

GUIDELINES FOR FOODBORNE DISEASE OUTBREAK RESPONSE



OUTBREAK INVESTIGATION

Population at risk

Category	Percentage
Male	25%
Female	25%
Other	50%

Health Status

Area	Healthy	Mildly Sick	Seriously Sick	Undeclared
Area 1	5	3.0	2.0	3
Area 2	3	3.0	5.0	7
Area 3	8	11.0	16.0	12
Area 4	4	6.0	6.0	7

Prevalence and Incidence

Week	Prevalence	Incidence
Week 1	1.00	0.10
Week 2	0.90	0.02
Week 3	0.87	0.11
Week 4	0.84	0.15
Week 5	0.76	0.20
Week 6	0.60	0.16
Week 7	0.70	0.17

Population Pyramid

Age Group	Male	Female
0-14	100	100
15-24	100	100
25-34	100	100
35-44	100	100
45-54	100	100
55-64	100	100
65-74	100	100
75-84	100	100
85+	100	100



Table of Contents

FOREWARD	5
ACKNOWLEDGMENTS	6
CHAPTER 1 The Evolving Challenge of Foodborne Outbreak Response ..	15
1.0 Introduction.....	16
1.1 The Burden of Foodborne Illness in the United States.	16
1.2 Growing Complexity of the Food Supply	18
1.3 Enhanced U.S. Foodborne Illness Surveillance Systems	21
1.4 Foodborne Outbreak Response and Systems Change	24
CHAPTER 2 Legal Preparedness for the Surveillance and Control of	
Foodborne Illness Outbreaks	27
2.0 Introduction.....	28
2.1 Public Health Legal Preparedness.....	28
2.2 Legal Framework for Surveillance and Disease Reporting ..	31
2.3 Protection of Confidentiality and Authority to	
Access Records	34
2.4 Legal Framework to Prevent or Mitigate Foodborne	
Illness Outbreaks.....	36
2.5 Evolving Legal Issues.....	40
2.6 Public Health Investigations as the Basis for Further Action ..	41
2.7 CIFOR Legal Preparedness Resources.....	42

Table of Contents

CHAPTER 3 Planning and Preparation: Building Teams	47
3.0 Introduction.	48
3.1 Roles	48
3.2 Outbreak Investigation and Control Team	56
3.3 Planning to Rapidly Expand and Contract Investigation and Control Team Structure	58
3.4 Response Resources.	59
3.5 Communication Plans	61
3.6 Planning for Recovery and Follow-Up	63
CHAPTER 4 Foodborne Illness Surveillance and Outbreak Detection	67
4.0 Introduction.	68
4.1 Pathogen-Specific Surveillance	70
4.2 Complaint Systems	77
4.3 Syndromic Surveillance.	84
CHAPTER 5 Cluster and Outbreak Investigation	87
5.0 Introduction.	88
5.1 Outbreak Investigation Initiation	96
5.2 Define and Find Cases.	98
5.3 Generate Hypotheses about Likely Sources	100
5.4 Test Hypotheses.	103
5.5 Evaluate Evidence to Solve Point of Contamination and Source of the Food	111
5.6 Implement Control Measures, Investigation Close-Out, and Reporting	113

Table of Contents

CHAPTER 6 Control Measures and Prevention	115
6.0 Introduction	116
6.1 Information-Based Decision Making	116
6.2 Communications With the Public	118
6.3 Communications With Response Partners and Stakeholders	120
6.4 Control Measures	121
6.5 Outbreaks Involving Commercially Distributed Foods	126
6.6 Outbreak Wrap-up Activities	130
CHAPTER 7 Special Considerations for Multijurisdictional Outbreaks	137
7.0 Introduction	138
7.1 Categories and Frequency of Multijurisdictional Outbreaks	138
7.2 Multijurisdictional Outbreak Detection	140
7.3 Identifying and Investigating Sub-Clusters	142
7.4 Coordination of Multijurisdictional Investigations	143
7.5 Multijurisdictional Outbreak Investigation After-Action Reports and Reporting to NORS	146
CHAPTER 8 Performance Metrics for Foodborne Illness Programs	147
8.0 Introduction	148
8.1 Purpose and Intended Use	148
8.2 Performance Metrics	150



Foreword

Foodborne diseases and outbreaks remain a substantial cause of preventable morbidity and mortality in the United States and worldwide. It is estimated that over 9 million cases of foodborne illness occur in the United States each year. Of these, only a small fraction are associated with recognized outbreaks. It is widely believed, however, that outbreaks are substantially under-recognized and under-reported, and as our ability to detect and investigate clusters of illness improves, the proportion that are due to outbreaks or an identified source will inevitably increase. This is of great importance, as outbreaks provide an opportunity to identify food safety practices, environmental and other contributing factors, clarify attribution of illness to specific commodities, and improve mitigation and prevention of future events.

The Council to Improve Foodborne Outbreak Investigations (CIFOR) is a multidisciplinary collaboration of national associations and federal agencies working together since 2006 to improve methods to detect, investigate, control and prevent foodborne disease outbreaks. Council members represent large agencies and groups with substantial expertise in epidemiology, environmental health, public health laboratory activities and food regulation at the local, state and federal levels. While a variety of discipline-specific materials are available, these Guidelines are intended to be a unique resource combining the perspectives of multiple disciplines and jurisdictional levels, emphasizing the importance of teamwork, coordination, and communication that are critical for rapid, efficient and successful outbreak response.

This 3rd Edition of these Guidelines provides important updates and a more streamlined format compared to earlier versions. It also addresses rapid and continuing changes in many aspects of food safety, including laboratory technology, data sharing, improved disease detection methods, increasing centralization of food production, and changing eating habits.

Previous editions of these Guidelines (along with a Toolkit and numerous other materials available from CIFOR at <http://www.cifor.us/>) have been widely used, and have provided a base for numerous training sessions of local and state agencies, and a model for development of jurisdiction-specific guidelines. They have also been used internationally (including a Chinese translation), and we hope that this edition is even more widely utilized.

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The Evolving Challenge of Foodborne Illness Outbreak Response

CHAPTER SUMMARY POINTS

- Foodborne illness strikes tens of millions, hospitalizes more than 100,000, and kills an estimated 3,000 people in the United States each year.
- The U.S. diet has changed in response to numerous factors creating new food-safety challenges.
- Important advances in clinical laboratory techniques and public health approaches to detect and investigate clusters of illness are being used to better define the scope and nature of foodborne illness.
- Information systems and food-supply investigation techniques are developing to enhance our ability to trace contaminated foods, identify and control contamination sources, and remove contaminated food from circulation.
- Industry-driven and regulatory food-safety standards are being changed to better address risks identified by foodborne illness outbreak investigations to prevent similar outbreaks.

URLs in this chapter are valid as of July 11, 2019.

1.0 Introduction

Outbreaks of foodborne illness and their detection, investigation, and control are functions of several constantly changing factors. The U.S. diet has changed in response to public health recommendations; economics of food production and distribution; and the growing demands for convenience in food service, as well as diversity and freshness of foods in the marketplace. Important advances have been made in clinical laboratory techniques to diagnose foodborne illnesses and in public health approaches to detect and investigate clusters of illness. Information

systems are developing to enhance our ability to trace contaminated food and eliminate it from circulation and to glean lessons learned from these investigations to prevent similar outbreaks. In addition, industry-driven and regulatory food-safety standards are being changed to better address risks identified by foodborne illness outbreak investigations to prevent similar outbreaks.

This chapter provides an overview of these ever-changing factors. Subsequent chapters detail specific approaches used by investigators.

1.1 The Burden of Foodborne Illness in the United States

1.1.1 In 2011, the Centers for Disease Control and Prevention (CDC) estimated that each year in the United States 47.8 million illnesses, resulting in 128,000 hospitalizations and 3,000 deaths, were attributable to contaminated food (1, 2). Of these illnesses, 9.4 million are caused by 31 known agents of foodborne illness, and the remaining 38.4 million by unspecified agents. Tracking overall changes in the burden of foodborne illness from year to year is not currently possible, but trends are evident in known foodborne illnesses tracked by FoodNet (<https://wwwn.cdc.gov/foodnetfast>). Most notably, the incidence of *Escherichia coli* O157:H7 infections dropped from approximately 2.5 cases per 100,000 population during the mid-1990s to fewer than 1 case per 100,000 by the mid-2000s, accomplishing a goal of Healthy People 2010. Following early declines in the incidence of *Listeria* and *Campylobacter* infections, rates remained stable throughout the 2000s, whereas the incidence of *Vibrio* infections increased. Overall rates of *Salmonella* infections remained stable; the incidence of infection by serotypes Typhimurium and Heidelberg decreased; and infection by serotypes Enteritidis, Javiana, and

the monophasic variant of Typhimurium, serotype I 4,[5],12:i:-, increased (3).

Because not all illnesses caused by foodborne pathogens are individually reportable, recognition of other pathogen-specific trends relies on surveillance of foodborne illness outbreaks. CDC's National Outbreaks Reporting System (NORS) logged 20,854 outbreaks comprising 403,110 illnesses, 16,517 hospitalizations, and 392 deaths during 1998–2017 (<https://wwwn.cdc.gov/norsdashboard/>). Reporting of foodborne illness outbreaks caused by norovirus increased during 1998–2004, but since 2010, annual totals have varied little, hovering around 300 per year. A comparison of etiologies causing single-agent outbreaks during 2012–2017 with those during 2002–2011 showed that outbreaks caused by agents associated with poor food-holding practices in commercial food-service establishments decreased: *Bacillus cereus*, down from an average of 17 outbreaks per year to 10 per year; *Clostridium perfringens*, from 40 to 32 per year; scombroid or histamine, from 23 to 17 per year; and *Staphylococcus aureus*, from 27 to 12 per year. These changes most likely represent actual reductions in outbreak

1.1 The Burden of Foodborne Illness in the United States

occurrence because the percentage of reported outbreaks for which no etiologic agent was identified dropped from 59% in 1998 to 23% in 2017 (4).

1.1.2 In 2014, the U.S. Department of Agriculture’s Economic Research Service (USDA–ERS) estimated the average annual economic burden of foodborne illness at \$15.5 billion (5). USDA–ERS based

this burden on cost estimates of foodborne illness caused by 15 major pathogens in the United States (Table 1.1). These 15 pathogens account for 95% of illnesses and deaths from foodborne illness acquired in the United States for which a pathogen was identified. These estimates include costs associated with medical treatment of acute and chronic illness, lost wages of persons who recovered, and costs associated with premature deaths.

Table 1.1. Estimated Annual Cost of Foodborne Illness, Estimated Total Foodborne Cases, and Average Cost per Case Identified, United States, 2013

PATHOGEN	TOTAL COST	ESTIMATED TOTAL FOODBORNE CASES	COST PER CASE
<i>Vibrio vulnificus</i>	\$319,900,000	96	\$3,332,000
<i>Listeria monocytogenes</i>	\$2,834,400,000	1,591	\$1,782,000
<i>Toxoplasma gondii</i>	\$3,304,000,000	86,686	\$38,100
<i>Vibrio</i> spp. (other noncholera)	\$72,800,000	17,564	\$8,100
Shiga toxin–producing <i>Escherichia coli</i> O157	\$271,400,000	63,153	\$4,300
<i>Salmonella</i> spp. (nontyphoidal)	\$3,666,600,000	1,027,561	\$3,600
<i>Yersinia enterocolitica</i>	\$278,000,000	97,656	\$2,900
<i>Campylobacter</i> spp.	\$1,928,800,000	845,024	\$2,300
<i>Vibrio parahaemolyticus</i>	\$40,700,000	34,664	\$1,200
<i>Shigella</i> (all species)	\$138,000,000	131,254	\$1,100
<i>Cryptosporidium parvum</i>	\$51,800,000	57,616	\$900
Norovirus	\$2,255,800,000	5,461,731	\$410
<i>Clostridium perfringens</i>	\$342,700,000	965,958	\$360
Non-O157 Shiga toxin–producing <i>E. coli</i>	\$27,400,000	112,752	\$240
<i>Cyclospora cayetanensis</i>	\$2,300,000	11,407	\$200

Source: U.S. Department of Agriculture. Cost estimates of foodborne illnesses. <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses>

1.1 The Burden of Foodborne Illness in the United States

1.1.3 The impact of foodborne illness on the food industry varies greatly, and the costs seldom are limited to one company.

This impact is evident when the distribution network of the food supply is considered. The impacts of recalls on the food industry are far-reaching, in some cases topping \$10 million in direct costs.

Direct costs of recalls include notification of regulators, supply chain, and consumers; product retrieval, storage, and destruction; unsalable product; and the additional labor associated with these activities. These direct costs do not include litigation, increased regulatory compliance, and the impact to the company's market value and brand reputation.

The outbreak of *E. coli* O157:H7 infection associated with romaine lettuce grown in the Yuma, Arizona, growing region in April 2018 provides a good example of the indirect costs to the industry associated with lost sales and brand damage (6). This outbreak sickened 210 people in 36 states. During the week that followed the initial news of the outbreak, sales of romaine lettuce fell 20% (7). In addition, data from Nielsen also showed marked drops

in sales of iceberg lettuce, red leaf lettuce, and endive. The impact of a second, although unrelated, outbreak of *E. coli* O157:H7 associated with romaine lettuce in November 2018 (8) was even more dramatic because CDC advised consumers to avoid eating romaine lettuce from any source in an effort to remove potentially contaminated romaine from commercial distribution channels.

With a more comprehensive accounting of potential costs, researchers at the Johns Hopkins Bloomberg School of Public Health suggested that the cost to a restaurant for a single foodborne illness outbreak can range from \$4,000 to \$2.6 million, depending on the pathogen, type of restaurant involved, and size of the outbreak. For example, a foodborne illness outbreak in which five people became sick in a fast food restaurant would result in costs of approximately \$4,000 if there was no loss in revenue and no lawsuits, legal fees, or fines. In contrast, a single outbreak of listeriosis involving 250 persons in a fine dining restaurant could cost upwards of \$2.6 million in lost sales, lawsuits, legal fees, fines, and higher insurance premiums (9).

1.2 Growing Complexity of the Food Supply

U.S. food-consumption patterns change continuously. Changes in diets and food preferences have resulted in a greater demand for a broader variety of fruits, vegetables, and other foods. Moreover, Americans expect to consume these foods year-round, driving importation from areas of the world with the growing seasons necessary to meet U.S. demand. Meeting global supply-chain demands also has increased the complexity and logistics of how food is transported from farm to fork.

1.2.1 A major indicator of changing diets is the consumption of fresh fruits and vegetables.

From 1996 to 2017, loss-adjusted per capita availability of fresh fruit increased 7% from 55 to 59 pounds (10). Consumption of fresh vegetables increased only marginally from 68 to 70 pounds per person. During the same time, per capita consumption of chicken increased 30% from 40 to 52 pounds, whereas that of beef declined 17% from 49 to 41 pounds (10). Within the arena of fresh produce, consumption of head lettuce declined 34% from 12 to 8 pounds per capita, whereas consumption of romaine and leaf

1.2 Growing Complexity of the Food Supply

lettuce doubled from 3 to 6 pounds per capita, and consumption of fresh spinach nearly tripled from 0.3 to 0.9 pounds per capita. Consumption of fresh berries also increased substantially. The general pattern of these dietary changes reflects public health recommendations toward healthier eating (10).

The food industry has met this demand through routine importation of items once considered out of season or exotic. According to reports by USDA-ERS (11), the proportion of imported fresh fruits increased from 39% in 1996 to 53% in 2016. Excluding bananas, for which there is no domestic production, the share of imported fruits increased from 16% to 38%. Similarly, the percentage of imported fresh vegetables increased from 14% to 31%. Although a high proportion of some fresh produce items, such as mango and papaya, always have been imported, an increasingly more conventional produce items are also imported. For example, the percentage of imported avocados increased from approximately 14% in 1996 to 89% in 2016, and that of blueberries increased from 24% to 57% during that same period (11).

The safety of imported food products depends largely on the public health and food-safety systems of other countries. Recent analyses of foodborne illness outbreaks reported to CDC support the existence of food-safety problems in other countries. During 1996–2014, the number of confirmed foodborne illness outbreaks associated with imported foods increased from 3 per year to 18 per year. *Salmonella* and *Cyclospora* accounted for about one third of the outbreaks and 75% of cases, most due to contaminated produce from Latin America (11).

1.2.2 Culinary preferences for undercooked or raw foods also contribute to more frequent infections and outbreaks caused by the microorganisms associated with these foods. These include classical outbreaks

of Shiga toxin-producing *E. coli* (STEC), *Salmonella*, *Campylobacter*, and *Listeria* infections associated with raw milk and raw milk cheeses; *Salmonella* associated with raw tuna in sushi; and *Campylobacter* and *Salmonella* in minimally processed liver pates. A corresponding trend for raw pet foods made from meat and poultry products also has led to outbreaks among people from handling the raw pet food, exposure to ill animals, or environmental contamination in the household.

Foodborne illnesses also can be associated with ingestion of products not typically thought of as food. During 2017–2018, kratom, a tree leaf with stimulant and opioid properties, caused illness by a variety of *Salmonella* serotypes. Smoking marijuana caused an outbreak of salmonellosis in 1981 (12); and a cannabis-associated toxidrome among four persons who attended the August 2014 Denver County Fair was associated with consumption of chocolate bars obtained at the “LoveAll” booth at the fair’s “Pot Pavilion” (13). The full legalization of cannabis products in at least nine other states and the District of Columbia since 2014 and associated sales of cannabis-infused edibles could lead to more foodborne illness outbreaks. However, no outbreaks from cannabis products were reported to NORS from 2015 to 2018.

1.2.3 Changes in how food is cultivated or raised, processed, and distributed and where, how, and by whom food is prepared also contribute to changing patterns of foodborne illness. The demand for processed and ready-to-eat foods has led to the industrialization of food production with increasingly intense agricultural practices and broadening distribution of food products. Changes in agricultural, processing, or packaging methods might facilitate bacterial contamination or growth. Large multistate STEC outbreaks associated with leafy green vegetables reflect the challenges of intensive

1.2 Growing Complexity of the Food Supply

animal and fresh produce production in a shared environment. The scale of these operations magnifies the impact of food-safety system failures, resulting in thousands of exposures and potential illnesses across multiple states, and even multiple countries.

Increasingly complex food-distribution systems span the globe. Products move from farm to fork through a network of farms, processors, manufacturers, packers, importers, brokers, storage facilities, distribution centers, and retail outlets. In some instances, food from a farm can change hands more than 10 times before it reaches a consumer. These complex supply chains are maintained by a wide variety of record-keeping systems; outbreak investigators charged with tracing foods back through the supply chain are left to decode these systems and piece together, step by step, how a food reached its final destination.

At the same time, a counter-trend promoting local food sources and small-scale farm-to-table distribution networks (sometimes termed the “locavore movement” or “community-supported agriculture”) has emerged. The number of small food producers and direct-to-consumer marketing avenues (e.g., farmer’s markets, farm stands, farm-to-school programs, and “pick-your-own” operations) also has risen. According to national agriculture census data, from 1997 to 2017, direct sales of agricultural products to the public increased by 374%, compared with an increase of 93% for all agricultural sales. During the same period, the number of farms selling directly to consumers increased by 18%, compared with an 8% decrease in the total number of farms (14). In addition, most states have “cottage food” laws, allowing small producers to cook, can, or pickle outside of licensed kitchens certain foods that are typically considered low-risk.

The effect of increased consumption of locally produced foods is yet to be determined,

but the consequences of eating unsafe food apply to both small and large producers. For an individual, it is equally as bad to get STEC infection from farm-fresh strawberries harvested from a local field frequented by wild deer as it is to get STEC infection from romaine lettuce shipped hundreds of miles after contamination with runoff from a cattle feed lot. Although a small producer’s limited distribution system might affect fewer people, implementing improved food-safety measures might be more challenging for the small producer. In addition, farm direct sales (i.e., farmers selling produce, eggs, and other foods they produced directly to retail customers, such as through farmers’ markets and farm stands) are not included among food facilities in the 2011 Food Modernization and Safety Act (FMSA) (15). In some states and local jurisdictions, these sales have been exempted from food-safety regulations that pertain to other food facilities.

By whom and where our food is prepared also plays a role in foodborne illness occurrence and outbreaks. Americans increasingly eat away from home, spending more than 50% of food dollars away from home, since 2010 (16). During this period, there was considerable growth in limited service “fast casual” restaurants that featured more complex food handling than traditional fast-food restaurants. The increased number of meals eaten away from home most likely influenced the increase in foodborne illness. In an analysis of foodborne illness outbreaks reported to CDC during 2009–2017, 62% were associated with restaurants (4, 17). In addition, studies of sporadic and outbreak-associated foodborne illness, including infection with STEC O157, *Salmonella enterica* serotypes Enteritidis and Typhimurium, and *Campylobacter jejuni* suggest that commercial food-service establishments, such as restaurants, play an important role in foodborne illness in the United States (18).

1.2 Growing Complexity of the Food Supply

Finally, the growing e-commerce in delivery of groceries and restaurant food directly to consumers' homes provides foodborne illness investigators with opportunities for

verifying food purchases and dates. Whether an increased risk for illness accompanies these means of food distribution remains to be determined.

1.3 Enhanced U.S. Foodborne Illness Surveillance Systems

A variety of surveillance systems have been developed to identify foodborne illness and detect outbreaks. Some systems focus on specific pathogens likely to be transmitted through food and have been used extensively for decades. More recently, new surveillance methods have emerged that provide data on food vehicles, settings, pathogens, contributing factors, and environmental antecedents. Effective surveillance to track cases of foodborne illness and outbreaks is critical to developing effective control strategies.

1.3.1 Changes in surveillance for human illness have affected how outbreaks are detected (Chapter 4) and investigated (Chapter 5). All states and territories have legal requirements for the reporting of certain illnesses and conditions, including illnesses likely to be foodborne (e.g., salmonellosis, campylobacteriosis, and STEC infection), by healthcare providers and laboratories to the local, state, or territorial public health agency (Chapter 2). Local and state agencies also receive and respond to complaints of illness directly from the public. The adoption of new testing methods in clinical and public health laboratories, as well as improved information management systems and social media, are transforming surveillance activities.

- Molecular subtyping by public health laboratories has been the basis for national pathogen-specific surveillance since the initiation of PulseNet in 1996. The use of pulsed-field gel electrophoresis (PFGE) increased the ability to link isolates from distant locations and thereby

to infer epidemiologic relatedness; PFGE revolutionized the detection and investigation of foodborne illness outbreaks and led to prevention of illnesses. However, PFGE provided limited information about the organism itself. Rapid bacterial sequencing technology and the informatics tools needed to accommodate whole-genome sequencing (WGS) have been developed and in 2019 rapidly deployed to public health laboratories across the United States. On July 15, 2019, WGS replaced PFGE as the primary molecular subtyping tool for pathogen-specific surveillance.

- Concurrent with the development of WGS to improve molecular subtyping, clinical laboratories have moved away from traditional fecal culture in favor of culture-independent diagnostic tests (CIDTs). These methods can rapidly identify pathogens and expedite treatment decisions, but they do not yield the bacterial isolates required by public health officials. Many public health jurisdictions require submission of CIDT-positive specimens for subsequent culture and subtyping—but this shifts the burden of isolation from the clinical laboratory to the public health laboratory and delays cluster recognition. Conversely, CIDTs may be more sensitive and offer the prospect of detecting pathogens (e.g., enterotoxigenic *E. coli*) that may elude detection by culture. FoodNet, the 10-site active surveillance program for infections often transmitted through foods, has increased collection of data on use of CIDTs and on the frequency and results of reflex cultures.

1.3 Enhanced U.S. Foodborne Illness Surveillance Systems

- Newer technologies are likely to lead to recognition of more clusters and reduced cluster sizes than with PFGE. They also take longer, delaying cluster recognition by this means.
- Improved epidemiologic investigation practices have been developed. These include the standardization of common data elements for interviewing case-patients, use of standardized hypothesis-generating questionnaires, increased use of consumer product purchase (e.g., “shopper card”) data, aggregation of case-patient exposures and comparison with population reference standards, and improved subcluster investigation and informational traceback methods to improve the specificity of exposure assessments.
- The principles of foodborne illness complaint surveillance are being standardized (Chapter 4). The value of using electronic databases to review and analyze complaints and to link complaints with pathogen-specific surveillance systems has been demonstrated. Numerous social media platforms have been evaluated to assess their potential utility to enhance conventional complaint surveillance. To the extent these can facilitate linking illnesses with exposure, rather than just reinforcing the “last meal eaten” bias, they may warrant attention from public health agencies.
- Standards and procedures for outbreak reporting have been developed for NORS. NORS supports outbreak reporting from state, local, and territorial health departments in the United States. NORS Dashboard is a public-facing, web-based tool containing limited and cleaned NORS data that can be filtered using an interactive interface that produces summary data, statistics, and a variety of graphs based on user preferences (<https://wwwn.cdc.gov/norsdashboard>). CDC, USDA’s Food Safety and Inspection Service (FSIS), Food and Drug Administration (FDA), and other investigating agencies analyze these data to improve understanding of the impact of foodborne illness outbreaks on human health and of the pathogens, foods, and settings involved in these outbreaks.
- Specialized surveillance networks have been developed for specific pathogens. For example, CaliciNet is a norovirus outbreak surveillance network of local, state, and federal public health laboratories. Network partners perform viral sequencing and upload sequences into CaliciNet to monitor circulating strains, and identify newly emerging norovirus strains. CaliciNet outbreak lab data are linked to matching outbreak data in NORS. CryptoNet, the first U.S. national molecular tracking system for a parasitic infection, was formally launched in 2015 to collect specimens and to characterize the molecular epidemiology of infection by *Cryptosporidium* spp., only some of which are pathogenic for humans but which are typically indistinguishable morphologically.

1.3.2 Surveillance for food-preparation hazards and environmental assessments of outbreaks have been developed to identify root causes (Chapter 5) and improve preventive controls (Chapter 6).

Routine food-safety inspections are conducted for all licensed food-service establishments by approximately 3,000 local and 75 state and territorial agencies. Although traditionally conducted to ensure that food-service establishments were operating within the provisions of state food codes, many of which are adopted from the FDA Model Food Code (19), inspection results are being increasingly displayed at the point of service or online to provide information to consumers about potential food-safety risks. A growing body of evidence suggests that such public disclosure of inspection results might improve restaurant

1.3 Enhanced U.S. Foodborne Illness Surveillance Systems

inspection results and reduce the risk for illness transmission to patrons.

- To standardize assessment of retail food risk factors, FDA initiated the Retail Food Risk Factor Study to measure practices and behaviors commonly identified as contributing factors in foodborne illness outbreaks (20). Data from the initial study, collected during 1998, 2003, and 2008, documented progress toward the goal of reducing contributing factors (<https://www.cdc.gov/nceh/ehs/nears/cf-definitions.htm>) at retail establishments: five of the nine facility types showed a statistically significant improvement in compliance for all 42 contributing factors during the study period. A second round of the Retail Food Study was initiated in 2013 to assess food-protection manager certification and food-safety management systems. One important finding from the study was that fewer food-safety items were out of compliance in restaurants having well-developed and documented food-safety management systems (20).
- The Environmental Health Specialists Network (EHS-Net) of environmental health specialists and epidemiologists from local and state health departments, FDA, FSIS, USDA's Food and Nutrition Service, and CDC developed the National Environmental Assessment Reporting System (NEARS) to systematically monitor and evaluate root causes of foodborne illness outbreaks, including contributing risk factors and environmental antecedents. This system is cross-referenced with NORS and collects information from detailed environmental assessments on factors contributing to the outbreak and the underlying conditions that led to it. The information collected through NEARS can inform hypothesis generation about antecedents to foodborne illness outbreaks and strengthen the ability of food-control authorities to formulate and evaluate the effectiveness of food-safety actions.

1.3.3 The food supply and associated environments are tested by local, state, and federal regulatory officials and the food industry. Food testing is a tool used to assess whether an establishment's food-safety system is functioning adequately to address hazards in food production and manufacturing and prevent foodborne illnesses. Food and environmental testing data, including molecular subtyping data, can be used to inform hypothesis generation during outbreaks. Food testing data also can be used to estimate the fraction of selected foodborne illnesses caused by specific food sources, to assess changes in food contamination over time, and to assess the success of regulatory measures. Foodborne pathogens of interest that are isolated from food or from animal or environmental sources during various government testing programs are being characterized by WGS and the sequence data added to FDA's GenomeTrakr BioProjects housed at NIH NCBI, where they can be compared with data from human isolates directly on NCBI Pathogen Browser and/or in the CDC-PulseNet National Database. No formal framework exists to link industrywide testing to public health surveillance data. Mechanisms have been discussed that would provide access to aggregated, or blinded industry data to avoid regulatory penalties to individual companies.

To ensure technical competence and the ability to generate reliable data, food testing laboratories within FDA and FSIS maintain accreditation in the International Organization for Standardization/International Electrotechnical Commission 17025 standard—the main international standard used by testing and calibration laboratories. Additionally, FDA is leading an effort to bring state human and animal food testing laboratories into International Organization for Standardization/International Electrotechnical Commission 17025 accreditation to enhance efforts to protect the food supply. Data

1.3 Enhanced U.S. Foodborne Illness Surveillance Systems

generated by accredited laboratories will be made available for consideration during FDA enforcement actions, as well as for surveillance purposes and during local, state, or federal response to foodborne illness outbreaks.

Laboratory accreditation also will assist state manufactured food-regulatory programs in achieving conformance with the Manufactured Food Regulatory Program Standards.

1.4 Foodborne Illness Outbreak Response and System Change

1.4.1 Although foodborne illness surveillance and response are rooted in individual states' laws, the growing trend in multistate outbreaks associated with widely distributed foods requires increasing standardization of methods, integration of activities, and federal support and oversight. In response to the emergence of *E. coli* O157:H7 and other foodborne pathogens during the 1990s, CDC developed the active surveillance network FoodNet, with funding assistance from FSIS and FDA, to conduct comprehensive surveillance of diagnosed illnesses within defined populations to assess and monitor trends in the burden of illness associated with specific agents. Simultaneously, CDC established the national molecular subtyping network PulseNet to improve laboratory-based surveillance for bacterial pathogens routinely detected by clinical laboratories. PulseNet increased detection of multistate outbreaks, and FoodNet provided a framework to interpret the impact of food system changes in response to improved outbreak detection and regulatory activity.

In 2005, CIFOR was established to identify barriers to effective surveillance and investigation of foodborne illnesses and outbreaks. One of the first CIFOR projects was to develop guidelines for outbreak detection and response. The First Edition of the CIFOR Guidelines, published in 2009, established model practices for foodborne disease surveillance at local and state levels,

with specific reference to coordination of multijurisdictional outbreaks investigations and development of performance indicators to measure the effectiveness of surveillance activities. The Second Edition of the Guidelines was published in 2014.

During this time, CDC began providing dedicated funding to support state-level foodborne illness outbreak response through Epidemiology and Laboratory Capacity cooperative agreements. This led to development of several CDC programs: OutbreakNet, CDC's Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE), and the Integrated Food Safety Centers of Excellence and OutbreakNet Enhanced (OBNE). The CDC Integrated Food Safety Centers of Excellence were created by FSMA. These programs are intended to work together to enhance the development and evaluation of foodborne illness surveillance and outbreak response activities across the United States.

In conjunction with CDC's investments in the performance of public health agencies, FDA has used additional resources provided by FSMA to develop a network of Rapid Response Teams (RRT) to enhance coordination between public health and food-regulatory agencies at the state level and formed a Coordinated Outbreak Response and Evaluation (CORE) Network to centralize coordination of outbreak response activities within FDA. FSIS has developed parallel outbreak response capacity (Chapter 3).

1.4 Foodborne Illness Outbreak Response and System Change

With a stated goal of building an Integrated Food Safety System, FDA established the Partnership for Food Protection in 2008, bringing together local, state, territorial, tribal, and federal representatives with expertise in food; feed; epidemiology; laboratory; and animal, environmental, and public health. The Partnership for Food Protection (PFP) brings the collective expertise of the above stakeholders to work on projects that enhance human and animal food safety in the United States.

Coordination of activities on the federal level is accomplished through mutual liaisons between agencies, and joint participation in the Intergovernment Food Safety Analytics Collaboration (IFSAC) which seeks to improve the use of outbreak surveillance in foodborne illness attribution models and thus better guide food-safety regulation. Chapter 3 details the agencies currently involved in foodborne illness outbreak response, along with their respective roles and responsibilities. Issues posed in the response to multijurisdictional outbreaks are discussed in Chapter 7.

1.4.2 Food-safety standards are changing to better control food-safety risks identified by foodborne illness outbreak investigations. Both industry-driven standards (e.g., from the Global Food Safety Initiative, <https://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html>) and government-driven regulatory requirements are being updated to identify and manage food-safety hazards more rapidly. Examples of noteworthy regulatory changes in the United States include

- The 2011 FSMA—the first major reform of the FDA’s food-safety authority since the 1938 enactment of the Food, Drug, and Cosmetic Act. Since the Second Edition of the CIFOR Guidelines, some key provisions of FSMA have been rolled out in seven federal regulations (Chapter 2), which provide FDA with additional legal authorities and resources to strengthen food-safety

systems. They enable FDA and its food-safety partners, to focus on preventing food-safety problems and to address food-safety risks more rapidly when they are identified. FSMA and its associated regulations grant FDA substantial new authority to protect food all along the farm-to-fork line, covering preventive controls, inspections, laboratory testing, product tracing, mandatory recall authority, importer accountability, authority to deny entry to the U.S. market, state and local capacity building, and other areas.

