)_____

_____

OTHER CONTACTS

Name		Phone	Associated Meal and/or Location
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____
_____	❑ Ill ❑ Well	_____	_____

OTHER EXPOSURES

Other Possible Non-food Exposures within Past 2 Weeks: (swimming pool, river, lake, etc.)

Travel outside the US: Y N **Location(s)** _____

Water consumed outside residence Y N **Location(s)** _____

Well water consumed Y N **Location(s)** _____

Exposure to recreational water Y N **Location(s)** _____

Exposure to the following:

❑ Petting zoo ❑ Ill person at home or outside of home ❑ Birds or reptiles

❑ Mass gatherings ❑ Domestic animals or livestock ❑ Diapered kids or adults

❑ Daycare facility ❑ Ill animal ❑ Visit nursing home

❑ Other _____

Notes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

72-HR FOOD HISTORY

DATE:

This section is to be used to collect information about what the consumer ate and drank in the past 72-hor period prior to the complaint.

Day of Illness Onset:

Breakfast:_____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Lunch: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Dinner: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Other: _____ **Location**_____ **Time:**_____AM/PM

Food or _____ _____ **Suspect Meal?** Y N

Water _____ **Contacts** _____

72-HR FOOD HISTORY

DATE:

One Day Prior to Illness Onset:

Breakfast:_____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Lunch: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Dinner: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Other: _____ **Location**_____ **Time:**_____AM/PM

Food or _____ _____ **Suspect Meal?** Y N

Water _____ **Contacts** _____

72-HR FOOD HISTORY

DATE:

Two Days Prior to Illness Onset:

Breakfast:_____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Lunch: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Dinner: _____ **Location**_____ **Time:**_____AM/PM

_____ _____ **Suspect Meal?** Y N

_____ **Contacts** _____

Other: _____ **Location**_____ **Time:**_____AM/PM

Food or _____ _____ **Suspect Meal?** Y N

Water _____ **Contacts** _____

F. Appendix 2: Key elements of complaint system operational guidelines

Key Elements of Complaint System Operational Guidelines
Soliciting and receiving reports
• Complaints received by telephone should be documented with a standard intake form to record complainant information. Complaints received through other formats warrant follow-up to fully document the complaint. • All information collected should be entered into the complaint database. • Refer complaints to other jurisdictions (local, state, or federal), as needed.
Detection of clusters/outbreaks
• Collect as much information as possible during the initial report. Get details about symptoms, onset date and time, and recovery date and time. These are needed to determine the likely etiology and determine which establishment (if any) was the most likely source of illness. Food histories and other exposures are critical to detecting clusters. • Set up the reporting process so all reports go through one person or one person routinely reviews all reports to increase the likelihood that patterns among individual complaints will be detected. • As new complaints are received, review previous complaints to recognize multiple persons with a similar illness or a common exposure. • Compare exposure information collected through the complaint system with data from pathogen-specific surveillance to reveal potential connections between cases and increase the likelihood of detecting an outbreak. • Cross-reference complaints to identify multiple independent complaints about a food establishment or event.
Responding to complaints
If only one person was ill or all ill persons live in the same household: • Collect 3-day food history. Outbreaks are frequently associated with food consumed 2 or 3 days back in the food history, and not at the source that the complainant suspects. If clinical or laboratory evidence is available to suggest a specific agent with a longer incubation period, collect food history for incubation period corresponding to the agent*. If a complaint reports ill persons from multiple households: • Collect info only on common meals or environmental exposures (i.e., water). • Collect names and contact information for other ill people reported by the complainant; if they are reluctant to provide this information, ask them to give your telephone # to the ill people to call (and stress the importance of them doing so). Illness information from other ill people is critical in determining if an outbreak actually occurred, the likely etiology, and on which food source an investigation should be focused.

Key Elements of Complaint System Operational Guidelines

Complaint assessment and follow-up

- Evaluate the clinical profile of reported illnesses (incubation periods, symptoms, and durations). If symptoms and likely incubation period are consistent with known foodborne illness, and a suspect food source is identified, an environmental assessment should be conducted by a trained environmental health specialist.
- If the complaint provides evidence of multiple illnesses that warrant the initiation of an outbreak investigation, the appropriate epidemiology and environmental health jurisdictions should be notified, and a conversation between appropriate agencies should take place to plan and initiate the investigation.
- If an etiology has been confirmed, that information should guide the EH assessment. If the etiology is not confirmed, use the clinical profile of reported illnesses (distribution of incubation periods, symptoms, and durations) to guide the EH assessment.
  - E.g., short incubation, little or no fever - suggestive of foodborne intoxication, focus on time-temperature abuse.
  - E.g., norovirus profile, focus on food worker illness, handwashing, and bare-hand contact with ready-to-eat foods.
- In an outbreak investigation, obtain and test clinical specimens from several members of the ill group. This may identify links to other outbreaks or sporadic cases.
- If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. Test only after epidemiologic or environmental investigations implicate the food.
- Store food specimens as appropriate to the sample. Refrigerate perishable food samples but keep foods that are frozen when collected frozen until examined. In general, if perishable food samples cannot be analyzed within 48 hours after receipt, freeze them (–40 to –80o C).

* https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html

G. Appendix 3: Participants and reviewers who contributed to the development of the guidelines for foodborne illness complaint systems

Craig Hedberg, UMN School of Public Health
Thuy Kim, CSTE Project Manager
Dhara Shah, CSTE
Shari Shea, APHL
Jennifer Li, NACCHO
George Nakamura, AFDO
Joe Russell, Flathead City-County Health Department
Gina Bare, Boulder County Health Department
Roberta Frick, Alameda County Environmental Health
Michele Dimaggio, Contra Costa County Health Services
Roshan Reporter, LA County Health Department
Scott Holmes, Lincoln-Lancaster County Health Department
Danny Ripley, Nashville Metro Public Health Department
Rachel Jervis, CO Department of Public Health and Environment
Chad Bailey, FL Department of Health
Jamie DeMent, FL Department of Health
John Tilden, MI Department of Agriculture and Rural Development
Kirk Smith, MN Department of Health
Josh Rounds, MN Department of Health
Carlota Medus, MN Department of Health
Marijke Decuir, MN Department of Health
Paula A Pennell-Huth, NY Department of Health
Hillary Booth, OR Public Health Division
Ernest Julian, RI Department of Health
Tamara Chavez-Lindell, TN Department of Health
Robyn Atkinson-Dunn, Utah Department of Health
Dale Morse, CDC
Donald Sharp, CDC
Gwen Biggerstaff, CDC
Ian Williams, CDC
Vince Radke, CDC
Adam Kramer, CDC
Erik Coleman, CDC
Susan Lance, FDA
Karen Becker, FSIS
Thomas Collaro, FSIS
Kristal Southern, FSIS