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.

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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

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• 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.