- Since enactment of its Pathogen Reduction, Hazard Analysis and Critical Control Point Systems rule to reduce risks associated with meat and poultry in 1996, FSIS has continued to address food-safety hazards. In 2011, FSIS established raw poultry performance standards for *Campylobacter* and updated existing ones for *Salmonella*. In 2012, FSIS added six non-O157 STEC serogroups as “adulterants” in raw beef. In 2015, after agency investigators noted they often were impeded in efforts to trace ground beef to its source during outbreak investigations and in response to STEC-positive sample results, FSIS required its regulated establishments and retail stores to maintain detailed records to identify all ground-beef source materials.

In summary, the foods we eat and the processes by which they are produced, distributed, and prepared; the means for diagnosing illness and detecting outbreaks; the methods whereby outbreaks are investigated; and the response of government and private partners are always changing. The following chapters provide updated guidance to responders with these changes in mind. The final chapter (Chapter 8) provides and references metrics for evaluating an agency’s progress toward optimizing its response to foodborne illness outbreaks.

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Legal Preparedness for the Surveillance, Investigation, and Control of Foodborne Illness Outbreaks

CHAPTER SUMMARY POINTS

- The authority to identify, investigate, and control foodborne illness outbreaks is shared across local, state, and federal, governments and requires ongoing cooperation. Legal preparedness is the assurance that agencies and jurisdictions are equipped with sufficient legal authorities to conduct effective disease surveillance and control and have staff trained to use these authorities.
- Local and state statutes and regulations authorize the reporting and investigation of foodborne illnesses. The communicable disease control regulatory process is often used to specify diseases and conditions to be reported, the information to be reported, and the process for making a report. State laws and regulations also address the confidentiality of disease reports and enforcement of reporting requirements.
- Local and state agencies need to regularly access confidential records when investigating reports of foodborne illness. They must navigate differing local, state, and federal legal authorities and requirements as they seek to access and share information with other government agencies and respond to media inquiries.
- Shared goals of the public and private sectors are to prevent as many outbreaks as possible and to mitigate those that occur. In the public sector, local, state, and federal agencies accomplish those goals by working independently and together to exercise their legal authorities to, among other things, inspect, seize or destroy foods, and close establishments.
- Although reporting, surveillance, and mitigation of foodborne illness outbreaks are well established in local, state, and federal law, issues continue to arise that demonstrate differences among state and federal laws and the need for ongoing communication and collaboration among state, local, and federal officials who are united in the common goal of protecting the public's health.
- During foodborne illness investigations, public officials may find issues that require the initiation of administrative actions or even civil or criminal proceedings. Data collected during a foodborne illness investigation can become the basis for further action by local, state, and federal agencies.

2.0 Introduction

2.0.1 Understanding and appropriately using law is a fundamental part of protecting the public’s health from foodborne illness. Local, state, and federal government agencies share the authority to identify, investigate, and control foodborne illness outbreaks, but each level of government and each agency within it has specific roles, responsibilities, and legal authorities. The success of a public agency’s efforts to combat foodborne illness also greatly depends on its cooperation and communication with multiple parties in the food, agriculture, healthcare, and laboratory sectors. Ultimately, the goal is to become more effective at protecting public

health and preventing disease by leveraging legal authorities across local, state, and federal jurisdictions.

2.0.2 This chapter addresses legal preparedness in the various aspects of foodborne illness outbreak surveillance and control—reporting, surveillance, investigation, mitigation, and prevention—through the perspective of local, state, and federal agencies. It also discusses critical issues that arise during outbreak investigations, such as confidentiality of data and use of public health investigations as the basis for regulatory actions or criminal prosecutions.

2.1 Public Health Legal Preparedness

Legal preparedness is an indispensable part of a comprehensive preparedness plan for public health threats. The Centers for Disease Control and Prevention (CDC) defines public health legal preparedness as the attainment by a public health agency or system of specified legal benchmarks or standards of preparedness for specified public health concerns (*1*). Public health legal preparedness has four core elements:

- Laws and legal authorities;
- Competency in understanding and using law;
- Coordination across sectors and jurisdictions in the implementation of law; and
- Information about best practices in using law for public health purposes.

These core elements apply to all areas of public health, especially in the areas of food safety and foodborne illness outbreaks. Because the U.S. food system is highly complex, public health, food, and agriculture officials responding to foodborne illness outbreaks face the challenge of rapidly gathering and

processing information to identify and mitigate the source of an outbreak while protecting confidentiality and preserving rights.

2.1.1 Legal preparedness within the context of surveillance, investigation, and control of foodborne illness outbreaks requires state and local officials to ensure their agencies and jurisdictions have the following:

- Laws and legal authorities needed to conduct all functions essential to effective surveillance, investigation, and control (e.g., reporting, enforcement, prevention, mitigation, investigation, and regulation).
- Trained professional staff with demonstrated competency in applying relevant laws.
- Mutual aid agreements or memoranda of understanding in place to facilitate investigation and response across jurisdictions and agencies.
- Access to information about model practices in using relevant legal authorities and applying them.

2.1 Public Health Legal Preparedness

Box 2.1. Partnering with Your Agency's Attorney (2)

To prepare for an outbreak:

- Meet with your agency's attorney to discuss specific legal authority and responsibilities contained in local, state, and federal law relative to disease reporting, investigations, and food-regulatory actions (e.g., permit suspension and closure, employee restrictions).
- Identify outbreak settings or conditions for which legal assistance might be needed.

Outbreak settings or conditions for which legal assistance might be needed:

- There is a reasonable chance the public's health is or might be threatened without specific public health intervention.
- Your ability and authority to address the situation is unclear.
- The event or circumstance could expose your agency or organization to potential liability, or political pressure.

In an outbreak situation in which you might need legal assistance:

- Contact your agency's attorney as soon as possible for legal input.
- Be candid and open; give all the facts—don't allow for surprises.
- Proactively include your agency's attorney in discussions rather than seeking ratification of decisions later.

If you do not understand or you disagree with the advice provided by your agency's attorney, ask for clarification or discuss other options with him or her rather than requesting different advice from another attorney.

The adequacy of local and state legal preparedness for foodborne illness outbreaks also should be evaluated regularly through exercises and after-action reviews from actual outbreaks.

As part of ensuring their jurisdictions' legal preparedness, local and state officials should consult with their legal counsel (Box 2.1) and with counterparts in other government agencies that have authority relevant to ensuring successful surveillance and control of foodborne illness outbreaks. These include food and agriculture regulatory and law enforcement agencies, legal counsel to local and state governments, and local and state courts and court administrators.

Private organizations also must be aware of their legal duties regarding food safety and disease reporting). These duties vary by state. Relevant private entities include private laboratories, food firms, hospitals, and other health institution food services. Food-industry entities should be prepared to address both

regulatory requirements and the way these requirements might affect their internal policies on sharing information (3). Where possible, both public and private entities should be included in foodborne illness exercises to test their understanding of their legal authority and duties related to outbreaks.

2.1.2 As government entities, public health, food, and agriculture agencies operate within the context of the U.S. Constitution, state constitutions, federal and state statutes and regulations, local charters and ordinances, court decisions, and more.

Thus, these agencies are empowered and limited within this context and must navigate the country's foundational legal principles, i.e.,

- **A system of checks and balances.** Public health, food, and agriculture agencies belong to the Executive Branch and are broadly charged with implementing laws enacted by the legislature and interpreted by the courts.
- **Federalism.** The U.S. Constitution enumerates specified powers for the federal

2.1 Public Health Legal Preparedness

government and reserves other powers to the states (tribes are autonomous or sovereign bodies). In addition, state and local governments possess inherent police powers to protect the health and safety of the public.

- **Protection for civil liberties and property rights.** The Fourth, Fifth, and Fourteenth Amendments protect citizens from unreasonable searches and from deprivation of life, liberty, and private property without due process of law. State constitutions, statutory law, and court rulings provide additional protections relevant to the conduct of foodborne illness surveillance and operations by public agencies.

2.1.3 The legal authority supporting local and state public health agencies' role in the protection and promotion of the public's health stems from constitutional, statutory, regulatory, and judicial case law, as well as from the general police powers.

However, these powers are not unlimited. Important legal parameters for public health authority and practice were articulated in the foundational 1905 U.S. Supreme Court ruling in *Jacobson v. Massachusetts* (4):

- With compelling reason, individual liberties can be subordinated to the well-being of the community.
- The police power of the state authorizes issuance and enforcement of reasonable regulations to protect the health of the community.
- Courts defer to the authority that legislative bodies give to public health agencies if that authority is exercised on the basis of persuasive public health and medical evidence.
- Public health agencies cannot act in an arbitrary manner or pose unreasonable risks for harm.

In general, these parameters apply to state and local public health agencies' surveillance and control of foodborne illness outbreaks. Those activities, however, are further authorized and conditioned by the statutes, regulations, ordinances, and case law of the individual jurisdictions. Some of these laws relate specifically to foodborne illnesses, but in many jurisdictions, public health agencies rely on laws (state statutes and local ordinances) that authorize surveillance for infectious diseases generally.

2.1.4 CDC operates under congressionally enacted statutory law and, especially in the case of foodborne illness surveillance, under provisions of the Public Health Service Act (5). CDC is not authorized to mandate reporting of diseases and conditions by state and local governments or by private entities. However, states do mandate reporting pursuant to state laws.

Among many other provisions, the Public Health Service Act authorizes CDC to gather data on nationally notifiable diseases pursuant to guidelines CDC develops in partnership with state and local public health agencies and professional societies. Many of these data come from state and local public health agencies. CDC partners with the Council of State and Territorial Epidemiologists to establish (and modify as needed) case definitions for diseases. These guidelines and case definitions, however, are not legally binding. States have the autonomy to adopt these Council of State and Territorial Epidemiologists–developed case definitions or develop their own definitions for use in their states. CDC does not collect personal identifiers on routine surveillance data that it receives from public health departments.

The Public Health Service Act also authorizes CDC to perform laboratory tests on specimens received from state and local governments (and from other sources) to identify pathogens, confirm serotypes or molecular subtypes,

2.1 Public Health Legal Preparedness

perform diagnostic assays, and report findings to appropriate state and local health departments. Virtually all enteric illness specimens tested in CDC laboratories are initially tested in state or local public health laboratories.

Additionally, CDC may participate in an outbreak investigation within a state if invited by the state. Multistate investigations are typically led by CDC or the state health department where most of the cases occurred.

2.2 Legal Framework for Surveillance and Disease Reporting

Investigation of enteric illnesses to determine the source of exposure, risk factors for infection, and contacts of a person with a contagious disease is usually considered part of surveillance and disease control activities authorized by local and state statutes. Likewise, state and local authority to mandate disease reports arises from state law. The regulatory process is used to specify diseases and conditions to be reported, the information to be reported about a case, and the process for making a report. State laws and regulations also address the confidentiality of disease reports and enforcement of reporting requirements (Box 2.2).

Box 2.2. Communication with Laboratories and Hospitals

Ongoing communication arrangements should be established with national or regional commercial and clinical laboratories to ensure that the investigating agencies receive results for relevant cases, even when those tests are conducted out of state. Similar communication channels also should be established with in-state and out-of-state hospitals that serve a population within the community affected by the outbreak.

2.2.1 Local and state health agencies learn about foodborne illnesses through a variety of sources that vary in reliability and traceability. As discussed further in Chapter 4, these include

- Reports through the state’s mandatory disease and conditions reporting system;

- Surveillance reports for enteric pathogens;
- Requests for antitoxin for botulism;
- Reports of food poisoning or gastrointestinal illness in individuals or defined groups, such as diarrhea and vomiting among residents of a nursing home or hospital, attendees at schools or childcare centers, or attendees at a work-related meeting;
- Reports to poison control centers;
- Reports of enteric illness suspected of being caused intentionally;
- Complaints of suspected foodborne illness or alleged exposure to contaminated, adulterated, or improperly cooked food purchased from stores or in restaurants and reported voluntarily by the public;
- Syndromic surveillance using de-identified emergency department or pharmacy data; and
- Reports directly from the food industry of consumer complaints of illness.

2.2.2 The state legislature generally gives broad statutory authority to the state health department to collect information and to require reports of diseases, conditions, and outbreaks of public health importance.

Generally, the state legislature also gives the state health department the authority to adopt rules or regulations that specify which diseases or conditions must be reported, who must report them, and how to report (Table 2.1).

2.2 Legal Framework for Surveillance and Disease Reporting

The list of reportable diseases and conditions and laboratory findings is maintained and updated by epidemiologists and health officers in state and local agencies, with review and approval by the body overseeing the health department.

In addition to broad authority, states typically have several disease-specific statutes, such as those for human immunodeficiency virus/acquired immunodeficiency syndrome, tuberculosis, and vaccine-preventable diseases, which authorize surveillance and control activities. All states also have statutes addressing reporting and response to bioterrorism incidents.

Table 2.1. Reporting Processes Typically Specified by Statutes and Regulations

PROCESS	REQUIREMENT	COMMENT
Sources of reports	<p>The usual sources of mandatory reports are</p> <ul style="list-style-type: none"> • Laboratories <ul style="list-style-type: none"> ○ Hospital-based laboratories; ○ Clinical laboratories; ○ National or regional commercial referral laboratories; ○ Local or state health department laboratories; and ○ CDC laboratories; • Health care institutions <ul style="list-style-type: none"> ○ Hospitals (e.g., hospitalized patients reported by infection control practitioners); ○ Emergency departments; and ○ Long-term-care facilities or nursing homes; • Physicians; • Schools and childcare centers; • Food establishments (e.g., restaurants); and Other state health departments. 	<p>The source of a report does not affect the legal status of the information; if it is required information, it is protected by statutes and regulations.</p> <p>Conversely, reports to the agency of an illness not listed as a reportable condition might not be subject to disease surveillance regulations and confidentiality protections.</p>
Time frame and content of reports	<p>Statutes and regulations usually specify the following aspects of disease reports:</p> <ul style="list-style-type: none"> • Time frame for reporting (e.g., within 7 days after diagnosis, within 24 hours after diagnosis, immediately); and • Information to be reported (e.g., diagnosis; personal identifying and locating information; date of onset or diagnosis regardless of whether the case is suspected or confirmed). 	
Reporting methods	<p>A state or municipality can use a variety of methods for reporting. Specifics vary from one locale to another. These methods include</p> <ul style="list-style-type: none"> • Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies; • Reports sent by email; • Automatic electronic submission through health information exchange; • Telephone; and/or • Hard copy (fax or mail). 	

2.2 Legal Framework for Surveillance and Disease Reporting

Table 2.1. Reporting Processes Typically Specified by Statutes and Regulations
Continued

PROCESS	REQUIREMENT	COMMENT
Required submission of laboratory specimens	<p>Many public health agencies have adopted regulations that require laboratories to submit isolates of specific pathogens to a state or local health department laboratory for further confirmatory and/or genomic testing, such as pulsed-field gel electrophoresis and/or whole-genome sequencing, to improve surveillance for foodborne disease (see also 6). When the clinical laboratory does not obtain isolates, some states require or request submission of primary clinical material or enrichment broths. The regulations often include a time frame for submission of such materials.</p> <p>With the increasing development and use in clinical settings of culture-independent diagnostic tests (CIDT), which do not produce an isolate, there is growing concern that the supply of isolates to health departments will be depleted, hindering public health surveillance activities. To address these concerns, states have begun to amend their laws. A few states have added language that gives specific submission instructions to a clinical laboratory that has used CIDT methods to make a diagnosis. Other states have expanded their list of acceptable materials for submission beyond only an "isolate" to include "specimen," "primary clinical material," "enrichment broths," and other alternative materials to submit if the preferred isolate is not available. States may continue to amend their disease reporting laws, in various ways to fit the needs of the jurisdiction, as CIDT continues to develop for a broader number of pathogens.</p>	In some locales, voluntary submission of specimens achieves the same goal.

2.2.3 Reliable reporting by persons and institutions mandated to submit disease reports is the foundation of the reporting system. When enteric illnesses are not reported, a foodborne illness outbreak may be missed. Because of the problem of nonreporting, redundant reporting systems have been established to ensure a case will be reported (e.g., a *Salmonella* infection might be separately reported by physicians, laboratories, and healthcare institutions). Because health agencies want to encourage compliance, ongoing education and communication with persons and institutions mandated to report is imperative to reinforce the importance of reporting requirements.

Education is the preferred method to obtain reporting compliance, but when violations arise, statutes and regulations mandating disease reporting also contain enforcement

and penalty provisions. Depending on the jurisdiction and the frequency and severity of nonreporting, sanctions can range from notification to a state licensure board to civil fines and/or criminal penalties.

Reporting may be difficult to enforce with a laboratory or healthcare provider outside an agency's jurisdiction, such as when a state seeks reports from a reference laboratory located in another state. In that situation, lack of reporting usually results from misunderstanding of how to report. Occasionally a laboratory will assert that it complies with requirements of the public health agency in the state in which it is physically located—which might or might not require reporting of the specific disease, infection, or laboratory result. Again, ongoing communication with the parties required to report and coordination with the state health agency in the parties' home state can improve reporting.

2.3 Protection of Confidentiality and Authority to Access Records

State and local health agencies need to regularly access confidential records when investigating reports of foodborne illness. However, when doing so, federal and state laws mandate the protection of confidential personal information during these public health investigations.

Typically, the broad authority to conduct surveillance includes authority to investigate and control diseases of public health significance, including review of relevant and pertinent medical and laboratory records and reports (i.e., information that is not necessarily included in the basic case report). Although medical and laboratory staff might be concerned about potential violations of federal Health Insurance Portability and Accountability Act (HIPAA) (7) and state privacy laws in releasing records, exceptions for public health and other government agencies allow access to records. Consulting with an agency attorney is advisable whenever questions or concerns arise about accessing or disclosing confidential information (Box 2.3).

Box 2.3. Prepare for Questions about Authority to Access Information

Staff in an organization that might be required to provide information to local, state, and federal officials about foodborne illnesses and outbreaks might not be familiar with the authority of government officials to access individually identifying and other privacy-restricted information under certain provisions of state and/or federal law.

These organizations might include those (e.g., childcare, elder care) that, depending on state law, might not have routine interaction with disease reporting and outbreak investigation systems.

Consult with your agency's attorney to prepare memorandum or information sheets tailored to different types of organizations that specify state and federal authority to access information.

2.3.1 HIPAA and its associated regulations limit access to a person's protected health information (PHI) (7, 8). PHI is information that can be used to individually identify a person through demographic data, diagnosis, treatment, or payment for treatment (9).

Important exceptions to HIPAA allow public health and other government agencies to access PHI, including

- **Required by Law.** Entities covered by HIPAA (e.g., doctors, healthcare plans) may use and disclose PHI without individual authorization if required by law (e.g., statute, regulation, or court order).
- **Public Health Activities.** Covered entities may disclose PHI under several circumstances related to public health activities, including
 - Public health authorities authorized by law to collect or receive information for preventing or controlling disease, injury, or disability;
 - Persons who might have been exposed to or contracted a communicable disease when notification is authorized by law; or
 - Entities subject to Food and Drug Administration (FDA) regulation for purposes such as tracking products or product recalls.

These exceptions in effect authorize a covered entity (e.g., doctor) to disclose otherwise confidential PHI. Explaining these exceptions to physicians or their staff often results in better compliance with reporting requirements. HIPAA does not restrict the use of de-identified information, which does not identify a person or provide a basis for identification (10).

2.3 Protection of Confidentiality and Authority to Access Records

2.3.2 Local and state health agency staff must know the requirements of their freedom of information laws and the exemptions from them. Personal identifying information (PII) (e.g., name, age, sex, race, ethnicity, residence, or date of diagnosis) in disease reports and investigation records is generally confidential and exempt from disclosure in response to freedom of information requests. Each state can define what it considers to be PII. The goal is to avoid releasing data that make it possible to directly or indirectly identify the affected person if the released data are combined with other information. When there are a large number of cases, it might be possible to release data *other than names and residences* in response to freedom of information requests. When there are too few cases among the population of a given area, an agency might have a policy of not releasing data to guard against potential identification of an individual person. This determination should be made in each instance in conjunction with agency epidemiologists, statisticians, and attorneys.

In addition to potential restrictions on sharing PII, state laws might restrict sharing of other types of information, such as confidential commercial information and predecisional/deliberative information. Furthermore, the federal Privacy Act can restrict the sharing of certain personal privacy information (PPI) by federal agencies (11).

Occasionally a public health agency must respond to a media inquiry in which the media have learned the identity of a particular case from another source. The agency's response to the media inquiry must be carefully structured to avoid unintentional confirmation of the patient's identity. Preparing final outbreak investigation summary reports without any PII can hasten and simplify release of those reports to attorneys or media.

2.3.3 A public health agency may be restricted from sharing PPI with other government agencies without the consent of the reported person. However, these restrictions are subject to several exceptions:

- Local and state health agencies are generally permitted to share information with other state, local, and federal agencies to confirm and track cases.
- Many state statutes contain an exception for sharing information when, in the agency's judgment, sharing is necessary to protect public health.
- Virtually every state has an exception for sharing information with law enforcement agencies for investigation of intentional contamination or a bioterrorism incident.

2.3.4 The U.S. Department of Health and Human Services (DHHS), FDA, has formalized arrangements for information sharing with local and state regulatory agencies.

FDA provides nonpublic information to state and local agencies under 20.88 agreements (12) and to certain state and local officials who have been commissioned by FDA (Box 2.4).

- 20.88 agreements are authorized under 21 CFR 20.88. 20.88 agreements allow FDA to share certain nonpublic information with state and local government officials. These agreements allow for the sharing of confidential commercial information, PPI, and predecisional information (PDI), and pre-deliberative information but not trade secret information. The receiving agency must commit to keep this information confidential (12, 13). FDA offers several types of 20.88 agreements:
 - Single-Signature Long-Term Information Sharing Agreements (Food and Feed, Pharmacy Compounding, Drug Security) (Long-Term 20.88) allows for the sharing of nonpublic information proactively or

2.3 Protection of Confidentiality and Authority to Access Records

on request related to food, animal food, cosmetics, pharmacy compounding, drug security with all employees who report to the signatory.

- Case-Specific 20.88 allows for the sharing of nonpublic information related to a particular incident involving an FDA-related industry (e.g., food, drugs, devices, biologics). A Case-Specific 20.88 can be expedited if FDA is made aware of the need for urgent processing. Each employee who will need access to the information must sign.
- 20.88 with Associations allows for proactive or upon request sharing of nonpublic deliberative processes and predecisional information only. Examples may include draft rules and/or draft guidance.
- **Commissioning.** FDA's commissioning process enables a state or local health, food, or drug official to be commissioned as an officer of DHHS (14). Commissioned officials may receive nonpublic information solely for the purpose of their work on behalf of FDA as a commissioned official. They may generally disclose that information to other FDA-commissioned officials (in their capacity as FDA commissioned officials) and FDA employees (15). Such information remains FDA information. Commissioning

also authorizes state or local officials to conduct inspections under the Federal Food, Drug, and Cosmetic Act (FFDCA) (16).

2.3.5 The U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) has a process for sharing information with government partners.

FSIS Directive 2620.5 addresses “procedures needed to share information concerning FSIS regulated products with State or local agencies, foreign government officials, and international organizations responsible for food inspection programs and laboratories” (17). To request outbreak-related information from FSIS, send an email to FoodborneDiseaseReports@usda.gov.

Box 2.4. Cross-Jurisdiction and Cross-Sector Coordination

Effective reporting of foodborne illness cases hinges on coordinated reporting across jurisdictions (e.g., local, state, tribal, and federal governments) and across sectors (e.g., healthcare and public health). Local and state health officials should periodically assess the need for memoranda of agreement (or other legal agreements) with partners in other jurisdictions and sectors to ensure timely and effective reporting. CDC has created several resources for assessing and improving cross-jurisdictional and cross-sector coordination (18,19).

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

Shared goals of the public and private sectors are to prevent as many outbreaks as possible and to mitigate those that do occur. Changes in technology and food production have brought opportunities and challenges. Improvements in laboratory and communication technologies have enabled agencies to link cases that

previously were thought to be sporadic and to identify and address implicated foods and sources. However, with continued globalization of food-production industries, more multistate and international foodborne illness outbreaks are being discovered, thus expanding the focus of outbreak investigations and control

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

measures. This section reviews the roles of local, state, and federal, agencies and the legal authorities empowering them to act.

2.4.1 U.S. law authorizes several federal agencies to undertake regulatory and nonregulatory actions over food safety at various stages on the continuum of food production, importation, processing, transportation, storage, and sale. Agencies regulating food have the authority to inspect, recall, and seize unsafe foods. All agencies coordinate and collaborate with states and localities in the prevention of foodborne illness and in multistate investigations. This section focuses on CDC, FDA, USDA, and the Environmental Protection Agency (EPA) and their legal authority related to food safety (see Chapter 3 for each federal agency's roles and resources).

- **DHHS, CDC**

The Public Health Service Act (5) authorizes CDC to identify and monitor foodborne diseases and to investigate foodborne illness outbreaks in coordination with local and state health agencies. CDC can lead investigations into multistate foodborne illness outbreaks and, when invited, work in partnership with the state where the most cases have occurred.

- **DHHS, FDA**

The FFDCA (16) authorizes FDA to regulate domestic and imported food, except meat, poultry, and processed egg products (i.e., frozen, dried, and liquid eggs), which are regulated by USDA.

- **FFDCA**

The primary legislation by which FDA exercises authority over food is the FFDCA. A goal of FDA is to prevent contamination of food products before distribution. FFDCA also empowers FDA to pursue:

- Voluntary compliance through the issuance of inspectional observations, untitled letters and warning letters;
- Civil action, such as an injunction to prevent future violations of the FFDCA (e.g., continued distribution of adulterated food);
- Seizure action to remove specific lots of adulterated food;
- Mandatory recall of food that presents a certain risk to public health;
- Criminal action against an individual or company that violates the FFDCA such as by causing food to become adulterated by inadequate processing and handling;
- Administrative detention of certain food for up to 30 days; and
- Suspension of the registration of a facility so that food from the facility cannot be introduced into commerce.

In some circumstances, FDA's authority under the FFDCA is limited by the requirement that food be in interstate commerce. However, under both the FFDCA and the Public Health Service Act, FDA can regulate intrastate commerce in certain instances. Even when authority exists for FDA action, relying on state agency action might be faster when state authorities are more expansive or flexible than FDA's authorities.

Amendments to the FFDCA in 2007 require registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to report to FDA's Reportable Food Registry when a reasonable probability exists that the use of, or exposure to, an item of food will cause serious adverse health consequences or death to humans or animals (20). FFDCA was further amended in 2011 by the Food Safety Modernization Act (21).

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

- FDA Food Safety Modernization Act**
 The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011, amended the FFDCA to enhance the federal government's ability to prevent and respond to contamination in the food supply (21). The law addresses prevention, inspection, compliance, and response activities.

FDA, the agency primarily responsible for implementing FSMA, has developed a series of rules and guidance documents to address the law's requirements. As of April 2018, FDA has finalized the following rules:

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (22,23).
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (24,25).
- Foreign Supplier Verification Programs (26,27).
- Mitigation Strategies to Protect Food Against Intentional Adulteration (28,29).
- Sanitary Transportation of Human and Animal Food (30,31).
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (32,33).
- Accredited Third-Party Certification (34,35).

FDA has also implemented a Voluntary Qualified Importer Program (36). It is a fee-based, voluntary program that provides importers meeting specified criteria with expedited review and import entry of human and animal foods. In addition to rules, FDA has issued multiple guidance documents

regarding implementation of FSMA and its rules. The FDA website (<https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>) provides details about the law, rules and updates on the status of FSMA implementation.

- FDA Food Code**

Although the FDA Food Code is not a federal law or regulation, this model code may be adopted or adapted by states, tribes, and localities as the basis for their jurisdictions' food-safety rules for retail and food-service establishments (e.g., restaurants, grocery stores, institutions) (37). The Food Code assists jurisdictions in updating their rules to be consistent with federal food-safety policy, although each jurisdiction undergoes its own rulemaking process to adapt the code to fit the jurisdiction's legal framework. Currently, FDA revises the Food Code every 4 years.

- USDA, FSIS**

USDA-FSIS has the legal authority to regulate meat, poultry, and egg products on the basis of the following statutes:

- Federal Meat Inspection Act (38).
- Poultry Products Inspection Act (39).
- Egg Products Inspection Act (40).

Each of these Acts is intended to protect the health and welfare of the consuming public by preventing the introduction of adulterated or misbranded meat, poultry, or egg products in interstate commerce. In addition, in states that do not have meat or poultry inspection programs "at least equal to" the federal programs, Federal Meat Inspection Act and Poultry Products Inspection Act provide for federal regulation and inspection of wholly intrastate operations and transactions to the same extent as if such operations and transactions were conducted in interstate or foreign commerce.

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

In carrying out its duties under these Acts, USDA-FSIS may pursue the following actions:

- Regulatory action for federally inspected facilities, such as retention of product, withholding actions, and notices of intended enforcement, suspension, or withdrawal;
- Civil action, such as an injunction to prevent future violations of the Acts (e.g., continued distribution of adulterated or misbranded products);
- Detention and seizure action to remove specific products from commerce;
- Criminal action against an individual or company that violates the Acts; or
- Voluntary compliance through notices of warning.

Specifically, in response to a foodborne illness outbreak, if a basis exists to conclude that a USDA-FSIS-regulated product contains a pathogen or is otherwise harmful to human health, and an outbreak investigation has identified a specific product, USDA-FSIS may recommend a product recall (41). A recall is a firm's action to remove a product from commerce to protect the public from consuming misbranded or adulterated products. Although it is a firm's decision to recall a product, USDA-FSIS coordinates with the firm to ensure it has properly identified and removed the recalled product from commerce by verifying the effectiveness of the firm's recall activities. USDA-FSIS also notifies the public about product recalls.

Alternatively, if after review of investigative findings, a basis exists for USDA-FSIS to conclude that a USDA-FSIS-regulated product contains a pathogen or is otherwise harmful to human health, but the investigation has not identified a product that can be recalled

(e.g., no specific brand name of product identified), then USDA-FSIS may issue a public health alert (41).

Further, depending on the evidence collected, and how strongly human illness is linked to a USDA-FSIS-regulated product, USDA-FSIS may take actions other than recommending a product recall or issuing public health alert. These actions may include increasing or enhancing inspection activities; increasing the frequency of microbial testing; conducting a Public Health Risk Evaluation; performing an in-plant Food Safety Assessment; or taking any of the actions listed above, such as effecting a regulatory control action or detaining and/or seizing product (41).

- **USDA, Animal and Plant Inspection Service (APHIS)**

USDA-APHIS is charged with protecting animal and plant resources from agriculture pests and diseases, including those that impact public health. USDA-APHIS operates under multiple statutes, including

- **Animal Health Protection Act.** This Act authorizes the prevention, detection, control, and elimination of diseases and pests in animals to protect animal health, public health and welfare, and economic and environmental concerns (42).
- **Plant Protection Act.** This Act permits regulation to prevent the introduction or dissemination of plant pests in the United States, including certain biological control organisms (43).

- **EPA**

EPA establishes the limits for pesticide residues in foods under the Food Quality Protection Act (44). EPA is also authorized to set standards for drinking water in the Safe Drinking Water Act (45).

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

2.4.2 State public health, agriculture, and food and drug agencies each play a role in mitigating and preventing outbreaks of foodborne illness. Each agency operates under one or more specific statutory and regulatory authorities. How these roles and authorities are structured and the assignment of responsibilities between the state and its localities vary by state. Local health departments in general operate under two frameworks: independent home rule and delegated authority.

State and/or local agencies are authorized to undertake a range of actions to mitigate and prevent outbreaks, including

- Requiring changes in food preparation;
- Temporarily removing persons with infectious illnesses from the workplace;

- Embargoing, seizing, or destroying contaminated food or requiring removal of contaminated lots from retail stores;
- Closing food establishments representing an imminent public health threat; and
- Issuing press releases

These actions are taken through agency authority granted by statute and implemented through rules or through administrative orders. In issuing an administrative order closing a restaurant, for example, such an order should contain time limits for the closure and specify the conditions that would permit the restaurant to reopen. If necessary, agencies can seek enforcement of their administrative orders through the court.

2.5 Evolving Legal Issues

Even though reporting, surveillance, and mitigation of foodborne disease outbreaks is well established in state and federal law, issues continue to arise that demonstrate differences in state and federal law. Such issues further demonstrate the ongoing need for communication and collaboration among local, state, and federal officials who are united in the common goal of protecting the public's health.

2.5.1 Food sovereignty initiatives are based on the idea that people should have the ability to democratically control their own food and agriculture policies. For some groups, the concept is tied to reducing poverty and providing healthy food through ecologically sound and sustainable metrics. These groups also focus on strategies to resist and dismantle corporate food production and increase local food production and control.

For other groups, deregulation is the primary focus of food sovereignty laws.

For example, Maine enacted a law in October 2017 authorizing municipalities to “adopt ordinances regarding local food systems and community self-governance that set forth provisions that apply exclusively to direct producer-to-consumer food exchanges and other traditional foodways” (46). The provisions essentially remove state oversight from certain food-production areas. The state, however, retains authority to implement and enforce rules related to the inspection of meat and poultry producers. This version of the statute took effect after USDA questioned whether the original version of the law would have enabled Maine to maintain its “at least equal to” status and continue to operate its meat and poultry inspection programs. The law also requires that anyone who “grows,

2.5 Evolving Legal Issues

produces, processes or prepares food or food products intended for any wholesale distribution or retail distribution outside of” a municipality to comply with state and federal food-safety laws, rules, and regulations (46).

2.5.2 While acknowledging the differing positions of the federal government and many states on the legality of marijuana use for medical and nonmedical purposes, food-safety concerns exist that are related to the incorporation of marijuana, hemp derivatives, and cannabidiol in food (edibles). States are continuing to work on the application of food-safety laws to the producers of such edibles. Some states subject those who produce edibles to state food worker restrictions and/or to local and state kitchen-related health and safety standards used for retail food establishments.

2.5.3 Cottage food laws collectively refer to state laws and regulations that allow for the sale, with restrictions, of certain foods produced in private homes. The

foods eligible for sale typically are considered safe from bacterial contamination and do not require time or temperature safety measures for production and/or storage (47). Examples include baked goods, candies, condiments, preserves, and dry mixes. Cottage food laws are viewed as promoting economic opportunities for home- and farm-based food businesses, while providing some regulatory safeguards of these businesses. As of June 2018, 49 states and the District of Columbia have some type of cottage food law; New Jersey did not have such a law (48,49).

Although cottage food laws vary among states, these laws generally address the types of foods permitted to be sold, who can sell, limits on sales, and labeling licensing, permitting and/or inspection requirements (50). In many states efforts are ongoing to expand the permitted foods or alter restrictions on sales. Any move to change existing cottage food laws, either by expanding them or adding limitations, should be done so with food safety and the public’s health in mind.

2.6 Public Health Investigations as the Basis for Further Action

The goal of a foodborne illness outbreak investigation is to identify and control the source of the outbreak. In the course of the investigation, officials may find issues that require the initiation of regulatory or administrative actions or even civil or criminal proceedings.

2.6.1 Data collected during a public health investigation can become the basis for further action by the health agency or other state and federal agencies. For example, if epidemiologic and laboratory data provide evidence linking illness to consumption of a particular food, an informational traceback investigation can result to identify the source of that food. Given the national

and international scope of food production, the informational and regulatory traceback investigations might involve multiple state and federal regulatory agencies. Violations of federal or state law that are identified during a regulatory traceback investigation may lead to further action, such as seizure of the implicated foods or injunctive remedies.

Local and state agencies also can initiate administrative actions over persons or businesses that violate state or local regulations. For example, if a restaurant has repeated food handling or food storage violations, it may be subject to administrative hearings leading to suspension or revocation of its food-service license.

2.6 Public Health Investigations as the Basis for Further Action

2.6.2 If during an investigation it is suspected or confirmed that a foodborne illness outbreak was caused because of criminally negligent behavior, intentional contamination or bioterrorism, additional state criminal, antiterrorism, and emergency response laws will enhance or dictate the course of the outbreak investigation and response. If the outbreak is multistate, then federal response resources and laws apply, and local and state public health agencies must work closely with other state and federal agencies.

Joint investigations by public health, food, agriculture, and law enforcement agencies can be hindered by the different legal powers and investigatory practices each agency brings to such an event. For example, officials from public health agencies are authorized to collect and test samples to determine their public health threat, whereas law enforcement officials can consider samples subject to seizure as evidence. Public health, food, agriculture, and law enforcement officials all must conform to constitutional standards (e.g., Fourth and Fifth Amendments) about collection of evidence,

especially in situations requiring a joint investigation. Laboratory specimens collected for regulatory purposes must be collected and submitted using procedures that ensure the chain-of-custody of the specimen is admissible in court (51). Chain-of-custody is a process that may be followed for evidence to be legally defensible and includes the following main elements: properly identifying the evidence, a neutral evidence collector, tamper-proofing and securing evidence at the collection site, and keeping physical control of the evidence.

Local and state officials, in collaboration with law enforcement agencies, should periodically assess the need for memoranda of understanding to clarify the roles of public health, food, agriculture, and law enforcement agencies in conducting joint investigations. Local and state officials who have roles in investigating foodborne illness outbreaks should understand and demonstrate competence in applying their legal authorities in conducting joint investigations. Resources for improving competency in joint investigations include CDC training curricula (52) and sample memoranda of understanding (53).

2.7 CIFOR Legal Preparedness Resources

CIFOR has created several resource documents to further assist local and state public health agencies in improving their legal preparedness to conduct surveillance for foodborne illness and respond to outbreaks within their jurisdictions and across multiple states and other jurisdictional boundaries. The CIFOR Law Project created the following three documents, each designed to address a discrete, but related, research need and audience. All the documents are available through the CIFOR website: <https://cifor.us/products/law-project>

- **Analysis of State Legal Authorities for Foodborne Disease Detection and Outbreak Response.** This document describes and analyzes the types of state legal authorities available to conduct foodborne illness surveillance and outbreak response activities. It highlights the patchwork of state laws and regulations across several topic areas—public health, communicable disease, food safety, food regulation, agriculture, environmental health, and general government authority—on which public health professionals and their legal counsel must rely to accomplish foodborne illness surveillance and outbreak response activities.

2.7 CIFOR Legal Preparedness Resources

- **Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response.** This document is a practical guide for public health professionals who perform key roles in foodborne illness surveillance and outbreak response. The handbook presents information and resources for practitioners charged with implementing their jurisdiction's legal authorities related to foodborne disease events. The handbook is a primer on the array of possible legal authorities (e.g., communicable disease laws, food-safety laws) that might be available and provides practitioners with checklists for identifying relevant agency actors and laws within their jurisdictions.
- **Menu of Legal Options for Foodborne Disease Detection and Outbreak Response.** This document provides a menu of legal options for state public health officials and policy makers to consider when reviewing their jurisdiction's legal authorities to conduct foodborne illness surveillance and outbreak response actions. The menu includes legal provisions relevant to activities conducted during foodborne illness surveillance and outbreak response—outbreak detection, outbreak investigation, outbreak control, and outbreak documentation. It is intended to be a resource for states to use in filling gaps and clarifying or enhancing their legal authorities.

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Planning and Preparation: Building Teams

CHAPTER SUMMARY POINTS

- This chapter describes the roles of the core outbreak investigation and control team members and major agencies and partners involved in foodborne illness outbreak response and highlights the resources, processes, and relationships that should be in place before an outbreak.
- Agency plans, training programs, and response partner working relationships must anticipate the need to rapidly expand and contract the scope and structure of investigation and control teams to address changing conditions.
- Key roles in outbreak detection and response include epidemiology, environmental health and public health, and laboratory practice.
- A core team should be involved in all outbreak investigation and control efforts, giving consistency to investigations, serving as the focal point for coordinating multidisciplinary and/or multiagency tasks, and enabling development of effective working relationships with external partners and advanced expertise among staff.

3.0 Introduction

3.0.1 This chapter describes the roles of the core outbreak investigation and control team members, major agencies, and partners involved in foodborne illness outbreak response and highlights the resources, processes, and relationships that should be in place before an outbreak.

Agencies must be prepared to mount and participate in effective single-agency and multiagency responses to incidents ranging from local to potentially national in scope. The authority to identify, investigate, and control foodborne illness outbreaks is shared across local, state, territorial, tribal, and federal government agencies. Each agency at every level of government has specific roles and responsibilities.

3.0.2 Agency plans, training programs, and response partner working relationships must anticipate the need to rapidly expand

and contract the scope and structure of investigation and control teams to address changing conditions. All agencies should maintain standard procedures and all-hazards emergency operations plans identifying the mechanisms for conducting routine and nonroutine investigations and responses. This chapter promotes practices that have been helpful in developing effective multidisciplinary foodborne illness investigation and control teams and provides links to related topics. These Guidelines contain detailed information about outbreak investigation and response. All responsible agencies should regularly work with their attorneys to anticipate legal issues that can arise during foodborne illness outbreak investigation and control. (See Chapter 2 for details about legal preparedness and the CIFOR law project that provides additional tools to help agencies and jurisdictions improve legal preparedness.)

3.1 Roles

3.1.1 Key roles in outbreak detection and response include epidemiology, environmental health, and laboratory.

These roles are distributed across the multiple entities—more than 3,000 local health departments, more than 50 state and territorial health departments, other state agencies, tribal organizations, and several federal agencies—that interact in a complex system to detect and respond to enteric and other human and animal foodborne illnesses. These roles include conducting surveillance to detect outbreaks through complaint-based, pathogen-specific, or other forms of surveillance (Chapter 4) and rapidly conducting outbreak investigation activities to identify the mode of transmission and vehicle (Chapter 5) and determine the potential for ongoing transmission and need for control procedures (Table 5.1 in Chapter 5; Chapter 6).

3.1.2 Agencies' roles, responsibilities, and resources influence outbreak responses.

The nature of the outbreak, including the type of pathogen or contaminant, severity of illness, suspected or implicated vehicle, number and location of affected persons, geographic jurisdictions involved, and local and state food safety rules and laws (Chapter 2) determine the individuals, disciplines (further discussed in section 3.2), and types of agencies that need to be involved. (Table 7.3 in Chapter 7 provides detailed information about multijurisdictional outbreak identification methods and required notification steps, by agency level).

Each agency's response plan should include its likely role in a foodborne illness outbreak investigation, staff (or positions) that may be involved, contact information for relevant external agencies, and communication and escalation procedures for working with those agencies.

3.1 Roles

3.1.3 Local and state (Table 3.1) and federal (Table 3.2) levels, other important cross-agency programs (Table 3.3), and nongovernment, industry and academic partners (Table 3.4) contribute to foodborne illness investigation and outbreak response. For local and state agencies, responsibilities vary depending on a state's organizational, legal, and regulatory structure; the distribution of responsibilities across different types of local and state agencies; and the size and capacity of the local agencies. Responsibilities for federal agencies follow regulatory jurisdictions for Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS), and public health surveillance and disease control mandates for the Centers for Disease Control and Prevention (CDC).

In addition to these primary federal agencies, several other federal jurisdictions may be relevant to outbreak investigations. The National Park Service may have exclusive or shared jurisdiction with state and local agencies depending on legislation designating the specific park. Local and state agencies whose jurisdiction contains or adjoins a

national park should establish relationships with the National Park Service Office of Public Health. On many other types of federal lands, state laws apply, but federal agencies may have overlapping responsibilities. The Department of Defense has autonomous authority over U.S. military bases, facilities (including food production, food service, and healthcare facilities), and vehicles.

Indigenous tribes have complete sovereignty and are completely autonomous. Investigations on tribal land may be conducted by tribal health staff, Indian Health Service staff, or state or local health agencies, but nontribal entities can become involved in an investigation only at the tribe's request. Memoranda of understanding may establish lines of communication and reciprocal support during public health emergencies.

Law enforcement agencies at multiple levels will become involved in an investigation if intentional contamination of food or other criminal activity is suspected. Agencies responsible for controlling foodborne illness outbreaks should establish relationships and communication pathways with law enforcement agencies before any outbreak.

Table 3.1. Examples of Typical Foodborne Outbreak Investigation Roles, Responsibilities, and Contributions of Local and State Agencies*

AGENCY	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
Local health agencies and laboratories	<p>Responsible for local policies to protect public health:</p> <ul style="list-style-type: none"> • Maintain communication and working networks with local populations and community businesses, healthcare providers and community organizations, and other local resources. • Regulate and inspect food service establishments and educate food workers about food safety. • Conduct complaint-based, pathogen-specific, and other forms of surveillance to identify local outbreaks. • Investigate and control potential foodborne illnesses using local authorities, policies, and resources. • Manage local public risk communication during foodborne outbreaks. • Coordinate investigation and communication activities with other agencies and response partners during multijurisdictional outbreaks. • Conduct after-action reviews to improve investigation effectiveness and prevent future outbreaks from the same causes.

3.1 Roles

Table 3.1. Examples of Typical Foodborne Outbreak Investigation Roles, Responsibilities, and Contributions of Local and State Agencies*
Continued

AGENCY	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
State health department and laboratories	Responsible for statewide public health protection: <ul style="list-style-type: none"> • Conduct statewide pathogen-specific surveillance; some states may also coordinate statewide complaint-based surveillance. • Provide technical assistance and surge capacity for local and state response partner agencies as needed; conduct investigations in local areas without local health agency jurisdiction. • Conduct and coordinate statewide or multijurisdictional investigations of outbreaks of human illness, including foodborne illness outbreaks. • Manage statewide public risk communication during foodborne illness outbreaks. • Serve as liaison with nongovernment response partners and stakeholders, including healthcare providers and food industry representatives. • Provide legal support for outbreak investigation and control activities. • Conduct after-action reviews to improve investigation effectiveness and prevent future outbreaks from the same causes.
State food safety regulatory authorities and laboratories†	Responsible for statewide policies to protect food safety: <ul style="list-style-type: none"> • Conduct routine regulatory inspections and activities for food establishments under their jurisdiction. • Maintain 1) knowledge of food industry practices in their jurisdiction and 2) working relationships with food industry managers, associations, and technical experts. • Conduct investigations of food producers, food establishments, and food supply chains within their jurisdiction, including product tracing investigations (traceback, traceforward), environmental health assessments, sampling, and implementation of regulatory control measures. • Provide technical assistance and surge capacity for local and state response partner agencies as needed. • Coordinate response actions with local, state, and national food supply stakeholders and response partners, including law enforcement for instances of suspected intentional contamination. • Conduct after-action reviews to improve investigation effectiveness and prevent future outbreaks from the same causes.

*The three core disciplines involved in foodborne outbreaks—epidemiology, environmental health/food regulatory program, and laboratory—may be housed in the same agency at the state or local level.

†Agencies with different names (e.g., Department of Agriculture, Health, or Environmental Health) may carry out these roles.

3.1 Roles

Table 3.2. Examples of Typical Foodborne Illness Outbreak Investigation Roles, Responsibilities, and Contributions of Primary Federal Agencies

AGENCY	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
U.S. Food and Drug Administration (FDA, DHHS)	<p>Responsible for investigation and regulation of most foods moving in interstate commerce (except products regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service [USDA-FSIS]) (Appendix)</p> <ul style="list-style-type: none"> • Perform regulatory activities, including facility registration, routine risk-based inspections, limited food supply surveillance testing, and compliance and enforcement. • Publish voluntary regulatory food safety standards for food service and retail food establishments (the model FDA Food Code) (1). • Coordinate and collaborate with international food regulatory agencies, and support capacity building and training in product-related aspects of investigation and laboratory methods pertaining to foods that FDA regulates. • Conduct outbreak investigations: The Coordinated Outbreak Response and Evaluation network (CORE) (2) for investigations of human illness potentially linked to human food, the National Shellfish Sanitation Program (NSSP) for human illness potentially linked to shellfish products, the Center for Veterinary Medicine for human illness potentially linked to animal food or feed, and the Office of Emergency Operations. • Coordinate with states on informational product tracing for use as part of exposure assessments in epidemiologic studies potentially linked to FDA-regulated products. • Conduct investigations and environmental health assessments of food establishments under their jurisdiction in coordination with other government partner agencies. • Conduct laboratory testing of product(s) obtained from commerce, consumer homes, or production. • Coordinate communication with states and with other federal agencies, particularly CDC, during foodborne outbreak investigations. • Implement short- and long-term control measures and follow-up activities as needed to protect public health consistent with regulatory authorities. • Conduct after-action reviews.

3.1 Roles

Table 3.2. Examples of Typical Foodborne Illness Outbreak Investigation Roles, Responsibilities, and Contributions of Primary Federal Agencies
Continued

AGENCY	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
FSIS, USDA	<p>Responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled:</p> <ul style="list-style-type: none"> • Perform inspection and regulatory activities to ensure industry compliance with applicable laws, pathogen reduction and hazard analysis and critical control point system regulations and other regulations, robust food supply surveillance testing, and compliance and enforcement. • Perform scientific and technical assessments of known and emergent hazards, including quantitative microbial risk assessments. • Conduct outbreak investigations: In-plant inspectors at FSIS-regulated establishments with operational knowledge of industry food safety systems (Office of Field Operations); in-commerce compliance investigators with expertise in sample collection and informational traceback (Office of Investigation, Enforcement, and Audit); and public health science personnel with expertise in performing epidemiologic and environmental assessments (Office of Public Health Science). • Perform informational traceback for use as part of exposure assessments in epidemiologic studies potentially linked to FSIS-regulated products, coordinating with states, where possible. • Conduct investigations and environmental assessments of FSIS-regulated establishments and in-commerce facilities in coordination with other government partner agencies. • Conduct laboratory testing of product(s) collected from FSIS-regulated establishments, in-commerce facilities, and consumer homes. • Assess testing results from non-FSIS laboratories to determine whether they can be used to support FSIS outbreak response. • Coordinate communication and exchange information with states and other federal agencies, particularly CDC, during foodborne outbreak investigations. • Implement short- and long-term control measures and follow up activities as needed to protect public health consistent with regulatory authorities. • Conduct after-action reviews.

3.1 Roles

Table 3.2. Examples of Typical Foodborne Illness Outbreak Investigation Roles, Responsibilities, and Contributions of Primary Federal Agencies
Continued

AGENCY	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
CDC, DHHS	<p>Responsible for conducting or coordinating surveillance for human illnesses caused by pathogens commonly transmitted through food and for outbreaks of foodborne illnesses of any cause:</p> <ul style="list-style-type: none"> • Lead and support national surveillance, communication and disease investigation networks, including National Notifiable Disease Surveillance System (NNDS), Foodborne Diseases Active Surveillance Network (FoodNet), The National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet), NEARS National Environmental Assessment Reporting System, Foodborne Disease Outbreak Surveillance System (FDOS), National Outbreak Reporting System (NORS), Foodborne Disease Centers for Outbreak Response Enhancement (FoodCORE), OutbreakNet Enhanced (OBNE), the Integrated Food Safety Centers of Excellence (COE), Norovirus Laboratory Surveillance Network (CaliciNet), and Norovirus Sentinel Testing and Tracking (NoroSTAT). • Develop and implement better tools for collecting and analyzing public health surveillance and outbreak-associated information. • Improve and standardize laboratory testing methods of clinical specimens for foodborne illness pathogens, including resources to develop new testing methods. • Provide training in epidemiologic and environmental health investigation and laboratory methods related to human enteric disease surveillance as mandated by the Food Safety Modernization Act (3) through the Centers of Excellence and under other longstanding CDC roles. • Conduct outbreak investigations: <ul style="list-style-type: none"> ○ Provide clinical, epidemiologic, and laboratory expertise in pathogens of public health importance; epidemiologic and environmental health expertise to assist with cluster evaluation and outbreak investigations; expertise in water systems and large-volume water sample collection. ○ Provide leadership, coordination, logistical support, surge capacity, and centralized data collection and analysis for multistate outbreaks. ○ Coordinate communication with collaborating state and local agencies, other federal agencies, and international partners. ○ Provide advanced laboratory testing of clinical specimens (and occasionally consumer-held food products), including identification of new or rare disease agents. • Lead after-action review of human health investigation component of multistate outbreak investigations.

3.1 Roles

Table 3.3. Examples of Typical Foodborne Outbreak Investigation Roles, Responsibilities, and Contributions of Cross-Agency Programs

PROGRAM	ROLES, RESPONSIBILITIES, RESOURCES, AND CONTRIBUTION
Rapid Response Teams (RRT)	<p>Responsible for implementing partnership between the Food and Drug Administration (FDA) and state programs to build food safety infrastructure and integrated rapid response for all-hazards human and animal food emergencies:</p> <ul style="list-style-type: none"> • Maintain and promote RRT Best Practices Manual (4) <ul style="list-style-type: none"> ◦ Food outbreak and all-hazard human and animal food emergency response procedures, specific disease agents, epidemiologic and environmental outbreak investigation, informational traceback and implicated product traceforward. ◦ Collection of environmental and food samples for chemical, radiologic, physical, and microbial contaminant analysis. • Provide training in outbreak response methods for local health agencies. • Conduct outbreak investigations. The RRT serves as the Outbreak Investigation and Control Team for multijurisdictional and state-level outbreaks: <ul style="list-style-type: none"> ◦ Lead, assist, and support investigations conducting facility inspections; informational traceback investigations; and food recalls that involve food products (manufactured, commercially produced, and retail) through consultation with health department investigators, federal food safety agency partners, and food industry firms. ◦ Initiate chain-of-custody, quality assurance, and safety procedures when collecting and submitting food samples to support regulatory response.
Food Emergency Response Network	<p>Responsible for prevention, preparedness, response, and recovery activities (5):</p> <ul style="list-style-type: none"> • Maintain an integrated network of local, state, and federal laboratories across the United States that are capable of rapid response to food-related emergencies and attacks on the U.S. food supply. • Detect and identify biological, chemical, and radiologic agents in food, and provide food testing surge capacity during national emergencies.

Table 3.4. Examples of Typical Foodborne Outbreak Investigation Roles, Responsibilities, and Contributions of Nongovernment, Industry, and Academic Partners

PARTNER	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
Healthcare Providers	<p>Responsible for appropriate testing, provision of patient care, and reporting of required illnesses and conditions:</p> <ul style="list-style-type: none"> • Maintain supplies (specimen collection kits) and trained staff to support outbreak investigations. • Speed detection, investigation, and control of foodborne illness outbreaks by <ul style="list-style-type: none"> ◦ Gathering of preliminary exposure and clinical history. ◦ Early recognition and reporting of possible outbreaks. ◦ Timely collection and submission of appropriate specimens for testing. ◦ Application of infection control measures. • Provide appropriate patient education and information to prevent further spread of disease.

3.1 Roles

Table 3.4. Examples of Typical Foodborne Outbreak Investigation Roles, Responsibilities, and Contributions of Nongovernment, Industry, and Academic Partners
Continued

PARTNER	ROLES, RESPONSIBILITIES, AND CONTRIBUTIONS
Industry*	<p>Responsible for maintaining the safety of food offered to the public:</p> <ul style="list-style-type: none"> • Firm Level: A specific point of sale, distributor, manufacturer, processor, or farm that is directly impacted by an ongoing outbreak investigation. <ul style="list-style-type: none"> ◦ Have detailed knowledge about the firm’s processes and organizational culture that are key to understanding possible <ul style="list-style-type: none"> ▪ Point(s) of contamination. ▪ Contributing factors. ▪ Underlying environmental root cause(s) (i.e., antecedent[s], underlying reason[s]) that lead to outbreaks. ◦ Communicate with employees, suppliers, government agencies, and customers during outbreaks. ◦ Implement control measures that can stop the current outbreak and prevent reoccurrence. <ul style="list-style-type: none"> ▪ Firm level controls, e.g., employee restrictions/exclusion, food process changes. ▪ In-distribution controls: cease distribution and initiate recalls See CIFOR Industry Guidelines for further details relevant to the food service and retail food sectors (https://cifor.us/products/industry). • Commodity-Specific and Regional Levels: Groups and associations focused on a specific commodity or product <ul style="list-style-type: none"> ◦ Can provide expertise on how the commodities or products are grown, processed, manufactured, packed, distributed, and served. ◦ Discussions with this level of industry can help investigators better understand how to investigate contamination issues. ◦ Have preexisting networks that can be used to <ul style="list-style-type: none"> ▪ Gather and provide information needed during the investigation. ▪ Communicate the findings of outbreak investigations to relevant individuals and entities. ▪ Build consensus regarding changes needed to protect public health and consumer confidence in their products. • National Level: Groups and associations that represent many food-related entities at the national level: <ul style="list-style-type: none"> ◦ Can provide expertise on how a range of food products are grown, processed, manufactured, packed, distributed, and served. ◦ Ongoing collaboration and partnership with these groups is important for changes to laws, regulations, policies, and initiatives that impact industries nationally.
Academic centers	<p>Responsible for providing technical assistance, training, and specialized laboratory support:</p> <ul style="list-style-type: none"> • Publish research results to help inform future outbreak investigations and implement control measures (e.g., NoroCORE) (6). • Conduct special laboratory analyses or provide additional resources. • Conduct applied food safety research to expand results of investigations.

* Partnerships with individuals and entities at each level should be well-established, and discussions should be ongoing, not occur just during an outbreak crisis.

3.2 Outbreak Investigation and Control Team

The responsibility for investigating foodborne illness outbreaks and implementing control measures rests on a team of people who each contribute different knowledge and skills. Depending on the size and scope of the investigation, the size of the team varies from a few people to hundreds. In smaller investigations, individuals may fulfill multiple roles concurrently. Regardless of the size or complexity of an individual investigation, investigation and control teams must be able to synthesize information from a variety of sources as they investigate individual cases, clusters, and outbreaks.

Job titles alone might not accurately indicate who does what. Team members' assigned tasks and their knowledge and skills define their roles. Members may come from different programs within an agency or from different agencies. Composition of the outbreak investigation and control team varies depending on the specifics of the outbreak. In many investigations, roles are defined relatively informally and may change as the investigation unfolds. In other investigations, roles are mapped to the formal structure of the National Incident Management System, which government agencies and Rapid Response Teams use (see Section 7.2.3 for specifics about the National Incident Management System and Incident Command System [ICS]) (7). The composition of core outbreak investigation and control team should be determined before any outbreaks.

3.2.1 A core team should be involved in all outbreak investigation and control efforts, giving consistency to investigations, serving as the focal point for coordinating multidisciplinary and/or multiagency tasks, and enabling development of effective working relationships with external partners and advanced expertise among staff. The approach for structuring an investigation and control team will not look the same for all agencies. In small

agencies with limited outbreaks, this might be accomplished by designating a few people who receive outbreak response training. In large agencies responding to more frequent and/or complex outbreaks, this might be a dedicated outbreak response team of epidemiologists, environmental health specialist, environmental scientists, and laboratorians who train and work together.

- **Team leader:** Sets and enforces priorities; coordinates all activities associated with the investigation; serves as the point of contact about the investigation; coordinates content of messages to the public through the public information officer; communicates with other organizations involved in the investigation; communicates recommended course of action determined by team to agency decision-makers.
- **Epidemiologist:** Identifies and interviews case-patients; develops hypotheses and strategies to test them; plans epidemiologic studies; re-interviews case-patients and healthy controls; provides insights and guidance to environmental health specialists (and federal regulatory partners) on cases and clusters for informational traceback, collects and analyzes investigation data using statistical analyses or collaborating with a statistician; reports results; collects clinical specimens; coordinates testing of clinical specimens and environmental samples; consults and coordinates with environmental and laboratory investigators.
- **Environmental health specialist:** Investigates food preparation sites across the food chain; reviews food inventory and food distribution records for informational traceback investigations in epidemiologic studies; collects environmental and food samples, maintaining chain-of-custody and coordinates testing with laboratorian; interviews food workers and managers; reviews food preparation and food

3.2 Outbreak Investigation and Control Team

handling records; observes and maps food flow, reviews firm's inspectional and enforcement records for prior food safety history; conducts environmental health assessments to determine contributing factors and environmental root causes (i.e., antecedent[s], underlying reason[s]).

- **Laboratorian:** Analyzes clinical specimens, food and environmental samples (depending on the state, the food and environmental samples may be tested in different laboratories than the clinical specimens); interprets test results and suggests follow-up testing; reports results; coordinates testing among laboratories; advises other team members about sampling requirements and testing, including collection, handling, storage, and transport of specimens; communicates laboratory testing methods and results and the maintenance of chain-of-custody to FSIS and FDA investigators or other food regulatory agency gathering evidence of food product adulteration.
- **Public information officer:** Develops general and specific messages for the public through the media; responds to media inquiries or identifies the appropriate spokesperson; coordinates communication with multiple agencies; disseminates information about outbreak status and overall policies, goals, and objectives to widespread and diverse audiences that include the executive and legislative branches of the government; local governments; the general public; and the local, state, and national news media.

Additional team members with other expertise may be needed, depending on the unique characteristics of the illness or outbreak.

3.2.2 Team members should have the expertise and training needed to competently fulfill assigned responsibilities and tasks for the types of outbreaks they will be expected to investigate and control.

They should understand the roles of the other team members, be able to recognize when an outbreak response exceeds agency resources, and know how to expand the investigation team and request additional resources when needed. Training and procedures should anticipate and address how response team members will manage increased coordination and communication workloads when outbreak investigations rapidly escalate. Ongoing training is critical for all members of the outbreak investigation and control team to ensure they are proficient at performing their assigned duties.

At a minimum, the outbreak investigation and control team should have training in specific protocols for routinely assigned tasks. The training should include continuing education to maintain and improve skills within their specialty and specific training in the agency's outbreak response protocols and the member's role on the team.

For a smaller agency with a limited number of outbreak investigations, special training opportunities should be arranged. Consider the use of webinar technology where little or no opportunity exists for travel. The CDC-supported Integrated Food Safety Centers of Excellence have approximately 150 tools and training courses available online at no charge (CoEFoodSafetyTools.org).

- Ensure all team members have a common understanding of the primary goal for outbreak response, which is to implement control measures as quickly as possible to prevent additional illness.
- Provide team members with continuing education and training opportunities, including cross-training/joint training.
- Conduct regional training with multiple agencies, including tabletop exercises. Such training can help identify problems that might arise during a multijurisdictional outbreak.

3.2 Outbreak Investigation and Control Team

- Offer just-in-time training to refresh the knowledge and skills of staff who do not routinely perform assigned tasks.
- Identify opportunities to collaborate with representatives of the food industry in training exercises, to foster understanding and develop communication strategies that can help streamline actual outbreak investigations.
- Use outbreak investigations as training opportunities to develop individual and organizational skills.

3.3 Planning to Rapidly Expand and Contract Investigation and Control Team Structure

Agency plans must anticipate the need to rapidly expand and contract the size and structure of investigation and control teams to address changing conditions, including to participate in multiagency investigation and control teams (Chapter 7).

3.3.1 The following practices can be used to scale up (escalate) and down (de-escalate) investigation and control teams to meet the often rapidly changing needs of an outbreak response.

- Ensure foodborne outbreak investigation team plans and procedures are updated regularly.
- Determine jurisdiction; investigations may require management in multiple jurisdictions.
- Identify criteria (triggers) used to indicate when the needs of investigation and control teams exceed agency resources, such as
 - Size of the outbreak.
 - Likelihood that resources will be exceeded.
 - New or rapidly emerging incident.
 - Long duration of incident.
- Identify resources that can be tapped for surge, and develop relationships and plans to facilitate quick access to these resources should the need arise. For example:
 - Cross-train persons from within the agency or from other organizations—such as other branches of government,

university students, volunteers (e.g., Medical Reserve Corps)—who have adequate skills or knowledge and would be willing to help conduct interviews or provide other support during a large-scale outbreak.

- Establish Memorandums of Understanding, Mutual Aid, or other agreements along with plans, procedures, communication strategies, and protocols before a foodborne illness outbreak.
- Consider using ICS principles and organizational structures, as appropriate, to manage outbreak responses—especially those that cannot effectively be managed using the agency’s standard operating procedures and chain of command.

3.3.2 Agencies involved in foodborne illness outbreak investigation and response should decide in advance whether and how to apply an ICS and, if applicable, incorporate the ICS into their response planning. Such planning should be coordinated with all other agencies that may be drawn into the investigation and response over time. Many foodborne illness outbreak investigations do not require formal activation of ICS, but outbreak investigation and control teams will benefit from training in ICS principles and methods (Chapter 7).

3.4 Response Resources

A critical aspect of preparing to investigate a foodborne illness outbreak is assembling the necessary resources; supplies, equipment, people, and outbreak investigation–related documents (some accessible via reference materials or pertinent databases) to ensure that everything needed in the investigation and response is quickly available. This enables the outbreak investigation and control team to move rapidly into the field.

3.4.1 Identify staff to support the Outbreak Investigation Team.

- **Administrative staff:** Support personnel to make phone calls, answer incoming calls from concerned members of the public, assist in travel arrangements and other logistics, enter data into a database, copy paperwork, and other administrative work.
- **Executive and financial staff:** Executive staff to guide response priorities and objectives, facilitate communication and role changes,

and financial staff to release funds, track expenditures, and assist in procurement of supplies and equipment.

- **Legal counsel**

3.4.2 Develop field investigation or “go” kits for environmental health investigators, including sampling utensils, thermometers, fecal collection kits, and appropriate forms (Box 3.1).

Ensure that relevant field investigators have access to these kits and are aware of where they are located and that the kits are available at all times. Foodborne illness outbreak investigation kits should be maintained in ready-to-use condition, with sterile sampling supplies, containers and implements. Establish, maintain, and review or verify inventory regularly. (Detailed information about kits and sample lists are included at the CIFOR Clearinghouse, <https://www.cifor.us/clearinghouse> and in the International

Box 3.1. Example Supplies for Outbreak Field Investigation Go-Kits

- Personal protective equipment to ensure safety and aseptic sampling techniques.
- Sterile and wrapped sample-collection supplies (e.g., gloves, spoons, scoops, tongue-depressor blades, spatulas, spongesticks, swabs, knives).
- Sterile sample containers (e.g., plastic bags, wide-mouth plastic and glass jars with screw caps, bottles, sterile sampling bags) and mailing instructions.
- Sterile fecal sample kits for food workers or case-patients.
- Sterilizing and sanitizing agents (e.g., 95% ethyl alcohol, sodium or calcium hypochlorite, alcohol swabs), hand sanitizers, and sanitizer test strips.
- Equipment to determine food characteristics (e.g., pH, water activity, sugar content).
- Temperature-checking probes and backups.
- Refrigerants (e.g., ice packs), insulated containers.
- Labeling and sealing equipment (e.g., fine-point or felt-tip permanent marking pen, roll of adhesive or masking tape, waterproof labels or tags, custody tape).
- Shipping boxes/coolers, prepaid shipping labels, and forms.
- Forms, including sample collection and blank laboratory submission forms, chain-of-custody and other forms for documenting activities.
- Camera or other method to visually document the investigation.
- Trash bags for the waste generated during the investigation (always take your trash with you).

3.4 Response Resources

Association for Food Protection *Procedures to Investigate Foodborne Illness* (<http://www.foodprotection.org/publications/other-publications/>). Procedures for routinely reviewing and replacing missing or outdated supplies and equipment should be part of an agency's outbreak response protocol.

In addition to the sampling supplies, ensure that staff have access to cellular telephones, two-way radios and other team communication devices appropriate to the response situation, including

- Capabilities and equipment for conference calls.
- Multiple phone lines.
- Computers, laptops, software (e.g., data entry, statistical), extension cords, multioutlet power strip surge protector, portable printers, paper, graph paper, pens, clipboards, camera.

3.4.3 Make sure investigation and control team members have access to necessary documents and forms and be trained to use them appropriately in a response situation. These include

- Chain-of-custody forms.
- Foodborne illness complaint worksheets.
- Blank disease-specific case report forms.
- Laboratory test requisition forms.
- Standardized outbreak questionnaires (available at <https://www.cdc.gov/foodsafety/outbreaks/surveillance-reporting/investigation-toolkit.html>).
- Environmental health assessment forms, such as hand hygiene assessment (examples available at <https://www.cdc.gov/nceh/ehs/EHSNet>).
- Shipping protocols, forms and required prepaid labels

These and other sample documents are available from the CIFOR Clearinghouse at <https://cifor.us/clearinghouse>.

3.4.4 Team members must have access and are trained (if applicable) to use key databases, communication platforms, and other resources before an outbreak.

Although not exhaustive, the following databases, listservs, and other systems are recommended:

- CDC Foodborne Outbreak listserv.
- PulseNet SharePoint website.
- System for Enteric Disease Response, Investigation, and Coordination (SEDRIC).
- NCBI Pipeline.

3.4.5 Assemble a reference library (including online resources) with information about foodborne illnesses, enteric illnesses, and control measures.

Where possible, include electronic resources that can be accessed by laptop computers or mobile devices during field investigations. Regularly review and update the contents of this reference library.

- Books, Web resources for support during outbreak (e.g., CDC's Diseases and Conditions A–Z index, FDA's Bad Bug Book).
- Latest version of the American Public Health Association's *Control of Communicable Diseases Manual* (8).
- *Procedures to Investigate Foodborne Illness* by the International Association for Food Protection (9).
- *Investigating Foodborne Disease Outbreaks* by the World Health Organization (10).
- FDA's *Investigations Operations Manual* (11).

3.4 Response Resources

FSIS online resources

- Template for Including FSIS in Foodborne Illness Outbreak Response Procedures: www.fsis.usda.gov/OutbreakProcedures.
- Information Helpful to FSIS During Foodborne Illness Investigations: www.fsis.usda.gov/InvestigationInfo.
- Resources for Public Health Partners: Foodborne Illness Investigation: www.fsis.usda.gov/PHPartners.

- Integrated Food Safety Centers of Excellence all products website: <https://coefoodsafetytools.org/AllCoEProducts.aspx>.
- CIFOR Guidelines: <https://cifor.us/products/guidelines>.

3.5 Communication Plans

Good communication is one of the most important factors in successful outbreak investigation and control. At all points in the outbreak continuum—from detection through investigation and response to debriefing—communication is critical. Without it, investigations and responses can be delayed, uncoordinated, and ineffective. Furthermore, good communication can help allay agency management and public concerns and improve industry support for actions to control outbreaks. To promote better outcomes, use the time before and between outbreaks to lay the groundwork for communication, such as developing and updating contact lists, defining communication processes, establishing relationships with key persons internal and external to the agency, and determining how confidential information will be stored, and whether and how it can be shared.

Although the following practices for communication are all recommended, full implementation may not be possible in some jurisdictions because of resource limitation. Implementing as many as possible as completely as possible will improve communication.

3.5.1 Prepare a list of people in the agency who should be contacted in the event of an

outbreak, including backups, and contact people in external agencies (adjacent local, territorial, state, tribal, and federal agencies). Ensure the list includes after-hours and weekend contact information, and update it regularly.

Assemble a contact list of resource persons who have expertise in specific disease agents and investigation methods with primary phone numbers and alternates, cell phone numbers, 24-hour numbers, home phone numbers, email, fax numbers, and addresses) of

- Core members of the outbreak investigation and control team.
- Other officials inside the agency, such as the chief of the epidemiology unit, director of the public health laboratory, director of environmental health, public health information officer, and the agency director.
- Critical contacts in other government agencies.
- Important food industry contacts, including trade associations (e.g., National Restaurant Association).
- Key healthcare provider contacts.
- Laboratory contacts.
- Primary media contacts.

3.5 Communication Plans

3.5.2 Define a formal communication process for the outbreak investigation and control team to use during outbreaks.

Anticipate what information and data response partners and agency leadership need, and at what frequency, to maintain situational awareness and guide decision-making about investigation and control measures. Options include daily meetings, daily phone calls, and email updates. Developing a consistent approach to internal communications during an outbreak helps everyone on the team know what to expect.

- Identify the persons responsible for communication on behalf of their organizational unit (epidemiology, environmental health, laboratory) and for the outbreak investigation and control team. Communicators must be brought in early as the outbreak develops for a more efficient response.
- Determine how nonpublic information will be saved and whether and how it can be shared. Local and state agencies can receive certain types of confidential information from FDA under a 20.88 information sharing agreement (12,13) (Chapter 7.3).
- Distribute a list of the agency's contacts to other agencies, and obtain their contacts.
- Establish processes for participating in multiagency, multijurisdictional conference calls, and train staff in appropriate conference call etiquette.
- Establish procedures for coordinating communication with the following entities to provide consistent messaging and accurate information flow:
 - Local, state, and federal authorities.
 - Local organizations, food industry, and other professional groups (including healthcare providers).
 - The public.
 - The media.
- Create templates for communications with the public (e.g., press releases, fact sheets), focusing on the most common foodborne illnesses. Sample materials are available at the CIFOR Clearinghouse (<https://www.cifor.us/clearinghouse>).
- Create and test online tools to communicate with the public (e.g., blast emails, surveys, social media).
- Guide staff on how to respond to and communicate during conflict situations, such as with upset food service workers, food protection managers, and members of the public.
- Identify people with clinical training, such as public health nurses or medical epidemiologists, to communicate with case-patients about the outbreak and actions they should take to protect their health and their family's health.
- Identify a person from an agency to talk to the media, ideally someone trained in media relations or a public information officer. Establish procedures for coordinating communication with the media to provide consistent messaging and accurate information flow.

3.6 Planning for Recovery and Follow-Up

Part of preparing for outbreak response is planning for the recovery and follow-up stages. This planning helps ensure appropriate actions are taken after each outbreak and helps identify and correct problems to prevent future outbreaks from the same causes. Establish a process to conduct hot-washes so participants can provide feedback. Create after-action

reports that identify lessons learned and action items for follow-up, including ways to improve. Report the root cause(s) of the outbreak and other key investigation findings to national foodborne outbreak and response databases, such as the National Outbreak Reporting System and the National Environmental Assessment. Reporting System (Chapter 6).

References

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- 4 Association of Food and Drug Officials. RRT best practices manual (November 2017 edition). <http://www.afdo.org/RRT-Manual>
- 5 Food Emergency Response Network. <https://www.fernlab.org>
- 6 USDA National Institute of Food and Agriculture. NoroCORE: a comprehensive approach to a near ‘perfect’ human pathogen. <https://nifa.usda.gov/blog/norocore-comprehensive-approach-near-perfect-human-pathogen>
- 7 Qureshi K, Gebbie KM, Gebbie EN. Implementing ICS within public health agencies. <https://ualbanycph.org/pinata/phics/guide/default.cfm>
- 8 American Public Health Association. Control of communicable diseases manual. <https://ccdm.aphapublications.org/doi/book/10.2105/CCDM.2745>
- 9 International Association for Food Protection. IAFP procedures to investigate foodborne illness. Revised. <https://www.foodprotection.org/about/news-releases/iafp-procedures-to-investigate-foodborne-illness-revised>
- 10 World Health Organization. Foodborne disease outbreaks: guidelines for investigation and control. <https://apps.who.int/iris/handle/10665/43771>
- 11 Food and Drug Administration. Investigations Operations Manual. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>
- 12 21 C.F.R. 20.88.
- 13 Food and Drug Administration. Information sharing. <https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/ucm472936.htm>

Appendix 3.1

Resources (current as of August 8, 2019)

Academia

- Colorado Integrated Food Safety Center of Excellence: <https://www.cdc.gov/foodsafety/centers/sites/colorado.html>
- Minnesota Integrated Food Safety Center of Excellence: <https://www.cdc.gov/foodsafety/centers/sites/minnesota.html>
- New York Integrated Food Safety Center of Excellence: <https://www.cdc.gov/foodsafety/centers/sites/newyork.html>
- Tennessee Integrated Food Safety Center of Excellence: <https://www.cdc.gov/foodsafety/centers/sites/tennessee.html>
- Cornell Department of Food Science: <https://foodscience.cals.cornell.edu>
- Washington Integrated Food Safety Center of Excellence: <https://www.cdc.gov/foodsafety/centers/washington.html>
- American Public Health Laboratories

Appendix 3.1

Federal Government

- U.S. Department of Agriculture, Food Safety and Inspection Service: <https://www.fsis.usda.gov/wps/portal/fsis/home>
- FoodSafety.gov: <http://www.foodsafety.gov>

Centers for Disease Control and Prevention

- Index for Foodborne Illness: <https://www.cdc.gov/foodsafety/diseases/index.html>
- List of Selected Multistate Foodborne Outbreak Investigations: <http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>
- Foodborne Diseases Active Surveillance Network (FoodNet): <http://www.cdc.gov/foodnet/index.html>
- The National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet): <https://www.cdc.gov/pulsenet/index.html>
- CDC Division of Food, Waterborne and Environmental Diseases: <http://www.cdc.gov/ncezid/dfwed/>
- Foodborne Disease Outbreak Surveillance System (FDOSS): <https://www.cdc.gov/fdoss/index.html>
- National Outbreak Reporting System (NORS): <https://www.cdc.gov/nors/index.html>
- System for Enteric Disease Response, Investigation, and Coordination (SEDRIC): <https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/sedric.html>
- CDC Vital Signs: <https://www.cdc.gov/vitalsigns/>
- CDC Zoonotic Diseases: <http://www.cdc.gov/zoonotic/gi/index.html>
- CDC Foodborne Outbreak Team: <http://www.cdc.gov/ncezid/dfwed/orpb/ort.html>
- Salmonella Reporting Timeline: <http://www.cdc.gov/salmonella/reportingtimeline.html>
- National Antibiotic Resistance Monitoring System for Enteric Bacteria (NARMS): <https://www.cdc.gov/narms/index.html>
- Norovirus information: <http://www.cdc.gov/norovirus/index.html>
- Burden of Foodborne Illness: Findings: <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>
- National Environmental Assessment Reporting System (NEARS) (<https://www.cdc.gov/nceh/ehs/nears/index.htm>) Integrated Food Safety Centers of Excellence: <https://www.cdc.gov/foodsafety/centers/index.html>

Food and Drug Administration

- FDA Investigations Operation Manual: <https://www.fda.gov/iceci/inspections/iom/default.htm>
- FDA Rapid Response Team Links: RRT Best Practices Manual (Edition 2017): <http://www.afdo.org/RRT-Manual>
- Best Practices for Improving FDA State Communications Recalls (Summer 2015): <http://www.afdo.org/RRT-Manual>
- Best Practices for Use of FoodSHIELD During Food and Feed Incidents (Summer 2015): <https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM524721.pdf>
- National Program Standards Crosswalk Resource Paper (September 2013): <https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM404725.pdf>
- Model for Local Federal/State Planning and Coordination of Field Operations and Training (October 2013): <https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM404726.pdf>
- Food/Feed Testing Laboratories Best Practices Manual—Draft (December 2013): <https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM404716.pdf>
- Quick Start Food Emergency Response Job Aids (Winter 2017): <https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM535097.pdf>

Other Organizations

- Association of Public Health Laboratories
 - APHL and Food Safety: https://www.aphl.org/programs/food_safety/Pages/APHL-Food-Safety.aspx
 - Food Safety Tools and Resources: https://www.aphl.org/programs/food_safety/Pages/Food-Safety-Tools-and-Resources.aspx
 - Food Safety: https://www.aphl.org/programs/food_safety/Pages/default.aspx

Appendix 3.1

- Association of Food and Drug Officials: <http://www.afdo.org>
- Association of State and Territorial Health Officials: <https://www.astho.org>
- Council of State and Territorial Epidemiologists: <http://www.cste.org>
- International Association for Food Protection: <https://www.foodprotection.org>
- International Food Protection Training Institute: <https://ifpti.org>
- National Association of County and City Health Officials: <https://www.naccho.org>
- National Association of State Departments of Agriculture: <https://www.nasda.org>
- National Association of State Public Health Veterinarians: <http://www.nasphv.org>
- National Environmental Health Association: <https://www.neha.org>



Foodborne Illness Surveillance and Outbreak Detection

CHAPTER SUMMARY POINTS

- Two general methods are used to detect most outbreaks: pathogen-specific surveillance and complaint systems.
- Recent technology changes have altered foodborne illness surveillance, including culture-independent diagnostic testing (CIDT) and whole-genome sequencing (WGS).
 - Molecular multitarget CIDTs that can detect up to 22 pathogens in an hour are replacing enteric pathogen culture in many clinical laboratories, shifting the burden of isolating bacteria for subtype and other characterization to public health laboratories.
 - WGS offers major improvements over traditional subtyping methods but currently takes longer than pulsed-field gel electrophoresis to complete, leading to potential delays in identification of clusters.
- 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.
 - 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 detected through pathogen-specific surveillance (e.g., *Salmonella* and Shiga toxin-producing *Escherichia coli*).
 - Regardless of who receives the complaint or how the complaint is received (phone, online), the complaint should be evaluated for the likelihood of a foodborne illness or outbreak associated with the establishment that is the subject of the complainant or other establishments identified in the food history.

4.0 Introduction

4.0.1 Foodborne illness surveillance identifies clusters of illness that may be caused by a common food source. This chapter reviews major features, strengths, and limitations of surveillance methods and provides recommendations for increasing the effectiveness of each.

In practice, detecting individual foodborne illness outbreaks involves multiple approaches. However, in general, two methods are used to detect most outbreaks: pathogen-specific surveillance and complaint systems (Table 4.1). A third method, syndromic surveillance, is used in some jurisdictions, but its role in detecting foodborne illness outbreaks is limited.

- **Pathogen-specific surveillance:** Healthcare providers and laboratorians report individual cases of illness when selected pathogens, such as *Salmonella enterica* and *Escherichia coli* O157:H7, or specific clinical syndromes, such as hemolytic uremic syndrome and botulism, are identified. Public health professionals gather exposure information through interviews with case-patients.
- **Complaint systems:** Healthcare providers or the public identify and report suspected illness clusters (group notifications) or individual complaints. Exposure information is acquired by interviews with ill people.
- **Syndromic surveillance:** This surveillance method generally involves systematic (usually automated) gathering of data on nonspecific health indicators that might reflect increases in illness, such as purchase of loperamide (an antidiarrheal agent), visits to emergency departments for diarrheal complaints, or calls to poison control hotlines. Exposure information is not routinely collected.

Although these methods are presented separately for descriptive purposes, they are most effective when used together and integrated with food, veterinary, and environmental monitoring programs (Chapters 4 and 5). The range of possible food vehicles detectable through foodborne illness surveillance includes all food or other substances contaminated at any link in the chain from production to ingestion. Foodborne illness surveillance complements regulatory and commercial monitoring programs by providing primary feedback on the effectiveness of prevention programs.

4.0.2 This chapter highlights how recent technology changes have altered foodborne illness surveillance; including the use of culture-independent diagnostic testing (CIDT) and whole-genome sequencing (WGS). Molecular multitarget CIDTs can detect up to 22 pathogens in an hour, which makes them very attractive for clinical laboratories (*I*). Molecular multitarget CIDTs are replacing enteric pathogen culture in many clinical laboratories. The use of CIDTs in clinical laboratories shifts the burden of isolating bacteria for subtype and other characterization to public health laboratories (PHLs). Another major change is the advancement of WGS at PHLs. WGS has replaced traditional methods used at PHLs, such as serotyping and subtyping by pulsed-field gel electrophoresis (PFGE), for the primary foodborne pathogens under routine surveillance.

4.0 Introduction

Table 4.1. Comparison of Foodborne Illness Surveillance Systems

FUNCTIONAL CHARACTERISTIC OF METHOD	SURVEILLANCE METHOD			SYNDROMIC
	PATHOGEN-SPECIFIC	COMPLAINT		
		GROUP NOTIFICATION	INDIVIDUAL COMPLAINT	
Inherent speed of outbreak detection	Relatively slow	Fast	Fast	Variable*
Sensitivity to widespread, low-level contamination events (best practices used)	High	Intermediate	Intermediate	Low†
Types of outbreaks (etiology) that method can potentially detect	Limited to clinically suspected or laboratory-confirmed diseases under surveillance	Any‡	Any, although effectiveness limited to agents with short incubation period§	Limited to syndromes (or indicators) under surveillance
Initial outbreak signal (at public health level)	Cluster of cases in space or time with common agent	Report of group illnesses recognized by healthcare provider, laboratory, or the public	Multiple independent reports with common exposures in space or time or unique clinical presentation recognized by the agency receiving the reports	Trend in health indicator different from expected, space/time clusters of diagnosed cases
No. cases needed to create initial signal	Low to moderate	Low	Low to moderate	High§
Signal-to-noise ratio	High¶ (after interview of case-patients and collection of appropriate food history). Even higher when combined with subtyping	High¶ (after interview of case-patients and collection of appropriate food history)	Low to moderate (after interview of case-patients and collection of appropriate food history)	Low**

* An advantage in speed is limited mainly to nonspecific health indicators (preclinical and clinical diagnostic data). Data must be analyzed, and a follow-up investigation is required, including comparison with standard surveillance, before public health action can be taken.

† Sensitivity is higher for rare, specific syndromes, such as botulism-like syndrome.

‡ Although outbreaks can be detected without an identified etiology, linking multiple outbreaks to a common source may require agent information.

§ The number of cases needed to create a meaningful signal is related to the specificity of the indicator. Indicators that offer an advantage in speed also tend to have low specificity.

¶ A high signal-to-noise ratio means that even a small number of cases stand out against a quiet background. A low ratio means a cluster of cases or events is difficult to perceive because it is lost in the many other similar cases or events happening simultaneously—similar to a weak radio signal lost in static noise. The signal-to-noise ratio for syndromic surveillance is lowest for nonspecific health indicators, such as loperamide use or visits to the emergency department with diarrheal disease complaints. The ratio increases with increasing specificity of agent or syndrome information. For highly specific, rare syndromes, such as botulism-like syndrome, the signal-to-noise ratio would approach that of pathogen-specific surveillance.

**Exposure histories are not typically obtained.

4.1 Pathogen-Specific Surveillance

4.1.1 The purpose of pathogen-specific surveillance is to systematically collect, analyze, and disseminate information about laboratory-confirmed illnesses or well-defined syndromes as part of prevention and control activities.

Surveillance for typhoid fever began in 1912 and was extended to all *Salmonella* spp. in 1942. National serotype-based surveillance of *Salmonella* began in 1963, making it one of the oldest pathogen-specific surveillance programs and the oldest PHL subtype-based surveillance system. The usefulness of pathogen-specific surveillance is related to the specificity with which agents are classified (i.e., use of subtyping and method), enabling grouping of individual cases of illness with other cases most likely to share a common food source or other exposure. The utility of bacterial surveillance increased during the 1990s with the development of PulseNet and molecular subtyping of selected foodborne pathogens, including *Salmonella*, Shiga toxin-producing *E. coli* (STEC) O157:H7, *Shigella*, and *Listeria*. Additional gains in usefulness are anticipated with the adoption of WGS in 2019.

4.1.2 Most illnesses included under pathogen-specific surveillance are reportable (i.e., notifiable) diseases. State or local health agencies establish criteria for voluntary or mandatory reporting of infectious illnesses, including those that might be foodborne (Box 4.1). These criteria describe the illnesses to report, to whom, how, and in what timeframe. For this type of surveillance, illnesses are defined by specific laboratory findings or by well-defined syndromes, such as hemolytic uremic syndrome.

- **Illnesses are reported primarily by laboratories, medical staff (e.g., physicians, infection-control practitioners, medical records clerks), or both.** Reports can be automatically generated from an electronic medical record or laboratory information system or reported through a secure website.

Legacy systems, such as telephone, mail, or fax reporting, also are used but are slower and more labor intensive and error prone.

- **Isolates or other clinical materials are forwarded from clinical laboratories serving primary healthcare facilities to PHLs** for confirmation and further characterization, as required by state laws or regulations or as requested by the local jurisdiction.

Molecular multitarget CIDs are replacing enteric pathogen culture in many clinical laboratories. Many clinical laboratories that perform enteric pathogen detection using CIDs do not culture the pathogens identified by the CIDT. Instead, the clinical laboratory sends the specimen to the PHL to perform culture to obtain an isolate for further testing, which is important for foodborne disease surveillance.

It is imperative that clinical laboratories send the specimens in a transport media (e.g.,

Box 4.1. Selected Nationally Notifiable Diseases that Can be Foodborne

- Anthrax (gastrointestinal)
- Botulism, foodborne
- Campylobacteriosis
- Cholera
- Cryptosporidiosis
- Cyclosporiasis
- Giardiasis
- Hemolytic uremic syndrome, postdiarrheal
- Hepatitis A virus infection
- Listeriosis
- Salmonellosis
- Shiga toxin-producing *Escherichia coli* infection
- Shigellosis
- Trichinellosis (trichinosis)
- Typhoid fever
- *Vibrio* infection

In addition, the following are nationally notifiable:

- Foodborne illness outbreaks
- Waterborne illness outbreaks

Source: Centers for Disease Control and Prevention. Nationally Notifiable Infectious Diseases. United States 2018. Historical. <https://www.cdc.gov/nndss/conditions/notifiable/2018>

4.1 Pathogen-Specific Surveillance

Cary Blair) to PHLs immediately to improve the chances of isolating the pathogen.

Immediate transport of specimens also helps identify potential clusters as soon as possible. The Association of Public Health Laboratories has produced guidelines for specimen submission for optimal isolate recovery from specimens that test positive for pathogens by CIDTs (2).

4.1.3 Laboratory staff record receipt of samples at the PHL and enter sample information into the laboratory information management system, or LIMS.

This process facilitates downstream information sharing with investigation partners. Patient information submitted with the sample may be provided to the epidemiology department for comparison with information from cases already reported and to enable reconciliation of case reports and laboratory samples and identification of previously unreported cases.

- If CIDTs have been used to detect the pathogen in the clinical laboratory, and a specimen is submitted, the PHL attempts to isolate that pathogen.
- Once the isolated pathogen is identified, it is further characterized (e.g., by serotyping, virulence assays, molecular subtyping, or antimicrobial susceptibility tests).
- WGS and PFGE (if conducted at the state level) data, along with accompanying metadata, are uploaded to local and national PulseNet databases. Consolidated daily reports, such as subtype frequency reports, often are used to facilitate cluster recognition. These reports may be automatically generated by laboratory or epidemiology information systems, extracted from the PulseNet database, or extracted from the System for Enteric Disease Response, Investigation and Coordination (SEDRIC).
- Specimen data (including detailed subtyping results) are uploaded to national surveillance

systems, such as Laboratory-based Enteric-Diseases Surveillance).

- PHLs issue reports either singly or in groups to the epidemiology department either through electronic systems such as laboratory information management system submission to the epidemiology database or manual entry. Reports also may be issued to submitters as permitted by local policies.
- Rapid identification of clusters in the laboratory and communication of the cluster to foodborne illness epidemiologists is vital to outbreak detection. Case cluster data are enhanced by inclusion of information about matching isolates or outbreaks through PulseNet from other jurisdictions and by matching isolates from food, animal, or environmental monitoring tests that provide information for hypothesis generation.

4.1.4 WGS has replaced traditional methods used at PHLs, such as serotyping using antiserum and subtyping PFGE.

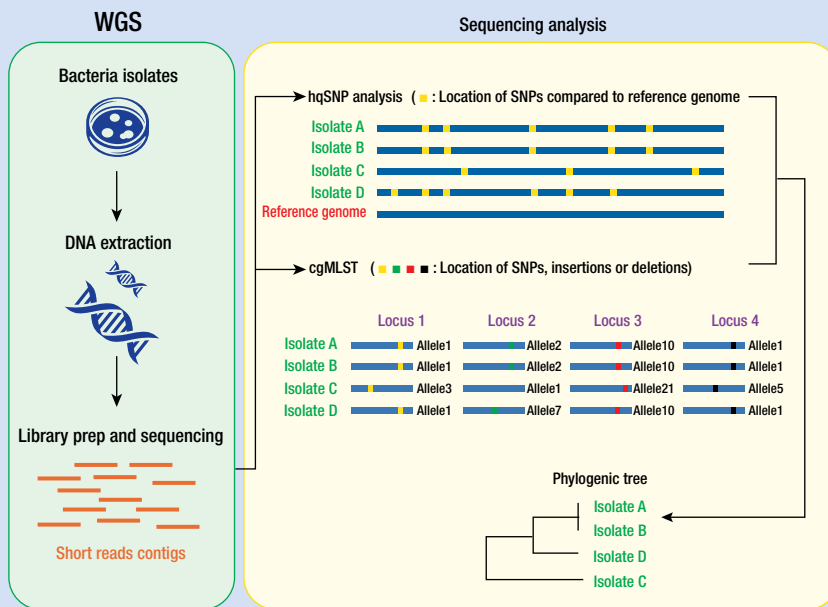
PFGE has been the predominant subtyping method for PulseNet since its inception in 1996, but was replaced by WGS in 2019 (3).

- WGS data generated from isolates are analyzed to compare isolate relatedness (Figure 4.1). Generally, this comparison is done using the complementary approaches of high-quality single-nucleotide polymorphism (hqSNP) analysis and core or whole-genome multilocus sequence typing (cg/wgMLST). hqSNP analysis identifies differences in single base pairs between closely related isolates, whereas cg/wgMLST analysis relies on a database of all potential genes, or loci, for a particular enteric pathogen. cgMLST looks at those genes in common between all isolates being compared and primarily is used for surveillance and outbreak detection, whereas wgMLST looks at both the genes in common and those that represent the diversity of the strains and is used to further characterize isolates that are

4.1 Pathogen-Specific Surveillance

Figure 4.1. Depiction of Whole-Genome Sequencing (WGS) and Sequencing Analysis.

WGS starts with extracted DNA from isolated bacteria. Library preparation is then performed by sequencing, which creates millions of short reads. The reads are combined to create long strands of DNA. DNA from one bacterium can be compared with others using the complementary approaches of high-quality single-nucleotide polymorphism (hqSNP) analysis and core genome multilocus sequence typing (cgMLST). hqSNP analysis identifies differences in single base pairs among closely related isolates, and the cgMLST analysis relies on a database of all potential genes, or loci, for a particular enteric pathogen. Both approaches identify differences between compared isolates and can be used to assign a threshold of genetic relatedness between isolates: for hqSNP isolates, it is a number of SNP, or base pair, differences; and for cgMLST, it is the number of allele, or gene, differences. A phylogenetic tree can be used to visualize the genetic differences using either SNP-based testing or cgMLST.



related and part of a cluster. Both of these approaches identify differences between compared isolates and can be used to assign a threshold of genetic relatedness between isolates. For hqSNP isolates, the threshold of relatedness is a number of SNP, or base pair, differences; for cg/wgMLST it is the number of allele, or gene, differences. Both methods can produce a phylogenetic tree, which aids in interpretation of results.

- Several “rules of thumb” based on the number of allele differences have been developed to help define a cluster by WGS. These rules vary by pathogen and mode of transmission.

Generally, PulseNet uses a definition of at least 3 cases within a 60-day window with 0–10 allele differences, where at least 2 of the cases differ by 5 or fewer alleles, for *Salmonella* and STEC. PHLs may consider a narrower definition (such as 0–5 alleles) to reduce the number of clusters that need to be investigated and to focus investigation resources. Similar to PFGE, there can be common sequence types or rare sequence types, which should be considered during cluster investigations. In addition, if the outbreak occurs over a long period or is zoonotic, more allele differences are detected than in an outbreak representing

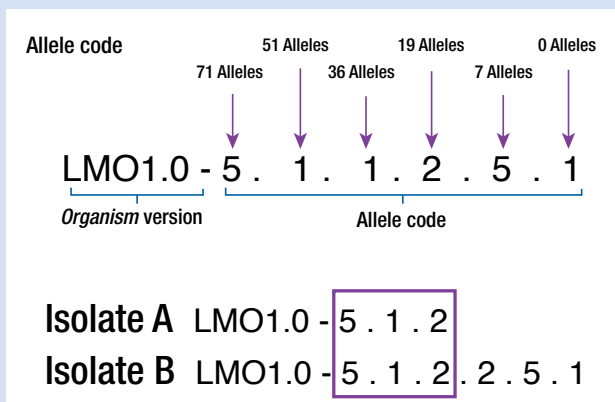
4.1 Pathogen-Specific Surveillance

a point source contamination event. When an outbreak source is contaminated with multiple diverse sequence types, known as a polyclonal outbreak, sequence data may be used to identify multiple independent clusters, which can then be used to identify the polyclonal outbreak. One strategy is to use a narrow cluster definition to identify clusters. That strategy will reduce the number of misclassified cases and will increase the measure of association. Once an outbreak is identified, the cluster definition can be expanded to identify additional cases that were missed because of the initial stringent cluster definition.

- cgMLST analyses are built from a stable database of genes so a pattern name, or allele code, can be assigned to the sequence data (Figure 4.2). Allele codes are built from a single linkage tree of all isolates for an organism, and cutoffs are set along certain points, which represent percentage similarity cutoffs, along the tree that produce a stable nomenclature and provide enough resolution to identify potential outbreak clusters. Using the allele code, which is a string of 5–7 numbers, similar to a ZIP code, closely related isolates can be identified and historic frequencies can be tracked. Each shared number along the allele code indicates
- the genetic relatedness of the isolates. For example, isolates A and B that have the same allele code, 1.1.1.1.1, are closely genetically related; a new isolate, isolate C, that has allele code 1.1.1.1.2 is more closely related than isolate D, with allele code 1.1.1.2.2. Additionally, the allele code can be used to identify clusters and combined with other information predicted from the WGS data, including virulence, serotype, and predicted antibiotic resistance, can be used to prioritize cluster follow-up as part of the triage process. A recent review provides additional information on use and interpretation of WGS data for surveillance (3).
- WGS data can be used to identify an organism, predict serotype and antibiotic resistance, and identify virulence genes. There are several tools for conducting these analyses, including tools available through the PulseNet database system.
- Although WGS offers major improvements over traditional subtyping methods and enables PHLs to have more efficient workflows, some challenges exist to using this technology in public health practice. WGS takes longer than PFGE to complete (a minimum of 4 days for WGS vs. 1 day for PFGE). In addition, if WGS replaces

Figure 4.2. Depiction of Allele Code Assembly.

Nomenclature is organism-specific with different thresholds for the digits. Organism-specific allele codes are built from a string of 5–7 numbers, similar to a ZIP code. Each shared number along the allele code indicates the genetic relatedness of the isolates. When sequences have partial names, they are singletons in clusters below their last digit. For example, isolates A and B are *Listeria monocytogenes* isolates that are approximately within 36 and 19 alleles of each other.



4.1 Pathogen-Specific Surveillance

traditional serotyping methods, identification of clusters using serotype is delayed. PHLs need to perform WGS in a timely manner to ensure clusters are identified as soon as possible, which can be difficult to do in a cost-efficient manner if the testing level of a jurisdiction is low.

4.1.5 Case-patients are usually interviewed one or more times about potential exposures and additional clinical and demographic information.

Routine collection of detailed exposure information as soon as possible after reporting (either CIDT- or culture-positive result) maximizes exposure recall, provides a basis for rapid cluster investigation, is critical to the environmental investigation, and is strongly recommended for high-consequence enteric pathogens, such as STEC O157:H7, *Salmonella*, and *Listeria monocytogenes*.

- The scope of routine interviews varies by jurisdiction, agent, and type of test result. Initial interviews typically cover basic descriptive information and exposures of local importance, such as attendance at a childcare facility, occupation as a food worker, and medical follow-up information. Whereas many local agencies collect information about a limited set of high-risk exposures, where resources are limited, detailed exposure interviews might be conducted only when clusters are investigated or outbreaks are recognized (Chapter 5).

Information the public health agency receives through multiple avenues, including basic clinical and demographic data from individual case-patients of specific laboratory-confirmed illness or well-defined syndromes, is reconciled and linked with case isolates or other clinical materials received in the PHL. Reconciled case reports are forwarded to higher jurisdictional levels (local health agency to state agency, state agency to federal agency) by a variety of mechanisms. In general, records are redacted

(stripped of individual identifiers) when they are sent outside the reporting states.

4.1.6 Initial cluster identification and cluster assessment might occur as two processes conducted, respectively, by the laboratory and epidemiology departments or might occur as a single process within epidemiology.

Agent, time, and place are examined individually and in combination to identify possibly significant clusters or trends. This is the critical first step in hypothesis generation. Clusters of unusual exposures, exposure frequencies, demographic distributions (e.g., predominance of cases in a particular age group), or connection to food, animal, or environmental monitoring studies might be identified. Clusters of cases are examined as a group and, if a common exposure seems likely, are investigated further (Chapter 5). In some jurisdictions, cluster detection and triage are a laboratory function (see section 4.2.5).

- A cluster is defined as two or more cases of disease linked by place, time, pathogen subtype, or other characteristic. Isolates closely related by genetic subtyping are more likely to share a common source than isolates that are not closely related by genetic subtyping.
- Clusters may be more or less recognizable and more or less actionable. This chapter focuses on case clusters and outbreaks, but for some high-consequence agents or syndromes (e.g., botulism or paralytic shellfish poisoning), even a single case might merit a prompt and aggressive public health response.
- Clusters are common and pursuing them all with equal vigor is not practical or productive. Laboratory staff often identify clusters when they detect an increase of a specific subtype or serotype. Incoming surveillance data are evaluated for unusual case counts based on historical frequencies

4.1 Pathogen-Specific Surveillance

(accounting for seasonality), the severity of disease, and molecular matches between human cases and food or animal monitoring samples. In general, cases clustered over a relatively short period are more likely to indicate an outbreak. The time window used to delimit clusters varies by agent. For example, a wider window is used to evaluate clustering of listeriosis cases than to evaluate salmonellosis cases because of differences in the natural history of each disease.

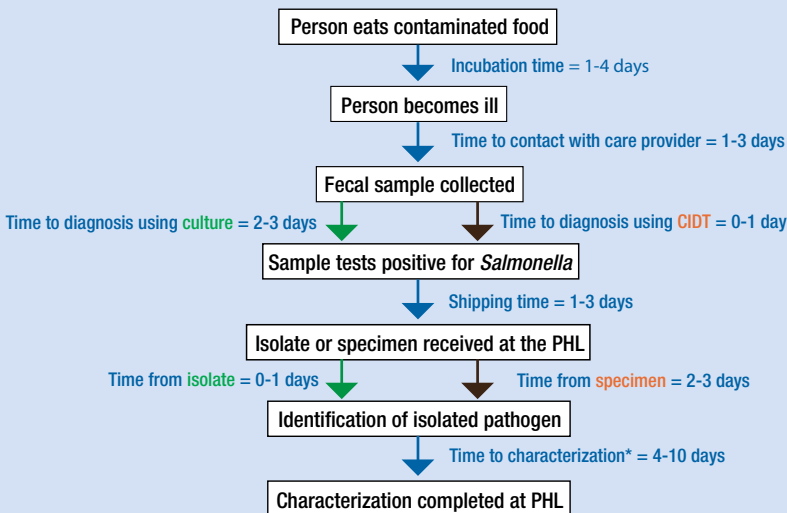
- Although cluster recognition software packages, such as SaTScan™, cumulative summary (cusum) outbreak detection algorithms, and query algorithms in the System for Enteric Disease Response, Investigation and Coordination have been developed, none have yet been validated for broad-based enteric disease data. The decision to report or pursue a cluster is an important part of the outbreak detection process but not one that is easily distilled into

simple best practices. For many organisms, clusters identified by WGS are more indicative of a close genetic relationship and epidemiologic relatedness than are clusters identified by PFGE. An increase in frequency of a strain is only one indication of a potentially significant cluster. Furthermore, absence of an increase in case numbers from expected values does not rule out significance.

4.1.7 The timeline for pathogen-specific surveillance covers a series of events from the time a person is infected through the time public health officials determine that person is part of a disease cluster.

The time from infection to cluster detection is one of the limiting factors of pathogen-specific surveillance. Minimizing delays by streamlining the individual processes improves the likelihood of overall success. A sample timeline for *Salmonella* case reporting is presented in Figure 4.3.

Figure 4.3. Sample Timeline for *Salmonella* Case Reporting*



*Time to complete characterization from an isolate:

- WGS = 4-10 days (can be performed in parallel to serotyping, if needed)
- PFGE=1 day (can be performed in parallel to serotyping)
- Traditional serotyping = 2 days

*Abbreviations: CIDT, culture-independent diagnostic testing; PFGE, pulsed-field gel electrophoresis; PHL, public health laboratory; WGS, whole-genome sequencing.

4.1 Pathogen-Specific Surveillance

- Incubation time:** the time from ingestion of a contaminated food to beginning of symptoms. For *Salmonella*, this typically is 1–4 days, sometimes longer. For more information about incubation times (also called incubation periods) of foodborne pathogens see the Outbreaks of Undetermined Etiology (OUE) Agent list from the CIFOR website (<https://cifor.us>) and the recent analysis of median incubation periods in outbreaks (4).
- Time to contact with healthcare provider or doctor:** the time from the first symptom to medical care (when a fecal sample will ideally be collected for laboratory testing). This time may be an additional 1–3 days, sometimes longer.
- Time to diagnosis:** the time from provision of a sample to laboratory identification of the agent in the sample as *Salmonella*. CIDT tests often produces same-day results, whereas culture-based diagnostic methods take 2–3 days.
- Sample/isolate shipping time:** the time required to ship the *Salmonella* isolate or positive specimen from the initial testing laboratory to the public health authorities who will perform serotyping and subtyping. This usually takes 1–3 days or longer, depending on transportation arrangements within a state and distance between the clinical laboratory and the public health department. Diagnostic laboratories are not required by law in many jurisdictions to forward *Salmonella* isolates to PHLs, and not all diagnostic laboratories forward any isolates unless specifically requested to do so. When a laboratory does submit an isolate or specimen to public health, the timeframe for submission is often based on convenience and cost effectiveness rather than public health considerations.
- Confirming isolated pathogen:** The time after a sample has tested positive for *Salmonella* to isolation and confirmation of *Salmonella*. Specimens identified as *Salmonella* by CIDTs require culture to isolate the organism from clinical samples that were used to perform CIDT, which takes 2–3 days. If culture-based methods are used at the clinical laboratory, the isolated bacteria is confirmed at the PHL, which takes 1 day.
- Time to pathogen characterization:** The time required for state public health authorities to serotype and to perform subtyping on the *Salmonella* isolate and compare it with the outbreak pattern. Serotyping typically takes 3 working days but can take longer. PFGE can be accomplished in 1 working day (24 hours), whereas WGS can take as little as 4 working days. However, many PHLs have limited staff and space and experience multiple emergencies simultaneously. In practice, serotyping and PFGE or WGS subtyping may take several days to several weeks in extreme cases. Data derived from WGS can be used to determine the serotype and subtype and predict the antibiotic resistance profile of an isolate, thereby streamlining laboratory processes into a single workflow. However, completion of WGS will take longer than traditional workflows. Additionally, most or all PHLs will have to perform some batching to reduce the cost of the sequencing. Batching should be minimized as much as possible, however, because faster turnaround for pathogen characterization is highly desirable.
- The total time from onset of illness to confirmation of the case as part of an outbreak is typically 2–3 weeks.

4.1.8 Routine testing for specific pathogens of food in production is conducted as part of larger food-safety verification programs operated by the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state agriculture agencies.

4.1 Pathogen-Specific Surveillance

- WGS is routinely performed on food isolates from FDA- and USDA-regulated products as part of the GenomeTrakr program, and the sequence data and limited metadata are uploaded to a genomic database housed at the National Institutes of Health, National Center for Biotechnology Information (NCBI) as well as to PulseNet. On NCBI, GenomeTrakr sequences are compared with sequences from the Centers for Disease Control and Prevention and other federal, academic, and international public health agencies; closely related isolates identified on the NCBI Pathogen Detection Portal (5) can be potential leads for cluster sources.
- Incorporating this routine food or animal monitoring or regulatory surveillance test data into the disease surveillance information stream enhances hypothesis generation and improves the sensitivity and timeliness of outbreak detection. In the United States, data streams from human disease surveillance, food-testing programs, environmental sources, and selected live-animal testing are co-mingled in the PulseNet database; however, important product details might not be readily available.

4.1.9 A key strength of pathogen-specific surveillance is its ability to detect widespread disease clusters initially linked only by a common agent. Most national and international foodborne disease outbreaks are detected in this manner.

Combining specific exposure information with case information from clusters recognized through complaints makes pathogen-specific surveillance the most sensitive method for detecting unforeseen problems in food- and water-supply systems caused by the agents under surveillance. The specificity of agent or syndrome information combined with specific exposure information obtained by interviews enables the positive association of small numbers of cases with exposures.

4.1.10 A key limitation of pathogen-specific surveillance is that it works only for diseases detected by routine testing and reported to a public health agency.

- Pathogen-specific surveillance is relatively slow because of the many steps required (Figure 4.1).
- Subtype-specific surveillance requires an isolate, which is challenging because of the use of CIDs in clinical laboratories.

4.2 Complaint Systems

Consumer complaint systems are an effective surveillance tool for detecting a variety of food-related incidents, including reportable pathogens. Notification or complaint systems are intended to provide agencies with a tool for documenting, evaluating, and responding to reports from the community about possible foodborne disease events. The information maintained in these systems also helps to conduct prevention and control activities.

4.2.1 The usefulness of consumer complaint systems to identify outbreaks

is based 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. 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 often indicate an outbreak and should be evaluated to determine whether

4.2 Complaint Systems

an investigation is warranted. In the absence of common, suspicious exposures shared by two or more case-patients, complaints of individual illness with nonspecific symptoms—such as diarrhea or vomiting—generally are not worth pursuing. Thus, sufficient exposure information about every independent complaint should be collected because reported exposures might become more significant when also reported by subsequent complainants. Complaint reporting involves passive collection of reports of possible foodborne illness from individuals or groups, such as the following:

- Reports from any individual or group who observes a pattern of illness affecting a group of people, usually after a common exposure: Examples include reports of illness among multiple persons eating at the same restaurant or attending the same event and reports from healthcare providers of unusual patterns of illness, such as multiple patients with bloody diarrhea in a short time span.
- Multiple independent complaints about illness in single persons or households. Group illness and independent complaints can be used together and linked with data obtained through pathogen-specific surveillance. In contrast to pathogen-specific surveillance, complaint reporting does not require identification of a specific agent or syndrome or contact with the healthcare system.

4.2.2 Detection of outbreaks based on multiple individual complaints requires a system for recording complaints and comparing food histories and other exposures reported by individuals. All complaints require some level of follow-up.

A telephone caller should be given some expectation for what follow-up is likely. A person sending a complaint by text, email, or online reporting system should be notified the complaint was received.

- Document complaints received by telephone with a standard intake form to record

complainant information. Complaints received through other formats may warrant additional follow-up to fully document the complaint.

- Questions should cover name and contact information of the caller, detailed illness information (including exact time of symptom onset and recovery), suspected food product and product packaging information (if applicable), name and location of retail or restaurant establishment, names and contact information of other members of the dining party (if applicable), and all potentially relevant nonfood exposures.
- When illness is limited to a single person or members of a single household, obtain food history for the 3 days before onset that focuses on meals eaten outside of the home. People often identify an incorrect exposure as the cause of their illness, often attributing it to the last thing they ate. However, only one in five complaints with a known etiology is caused by an agent with an incubation period shorter than 24 hours.
 - A food history of at least 3 days before illness onset should be collected for individual complaints because common exposures are the sole mechanism to link cases. A standardized form that includes both food and nonfood exposures is preferred.
 - Complaint systems that rely on Web-based reporting or other means of self-reporting should also ask for a 3-day food history, with emphasis on meals eaten outside the home; and should request contact information in case additional information is needed.
 - Efforts to capture complaints using social media should incorporate a link to online reporting, an online survey, or a phone number to the health department.
 - Given the ubiquity of norovirus infections, pay particular attention to

4.2 Complaint Systems

exposures in the 24–48 hours before onset whenever norovirus is suspected. As more information about the likely etiologic agent is collected, this approach can be modified.

- The complaint and subsequent interviews can lead to a hypothesis about the pathogen that leads to a different time frame for the exposure history (e.g., vomiting leads to a different hypothesis and exposure history time frame than does bloody diarrhea).
- When illness is reported among members of multiple households, collect information only for meals in common to members of the different households. Attempt to contact and interview ill meal companions reported by the original caller about symptoms and food consumption.
 - Focus interviews on the event shared by members of the group. However, be aware they might have more than one event in common and explore that possibility.
 - Ask about other possible exposures for the interviewee or for others he or she might have contacted, such as childcare attendance, employment as a food worker, or ill family members.
- Enter all information collected into the complaint database. Review interview data regularly to look for trends or commonalities. As part of the review of the data, consider running reports showing frequencies of specific restaurants or other exposures (such as recreational water venues).
- Set up the reporting process so all reports go through one person or one person routinely reviews reports. Centralization of the reporting or review process increases the likelihood that patterns among individual complaints and seemingly unrelated outbreaks will be detected.

4.2.3 To complement the review of individual complaints and patterns of complaints detected through the foodborne

illness complaint system, conduct standard interviews for foodborne illness cases detected through pathogen-specific surveillance (e.g., *Salmonella* and STEC).

Enter all food establishments at which affected persons reported eating within the 7 days before illness onset into the complaint database. Routinely examine a list of restaurants reported by complainants and case-patients in pathogen-specific surveillance to search for common establishments.

Complaint data and results of pathogen-specific surveillance are much easier to link if complaint systems are centralized at the same jurisdictional level as pathogen-specific disease surveillance. The link of data from pathogen-specific and complaint surveillance systems can occur at the level of the local health agency 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.

4.2.4 Environmental health assessment and follow-up is generally managed by environmental health staff at local health departments that also license and inspect restaurants and other food-service establishments.

In jurisdictions where visits are not required to every restaurant named in illness complaints, the investigation and control team must decide whether investigation of a commercial food establishment is likely to be beneficial. To make this decision, consider details of the complainant's illness and the foods eaten at the establishment (Box 4.2).

- If communicable disease surveillance staff receive the complaint, they should immedi-

4.2 Complaint Systems

ately share the complaint information with the responsible environmental health staff.

- Regardless of who receives the complaint or how the complaint is received (e.g., phone, online), the complaint should be evaluated for the likelihood of a foodborne illness or outbreak associated with the establishment that is the subject of the complaint or with other establishments listed in the food history. In addition, environmental health staff should review the establishment's inspection history, contact the establishment's manager, and determine the value of conducting an environmental assessment. Additional steps, such as an inspection, may be unnecessary if the complaint involves only one person (or persons in one household) and the illness reported is inconsistent with an exposure at the restaurant that is the subject of the complaint.
- All jurisdictions should have a process to ensure that complaints outside that jurisdiction are forwarded to the proper authority. This process includes forwarding complaints between local health agencies,

between local health agencies and state departments of agriculture or health, and between local health agencies and state agencies and federal agencies: USDA's Food Safety and Inspection Service (USDA-FSIS) for meat, poultry, and egg product-related complaints and FDA for complaints related to other food items.

- Nongovernment complaint systems that do not share all information with the appropriate jurisdiction(s) and that do not have the authority to investigate the complaint (inspect the establishment or conduct an epidemiologic investigation) are not useful if the goal is to protect the public's health. Such systems should clearly state that the complaint is not being filed with an agency that can act on the complaint and should refer the complainant to the appropriate jurisdiction.

4.2.5 Collection and testing of clinical specimens and food samples related to group illness. PHL activities are essential for determining etiology, linking separate events during the investigation, and monitoring the efficacy of control measures (Chapters 5 and 6).

Box 4.2. Considerations for Investigating a Commercial Food Establishment

In the following situations, investigation of a named commercial food establishment might be warranted:

- The confirmed diagnosis and/or clinical symptoms are consistent with the foods eaten and the timing of illness onset (e.g., a person in whom salmonellosis is diagnosed reports eating incompletely cooked eggs 2 days before becoming ill).
- The complainant observed specific food-preparation or serving procedures likely to lead to a food safety problem at the establishment.
- Two or more persons with a similar illness or diagnosis implicate a food, meal, or establishment and have no other shared food history or evident source of exposure.

Regular review of individual complaints is critical to recognizing that multiple persons have a similar illness or diagnosis and share a common exposure.

Clues that a follow-up investigation of a food establishment is unlikely to be productive include

- Confirmed diagnoses and/or clinical symptoms that are not consistent with the foods eaten at the establishment and/or the onset of illness (e.g., bloody diarrhea associated with a well-cooked hamburger eaten the night before illness onset).
- Signs and symptoms (or confirmed diagnoses) among affected persons that suggest they might not have the same illness.
- Ill persons who are not able to provide adequate information for investigation, including date and time of illness onset, symptoms, or complete food histories.

4.2 Complaint Systems

- Because of public health laboratory testing, links may be seen across jurisdictional boundaries and beyond; even national outbreaks may then be detected.
 - For instance, an outbreak associated with a particular restaurant may come to the attention of authorities solely on the basis of a report by a customer who observed illnesses among multiple fellow patrons. Laboratory testing and identification of *Salmonella* Typhimurium can result in refinement of the case definition used in this investigation, in additional testing and restrictions for workers found to be carriers, or in connecting this outbreak with other outbreaks (concurrent or historic) from a contaminated commodity.
- Obtain clinical specimens from at least five members of the ill group. Collect specimens as soon as possible after illness onset, ideally during active illness. For certain etiologies, clinical specimens need to be collected while the patient is still ill (bacterial intoxications); for many etiologies (norovirus, bacterial pathogens) it may be possible to detect pathogens in specimens collected days after illness recovery. Clinical specimens should be tested as soon as possible—some test types such as syndromic panels (commercially available tests that simultaneously tests for common bacterial, viral, and parasitic pathogens) require testing within 4 days of specimen collection for the results to be valid.
 - Because complaint systems are the primary tool for detecting outbreaks caused by pathogens not under surveillance, the clinical presentation and epidemiologic data should direct the testing priorities.
 - A number of references are available to help ascertain the etiology of an outbreak, e.g., CIFOR's Outbreak of Undetermined Etiology agent tables and interactive tool (6), Diagnosis and Management of Foodborne Illnesses, A

Primer for Physicians and Other Health Care Professionals (7), and 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea (8).

- If the presumed exposure involves food at a catered event, collect and store food from the implicated event, if feasible.
- Conduct all sampling using legally defensible procedures (e.g., chain-of-custody) and using protocols as guided by the laboratory that will conduct the analysis. Samples should be analyzed within 48 hours after receipt; however, generally test the food only after epidemiologic implication or identification of specific food-safety problems through an environmental health assessment. If the epidemiologic investigation is ongoing and a specific food item has not been implicated or is not suspected yet, food should be stored. Consideration include the following:
 - Storage under refrigeration can be longer than 48 hours, if necessary, but the length of the storage period is food-dependent. Because certain bacteria (e.g., *Campylobacter jejuni*) die when frozen, affecting laboratory results, immediate examination of samples without freezing is encouraged.
 - Perishable foods should be frozen (−40°C to −80°C).
 - Food samples that are frozen when collected should remain frozen until examined.
 - Food samples can be collected as part of the process of removing suspected food from service.

If food testing is determined to be necessary—for example, if a food has been epidemiologically implicated—official reference testing methods must be used at a minimum for regulated products (e.g., pasteurized eggs or commercially distributed beef).

4.2 Complaint Systems

Note: Food testing has inherent limitations because most testing is agent-specific, and demonstration of an agent in food is not always possible or necessary before implementation of public health action. Detection of microbes or toxins in food is most important for outbreaks involving preformed toxins, such as enterotoxins of *Staphylococcus aureus* or *Bacillus cereus*, where detection of toxin or toxin-producing organisms in human specimens frequently is problematic. In addition, organisms such as *S. aureus* and *Clostridium perfringens*, which are commonly found in the human intestinal tract, can confound interpretation of culture results.

Furthermore, food-testing results are often difficult to interpret. Samples collected during an investigation might not represent food ingested when the outbreak occurred. Subsequent handling or processing of food might result in the death of microorganisms, multiplication of microorganisms originally present in low levels, or introduction of new contaminants. If the food is not uniformly contaminated, the sample collected might miss the contaminated portion. Finally, because food usually is not sterile, microorganisms can be isolated from samples but not be responsible for the illness under investigation. Thus, food testing should not be routinely undertaken but should instead be based on meaningful associations identified through data analysis of interviews with suspected case-patients or during environmental health assessments at the implicated food-service establishment.

4.2.6 A key strength of complaint systems is their ability to detect outbreaks from any cause, known or unknown. Thus, the complaint system is one of the best methods for detecting nonreportable pathogens and new or reemerging agents. Recent examples include recognition of sapovirus as a significant agent in norovirus-like outbreaks [9], identification of *Arcobacter butzleri* as the likely

agent in an outbreak of gastroenteritis at an event [10], and atypical enteropathogenic *E. coli* at a restaurant (11). In one study, consumer complaint surveillance alone led to detection of 79% of confirmed foodborne outbreaks, including most norovirus outbreaks (12).

- For event-related complaints, food items eaten and other exposures are easily determined because items consumed at the event can be identified by menus or other means and specifically included in the interview.
- Complaint surveillance systems are inherently faster than pathogen-specific surveillance because the chain of events related to laboratory testing and reporting is not required. Exposure information gained through patient interviews has the potential for being high quality because patient recall is highest close to the exposure event.
- Because of the relatively limited number of exposures to consider, investigations of event-related notifications can be pivotal to solving widespread outbreaks detected through pathogen-specific surveillance. For example, a norovirus outbreak associated with contaminated imported raspberries used in commercially distributed ice cream was initially identified from complaints as multiple independent outbreaks (13). Complaint systems are key in identifying intentional contamination events that would not be detected in pathogen-specific surveillance, for example, an outbreak of methomyl poisoning caused by intentionally contaminated salsa at a restaurant (14).

4.2.7 The value of single complaints of possible cases of foodborne disease in detecting outbreaks is limited by a lack of exposure information to link to any other cases and by the lack of specific agent or disease information to exclude unrelated cases. The illness reported by individuals might or might not be foodborne, and illness presentation might or might not be typical.

4.2 Complaint Systems

- Without a detailed food history (either from the initial report or follow-up interview), surveillance of independent complaints is sensitive only for short incubation (generally chemical- or toxin-mediated) illness or illness with unique symptoms because most people associate illness with the last meal eaten before onset of symptoms, they are likely to be correct only for exposures with short incubation times. This is not a limitation if full interviews are conducted.
- Notification of illness in groups generally is less sensitive to widespread low-level contamination events than is pathogen-specific surveillance because recognition of a person–place–time connection among case-patients by a healthcare provider or member of the community is required.
- These limitations can be minimized by
 - Collecting a food history for the 3 days before illness onset to detect outbreaks caused by etiologic agents with longer incubations than bacterial toxins.
 - Looking for commonalities between the complete food histories for all complaints with case-patient interviews from pathogen-specific surveillance.
 - Promptly forwarding all complaint to the jurisdictions of establishments mentioned in the food histories for prompt follow-up and/or gathering of additional pertinent information.

4.2.8 Improve communication and cooperation among agencies that receive illness complaints. Consumers may submit complaints to multiple organizations and agencies, such as poison control centers, agricultural agencies, facility-licensing agencies, grocery stores, and online platforms and social media sites.

- Identify the agencies/organizations in the community that are likely to receive complaints. Establish regular communication

between agencies that receive illness complaints, epidemiology staff, and laboratory staff. Always keep contact information current. Because complaints might be made to multiple agencies, having a robust method of sharing information is important. If possible, set up a database that public health agencies can access and review. Information-sharing is particularly important in adjacent jurisdictions.

- Check complaint information against national databases, such as the USDA-FSIS Consumer Complaint Monitoring System (CCMS) (15). Consumers can report complaints to CCMS by contacting the USDA-FSIS Meat and Poultry Hotline (1-888-MPHotline [1-888-674-6854]) or using the USDA-FSIS online complaint reporting system, the Electronic Consumer Complaint Form (<https://foodcomplaint.fsis.usda.gov/eccf>).

4.2.9 To increase surveillance sensitivity, remove barriers to reporting by making the reporting process as simple as possible for the public. For example, provide one 24/7 toll-free telephone number or an online reporting form. Such systems enable callers to leave information that public health staff can check later.

Promote reporting by routine press releases that educate the public about food safety, and advertise the contact phone number or website for reports of illness. Use a telephone number that easily can be remembered or found online. Train food managers and workers about the importance of reporting unusual patterns of illness among workers or customers and Food Code requirements for disease reporting (16). Communicate the value of such reporting, not just to protect public health, but also to protect food establishments from unfounded allegations of foodborne illness.

4.3 Syndromic Surveillance

The concept of syndromic surveillance was developed in the 1990s and expanded after the 2001 postal system anthrax attacks in an attempt to improve readiness for bioterrorism.

The utility of syndromic surveillance for nonspecific health indicators for foodborne illness surveillance and outbreak investigation is very limited. In theory, the electronic collection of such indicators could permit rapid detection of major trends, including outbreaks. In practice, the right mix of sensitivity and specificity has proven difficult to find, and the utility of such systems might be marginal. Surveillance for highly specific syndromes, such as hemolytic uremic syndrome or botulism, is a critical public health function.

- Some groups (e.g., public health agencies, academic researchers, nongovernment organizations) monitor social media to identify potential outbreaks. The effectiveness of the use of social media tools to identify outbreaks is still being evaluated but may be useful to enhance traditional complaint systems.
- In theory, syndromic surveillance can be used as a tool to identify cases during an outbreak of an emerging or rare pathogen before laboratory testing protocols have been put into place or results have been received.
- Syndromic surveillance can help identify general enteric disease trends in a community (e.g., norovirus activity levels) to craft targeted prevention messaging (e.g., remind food-service establishments to exclude ill food-service employees).

Syndromic surveillance typically relies on automated extraction of health information, such as school and work absenteeism, posts or complaints on social media sites, emergency department chief complaint, lab test orders, or hospital discharge codes (ICD-10). Epidemiology or emergency preparedness

groups evaluate alerts triggered by the syndromic surveillance system, and interview case-patients to determine whether the alert represents a true outbreak.

4.3.1 Potential strengths of syndromic surveillance include the use of nonspecific health indicators to identify clusters of disease before definitive diagnosis and reporting.

- Syndromic surveillance may be able to detect large undiagnosed events, such as an increase in gastrointestinal illness among persons of all ages consistent with norovirus or an increase in diarrheal illness among young children consistent with rotavirus, and it may be helpful for monitoring health status after a natural disaster, if other surveillance systems are temporarily unavailable.

4.3.2 The lack of specificity for most syndromic surveillance indicators in the area of foodborne disease is a limitation that makes for an unfavorable signal-to-noise ratio, meaning that only the largest events would be detected, and many false-positive signals would be expected.

- Responding to false-positive signals substantially drains an agency's resources.
- Syndromic surveillance cannot replace routine surveillance.

The ultimate measure of success for any surveillance system is outbreaks detected. Because the usefulness of syndromic surveillance for detecting foodborne disease events is limited, additional investment would compete for resources with under-resourced standard surveillance systems; therefore, it should be used only under very special circumstances when routine surveillance is not possible.

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Resource

Cornell College of Agriculture and Life Sciences.
New York Integrated Food Safety Center of Excellence.
Molecular epidemiology and sequencing approaches in

public health. Webinars. <https://nyfoodsafety.cals.cornell.edu/molecular-epidemiology/webinars/>



Cluster and Outbreak Investigation

CHAPTER SUMMARY POINTS

- Outbreak investigations are conducted to rapidly identify the source of contamination and take action to prevent additional illnesses. These investigations require effective and timely integration of three types of data:
 - Epidemiologic data that describe illness distributions and reveal common exposures;
 - Informational traceback and environmental assessment data that identify common contamination points and factors in the distribution chain; and
 - Testing data that identify outbreak-associated strains in implicated foods or in environmental samples linked to the foods.
- How a potential outbreak of foodborne illness is initially recognized determines approaches taken to investigate.
 - Complaints identifying multiple illnesses associated with a common event or establishment will lead to an investigation to identify the agent and the mode(s) of transmission. Although most of these investigations will be local, some will be subclusters of larger, multijurisdictional outbreaks.
 - Clusters of cases identified through laboratory-based surveillance at the local or state level will lead to investigations to determine the mode of transmission or source of contamination. Multistate clusters of these cases suggest a commercially distributed food source.
 - Identification of a foodborne pathogen in a commercially distributed food product will lead to a search for illnesses caused by the same organism and an investigation to determine whether the food item was the source of the illness.
- A priority for all investigations is to establish the basis for implementing control measures to stop transmission and prevent additional illnesses.

5.0 Introduction

5.0.1 Outbreak investigations can help prevent illnesses. This chapter helps investigators quickly and accurately conduct the various steps of an investigation.

These steps are

- Detecting a possible outbreak (Chapter 4).
- Defining and finding cases.
- Generating hypotheses about likely sources.
- Testing hypotheses and evaluating evidence.
- Finding contamination sources.
- Controlling the outbreak (Chapter 6).

Because outbreak investigations are dynamic, multiple steps can occur simultaneously. In addition, as the outbreak investigation progresses, steps might need to be repeated.

When a potential foodborne illness outbreak is first detected or reported, investigators will not know whether the illness is foodborne, waterborne, or attributable to other causes. Investigators must keep an open mind in the early stages of the investigation to ensure that potential causes are not prematurely ruled out. Even though these Guidelines focus on foodborne illness, many of the investigation methods described in this chapter apply to a variety of enteric and other illnesses, regardless of source of contamination.

5.0.2 Recent developments in laboratory and epidemiologic methods impact cluster and outbreak investigation methods.

- Whole-genome sequencing (WGS) used by public health laboratories increases the specificity of pathogen-specific surveillance because case-patients with isolates that have the same DNA fingerprint are more likely to share a common source (Chapter 4). In addition, WGS increases confidence in the relationships between pathogens isolated from food/environments and historical samples, which provides better opportunities to identify outbreaks through food and environmental

surveillance sampling. However, WGS may increase the timeline for public health laboratories to characterize foodborne pathogens and thus delay the identification of clusters of cases that warrant investigation.

- Culture-independent diagnostic tests (CIDTs) used by clinical laboratories provide rapid test results but require follow-up culture to produce an isolate for WGS. CIDTs might increase the number of cases reported and decrease the timeline from onset of illness to report but also reduce the proportion of isolates available for WGS and increase the timeline for conducting WGS. CIDTs used by public health agencies may enhance additional case finding in an outbreak investigation by rapidly identifying the agent in fecal samples from suspected case-patients.
- Enhanced use of new exposure assessment methods streamlines epidemiologic investigations to identify common sources for clusters and determine whether they constitute foodborne illness outbreaks.

For purposes of outbreak reporting, the National Outbreak Reporting System (<https://www.cdc.gov/nors/downloads/guidance.pdf>) distinguishes the definitions of an outbreak and a cluster as follows:

- An *outbreak* is two or more cases of similar illness associated with a common exposure.
- A *cluster* is two or more cases of similar illness that are suspected to be associated with a common exposure, but investigators are unable to identify a shared food, animal, venue, or experience among ill persons.

Outbreak and cluster definitions vary by jurisdiction.

Regardless of how clusters are defined for surveillance purposes, the investigations needed to identify a common exposure include multiple, interrelated epidemiologic, environmental, and laboratory activities (Table 5.1, Figure 5.1).

5.0 Introduction

Table 5.1. Objectives and Investigation Activities that Can Be Conducted During Epidemiologic, Environmental Health, and Public Health Laboratory Investigations of Foodborne Illness Outbreaks*

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify etiologic agent.	<p>If outbreak is associated with event or establishment:</p> <ul style="list-style-type: none"> • Contact healthcare providers of case-patients who have sought medical attention. • Interview case-patients to characterize symptoms, incubation period, and duration of illness. • Obtain fecal specimens from case-patients. • Determine whether symptoms, incubation period, or duration of illness suggest a likely pathogen. • Establish case definition based on confirmed diagnosis or clinical profile of cases. 	<p>If outbreak is associated with event or establishment:</p> <ul style="list-style-type: none"> • Interview management to determine whether it has noticed any ill employees or any circumstances that could cause a foodborne illness. • Interview food workers to determine illness. This activity also could be conducted by nursing/healthcare staff. • Obtain fecal specimens from ill or all food workers. This activity could also be conducted by nursing/healthcare staff. • Obtain and store samples of implicated and suspected food items and ingredients. • Determine whether setting or food item suggests a likely pathogen. 	<ul style="list-style-type: none"> • Contact clinical laboratories that might have performed primary testing on case-patients, and obtain specimens or isolates. • Test fecal samples to identify agent. • Test samples of implicated food items to identify agent. • Subtype all isolates as soon as possible after receipt.
	If outbreak is identified by pathogen-specific surveillance: Agent is known.		

5.0 Introduction

Table 5.1. Objectives and Investigation Activities that Can Be Conducted During Epidemiologic, Environmental Health, and Public Health Laboratory Investigations of Foodborne Illness Outbreaks*		ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
OBJECTIVE	EPIDEMIOLOGY		
Identify persons at risk, and determine size and scope of outbreak.	If outbreak is associated with event or establishment: <ul style="list-style-type: none"> Obtain from event organizer a list of persons attending event or, if possible, list of persons patronizing the establishment during the outbreak period. Interview persons who attended event or patronized establishment to determine attack rates by time. Contact healthcare providers to identify additional persons seeking medical care whose illnesses meet the case definition. If identified agent is reportable, review recently reported cases to identify possible exposures to event or establishment. 	<ul style="list-style-type: none"> Obtain list of reservations for establishment, credit card receipts, receipts for takeout orders, inventory of foods ordered at establishment, or guest lists for events. Where possible, obtain information electronically. 	<ul style="list-style-type: none"> Contact clinical laboratories to identify additional fecal specimens being tested.
	If outbreak identified by pathogen-specific surveillance: <ul style="list-style-type: none"> Alert healthcare providers of possible outbreak to identify additional persons seeking medical care, and review laboratory reports and medical charts at hospitals or physicians' offices to identify possible cases. Ask case-patients if they know of others who are similarly ill. Depending on nature of outbreak, take additional steps as warranted. For example, review employee or school absences, review death certificates, survey population affected, or directly ask members of the public to contact the health department if they have the illness under investigation. 	<ul style="list-style-type: none"> Review foodborne illness complaints to identify undiagnosed cases that could be linked to outbreak. Contact restaurants, grocery stores, or other points of final service visited by multiple case-patients to identify employee illnesses or foodborne illness complaints from patrons. 	<ul style="list-style-type: none"> Contact clinical laboratories to identify additional fecal specimens being tested. Prioritize referral and subtyping of outbreak pathogen.

5.0 Introduction

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
<p>Identify mode of transmission and vehicle.</p>	<p>If outbreak is associated with event or establishment:</p> <ul style="list-style-type: none"> • Determine appropriate analytical study approach. • Interview identified case-patients and controls or well meal companions about all common exposure sources. • Calculate measures of association for specific exposures, appropriate to study design (i.e., odds ratios for case-control study or attack rates and relative risks for cohort study). <p>If outbreak identified by pathogen-specific surveillance:</p> <ul style="list-style-type: none"> • Interview case-patients as soon as possible with standardized detailed exposure history questionnaire to identify possible common exposures. • Establish case definition on the basis of characteristics of agent that led to detection of outbreak. • Characterize cases by person, place, and time, and evaluate this descriptive epidemiology to identify patterns possibly associated with particular food items or diets. • Compare detailed exposure history questionnaire frequencies against known or estimated background exposure rates, to identify suspected food item. • Interview nonill community controls or nonoutbreak-associated ill persons to obtain detailed exposure information to be used in a case-comparison analysis of exposures. 	<ul style="list-style-type: none"> • Obtain menu from establishment or event. • Interview food workers to determine food-preparation responsibilities. • Reconstruct food flow for implicated meal or food item. • Identify contributing factors and environmental antecedents. • Obtain samples of implicated food. • Obtain environmental samples from food contact surfaces or possible environmental reservoirs. 	<ul style="list-style-type: none"> • Test implicated food and environmental samples to confirm presence of agent. • Subtype all isolates as soon as possible after receipt. • Conduct applied food-safety research to determine ability of agent to survive or multiply in implicated vehicle and how vehicle might have become contaminated.
		<ul style="list-style-type: none"> • Contact restaurants, grocery stores, or other locations identified by multiple case-patients to verify menu choices, identify ingredients, and identify distributors and/or source(s) for ingredients and/or food items of interest. • Obtain samples of suspected food items. • Work with appropriate regulatory authority to ensure that food samples are collected and maintained with appropriate chain of custody. This will help the regulatory authority to take appropriate regulatory action. • Conduct an informational traceback to determine whether a suspected food vehicle from multiple case-patients has a distribution or other point in common. 	<ul style="list-style-type: none"> • Store collected food samples, pending results of epidemiologic analyses. • Culture implicated food samples to confirm presence of agent. • Conduct whole-genome sequencing to further characterize pathogen as necessary for investigation. • Conduct applied food-safety research to determine ability of agent to survive or multiply in implicated vehicle and how vehicle might have become contaminated.

5.0 Introduction

Table 5.1. Objectives and Investigation Activities that Can Be Conducted During Epidemiologic, Environmental Health, and Public Health Laboratory Investigations of Foodborne Illness Outbreaks*		PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH
Identify mode of transmission and vehicle.	<p>If outbreak identified by pathogen-specific surveillance:</p> <ul style="list-style-type: none"> Obtain shopper card information to identify and verify grocery purchases and possibly determine background rates of purchase of item. Document brand names and product code information for prepackaged food items. Analyze exposure information comparing cases to relevant comparison groups (e.g., nonill controls or cases not associated with outbreak) to implicate food item or nonfood exposure source. 	<ul style="list-style-type: none"> If specific food item or ingredient is implicated, conduct formal regulatory traceback.
Identify source of contamination.	<p>If outbreak is associated with event or establishment:</p> <ul style="list-style-type: none"> Combine descriptive and analytical epidemiology results to develop a model for the outbreak. 	<ul style="list-style-type: none"> Interview food workers to determine food-preparation responsibilities. Reconstruct food flow for implicated meal or food item. Evaluate food flow for implicated meal or food item to identify contamination event at point of preparation or service. If no contamination event identified, trace source of ingredients of implicated food item back through distribution to point where a contamination event can be identified or, if no contamination events can be identified during distribution, to source of production.
		<ul style="list-style-type: none"> Evaluate results of all outbreak-associated culture subtyping to highlight possible relations among isolates from clinical, food, and environmental samples. Conduct applied food-safety research to determine how vehicle might have become contaminated.

5.0 Introduction

<p>Identify source of contamination.</p>	<p>If outbreak is identified by pathogen-specific surveillance:</p> <ul style="list-style-type: none"> ● Combine descriptive and analytical epidemiology results to develop a model for outbreak. 		<ul style="list-style-type: none"> ● Trace source of implicated food item or ingredients through distribution to point where a contamination event can be identified or to source of production if no contamination events can be identified during distribution. ● Conduct environmental assessment of likely source of contamination, including <ul style="list-style-type: none"> ○ Reconstruct food flow for implicated food item. ○ Interview food workers to determine food-preparation responsibilities and practices before exposure. ○ Obtain samples of implicated food or ingredients. ○ Obtain environmental samples from food contact surfaces or potential environmental reservoirs. 	<ul style="list-style-type: none"> ● Evaluate results to highlight possible relations among isolates from clinical, food, and environmental samples. ● Conduct applied food-safety research to examine likely sources of contamination. ● Work with appropriate regulatory authority to ensure that food samples are collected and maintained with appropriate chain of custody. This will help the regulatory authority to take appropriate regulatory action.
<p>Identify contributing factors and antecedents (root causes)</p>	<p>If outbreak is associated with event or establishment:</p> <ul style="list-style-type: none"> ● Summarize information to identify confirmed or suspected agent. ● Summarize information to identify confirmed or suspected food vehicle. 		<ul style="list-style-type: none"> ● Evaluate results of environmental assessment, given identification of agent and results of epidemiologic investigation, to identify factors most likely to have contributed to outbreak and their environmental antecedents. 	<ul style="list-style-type: none"> ● Summarize information about testing results from clinical, food, and environmental samples.
		<p>If outbreak is identified by pathogen-specific surveillance:</p> <ul style="list-style-type: none"> ● Summarize information to identify confirmed or suspected food vehicle. 	<ul style="list-style-type: none"> ● Evaluate results of environmental assessment, given identification of agent and results of epidemiologic investigation, to identify contributing factors and antecedents. 	<ul style="list-style-type: none"> ● Summarize information about testing results from clinical, food, and environmental samples. ● Provide background statistics on pathogen prevalence.

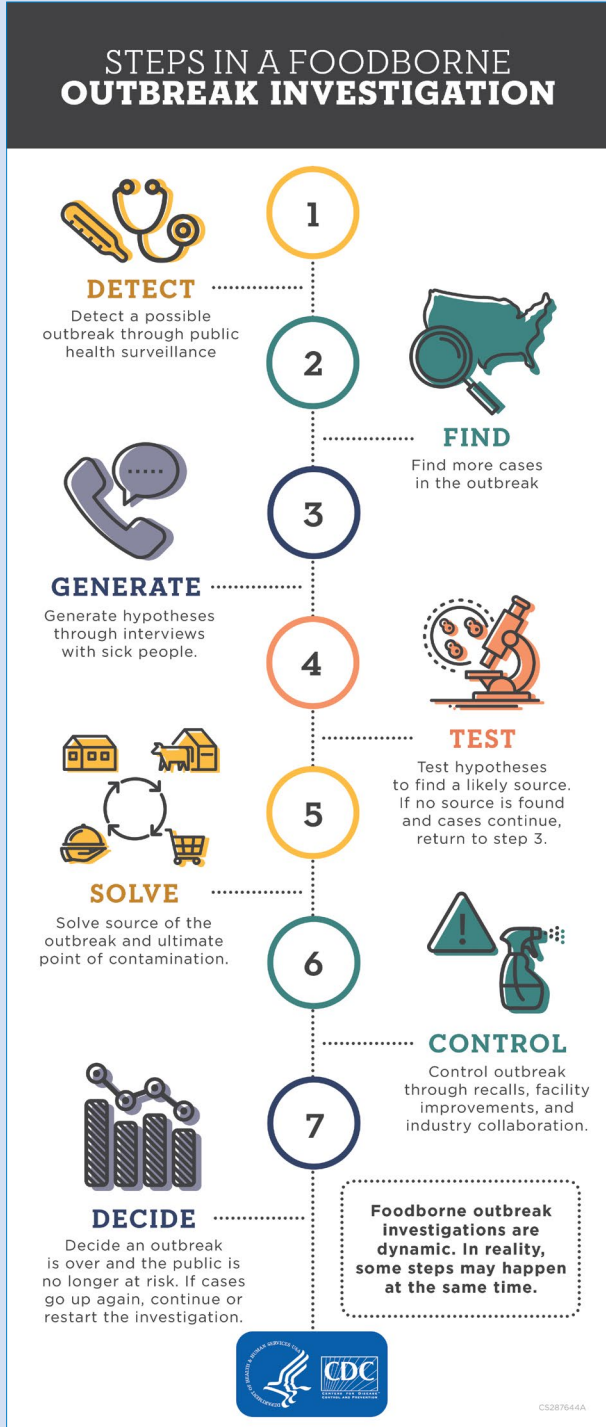
5.0 Introduction

Table 5.1. Objectives and Investigation Activities that Can Be Conducted During Epidemiologic, Environmental Health, and Public Health Laboratory Investigations of Foodborne Illness Outbreaks*		PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY	
OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	
Determine potential for ongoing transmission and need for abatement procedures.	If outbreak is associated with event or establishment: <ul style="list-style-type: none"> On the basis of agent, incubation period, and likelihood of secondary spread, create epidemic curve, and evaluate the course of the outbreak to determine whether additional cases may still be occurring. If outbreak appears to be ongoing, review possible control measures in collaboration with environmental health specialists. 	<ul style="list-style-type: none"> Implement control measures to prevent further exposures: <ul style="list-style-type: none"> Verify that all food workers who pose a risk for transmission have been excluded or restricted, as appropriate. Verify that potentially contaminated foods have been properly disposed of. Verify that food contact surfaces and potential environmental reservoirs have been adequately cleaned and sanitized. Train staff in safe food-preparation practices. Modify food-production and food-preparation processes with appropriate preventive controls. Modify menu. If any of these measures cannot be verified, review additional control measures, or if further exposure appears likely, alert public or close premises. 	<ul style="list-style-type: none"> Assess status of completed and pending testing to identify gaps that suggest a potential for ongoing transmission.
	If outbreak is identified by pathogen-specific surveillance: <ul style="list-style-type: none"> Create and evaluate epidemic curve to determine whether additional cases might still be occurring. If outbreak appears to be ongoing, continue surveillance, and review potential abatement procedures. 	<ul style="list-style-type: none"> Verify that food workers who might have been infected during outbreak and who pose a risk for transmission have been excluded or restricted, as appropriate. Verify that potentially contaminated foods have been removed from distribution. Train staff on safe food-preparation practices. Modify food-production and food-preparation processes by implementing appropriate preventive controls. Modify menu. 	<ul style="list-style-type: none"> Assess status of completed and pending testing to identify gaps that may suggest a potential for ongoing transmission.

*The table format highlights the major objectives of the investigation to help ensure coordination among epidemiologists, environmental health specialists, and laboratorians in meeting each objective. The assignment of investigation responsibilities to a particular discipline within each table is not intended to be prescriptive. The actual responsibilities for an individual vary by the practices of the jurisdiction responsible for the investigation, roles defined in the outbreak investigation and control team, and resources.

5.0 Introduction

Figure 5.1. Steps in a Foodborne Illness Outbreak Investigation



5.1 Outbreak Investigation Initiation

5.1.1 Alert outbreak investigation and control team leaders as soon as a possible outbreak is identified. Outbreaks are detected in several principle ways (Chapter 4). However, a common initial approach is to review descriptive features of the outbreak setting and relevant background information about the etiologic agent, establishment, or event:

- Most local investigations require coordination between epidemiologists, environmental health specialists, and public health laboratorians within the jurisdiction of the cases, event, or establishment.
- Multistate clusters also require communication and coordination of activities between local, state, and federal agencies to rapidly investigate a suspected vehicle (Chapter 7).

5.1.2 Assess the priority of the outbreak investigation. Although any outbreak might warrant investigation, give highest priority for investigation to outbreaks that

- Have a high public health impact:
 - Cause severe or life-threatening illness, such as infection with *Escherichia coli* O157:H7, *Listeria monocytogenes*, or botulism;
 - Affect populations at high risk for complications of the illness (e.g., infants, elderly persons, immunocompromised persons); or
 - Affect a large number of persons.
- Appear to be ongoing:
 - May be associated with food-service establishment in which ill food workers provide a continuing source of infection.
 - May be associated with a commercially distributed food product that is still being consumed.

If the scale or complexity of an outbreak investigation is likely to overwhelm agency resources, the agency should request assistance

as soon as possible for the additional resources and expertise required to respond to it (Chapter 3).

5.1.3 Assemble and brief the outbreak investigation and control team. Open communication between investigation members to plan, conduct, and evaluate outbreak investigation activities is critical to the success of the investigation.

- Investigation and control team leaders should assess the availability of staff to conduct the investigation. In particular, the team leader should ensure the presence of adequate staffing to interview case-patients within 24–48 hours. If sufficient staff are not available, request external assistance to conduct interviews.
- Outbreak investigation and control staff should be briefed on the outbreak, and their individual roles in the investigation. Ensure that all members of the investigation team—epidemiologists, laboratorians, and environmental health specialists—are familiar with and follow relevant state and federal laws and data handling practices.
- For outbreaks involving multiple jurisdictions, the outbreak investigation and control team should include members from all agencies participating in the investigation (Chapter 7).

5.1.4 Ensure that leadership of the investigation reflects the focus of investigation activities, which may change over time. During an investigation, the focus of activities may shift among the following:

- Laboratory studies to identify an agent, including microbiologic studies and applied food-safety research.
- Epidemiologic studies to identify transmission routes, exposure sources, or food vehicles and risk factors for illness.
- Regulatory investigations of food-production sources and distribution chains to identify

5.1 Outbreak Investigation Initiation

where, during production or distribution of the food, contamination occurred and facilitate recall of food items.

- Environmental assessments of food production, processing, and service facilities to identify routes of contamination, contributing factors, and environmental antecedents;
- Communication of investigation findings to the public and the food industry to support control and prevention measures.

5.1.5 Coordinate activities and set up good lines of communication between individuals and agencies involved in the investigation (Chapter 3, Chapter 7).

Investigations are rarely linear (Figure 5.1). Although the steps for investigating outbreaks follow a logical process—from determining whether an outbreak is occurring to identifying and controlling the source—most investigations feature multiple concurrent steps. Maintaining close communication and coordination among members of the outbreak investigation team is the best way to ensure that concurrent activities do not interfere with each other and important investigation steps are not forgotten.

5.1.6 Establish goals and objectives for the investigation. The primary goal for most investigations is to obtain enough information to implement specific interventions to stop the outbreak. The results of the investigation also should provide information to prevent a similar outbreak from occurring in the future. Secondary goals are to increase knowledge of the epidemiology and control of foodborne illnesses. Unanswered questions about the etiologic agent, the mode of transmission, or contributing factors should be identified and included in the investigation to add to the public health knowledge base.

Objectives for meeting these goals vary by type of outbreak.

- **Complaints identifying multiple illnesses associated with a common event or establishment** will lead to an investigation to identify the agent and the mode(s) of transmission. Most of these investigations will be local and require coordination between epidemiologists, environmental health specialists, and public health laboratorians within the jurisdiction of the event or establishment. Case-patients need to be rapidly interviewed to confirm illness and exposure details that may suggest a likely etiology and potential source of exposure. Environmental health specialists, guided by descriptive epidemiology, need to assess food-handling practices and food worker health and hygiene habits at the establishment. Public health laboratories need to test clinical specimens to confirm the etiology of the outbreak based on the description of signs, symptoms, and incubation periods (CIFOR Outbreaks of Undetermined Etiology Guidelines [7]). If the source of contamination was determined to be upstream from the establishment, the outbreak could involve multiple locations and require a multijurisdictional investigation (Chapter 7).
- **Clusters of cases identified through laboratory-based surveillance** at the local or state level will lead to investigations to determine the mode of transmission or source of contamination. Case-patients need to be rapidly interviewed with a thorough exposure assessment questionnaire to identify potentially common exposures or likely routes of transmission. Environmental health specialists and food regulators need to be prepared to help investigate subclusters associated with food establishments and to initiate product tracing for suspected food exposures. Public health laboratories need to rapidly confirm additional cases, and food-regulatory laboratories need to prepare to rapidly test suspected food products.

5.1 Outbreak Investigation Initiation

- **Multistate clusters of cases** suggest a commercially distributed food source (Chapter 7). Product tracing may be needed for successful exposure assessment. Communication and coordination of activities between local, state, and federal agencies must be established at the onset of the investigation.
- **Identification of a foodborne pathogen in a commercially distributed food product** will lead to a search for illnesses caused by the same organism and an investigation to determine whether the food item was the source of the illness. This type of outbreak presentation will most likely increase with the use of WGS to link isolates from food or environmental samples with cases identified through pathogen-specific surveillance. In all instances, investigating the possible link between contaminated food product and illnesses requires multijurisdictional investigation to assess the likelihood the cases are attributable to the suspected food exposure.

5.2 Define and Find Cases

5.2.1 Developing case definitions. Initially, case definitions reflect the cluster recognition methods.

- A cluster of illnesses linked to foodborne illness complaints most likely will be defined by similar features of the illness and by common suspected source of exposure, such as time, place, or person. As case-patients are interviewed, a distinctive clinical profile may emerge that suggests an etiology. If testing of clinical specimens confirms an agent, the features of that agent can be used to establish a clinical case definition.
- Clusters of cases identified by pathogen-specific surveillance are usually defined by common phenotypic or molecular characteristics (serotype, pulsed-field gel electrophoresis [PFGE] pattern, WGS), time frame when the cases occurred, and geographic distribution of the cases. CIDTs are a challenge to this approach. Although the initial CIDT-positive result may be available within a few days after onset of illness, the need to perform culture and then subtype the isolate means that some cases will not be subtyped, and the timeline will be longer for those that are cultured and subtyped.
- **During the early stages of the investigation, case definitions should be made specific to increase the likelihood that the detected cases share a common exposure.** Including unrelated cases in an outbreak investigation makes recognizing a common exposure more difficult and dilutes observed measures of association in analytic studies. For example, in an outbreak of salmonellosis, case-patients may share common symptoms of diarrhea and fever and all their illnesses might be caused by isolates with the same serotype that have a distinctive PFGE pattern and are closely related by WGS. Each of these additional points of identity increases the likelihood that the cases are related and the source may be identified.
- **After a common source has been identified, changing the case definition might be necessary or desirable to better assess the magnitude of the outbreak.** A change might be needed when additional pathogens, or strains of a pathogen, are linked to the same source. Although outbreaks are detected through monoclonal surveillance for highly defined clusters, many food-contamination events are polyclonal, i.e., involve multiple strains of pathogenic bacteria. The true

5.2 Define and Find Cases

nature of these events is usually not discovered until late in the investigation. In addition, after a common source has been identified, accounting for illnesses that occurred after exposure to the source that were not confirmed but had similar clinical characteristics to the confirmed cases can help provide a better estimate of the size, scope, and public health impact of the outbreak.

5.2.2 Reviewing current surveillance systems for illnesses that meet the case definition. Once a case definition has been established, investigators should search for more illnesses related to the outbreak.

- **For clusters of illnesses reported through complaints, review complaint logs or databases to find other complaints that identify exposure to the suspected event or establishment.** Although many complainants focus on their most recent exposure, reviewing all exposures in a 3-day food history could link unrecognized cases to the outbreak. A 3-day history may not cover the exposure window for all cases, but it covers the most common foodborne illness incubation periods and saves resources.

In addition, if the confirmed etiology of the complaint-based outbreak is *Salmonella*, Shiga toxin-producing *E. coli*, or other foodborne pathogen for which case-patients are routinely interviewed, reviewing all exposures for case-patients interviewed during the likely outbreak period could link unrecognized cases to the outbreak.

- **For clusters identified through laboratory-based surveillance, review regular surveillance reports and laboratory reports.** In addition, for restaurants and retailers identified in the relevant exposure window, review the complaint database to identify potential subclusters of cases.

5.2.3 Supplement case-finding activities. Ask local clinical and laboratory professionals to report cases as soon as they suspect the diagnosis, alert health officials in surrounding areas to watch for illnesses that might be related, and survey groups that may have been exposed.

5.2.4 Plot Cases on an Epidemic Curve to Track Illnesses Over Time. The epidemic curve (epi curve) shows progression of an active outbreak over time. The horizontal axis (x-axis) is the date a person became ill (date of onset). The vertical axis (y-axis) is the number of persons who became ill on each date. These numbers are updated as new data come in and thus are subject to change. The epi curve is complex and incomplete. Several issues are important in understanding it:

- An inherent delay exists between the date of illness onset and the date the case is reported to public health authorities. For example, for *Salmonella* infections, this delay is typically is 2–3 weeks. Therefore, a person who became ill last week is unlikely to have been reported yet, and a person who became ill 3 weeks ago might just now be reported. (See *Salmonella* Outbreak Investigations: Timeline for Reporting Cases [Chapter 4, Figure 4.1].)
- Some cases are background cases of illness that most likely would have occurred even without an outbreak; therefore, determining exactly which case is the first in an outbreak is difficult. Epidemiologists typically focus on the first recognized cluster or group of cases rather than on the first case. Because of the inherent reporting delay, a cluster sometimes is not detected until several weeks after people became ill.
- For some cases, date of illness onset is not known because of the delay between reporting and case-patient interview. Sometimes an interview never occurs. If the date an ill person brought his or her specimen to the

5.2 Define and Find Cases

laboratory for testing is known, date of illness onset can be estimated as 3 days before that.

- Determining when cases start to decline can be difficult because of the reporting delay but becomes clearer as time passes.

- Because of the reporting delay, determining the end of an outbreak can be difficult. The curve for the most recent 3 weeks always makes the outbreak appear to be ending, even it is ongoing. The full shape of the curve is clear only after the outbreak ends.

5.3 Generate Hypotheses about Likely Sources

To narrow the focus of an investigation and most effectively use time and resources, investigators should begin to generate hypotheses about potential sources of the outbreak during the earliest stages of the investigation and refine them as they receive information. Hypotheses may emerge from common case characteristics, shared exposures, or historical information about the agent. The process comprises several key steps.

5.3.1 Review demographic information, including age, sex, and geographic and temporal distributions of case-patients.

The Centers for Disease Control and Prevention (CDC) developed the System for Enteric Disease Response, Investigation, and Coordination to help organize and visualize cluster-associated data (2). Patterns in the distributions of these characteristics may suggest possible sources. On a local level, case surveillance data should be reviewed with data from foodborne illness complaints.

5.3.2 Review previous exposure sources linked to the agent. Identify previous vehicles associated with outbreaks and isolation of the agent from food items or food-production environments. However, avoid focusing only on historic sources because they could miss a new or previously unknown source.

5.3.3 Use standardized data collection forms, and compile data from case-patient interviews. CDC, in collaboration with states, developed a National Hypothesis Generating

Questionnaire (NHGQ) to collect information on a broad range of food and nonfood exposures (http://cifor.us/downloads/clearinghouse/NHGQ_v2_OMB0920_0997.pdf).

The NHGQ contains a mix of closed- and open-ended questions designed to elicit likely exposure sources. However, the NHGQ cannot capture detailed source information about all possible exposures, and supplemental approaches may be needed. A key to identifying the source of an outbreak is to collect detailed information on both the food item and its source for as many cases as possible as early in the process as possible.

When conducting hypothesis-generating interviews, use the following interview techniques to improve food recall:

- Question case-patients as soon as possible after their illnesses are reported.
- Encourage them to remember information by asking them to elaborate on where they ate, with whom they ate, and events associated with the meals. Ask them to look at a calendar from the appropriate time periods to jog their memory.
- Interview persons who prepared meals during the period of interest.
- Ask case-patients whether they keep cash register or credit card receipts, or review online banking or bank statements to indicate where or what they ate. Purchase receipts can often be reproduced if the case-patient paid with a credit card.

5.3 Generate Hypotheses about Likely Sources

- Shopper card data or reproduced receipts from credit card purchases to compare grocery store or online meal purchases

In practice, the generation and testing of hypotheses is an iterative process, and the hypothesis is modified as more information is obtained.

5.3.5 Investigate subclusters. When a group of case-patients within a cluster identifies exposure to the same individual point of service, such as a restaurant, cafeteria, grocery store, or institution, this group of cases is termed a subcluster and represents an invaluable opportunity to solve the outbreak because the outbreak vehicle was most likely served or sold by the common establishment. Thus, subcluster investigations represent a hybrid of hypothesis-generating and hypothesis-testing approaches and are a useful model of the general approach to outbreak investigations.

- **Commit all available resources to rapidly and comprehensively investigate such a subcluster to increase the investigation's likelihood of success.** If resources are not available to conduct an investigation fully and rapidly, seek assistance from other agencies.
- **Ascertain additional cases associated with subcluster locations.** In their initial interview, ask all newly identified case-patients within a cluster to identify all dining locations at which they ate during the exposure period. Case-patients often do not recall eating at some locations outside the home when asked open ended questions on initial interview (e.g., “What restaurants did you eat at?”). Ask all newly identified case-patients in a cluster specifically about the list of dining locations named by previously interviewed persons. Ascertain additional subcluster cases by contacting additional patrons of the subcluster establishment (e.g., through credit card receipts, online orders, or reservations).
- **Once a subcluster is identified, reinterview previously interviewed case-patients and ask specifically about the subcluster establishment.** Ask all newly identified cluster case-patients specifically about the subcluster establishment during their first interview. Ask them to check credit/debit card statements to improve recall. Obtain and analyze shopper card records for cases linked to common grocery store chains; grocery store receipts also can often be reproduced if the purchase was made with a credit card, even for a store without a shopper card program. Pinpointing the purchase date and meal date to the extent feasible is important. (If a receipt or credit card statement is not available, record the case-patient's level of confidence about the purchase or meal date.)
- **Gather detailed food-consumption data for subcluster cases.** Interview case-patients using the subcluster establishment's menu or, if an event cohort with a limited discrete menu is identified, a more defined menu.
 - Ask case-patients about additions or subtractions to the menu item(s) they ordered.
 - Interview the establishment manager and/or chef to obtain ingredient lists for menu items.
 - Compile a frequency distribution of ingredients consumed by case-patients. Include every ingredient consumed by at least one case-patient.
- **Conduct an analytical study at the subcluster establishment.** Conduct an ingredient-specific case-control study. There is no rule as to a minimum number of cases necessary to initiate such a study, but it is reasonable to do so with as few as three cases.
 - Identify additional cases and enroll controls by
 - Asking case-patients for meal companions;

5.3 Generate Hypotheses about Likely Sources

- Obtaining credit card receipts, reservation lists, takeout orders, and/or lists of workers or students (if a school cafeteria) for patrons who dined at the establishment on the implicated meal dates.
 - Ascertain additional cases (and increase the number of controls) to increase the likelihood of meaningful results and your confidence in those results.
 - Make the clinical case definition specific for the pathogen of interest (e.g., for Salmonella use “fever and diarrhea” or “diarrhea duration >3 days”) to minimize the likelihood that unrelated illness will dilute associations.
 - **Include every plausible ingredient** in the study. Be systematic—do not focus solely on one or two ingredients case-patients commonly reported. Some ingredients (e.g., spices, garnishes) may be used in multiple menu items and thus could be overlooked.
 - **Trace back suspected vehicle(s)**. If there are multiple subclusters (i.e., multiple points of service), trace back ingredients implicated in analytic studies or, if analytic studies cannot be done, ingredients that case-patients most frequently consumed. Do not exclude food ingredients from an analytic study based on apparent differences in distributors for ingredients used by the subcluster establishments because commonalities in the source of food items might not occur until farther back in the distribution chain.
- **Link subclusters in multistate outbreak to look for common distribution links between establishments** (possible even if there are too few cases for a case-control study). Traceback of individual cases also can provide important information to corroborate subcluster data.

5.3.6 Maintain open, regular communication between public health and regulatory partners to discuss new or updated information about the epidemiologic investigation and food/establishment findings.

5.4 Test Hypotheses

Much of the work of outbreak investigations involves developing sound hypotheses that explain the patterns of illnesses observed. Testing these hypotheses requires epidemiologic analysis of common exposures, typically combined with informational traceback and environmental assessment data that identify common contamination points in the distribution chain and testing data that identify outbreak-associated strains in implicated foods or in environmental samples linked to the foods.

5.4.1 Analytic studies: characteristics, use, and limitations. Epidemiologic studies to analyze the association between illness and exposures take different forms depending

on the setting of the outbreak, number of cases reported, and public health resources available. In recent years, approaches to using these study methods have evolved that have resulted in fewer large community case-control studies. Instead, investigators now often use case-aggregation methods with comparisons to reference data or, for very specific product identification (e.g., brand names and lot numbers), direct intervention with no analytic study whatsoever.

- **Cohort study.** Cohort studies are limited to outbreaks with defined exposure settings in which exposed persons can be identified without respect to illness status, e.g., a banquet with a defined guest list.

5.4 Test Hypotheses

Interviewing persons without respect to their illness status enables determination of attack rates to assess the magnitude of the outbreak and calculation of relative risks for individual exposures. Because many of these settings involve a defined menu and guest list, developing an online survey to rapidly collect illness and exposure information might be possible.

- **Establishment-specific case-control study.** In defined setting outbreaks where it is more feasible to identify individual cases than groups of exposed persons, conduct an establishment-specific case-control study (similar to a subcluster study).
- **Community case-control study.** Community case-control studies are a staple of outbreak investigations. Comparing food exposures among case-patients in an outbreak with food exposures among healthy controls has great power to identify foods associated with the illnesses. For example, in a nationwide outbreak of *Salmonella* associated with commercially distributed ice cream, the source was identified based on interviews of 15 case-patients and 15 community controls (3). Although results of the case-control study implicated an exposure source within 3 days after initiating the case-control study, regulatory testing to confirm the source of contamination required an additional 10 days.
 - Having a stringent case definition is important to reduce the likelihood of including unrelated cases in the study. Because unrelated cases would not share the same exposure source, they would reduce the apparent odds ratio, and make it difficult to implicate the exposure source. WGS subtyping enables stringent case definitions. Along with specific case definitions, having detailed exposure source information is critical.
- **Case-case comparison studies.** Case-case comparison studies provide many of the same benefits as community case-control studies but are logistically easier to conduct. Molecular subtype-specific surveillance based on PFGE or WGS makes it possible to compare cases caused by an outbreak-associated strain with cases caused by unrelated strains. Because cases caused by unrelated strains have many different sources of exposure, they make an efficient control group. When persons with sporadic cases are routinely interviewed with detailed food-exposure questionnaires, case-case comparison studies can be conducted. For example, in the 2011 outbreak of listeriosis identified by the Colorado Department of Public Health and Environment, cantaloupe was implicated by comparing exposures from reported outbreak-associated case-patients to aggregated exposures of nationally reported cases collected by CDC's *Listeria* Initiative (4).
 - Case-case comparisons produce the same measures of association as case-control studies and are interpreted the same way. The increased stringency of WGS to discriminate outbreak-associated from unrelated cases makes case-case comparisons a desirable alternative to case-control studies when aggregate case exposure data are available.
- **Case series with binomial exposure assessments.** The use of case series with binomial exposure assessments was pioneered by the late Bill Keene at the Oregon Health Authority, who also

5.4 Test Hypotheses

developed a simple binomial calculator to test the significance of differences between case and population exposure proportions. Like the other analytic study methods, it requires that outbreak-associated case-patients to be systematically interviewed using a detailed exposure questionnaire. However, instead of comparing case exposure histories with community controls or unrelated cases, the case exposures are compared with an expected value based on population survey data. FoodNet’s Atlas of Exposures (5) has been the most commonly used source of population exposure data. However, changing food consumption patterns limit the usefulness of 2006 Atlas data for some exposures. A survey to collect updated population exposure data was conducted in December 2017 through July 2019. Identifying current, local population exposure data is preferred. The Oregon Health Authority is compiling multistate sporadic *Salmonella* case exposure data known as Project Hg, for case–case binomial comparisons (6).

- The binomial comparison functions as advanced hypothesis generation. It identifies associations that must be confirmed by product source tracing and corroborated by other investigation findings. Statistically, binomial comparisons emulate very large case–control studies. Results must be cautiously interpreted to avoid spuriously significant results that could lead to errors in identifying the source of an outbreak.

For all analytical studies the significance of results depends on the strength of the association and the size of the study. Thus, studies with large numbers of cases are more likely than studies with few cases to yield statistically significant results. However, the goal of outbreak investigations is to rapidly identify the source to prevent additional cases. In this regard, WGS will improve the efficiency

of these studies by providing precise case definitions. Increasing the specificity of food exposures will similarly increase the efficiency of the study. However, with WGS, the expected increase in small cluster investigations limits the usefulness of any of these study designs to produce “significant” results. For clusters involving fewer than five cases, product source tracing and corroborating evidence are needed to confirm the source.

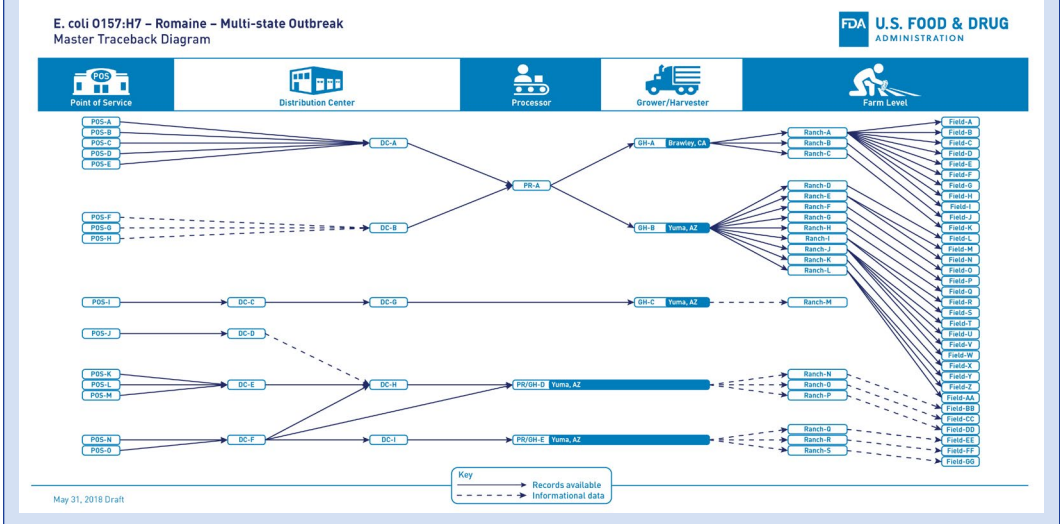
5.4.2 Product tracing. Tracing the source of food items or ingredients through distribution to source of production can be critical to identifying epidemiologic links among cases or ruling them out. For nonbranded commodities, such as produce items, the identification of a common point in multiple distribution pathways that provided a suspected product to case-patients may identify the point where the food(s) became contaminated (Figure 5.3). An onsite environmental assessment of this point (farm, ingredient supplier, processor, restaurant) can then be conducted to identify the contributing factors and environmental antecedents that caused the outbreak. Once the source is identified, tracing products forward through distribution can help identify additional cases or help remove contaminated product from the marketplace. Product tracing is an important tool to inform the epidemiologic investigation, test the hypothesis, and control the outbreak.

Two types of product tracing tools can be used to investigate outbreaks. **Traceback** investigations are used to trace a product suspected to cause the outbreak through the supply chain to determine whether it converges on a common source or supplier. Once a common source or supplier of the contaminated product is identified, **traceforward** investigations are used to determine other locations that received the contaminated product. Both traceback and traceforward activities can be conducted

5.4 Test Hypotheses

Figure 5.3. Exposure Distribution Pathways Documented During Informational Traceback of Romaine Lettuce during an *Escherichia coli* O157:H7 Outbreak.

Romaine lettuce from multiple growers in the Yuma, Arizona, growing region were implicated as the source of the outbreak. The lack of association with a single grower ultimately reflected the use of contaminated surface water by multiple growers (7).



as informational or regulatory endeavors. Informational product tracing needs to be conducted quickly to be incorporated into the epidemiologic studies. Formal regulatory product tracing may be subsequently needed to confirm the distribution of implicated products.

Traceback Investigations. Traceback investigations begin at the point of service where a case-patient was exposed to the product. Informational, traceback investigations are conducted to help inform the epidemiologic investigation and can be the final step in confirming the outbreak vehicle (<http://mnfoodsafetycoe.umn.edu/wp-content/uploads/2015/10/Product-Tracing-in-Epidemiologic-Investigations.pdf>).

- If two or more case-patients report the same point of service, specific information must be collected from this subcluster so a traceback investigation can be initiated.
 - Ideal subclusters contain case-patients who can provide the following

information: precise illness onset dates, exposure dates to the product of interest, and relative certainty about what foods they ate before illness onset.

- Traceback of individual cases can provide important information to corroborate subcluster data.
- As informational tracebacks progress and a single product of interest is identified, regulatory traceback can be performed if necessary to assist in confirming the vehicle. These regulatory tracebacks enable detailed record collection and documentation of the product of interest through the supply chain.
- Once an informational traceback is initiated, specific information is necessary from the case-patients within the subcluster and from the point of sale. As the traceback continues, establishment types will change and questions about the handling of the product of interest, time frames, and available record need to be amended accordingly.

5.4 Test Hypotheses

Information collected from each subcluster serves as one leg of the overall traceback investigation. Distribution chains from multiple traceback legs are documented and compared to identify commonalities. Convergence of multiple legs of a traceback on a specific facility assists in targeting resources for environmental assessments, inspections, and/or sampling. In addition, information from the traceback is continuously evaluated as part of the evidence for the overall outbreak investigation; convergence reinforces the hypothesis generated by the epidemiologic investigation.

Informational traceback investigations continue until the product of interest is followed as far back through the supply chain as possible. Interpretation of the traceback can be challenging and should not be done without consideration of the epidemiologic, laboratory, and environmental information collected during the investigation. If no convergence on a single supplier is identified, reevaluate the hypothesis. Informational tracebacks are challenging and can be limited by a case-patient's ability to accurately remember his or her food history, poor record-keeping, lack of common product identifiers through the supply chain, co-mingling, and many other factors. Therefore, lack of convergence of a traceback does not necessarily rule out a vehicle as the source of the outbreak.

Important information for initiation of informational tracebacks:

- **Subcluster information**
 - Exposure dates to product at point of sale (including location name and address).
 - Identification of specific menu items or purchases.
 - Documentation of purchase of product (e.g., credit card, shopper card).

- **Point-of-sale information**

- List of ingredients in menu items or purchases of interest.
- Time frame of interest for distribution record collection (determined by considering case-patient exposure dates, product shelf life, shipment frequency, and other pertinent factors).
- Identity of all suppliers of the product of interest to the point of sale.
- Frequency the product of interest is ordered by the point of sale.
- Product handling and inventory management in the facility (example: First in First Out).
- Point of sale handling of shipments and documentation of receipt of the product of interest.
- Storage and transportation practices, potential cross contamination; products with common source materials.
- Distribution records (e.g., invoices, order forms, bills-of-lading) for the time frame of interest that are available at the point of service/sale. Note gaps in or concerns about record keeping.

Traceforward investigations. Tracing products forward in the supply chain can determine where contaminated products were distributed and enable their removal from the supply chain (Chapter 6). Traceforward investigations also are an important tool to identify additional case-patients who were exposed to contaminated products. In the hypothesis-testing phase of an outbreak investigation, tracing a suspected product forward can identify additional points of sale that received the suspected product. Enhanced surveillance efforts in areas where suspected products were distributed can be an effective way of identifying new clinical cases. Linking points of sale of suspected products with

5.4 Test Hypotheses

additional clinical cases provides additional evidence about the outbreak source.

Communication of product tracing information. Product tracing is always multijurisdictional and requires strong collaboration between public health and regulatory agencies. Predetermined lines of communication should be in place to effectively move information between the necessary parties. Updates on the epidemiologic investigation being conducted by the public health agency may greatly impact the traceback being conducted by the regulatory agency and vice versa.

Special considerations need to be given to distribution information collected by regulatory agencies because it may be protected from disclosure by confidentiality agreements. Investigational partners should have agreements in place to allow for the lawful exchange of the information (Chapters 3 and 7).

5.4.2 Environmental assessments. When a food-production, food-processing, or food-service establishment is identified as being associated with a foodborne illness outbreak, environmental health and/or regulatory officials should conduct an environmental

assessment. To stop the current outbreak and prevent future ones, investigators must identify both how (contributing factors) and why (environmental antecedents/root causes) the food became contaminated so effective controls can be put in place (Table 5.2).

Goals of an environmental assessment:

- **Identify contributing factors**
 - Factors that introduce or otherwise permit contamination and relate to how the agent got onto or into the food vehicle.
 - Factors that enable proliferation or growth of the agent and relate to how the bacterial agent could increase in numbers and/or produce toxins before the vehicle was ingested.
 - Factors that enable survival or fail to inactivate the contaminants and refer to processes or steps that should have eliminated or reduced the microbial agent.
- **Identify environmental antecedents (root causes) that enabled the system failure**
 - Assessing the internal system components (e.g., people, equipment, processes, foods, and economics) and their effect on allowing the system failure to occur

Table 5.2. Differences between Routine Inspections and Environmental Assessments

ROUTINE INSPECTION	COMMENT
<ul style="list-style-type: none"> • Nontargeted • Regularly scheduled • Snapshot of current day • Code/regulation-based • Assessment of current conditions • Identification of violations 	<ul style="list-style-type: none"> • Targeted • Response to an outbreak • Focus on the past • Outbreak information-based • Examination of processes and problems during outbreak • Identification of system failures • Identification of underlying factors that enable the system failure

An environmental assessment is a systematic, detailed, science-based evaluation of environmental factors that contributed to the introduction and/or transmission of agents that cause an illness in an outbreak. Environmental assessments are conducted in response to an outbreak and address specific food and process(es) to identify the outbreak's cause. The environmental assessment is guided by epidemiologic and laboratory information and examines how the causative agent, host factors, and environmental conditions interacted to result in the system failure and people becoming ill.

5.4 Test Hypotheses

- Identifying and address root causes of outbreaks that appear to be part of a pattern.

Five main steps in conducting an environmental assessment:

- Plan and prepare:** Members of the outbreak investigation team review epidemiologic information, product tracing information, laboratory results, and food facility information. Roles and responsibilities, intended outcomes, sampling plans, and ways the team will communicate during the site visit should be determined at this step.
- Visit the site:** Observe the facility, and evaluate its practices. Collect records and samples pertinent to the investigation. Information that can be collected as part of the visit includes
 - How food moves through the establishment (physical flow diagram).
 - How food is processed and handled within the establishment (process flow diagram).
 - Policy and procedures in place at the establishments and interviews with responsible parties about the execution of policies and procedures.
 - Ill employee records.
 - Sales records for the suspected food item.
 - Employee interviews.
 - Product coding and distribution information if food is suspected to have arrived at the facility contaminated.
- Assess information:** Review information to identify the outbreak's contributing factors and environmental antecedents.
- Recommend prevention and control strategies:** Control strategies reflect steps that should be taken immediately to stop the outbreak and prevent further spread of the agent. Longer term strategies reduce the likelihood of future outbreaks at this type of establishment (Chapter 6).

- Complete the report:** Prepare a summary of the findings that includes detailed diagrams, descriptions, and results. Incorporate this report into the outbreak investigation report.

The timing of an environmental assessment depends largely on the specifics of the outbreak and available information but should be initiated as soon as possible (ideally an initial site visit within 24–48 hours after identification of the establishment). Early investigation and collection of food and environmental specimens will best reflect the conditions at the time of the outbreak. In addition, possible food vehicles can be discarded or grow old, and persons involved in the production, processing, storage, transportation, or preparation of the item can change their practices and procedures. If investigators have identified a common location and a profile of symptoms among ill persons that indicates whether the illness agent is likely to be viral, bacterial, toxic, or chemical, they often can begin an environmental assessment based on possible factors more likely to be associated with that illness-causing agent. As more information becomes available, investigators may need to make additional trips to the establishment to investigate the additional lines of inquiry.

Communication of environmental assessment findings is vital. Share results of the environmental assessments with the outbreak investigation team as soon as possible. This information may change the course of the investigation or confirm the suspected food item causing the outbreak. Sharing findings with industry partners on the contributing factors and environmental antecedents that led to contamination is key to improving hazard identification and implementing control measures (8).

5.4.4 Laboratory testing of food products and environments. Targeted sampling of food items and environments of interest in the outbreak investigation can help confirm the

5.4 Test Hypotheses

food causing illness. Targeted sampling occurs when partners working on the epidemiologic and traceback investigations share information about products and establishments of interest. Coordinate with the testing laboratory and consider sampling products and storing appropriately for potential future testing to reduce the chance the product of interest will be unavailable for sampling later.

- Sampling products of interest early in the epidemiologic investigation can help quickly bring an investigation together, especially if the products of interest are shelf stable. In 2017, state and local authorities sampled soy nut butter reported by case-patients associated with an outbreak of *E. coli* O157:H7 (9). The positive samples generated by that early sampling was used as evidence to suspend the registration of the facility manufacturing the product. Not all product sampling occurs at the outset of an investigation. Traceback investigations can identify locations along the supply chain to collect samples.
- Food and environmental sampling enables investigators to directly test hypotheses generated during an investigation, often picking up where analytic studies leave off. By gathering information about items of interest (such as food items or ingredients commonly consumed at a restaurant in question; animals to which case-patients were exposed before illness; or other less common environmental exposures, such as contaminated milk crates), investigators can target very specific items or areas to sample for microbiologic testing. When combined with the case series with binomial exposure assessments, such testing can quickly hone a list of suspected products to a single source.
- Sampling also can be used to illuminate the root cause of product contamination, especially when done in partnership with the grower or product manufacturer. Pathogens such as *Salmonella* and *L. monocytogenes* are

known to persist in manufacturing and processing environments. Identification of a pathogen in a processing environment that was linked by epidemiologic and traceback information to clinical cases supports confirmation of the outbreak vehicle.

- WGS is being used to perform molecular subtyping on pathogens recovered from foods and environments impacting foods. The high resolution of WGS increases confidence in the relatedness of pathogens from products and environments to clinical samples. Food or environmental samples that are closely related by WGS can launch retrospective outbreak investigations, in which laboratory evidence from the products or environments drives the epidemiologic investigation. Retrospective outbreak investigations often lead to the swift identification of the outbreak source.

5.4.5 Coordination of epidemiologic, traceback, and sampling activities.

Whether the outbreak is restricted to one jurisdiction or involves multiple jurisdictions, notification and updates should be provided to other interested agencies following the Special Considerations for Multijurisdictional Investigations (Chapter 7).

- Arrange for the outbreak investigation and control team to meet daily and to regularly update the entire outbreak control team. In particular, if the outbreak has gained public attention, the public information officer needs to prepare a daily update for the media.
- During investigation of outbreaks involving events or establishments, maintaining close collaboration between epidemiology and environmental health is particularly important. Interview results from persons who attended the event or patronized the establishment will help environmental health specialists focus their environmental assessments by identifying likely agents and food vehicles. Similarly, results of

5.4 Test Hypotheses

interviews of food workers and reviews of food preparation can identify important differences in exposure potential that should be distinguished in interviews of persons attending the event or patronizing the establishment. For example, environmental health investigators might determine that food items prepared only on certain days or by certain food workers are likely to be risky. These refinements also can help establish the need for or advisability of collecting fecal samples from food workers or food and environmental samples from the establishment.

- During the earliest stages of the investigation, patrons need to be interviewed rapidly. However, the focus of outbreak activities is likely to shift to interviews of food workers, environmental assessments of the establishment, and review of food-preparation procedures as the investigation progresses.
- During investigation of outbreaks detected by pathogen-specific surveillance, the public health laboratory needs to immediately

forward case information to epidemiologists for every new potentially outbreak-associated case they receive. Doing so ensures rapid enrollment of new cases in the outbreak investigation studies. Similarly, as investigators acquire information from case-patients about exposures in restaurants and other licensed facilities, they should rapidly forward that information to environmental health specialists to ensure rapid identification of commodity ingredients and their distribution sources.

- During the early stages of an investigation, efforts to identify mode of transmission and food vehicle require close coordination of the outbreak team under the leadership of epidemiology. After identification of a likely food vehicle, efforts to identify the source of contamination and contributing factors require engagement of local, state, or federal food-regulatory programs. As the investigation proceeds, the outbreak investigation and control team should always consider whether any information indicates the outbreak might be multijurisdictional (Chapter 7).

5.5 Evaluate Evidence to Solve Point of Contamination and Source of the Food

5.5.1 Evaluate evidence. Identifying the source of contamination and taking action to prevent additional illnesses requires effective and timely integration of three types of data:

- Epidemiologic data that describe illness distributions and enable analysis of common exposures.
- Traceback and environmental assessment data that identify common contamination points in the distribution chain.
- Testing data that identify outbreak-associated strains in implicated foods or in environmental samples linked to the foods.

Evidence from each of these pillars of the outbreak investigation is evaluated in concert to determine whether the data support the conclusion that a suspected food or other exposure caused the outbreak. Investigators typically determine that they have identified the likely source of the outbreak when they have clear and convincing evidence from two pillars. In rare instances, data from one pillar alone might be sufficient to determine the likely source of an outbreak (e.g., complaints or point source clusters linked to a meal or single event). In investigations of products with a short shelf life (e.g., unpasteurized milk or leafy greens), conducting testing on products

5.5 Evaluate Evidence to Solve Point of Contamination and Source of the Food

during the likely period of contamination might be impossible and investigators must rely on evidence from the other pillars to determine the likely source of the outbreak.

5.5.2 Solve point of contamination and source of the food. The outbreak investigator's job is to use all available information to construct a coherent narrative

Box 5.1. Questions to Consider When Associating an Exposure with an Outbreak

Strength of association

- How strong was the association between illness and the implicated item? (The strength of the association increases with the size of the odds ratio or relative risk: 1 = no association; <5 = relatively weak association; 5–10 = relatively strong association; >10 = very strong association.)
- Was the finding statistically significant? (<0.05 is a traditional cutoff p value, but in small studies, even relatively strong associations might not reach this level of significance. Conversely, in large studies examining many exposures, relatively weak associations might reach this level of significance by chance or as an effect of confounding.)
- Were most ill persons exposed to the implicated item? "Yes" is desirable but might not always be apparent if the implicated item is an ingredient in multiple food items.)

Timing

- Did the exposure to the implicated item precede illness by enough time for a reasonable incubation period?
- Do the time windows obtained during traceback and traceforward investigations correlate with reported dates of production, distribution, and purchase of the implicated item?

Dose–response effects

- If assessed, were persons with greater exposure to the implicated item more likely to become ill or have more severe clinical manifestations?

Plausibility

- Is the association consistent with historical experience with this or similar pathogens? Can investigators develop a rational explanation for opportunities for contamination, survival, and proliferation of the pathogen in the implicated item? (If otherwise strong and consistent results cannot be readily explained, the outbreak might herald emergence of a new hazard, which will require additional studies to confirm.)
- Is the geographic location of ill persons consistent with the distribution of the implicated item? (Discrepancies might be explained by gaps in surveillance, product distribution data, or involvement of additional food products.)

Consistency with other studies

- Studies associated with current investigation
 - Do the results of traceback and traceforward investigations suggest a common source?
 - Have environmental health assessments identified problems in the production, transport, storage, or preparation of the implicated item that would enable contamination, survival, and proliferation of the pathogen in that item?
 - If the pathogen was isolated from ill persons and from the implicated item, do subtyping results (e.g., WGS analysis) confirm the association?
- Studies not associated with current investigation
 - Is the association between the pathogen and the implicated item consistent with other investigations of this pathogen?

5.5 Evaluate Evidence to Solve Point of Contamination and Source of the Food

of what happened and why. This begins with the initial detection of the outbreak and formation of hypotheses based on the agent's ecology, microbiology, and mechanisms of transmission in addition to the descriptive epidemiology of reported cases. Results of subsequent analytic studies (e.g., cohort or case-control study results) must be integrated with results of product tracing, food worker interviews, environmental assessments, and

food-product and environmental testing. When all of these data elements support and explain the primary hypothesis, investigations can draw very strong conclusions (Box 5.1).

Outbreak investigators should be open to new developments and new twists to old problems. New hazards are frequently identified through outbreak investigations. However, they should be wary of explanations that depend on implausible scenarios.

5.6 Implement Control Measures, Investigation Closeout, and Reporting

5.6.1 Deciding an outbreak is over (Chapter 6). Outbreaks end when cases are no longer detected or reported. Outbreak investigations can continue after the outbreak ends, given product tracing and observations on practices at suspected firms may take longer to obtain. In addition, control measures need to be evaluated if the source of the outbreak was identified. For outbreaks where the source has not been identified, consideration to the prioritization of resources and expected outcome of the investigation should be

considered before continuing investigational activities. Experience reminds us—again and again, unfortunately—that even seemingly well-executed investigations can be inconclusive. Small sample sizes, multivehicle situations, “stealth” food items that may not be recognized, and foods with high background rates of consumption are only some of the factors that can reduce the effectiveness of standard epidemiologic methods and make investigations extremely difficult.

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Control Measures and Prevention

CHAPTER SUMMARY POINTS

- Effective control measures include a combination of immediate controls to stop the current outbreak and longer term controls to prevent future outbreaks.
- Effective and timely information sharing among investigation and response partner agencies, impacted food industries, and the public is essential to control foodborne illness outbreaks.
- Appropriate control measures vary depending on whether the implicated food was contaminated
 - At a single local food-service or retail food establishment, or
 - Before being commercially distributed.
- Three strategies used to stop foodborne illness outbreaks are
 - Controlling contaminated foods at their source.
 - Controlling contaminated food products that have left the source (e.g., recalls).
 - Preventing secondary spread of infection.
- To identify appropriate control measures, information from different sources, such as epidemiology, laboratory, and environmental health should be integrated into the outbreak response.
- General control measures are often followed up with more specific controls as investigators learn more about the source(s), contributing factor(s) and root cause(s) (i.e., antecedents, underlying reasons) of the outbreak.
- Investigation and control teams should use the after-action review processes to:
 - Assess the strengths and limitations of past responses.
 - Identify action steps to improve future responses.
 - Track corrective actions using the organization's continuous process improvement programs.
 - Prevent outbreak recurrence by applying lessons learned regarding root cause and contributing factors.
- Foodborne illness investigation reports are used to accurately document actions and conclusions to improve future investigation practices and make changes to prevent future outbreaks.

6.0 Introduction

6.0.1 The purposes of outbreak investigations are to stop the current outbreak, determine how contamination occurred, and implement measures to prevent future outbreaks by addressing the root cause(s) in the implicated, and potentially other, facilities. Whereas the investigation is critical for understanding the cause, effective and timely control measures are critical for stopping the outbreak and preventing reoccurrence of illness. Identifying the root cause(s) of foodborne illness improves the effectiveness of prevention efforts.

The rapid and accurate response to foodborne illness is critical.

Investigators from all three primary disciplines (epidemiology, environmental health, and laboratory) must quickly assess information and identify suspected foods or facilities to prevent additional illnesses.

There are generally two types of foodborne disease outbreaks, and each requires different control measures.

- **Local outbreaks** may be associated with food-preparation errors or contamination of food by food workers at the site of preparation or distribution, e.g., foods prepared at home, food-service, and retail food establishments. Local outbreaks typically are controlled through local actions.

- Outbreaks associated with contaminated **commercially distributed foods** may originate from a commercial food manufacturer or agricultural commodity distributed to multiple sites. The resulting foodborne illness may be linked to a variety of food establishments or to foods prepared in the home. These outbreaks are usually multijurisdictional and require coordinated intervention by local, state, territorial, tribal, and federal agencies and the industry.

6.0.2 Effective communication between team members and with other response partners is essential during all phases of the investigation to ensure opportunities to quickly implement or improve control measures are not missed. The exchange of specific actionable information is paramount to success. Communication within the response team and with other stakeholders during an outbreak response is of primary importance. For all foodborne illness outbreaks, early sharing of information between epidemiologists, laboratory staff, and environmental health specialists is critical to determine what control measures to implement to prevent foodborne illness. Timely food-supply investigations, such as product tracing and environmental assessments, can better define the food vehicle(s) that need to be controlled and identify the contributing factors and environmental root causes that led to foodborne illness (Chapter 5).

6.1 Information-Based Decision Making

6.1.1 Investigation and control teams should be prepared to act at any point in the investigation when credible information identifies opportunities to control or mitigate disease transmission. Controls can be implemented concurrently with product tracing (i.e., traceback,

traceforward) investigations, environmental assessments, or other investigative processes. Waiting for laboratory results, medical diagnosis confirmation, or implication of a specific food may not be necessary before implementation of initial control measures to prevent additional exposures.

6.1 Information-Based Decision Making

Control measures typically progress from general to specific as investigations gather more information and should be implemented immediately whenever their need becomes apparent. General precautionary control measures that have high potential for public health benefit and low impact on business operations are usually not controversial and can be implemented relatively quickly in the field by the regulatory authority. Examples include holding a suspected nonperishable food from sale or screening for and excluding an ill employee. Decisions to implement more costly controls, such as recalling a food from distribution or closing a facility, should be based on clear and convincing evidence that food from the facility caused illness or that an imminent hazard to health exists. These decisions should involve input from the entire response team, including risk communication specialists and legal advisors (Chapter 2). Depending on the complexity of the outbreak, input from federal agencies, trade associations, or other industry and academic experts may be necessary.

6.1.2 Investigation and control teams should use a systematic process to evaluate information and regularly reassess control measure decisions. Sometimes the type of control measures needed to stop an outbreak is readily apparent early in the investigation (e.g., significant food temperature or risk factor violations). More commonly, however, key information is initially unavailable about the source, contributing factors, and root causes of foodborne illness outbreaks.

Typical steps in the evaluation include the following:

- Send a team to the likely source as soon as possible.
- Inform and involve the owner or manager of the implicated establishment.

- Assess potential risks on the basis of information provided by each discipline.
- Assess availability of resources needed to implement controls (e.g., legal authorities, equipment, and staff).
- Identify priority control measures, and clarify expectations among team members about the timeliness and completeness of control efforts.
- Implement control measures.
- Reassess and adjust control measures as additional information is gathered.

The quality of information is related to multiple factors (Chapter 5). Evaluate epidemiologic, laboratory, environmental health, and other evidence together to determine the degree to which the integrated data are consistent with each other, biologically plausible, and sufficiently strong to support implementation of control measures.

6.1.3 Investigation and control teams must balance the likelihood that control measures will prevent further illness against other consequences (Box 6.1).

Inaction or delayed action in the face of ongoing exposure can result in additional illnesses. Conversely, aggressive control interventions, such as recalling food or closing a food establishment, can have legal or economic consequences for food workers, employers, communities, and entire food industries. Investigation and control team members should not delay initiating steps to protect public health if available information indicates the need to act.

6.1 Information-Based Decision Making

Box 6.1. Questions to Address when Considering Control Options

- Is the contaminant causing the disease highly pathogenic, virulent, or toxic? Are susceptible populations exposed?
- Is the causative microorganism highly infectious and likely to be a source of secondary infections in the community?
- How effective, and how costly, is the proposed control measure likely to be?
- Who would play a role in implementing the control (government agency, food industry, or others)? What information will they need to act?
- Is a narrow, focused action possible—such as recalling a specific group of products or notifying only the persons most likely to have been exposed—rather than a more general recommendation to avoid consuming a general category of food or notifying the public?
- Will the actions affect only one business or an entire industry? How much economic or operational burden will be placed on the public who will need to respond on the basis of the proposed action?
- As they ponder these questions, investigation and control team members must recognize that a rapid response is critical if the threat of serious illness and death is ongoing.

Studies not associated with current investigation.

6.2 Communications With the Public

Agencies should anticipate, prepare for, and allocate resources to respond to and manage public concerns related to any public health messaging about the investigation. All members of the outbreak investigation and control team (epidemiology, environmental health, and laboratory) and health department leadership should provide input into the decision to make a public notification (Box 6.2)

6.2.1 Messages to the public about foodborne disease outbreaks should follow best practices for risk communication and provide objective, fact-based information about the outbreak.

- Ideally, before an outbreak occurs, prepare templates for public messages and have them reviewed by appropriate staff, including legal counsel. Use the templates consistently during the investigation. For examples of communication templates, see the CIFOR Clearinghouse (<https://cifor.us/clearinghouse/cifor-toolkit-focus-area-3-communications>).
- Follow agency communication protocols. Prepare communication following the agency's risk communication protocols. Seek assistance from the agency public information officer or the public information officer at another agency if the agency with jurisdictional responsibility does not have this resource.
- Provide information about the disease, including symptoms, mode of transmission, prevention, and actions to take if illness occurs.
- Include information about what is known, what is not known, and what officials are doing to learn more.
- Do not speculate about the outbreak. Sharing preliminary or unconfirmed information with the public may result in undue worry if there is no definite action to be taken (i.e., avoidance of a certain food). Such announcements often result in inquiries from concerned citizens and the media, and the resulting expanded workload can rapidly

6.2 Communications With the Public

Box 6.2. Questions to Address when Considering Whether Public Notification is Necessary

- What is the potential severity of disease and risk for additional illnesses (e.g., secondary infections in the community)?
- Is medical treatment necessary for persons who might have been exposed to the etiologic agent? If so, urgent public notification is critical.
- Is public reporting of suspected illness necessary to determine the scope of the outbreak? If so, public notification might be appropriate.
- Does risk for exposure still exist? People take food home from restaurants, so public notification still might be appropriate.
- Are large numbers of unknown persons likely to be ill with highly infectious agents, such as norovirus or *Shigella*? If so, an advisory that ill persons should stay out of work or restrict activities may help prevent secondary transmission at other food establishments, day care, and healthcare facilities.
- Is the source of the outbreak past its shelf life so no further risk exists to the public? If so, public notification may not be needed.

divert resources from the investigation and control team and increase pressure to quickly name the source of the outbreak.

- Ensure that officials prepare talking points to respond to media inquiries and social media questions, if needed. The Colorado Integrated Food Safety Center of Excellence developed the Communications Toolkit: Media Relations to help agencies work constructively with the media during foodborne illness outbreaks (1).
- Work closely with public information officers to ensure that consistent messaging is used to answer inquiries. This collaboration can reduce the potential for confusion or panic among consumers and industry.
- Maintain effective, accurate, and consistent communication with other agencies (i.e., local, state, territorial, tribal, and federal) involved in, or impacted by, the investigation.

6.2.2 Notify the public when actionable information is available that the public can act on to prevent additional illness (Box 6.3). Attempt to reach all members of the population at risk, including non-English-speaking and low-literacy populations.

- Means of notification depend on the public health risk and the target population and might include press releases, radio, television, fax, telephone, text messaging, email, Web posting, social media, or letters.
- Provide clear and actionable information about how to handle a suspected product (discard, special preparation instructions, or return to place of purchase) or whether the local jurisdiction is interested in obtaining the product from households that still have it.
- Consider notifying area clinicians and healthcare facilities if an increase is expected in the number of people seeking healthcare after public notification.

6.2.3 If public notification is expected to generate considerable public concern and/or media inquiries, consider setting up an emergency hotline for the public and media. Train people answering the phones to give consistent responses. Give them talking points or frequently asked questions and answers. Consider staffing the hotline after hours to answer phones after the early evening news or to respond to questions posed on social media.

6.2 Communications With the Public

Box 6.3. Notifying the Public About Actionable Information

Early public announcements should reinforce basic food safety messages and inform the public about how to contact appropriate authorities to report suspected foodborne illnesses.

Educational materials on food safety targeted at the public are available from the Partnership for Food Safety Education (<http://www.fightbac.org>) and the Centers for Disease Control and Prevention's Food Safety website (<https://www.cdc.gov/foodsafety>). The following specific food safety messages are important to communicate to the public.

- Personal protection from disease outbreak:
 - Thoroughly wash hands with soap and warm water after using the bathroom and before preparing or eating food. Also wash hands after changing diapers, assisting a child at the toilet, and handling animals or animal waste. Hand washing is the single most important measure to protect the public's health.
 - At home or at a social gathering (e.g., potluck dinner), avoid eating food that has not been handled properly (e.g., hot food that has not been kept hot, cold food that has not been kept cold).
- Proper food preparation:
 - Thoroughly cook food; keep hot food hot and cold food cold; thoroughly clean all food-preparation surfaces and utensils with soap and water; avoid contaminating food that will not be cooked, such as salads, with food that must be cooked, such as raw meat or chicken products; and wash hands frequently with soap and water.
 - If you are ill with diarrhea or vomiting, do not prepare food for others until at least 72 hours after you are free of diarrhea or vomiting.
 - Wash hands before and during food preparation.
- Actions if someone in the household or childcare, or institutional setting has diarrhea or vomiting:
 - If a norovirus-like illness is involved, emphasize the importance of thorough cleaning and sanitation of high-risk transmission surfaces, such as toilet seats and flush handles, washbasin taps, and washroom door handles.
- Appropriate community guidance, references, and educational materials are available at <https://www.cdc.gov/norovirus/preventing-infection.html>.

6.3 Communications With Response Partners and Stakeholders

Early communication with healthcare providers, the food industry involved, and others impacted by the outbreak can increase case detection, reduce the risk for secondary transmission, and help identify the source of contamination. If the pathogen causing enteric illnesses is known, use of general communicable disease control measures may limit further spread, even before the mode

of transmission is clear or a food or facility has been implicated. Control measures at this point typically focus on preventing secondary spread by known cases and communicating with healthcare providers and the public about precautionary measures they can take to prevent illness transmission of the identified pathogen.

6.3 Communications With Response Partners and Stakeholders

6.3.1. Effective communication with other agencies involved in the investigation or potentially impacted by the response helps staff from multiple agencies take timely actions to prevent further illnesses. During multistate outbreaks, others involved might include agencies and organizations at the local, state, territorial, tribal, and federal public health and regulatory levels (Chapter 7). A consistent public message alleviates confusion and reduces the potential for panic among consumers.

6.3.2 Communications with healthcare providers should include reminders and instructions to be shared with ill persons about personal hygiene, ways to avoid spreading infection, and infection control precautions for hospitalized patients and residents of long-term-care facilities. Instruct healthcare providers to report suspected illness to local health departments for follow-up and interviews, especially when ill persons work in settings where the risk for disease transmission is most likely, such as in food establishments and childcare and healthcare facilities. Advise healthcare providers about whether to collect clinical samples for analysis, if indicated.

6.3.3 Early communication with impacted food establishments, commodity groups, or food industries likely impacted by the public notification can assist them to

- Prepare for media enquiries.
- Consider how they can cooperate with the investigation to identify the cause(s).

- Implement control measures to prevent further cases.

Food-industry representatives often have detailed knowledge about typical food-handling, storage, and distribution practices that can guide investigation and control efforts. Early sharing of clear, credible, and objective information often motivates firms to voluntarily bolster efforts to comply with standard food safety and communicable disease control measures, such as

- Excluding or restricting ill persons from food handling.
- Eliminating bare-hand contact with ready-to-eat foods.
- Proper handwashing.
- Thorough cooking.
- Effective cleaning and sanitizing procedures.

It is often helpful to provide a written summary identifying key information, including the type of agent (viral, bacterial, chemical, toxic), the exposure time period (particularly if exposure is potentially ongoing), and whether a single point source or multiple different exposures most likely caused the illnesses.

The Communications Toolkit: Industry Relations developed by the Colorado Integrated Food Safety Center of Excellence is an example of resources available to help agencies communicate effectively with the food industry during foodborne illness outbreaks (*1*).

6.4 Control Measures

Although most reported foodborne illness outbreaks are investigated and controlled at the local level, site-specific food-safety controls

may be needed at multiple points along the distribution network and in the impacted communities (Figure 6.1).

6.4 Control Measures

Figure 6.1. Controlling the Source and Communicating with the Public



At the source:

Stop further production of contaminated food at the implicated food establishment.

Control any contaminated food remaining at the establishment.

In distribution:

Remove contaminated food from commercial distribution.

In the community:

Notify the public not to consume contaminated products that may be in their homes.

Appropriate control measures vary depending on whether the implicated food is associated with a food-service/retail food establishment or is a manufactured food that has been commercially distributed. The outbreak response team must determine as soon as possible whether one facility or multiple facilities are involved.

6.4 Control Measures

6.4.1 Implement initial control measures at an implicated facility on the basis of investigation findings and review of what is known about other outbreaks caused by the agent and the food establishment's food-safety history. Credible epidemiologic, laboratory, and environmental health evidence can support early implementation of nonspecific control measures at an implicated facility, even though a specific food has not yet been identified.

- Adjust control measures on the basis of knowledge of the agent and whether a food item is suspected. An outbreak caused by *Clostridium perfringens* has very different contributing factors and control measures than one caused by norovirus. Controls for a *C. perfringens* outbreak focus on time and temperature for food safety, including rapid cooling, proper hot holding, and reheating. Controls for a norovirus outbreak focus on identifying and excluding ill employees. Also ensure proper hand-washing, no bare-hand contact of ready-to-eat foods, disposal or embargo of ready-to-eat foods when bare-hand contact occurs and thorough cooking is not possible, enhanced cleaning and sanitizing procedures, and (possibly) changes in the source of suspected high-risk foods used in the facility. Focusing on pathways commonly linked to the agent are most likely to identify and address the root causes of the outbreak.
- Review the establishment's history for recurring foodborne illness risk factors, previous outbreaks, illness complaints, recall, positive food samples, and correction of serious food-safety hazards. This information can indicate management's capability and willingness to consistently maintain food-safety controls. Understanding the facility's existing level of active managerial or process control can guide how the investigation and control team works with management to implement changes needed to address

contributing factors and the environmental root causes that led to the outbreak.

6.4.2 Coordinate onsite investigation, environmental assessment, and control measures at the implicated facility.

Most foodborne illness outbreaks are local events investigated and controlled by staff from local public health agencies. For large-scale or multijurisdictional outbreaks, staff from multiple disciplines or agencies may be involved. Staff should identify investigation and control objectives and clarify agency roles and responsibilities before arriving at the implicated food establishment. Initial clarification of both types of objectives helps ensure that appropriate staff visit the facility.

- A team approach is often needed to effectively conduct the onsite investigation and implement control measures. When conducting any environmental assessment, at least two environmental health specialists should be deployed in the field to ensure both investigative and control measure objectives are achieved. Environmental assessment teams visiting facilities for the first time must often simultaneously seek to complete multiple objectives. A few examples include communicating with firm management to enlist its cooperation, ensuring the safety of foods being served/sold, placing seizures/embargoes/holds on implicated or suspected foods or leftovers, interviewing food workers, assessing foods served and processes during the period of interest, and collecting documents and samples as needed.
- Rapid initial assessments to identify conditions requiring immediate control measures should be coordinated with ongoing investigation activities. Effective control measures address both the contributing factors that resulted in foodborne illness (what went wrong) and the root cause(s) of the outbreak (why it went wrong at this location).

6.4 Control Measures

6.4.3 Gather samples while they are still available. Early collection of samples while they are still available can greatly aid in determining the root causes of foodborne illness (Chapter 5). Discarding suspected food can help stop the outbreak, but isolating the etiologic agent from the food provides the most convincing evidence a food was the source of the outbreak. Use both epidemiologic data and guidance from the laboratory to inform decisions about what samples to collect and how to handle them.

6.4.4 Control measures for localized events associated with a single food-service or retail food establishment will usually be established by local public health agencies or state and local food-regulatory agencies. Although all of the following control measures are recommended, some may be more appropriate than others in specific outbreaks, and full implementation might not be possible in some jurisdictions. Implementing the most appropriate control measures as completely and promptly as possible improves the effectiveness of those measures. Before using any control measure, the environmental health/regulatory specialist must understand applicable laws and procedures for implementing them (Chapter 2).

- **Inform and engage facility management in implementing controls.** Environmental health specialists should work with the food establishment's person-in-charge (PIC) to implement active managerial controls and create a risk-control plan or consent agreement. Active involvement of the PIC uses his or her expertise and often increases commitment to implement controls to stop the current outbreak and prevent additional outbreaks. The CIFOR Industry Guidelines outlines, clarifies, and explains the recommended role of owners, operators, and managers of food establishments in a foodborne illness outbreak investigation (2).
- **Remove food from sale or prevent consumption.** If evidence from the epidemiologic, laboratory, and environmental assessment/root cause analysis supports the action, implicated or potentially unsafe foods should be embargoed, seized, placed under regulatory hold, or otherwise removed from service or sale. Fully document the information that led to the decision and the process used to make the decision. Issuing a written hold or embargo order establishes clear expectation and regulatory requirements and prevents the establishment owner from serving or destroying the food before the investigation is complete.
- **Clean and sanitize.** If evidence from the outbreak investigation identifies the potential for onsite contamination during the outbreak, the environmental health specialist must ensure involved equipment and areas of the facility are thoroughly cleaned and sanitized. This process includes disassembling all equipment and retraining staff on proper cleaning and maintenance procedures for the equipment. The cleaning and sanitizing process is particularly important if *Salmonella*, *Listeria monocytogenes*, or norovirus contamination of food is suspected. Industry guidance documents are identified under references.
- **Train food managers and workers.** Assess to what degree the presence of food-safety risks is due to inadequate food worker knowledge, inadequate supervision, or lack of active managerial control. Ensure the firm's food-safety management system is adequate to ensure that managers and food workers receive consistent food-safety training appropriate for their job duties. Ensure remedial training is provided, as needed so that food managers and workers have a functional understanding of the disease (e.g., symptoms, modes of transmission) and the food-safety practices (e.g., use of procedures for rapid cooling and thorough cooking

6.4 Control Measures

and reheating of foods) needed to stop the outbreak and prevent recurrence.

- **Modify a food process.** Assess food-production or food-preparation processes at the establishment using both investigation findings and the best available scientific information. Examples of critical steps and controls include process times, temperatures, parameters (pH, water activity level), and label instructions. Implement changes needed to consistently prevent contamination of food or the survival and proliferation of disease-causing microorganisms.
- **Modify the menu.** Eliminate implicated foods from the menu until adequate control measures are in place to ensure food safety. For example, if shell eggs are implicated, remove all foods that contain shell eggs, and substitute pasteurized egg product until the investigation is complete and proper controls are in place.
- **Remove infected food workers.** Ensure that ill or infected food workers are excluded from the workplace or restricted in accordance with the Food Code (3) or other regulatory requirements unless evidence gathered by the investigation team indicates that a longer exclusion period is needed (e.g., evidence exists of ongoing norovirus transmission within the food establishment). Because many food workers are employed by more than one food establishment, ensure ill workers are excluded or restricted from all food establishments where they work.
 - Food establishment management should conduct daily monitoring of worker health to prevent further contamination of food by ill or infected workers. For example,
 - A person ill with vomiting or diarrhea should be excluded from the facility.
 - Pathogen-specific guidance and other information about restricting and excluding food workers is available in the latest version of the Food and Drug Administration (FDA) Food Code (3).
 - In *Salmonella* and *Shigella* outbreaks, fecal samples should be analyzed for the pathogen because of the likelihood of asymptomatic but infectious food workers. Restricting activities of food workers who do not comply with the request might be necessary.
 - Excluding ill food workers is not as simple as it might seem. Food workers may be reluctant to inform managers of illness because of fear of lost wages, reprisal, or leaving their co-workers short-handed. Conversely, managers underappreciating the risk to public health and their firm's economic viability may be reluctant to relieve food workers of their duties or may themselves work while ill.
 - Facilities with a strong food-safety culture ensure that both managers and food workers are well informed about alternatives to coming to work while sick, including alternate jobs that ill food workers can perform and allowing ill employees to trade for shifts when their exclusion has been lifted.
- **Use risk-control plans.** Written risk-control plans or other agreements are used to identify and focus control measures that establishments need for safe operation. Important aspects of these plans include
 - Process changes, such as recipe adjustments or development of a Hazard Analysis and Critical Control Point plan.
 - Worker training.
 - Adequate oversight measures to ensure workers follow proper procedures.
 Plans may require
 - Increased focus on regulatory requirements (e.g., additional measures to ensure appropriate handwashing by all employees).

6.4 Control Measures

- Additional measures above and beyond regulatory minimum requirements (e.g., extra temperature checks and logging of temperature).
- Close food establishments.** Facilities that cannot safely remain in operation must be closed in accordance with applicable local and/or state regulations. A facility linked to an ongoing foodborne illness outbreak, in which significant noncompliance with regulatory food-safety standards is documented, is an imminent or substantial health hazard.
- Communicate findings.** Effective communication of the evidence gathered by the investigation and control team can be a powerful motivator for establishment management to close or significantly modify operations. Voluntary actions are often the most efficient and timely way to reduce risks to the public. If the owner cannot or will not take immediate corrective action to eliminate ongoing food-safety hazards, mandatory closing of the premises may be necessary.
- Notify the public.** As control measures are implemented at the source, public notification can be an effective way to prevent additional illnesses and further disease transmission, but it must be used judiciously. If the outbreak involves only one facility, carefully consider whether public notification is truly necessary. See 6.2 for details.
- Monitor control measures.** The strategy for monitoring short- and long-term correction of the factors within the food establishment that caused the outbreak should be identified in writing. Food establishments should integrate monitoring steps into their food-safety management systems (e.g., Active Managerial Control), and regulatory officials should provide the facility with timely follow up inspections so the effectiveness of control measures can be assessed, modified, or removed when appropriate. Public health officials should maintain enhanced surveillance of potentially exposed populations to ensure controls are effective, secondary spread of infections is not occurring, and systems are in place to prevent reoccurrence.

6.5 Outbreaks Involving Commercially Distributed Foods

6.5.1. Control measures associated with commercially distributed foods typically require coordination of multiple agencies across jurisdictional levels, especially when an implicated food item is subject to recall (Chapter 7). Careful coordination of control measures at the food-manufacturing facility, in distribution channels, and in consumer homes often is needed to stop outbreaks linked to commercially distributed foods. Food manufacturers can range from small facilities with limited local distribution to large, complex facilities capable of producing huge quantities of diverse products daily. Although contaminated products may still be stored onsite at the manufacturing

facility, the probability is much higher that they have moved through various points of often complex distribution networks that can span the globe and include a wide range of locations, including; warehouses, distributors, retail establishments, consumer homes, and food banks. Timely product tracing investigations often identify the point in the production and distribution process where the implicated food became contaminated and where contaminated products may have been distributed after that (Chapter 5). The type of food products involved and the extent of their distribution often determine which regulatory agency leads the implementation and coordination of control measures.

6.5 Outbreaks Involving Commercially Distributed Foods

- **Implement onsite controls at the food-manufacturing facility.** Depending on the scope of the outbreak and probable point of contamination, most of the specific onsite control measures for food-service and retail food establishments also will be appropriate to control contaminated foods and food-safety risks at other points in food-supply chains where contamination was introduced. Given the size and complexity of many of these establishments, timely sharing of the most specific and accurate information available (e.g., product descriptions, lot codes, and periods of interest) is vital to focusing control measures where they are most needed.
- **Determine whether a food recall is needed.** Public health and food-regulatory agencies need to determine whether the contaminated product is still in distribution

or consumer homes and, if so, decide how contaminated products can most effectively be removed from the market and consumers notified when appropriate (Box 6.4).

Food firms have the primary legal responsibility to initiate and conduct effective food recalls. If the food-regulatory agency has adequate information to implicate and accurately identify a contaminated food item, that agency will take the lead on working with the manufacturer to initiate recall activities. Consider the capabilities of the firm and involved agencies to: notify the public when appropriate, conduct recalls, and verify their effectiveness. Past recall experience and prior recall planning are often good indicators of likely future performance by the manufacturer.

Box 6.4. Considerations for Whether to Remove Food from Distribution

Questions to Ask

- Is risk to consumers ongoing?
- Is the product still in distribution based on product tracing information (Chapter 5)?
- Is the product likely to still be in the homes of consumers?
- Do the combined epidemiologic, laboratory, and environmental health data support removing food from the market?

Remove the food if

- Specific exposure information links the illness with consumption of that food (e.g., through a quality analytic study or other epidemiologic method), even if the pathogen has not been isolated from the food OR
- Definitive lab results show the outbreak pathogen is present in the product. The results must be based on a food sample that is representative of the food eaten by case-patients and has been handled properly to avoid cross-contamination OR
- An investigation at the source reveals adulterated products or other conditions that pose an imminent hazard to health OR
- Epidemiologic association is not significant, but the pathogen, chemical, or other contaminant is so hazardous that the risk to the public is very high (e.g., botulism). Under these circumstances, there may be no analytic controlled studies, but if the descriptive epidemiology (e.g., demographic characteristics of case-patients, geographic distribution, or illness onset) suggests an association between the disease and the suspected food, then removing food from the market might be warranted, even in the absence of confirmed laboratory findings.

6.5 Outbreaks Involving Commercially Distributed Foods

- **Contact the federal or state regulatory agency that has jurisdiction over the product.** FDA regulates the safety of most foods moving in interstate commerce, except meat, poultry, fish of the Order Siluriformes (including catfish), and most out-of-shell egg products (which are regulated by the U.S. Department of Agriculture’s Food Safety and Inspection Service [FSIS]) (Chapter 3).

Both FDA and FSIS have developed informational websites to assist their investigation and response partners. FDA developed a general website (4) with Resources for Regulatory Partners, and FSIS developed a website with resources for its investigation partner agencies to improve communication and sharing of information during foodborne illness outbreak investigations (5).

- **Initiating a recall.** State agencies, FDA, FSIS, and the Centers for Disease Control and Prevention (CDC), often contact the manufacturer seeking to obtain its cooperation in initiating a food recall. In addition, the regulatory authority and/or the manufacturer may ask retail facilities to remove the product from their shelves and ask distributors to withhold the product from distribution.

Quickly determining the extent of a recall needed in a large manufacturing plant with multiple processing lines can be difficult. Although industry often wants to limit the recall to the production lots implicated in illnesses, the conditions or extent of contamination observed within the facility may warrant a more comprehensive recall. Was an ingredient identified as a possible source of illness used in multiple food processes? Often, implicated lots will be recalled while a hold is placed on other products until their safety can be determined through an environmental assessment and product sampling. Because recalls often expand as more contaminated products are

identified, some processors will voluntarily recall or be compelled to recall all suspected product to avoid the negative publicity and the economic impact associated with multiple recalls of their products.

Recall of food at the processor level generally requires federal and/or state action. In some jurisdictions, the local health jurisdiction will embargo (impound) the food (tagging the food to make sure it is not moved or sold, or ordering it destroyed). Under the Food Safety Modernization Act (6), FDA can order the embargo of food for up to 30 days without a court order.

- **Remove product from distribution.** Once a decision is made to remove food from the distribution, the food must be removed as quickly and efficiently as possible (Box 6.5). Foods with short shelf lives (e.g., fresh produce, dairy products) generally are consumed within the shelf life or discarded. Foods with longer shelf lives, especially frozen foods and foods that may be frozen, will be available for extended periods of time. Prevent additional exposure by ensuring effective recall practices and public notification.

Conduct product tracing (traceback, traceforward) investigations to better learn where contaminated products were distributed and how contaminated products were used. For example, a contaminated food may have been used as an ingredient in food(s) that were not subsequently treated to destroy the contaminant, and additional recalls may be necessary. An ingredient also may be indicated if a large number of illnesses are not linked to the foods from one implicated facility.

Detailed information and sample forms for use by food establishments are included in the “CIFOR Foodborne Illness Response Guidelines for Owners, Operators and Managers of Food Establishments” (7)

6.5 Outbreaks Involving Commercially Distributed Foods

Box 6.5. Steps to Improve the Effectiveness of Recall Measures and Industry Response

- Conduct recall effectiveness checks to assess whether efforts to remove products from distribution channels work.
 - Share distribution lists of recalled foods among government agencies and with the public
 - Develop a list of verification or control measures to implement immediately when an outbreak- related or illness-related recall has been identified.
 - Identify industry needs and develop guidance for
 - Interacting with public health or agriculture officials investigating an outbreak. Provide retailers and manufacturers with 24/7 contact numbers and emails for regulators at the local, state, and federal levels, including FDA and USDA's Food Safety and Inspection Service (USDA-FSIS).
 - Providing timely notification of customers, appropriate government agencies, and the public of recalls involving particularly hazardous contaminants.
 - Mitigating the impact of an outbreak- related or illness-related recalls. Examples: clean out the display cases, follow destruction for recalled product, recommended practices for disposing of returned product.
 - Develop guidance for communicating with the news media, including the preparation of talking points to answer inquiries. Have a plan for coordinating a news media telebriefing or video briefing, if needed. Identify a spokesperson.
 - Develop standard templates for press releases and social media messages for use during an outbreak that follow best practices for crisis and emergency risk communication (<https://emergency.cdc.gov/cerc>).
-
- **Food regulators should consider ways to immediately notify food facilities in their jurisdiction through text messaging, email, blast fax, or phone calls of recalls associated with high severity hazards (e.g., botulism associated with under processed canned foods) that have a reasonable probability of still being in commercial distribution.** Identifying subcategories of facilities is highly recommended so notices can be targeted to specific facilities (e.g., notices of a seafood recall sent specifically to seafood retail establishments). This process should include food bank donation centers and other sites that might have received food donations.
 - **If any distributors or retailers refuse to remove the food, issuance of a public health warning and order to require action might be necessary.** The appropriate agency for this action depends on the type of food and etiologic agent. Passage of the Food Safety Modernization Act gave the FDA the authority to order a responsible firm to recall a human or animal food when FDA determines that 1) there is a reasonable probability that the food is adulterated or misbranded and 2) consumption would cause serious adverse health consequences or death to humans or animals.
 - **The agency/jurisdiction should monitor to ensure the recall is effective in stopping illnesses and food is completely removed.** Are illnesses continuing after the recall? If so, why? Is there another contaminated product or lot number that has not been recalled? Was the product purchased after the recall? If so, from where? Was the consumer aware of the recall notice?
 - **Assessing recall effectiveness requires close cooperation among local, state, territorial, tribal, and federal agencies to accomplish risk-based recall effectiveness checks across the distribution system.** For example, many large-volume retailers

6.5 Outbreaks Involving Commercially Distributed Foods

routinely sell product to smaller retailers that may use cash for purchases. Participating in recall effectiveness checks can help local and state agency staff maintain proficiency in tracing contaminated products from the source(s) throughout distribution chains. If the product is not immediately removed, determine why.

- Did the manufacturer notify the distributor of the recall?
 - Did the distributor notify retailers of the recall?
 - Was the recall information clear and complete, including all lot numbers, use-by dates, bar codes?
 - Did notifications occur but no action was taken?
 - Was returned recalled product diverted and sold elsewhere?
 - If the recall is not effective, notify appropriate state, federal, and neighboring health and food-regulatory agencies.
 - Issue a public advisory if needed.
- **Post-recall reporting by the food business or manufacturer.** If a food business or manufacturer recalls a product, it should prepare interim and final reports about the recall. The contents of these reports are used to determine the need for further recall actions. The reports should include copies of all notices distributed to the public and through the distribution chain, as well as the following information:
 - Circumstances leading to the recall and actions taken.
 - Extent of distribution of the suspected food (documentation that can support traceforward investigations).
 - Result of recall (percentage of suspected food recovered).
 - Method of disposal or reprocessing of suspected food.
 - Difficulties experienced in recall and actions taken to prevent recurrence of food-safety problems and any recall difficulties.

6.6 Outbreak Wrap-up Activities

6.6.1 Most outbreaks are considered over when two or more incubation periods of the etiologic agent have passed with no new cases. However, outbreak investigation and control activities should not cease when new cases of human illnesses cease to be identified. Clusters with low attack rates and cases from some sources might appear intermittently for years. This is especially common with agricultural products, such as romaine lettuce, where outbreaks have occurred each year, around the same time of year, when products are harvested from the same contaminated farms. PulseNet data should be reviewed and monitored to make

certain control measures have been effective in preventing additional illnesses.

The outbreak is truly over when the source has been identified and controlled so it cannot cause additional illnesses. To prevent additional illnesses and future outbreaks, it is vital that investigation and control teams learn why the outbreak occurred so effective controls can be applied to address the contributing factors and root cause(s) (2). Sharing lessons learned from each outbreak with the food industry in that sector or commodity group can prevent future outbreaks in other locations.

6.6 Outbreak Wrap-up Activities

6.6.2 Restrictions put in place to prevent additional illnesses may be removed when no further risk to the public exists, such as when

- Risk factors in the facility have been eliminated and an effective system has been put in place to prevent their reoccurrence.
- Ill food workers have recovered and are no longer shedding pathogens (refer to the FDA Food Code for specific recommendations on restricted/excluded employees).
- Tests indicate no further contamination within the facility.
- Employees have been trained on proper methods to avoid the contributing factor(s) of foodborne illness.
- Managerial controls are implemented and integrated within day-to-day operations and the facility's operational culture (culture of food safety).

6.6.3 Monitoring plans should be developed to ensure the effective control of the outbreak.

- **Monitor the population at risk** for signs and symptoms of the foodborne illness to ensure the outbreak has ended and the source of illness has been eliminated. Epidemiologists and communicable disease control staff should consider conducting active surveillance, working with healthcare providers to increase their identification of associated cases, and collecting fecal samples from the population at risk. Monitor the Whole Genome Sequence (WGS)– PulseNet database to assess whether closely related cases have occurred in the region or nationally. An outbreak at a food establishment may be caused by a contaminated food ingredient or product that they received. Also monitor WGS-PulseNet over the next year for matching cases. *Listeria*, *Salmonella*, and Shiga toxin–producing *Escherichia coli* outbreaks often reoccur from

the same source. Another outbreak could recur the following year around the same time if contaminated produce from certain farms with unsafe water is the source.

- **Monitor the implicated foods or food establishments** to ensure agreed-to changes in food-safety management systems are maintained and that no additional contamination is occurring.
 - Identify needed changes in writing, such as with a Risk Control Plan or Standard Operating Procedure.
 - Maintain communication with managers of the implicated food establishment and give them additional information if it becomes available.
 - Increase the number of risk-based inspections at the implicated food establishment and sampling of implicated foods, as needed, to monitor the firm's development and implementation of preventive controls.

Outdated, unsafe practices often are difficult to change, and new practices might need to be reinforced multiple times before they become routine. Consider customized training to support the desired behavioral change. Determine whether behavioral change has occurred long term. Consider requiring that the establishment or firm hire a consultant to assist in developing safe systems and in monitoring if the facility has a history of unsafe practices.

6.6.4 Outbreak investigation and control teams should routinely meet and review all aspects of the investigation. Processes that systematically review investigation and control efforts after the response is over have two primary goals (Box 6.6):

1. Improve the effectiveness of future investigations and responses.
2. Prevent recurrence at the facility or in similar types of food operations.

6.6 Outbreak Wrap-up Activities

Box 6.6. Goals of Formal After-Action Meeting

- Improve the effectiveness of future investigations and responses:
 - Clarify resource needs, structural changes, or training needs to improve future outbreak response.
 - Identify factors that compromised the investigations, and seek solutions.
 - Identify necessary changes to current investigation and control guidelines and development of new guidelines or protocols as required.
 - Discuss any legal issues that might have arisen and the need for new laws to strengthen response (Chapter 2).
- Prevent recurrence at this facility or in similar types of food operations:
 - Identify the contributing factors and environmental root causes of the outbreak and measures (preventive controls) to prevent additional outbreaks at this and other food establishments.
 - Determine whether others need to be notified of lessons learned from the investigation to prevent outbreaks elsewhere.
 - Identify the long-term and structural control measures, develop a plan for their implementation, and determine surveillance and follow-up needed to ensure an outbreak does not reoccur.
- Assess the effectiveness of outbreak control measures and difficulties in implementing them.
- Assess whether further scientific studies should be conducted.

Assessments of the effectiveness of the investigation and control efforts should maintain a balanced approach that identifies strengths to be built upon and areas of improvement to be addressed. The complexity of the review depends on the size and complexity of the outbreak. For a small outbreak associated with a single facility or event, a quick meeting and short written summary may be sufficient.

For a large outbreak involving multiple agencies, a series of meetings resulting in a formal after-action report is appropriate.

Two types of meetings can be used as part of effective after-action review processes:

- **Hot wash/debriefings** involve investigation and control team members to gather input within 1–2 weeks after the investigation's completion while it is fresh in responders' minds. These are often less formal and single-agency in nature. Examples of typical agenda items include

- What went well?
- What did not go well?
- What resources were needed that were unavailable?
- What will be done differently next time?
- What follow-up is needed from root-cause analysis to ensure this does not happen again (Action Plan: who will do what by when)?

- **After-action review meetings** often involve response team members, response partners, and sometimes stakeholders. These meetings are more formal, systematic, and comprehensive and, because of the need to coordinate schedules and information sharing, might occur 1–2 months after the response.

Effective after-action review processes result from planning and the intentional dedication of resources to support these meetings. Share written summaries of each meeting with attendees and interested response partners. Lessons learned from outbreaks should be

6.6 Outbreak Wrap-up Activities

communicated appropriately so they can promote improvement; even the best lessons learned have minimal impact if they are not shared with relevant partners and stakeholders. Link formal action items identified by the process to the agency's continuous process improvement program(s) to ensure appropriate accountability for tracking and correction.

If additional information becomes available in the weeks or months after the outbreak and the official after-action meeting, disseminate that information to the outbreak investigation and control team and appropriate external partners.

6.6.5 Prepare reports for all outbreaks.

The report complexity depends on the size of the outbreak. For small outbreaks, a simple summary (following a template established by the agency) should suffice. Use the report to educate staff and share important investigation findings with others. When combined with other reports, this information can help identify trends across outbreaks that can be useful in future investigations.

Use outbreak reports as an opportunity for continuous quality improvement. If all the after-action reports cite the same areas for improvement, then nothing is being corrected. Outbreak investigation reports provide an opportunity to document both lessons learned during the investigation and the investigation's results.

Well-conducted and documented outbreak investigations guide prevention efforts by identifying foods at risk for contamination, locations within food-supply chains where contamination is introduced, factors directly contributing to contamination, and the root causes)

The final report for a large outbreak should be comprehensive, provide information by all team participants, and be disseminated to all participating organizations. Sample outbreak

and after-action reports are available at the CIFOR Clearinghouse (8).

1. Given that reports, especially those for large outbreaks, are likely to be subject to Freedom of Information Act (9) requests, they should be written with public disclosure in mind. The reports should not identify individuals or other protected information unless necessary and legally defensible. Proper care in writing the report will save time redacting information when the report is released to the public. Some jurisdictions allow or mandate the inclusion of identifying information, so review state and local laws and policies.
2. Submit a final report of the outbreak to CDC's National Outbreak Reporting System and National Environmental Assessment Reporting System databases (10,11). FDA-funded Rapid Response Teams have uploaded after-action reports into FoodSHIELD (12).

Control of contributing factors without addressing the root cause for their presence in the facility can result in a repetitive cycle of short-term correction followed by gradual loss of food-safety controls and outbreak recurrence. Sharing the root causes of outbreaks enables a broad range of food-safety stakeholders (e.g., agencies, food industries, academic institutions, and consumers) to coordinate work within their respective spheres of influence to strengthen food-safety systems worldwide.

6.6.6 The outbreak investigation findings may indicate the need for future research.

For example, investigators may determine that for certain pathogens in certain foods, standard control measures do not seem effective or routine handling practices and their role in outbreaks are not completely understood. The food-safety or public health agency or research centers should consider such observation for in-depth study. Regular review of reports of

6.6 Outbreak Wrap-up Activities

foodborne illness outbreak investigations can identify important trends and areas of undercontrolled risks. Questions raised by stakeholders and researchers include

- How common is this pathogen as identified to the subtyping level by WGS?
- Is there a recurring pattern every year around the same time?
- Is there a high baseline in this region of the country that may indicate an ongoing source that needs to be identified and eliminated?

6.6.7 If unusual findings characterized the outbreak (e.g., unusual exposure, presence of a pathogen in a food where it had not previously been reported or by the magnitude of the outbreak) or new methods were used in its investigation, disseminate the report more widely (e.g., through Epi-X, *MMWR*, or other national forum; peer-reviewed journals). Publish important lessons learned (such as new investigation methods that proved particularly helpful, control measures that seemed particularly effective, actions taken that seemed to shorten the outbreak) in an appropriate national forum.

6.6.8 An outbreak can identify the need for broad education of the public; the food-service, retail, food processing, and agricultural industries; food-safety regulators; or healthcare providers.

Public outreach, including public service announcements, can remind the public about food-preparation precautions. National training programs for food workers and managers are regularly revised to reflect current understanding of the root causes of foodborne illness. Food-safety management systems increasingly hold managers accountable for ensuring that training of food workers is appropriate for assigned job responsibilities. Healthcare providers might need continuing education focused on diagnosing, treating, or reporting foodborne diseases. Such actions can help prevent future

outbreaks or reduce the number of cases or severity of illness during an outbreak.

Trade associations, food-industry organizations, and national conferences often request presentations on outbreak investigations. These events provide an opportunity to educate representatives of the food industry, colleagues, and others about investigation procedures, outbreak management, preventive controls, and CIFOR.

6.6.9 Information gained during an outbreak is used to identify the need for new public health or regulatory policy at the local, state, territorial, tribal, or federal level. Different inspection practices, source controls, surveillance procedures, or recall process controls have been established on the basis of well documented investigation reports.

Ongoing and regular review of outbreak investigation reports, research, and industry practices identifies the need for new policy. FDA regularly updates the Food Code (4) to better address the leading foodborne illness risk factors identified by epidemiologic outbreak data. For example, an analysis of outbreaks by the Environmental Health Specialist Network identified an association between not having a manager certified in food safety and outbreaks (13). Similarly, FDA found an association between the presence of certain foodborne illness risk factors and the lack of a certified manager (14). These findings led to changing the FDA Food Code to require the person in charge of most retail and food-service establishments, those posing more than a minimal foodborne illness risk, be a Certified Food Protection Manager.

Consult other public health and environmental health agencies to determine whether concurrence exists on the need for new policy. If so, present the issue to the appropriate jurisdictional authority by using the appropriate policy development processes.

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Special Considerations for Multijurisdictional Outbreaks

CHAPTER SUMMARY POINTS

- A multijurisdictional outbreak of foodborne illness requires the resources of more than one local, state, territorial, tribal, or federal public health or food regulatory agency to detect, investigate, or control.
- Recognition of outbreaks with multistate exposures will continue to increase with implementation of whole-genome sequencing in foodborne illness surveillance.
- Special efforts may be needed to
 - Help agencies recognize when a multijurisdictional outbreak is occurring and then identify and engage key partners in the investigation.
 - Improve communication and coordination among agencies at all levels of government that are investigating multijurisdictional outbreaks.
 - Increase the speed and effectiveness of investigating and controlling multijurisdictional outbreaks.

URLs in this chapter are valid as of August 28, 2019.

7.0 Introduction

Multijurisdictional investigations range from different agencies and departments at a local level collaborating on a simple investigation to a large multistate outbreak with the potential identification of imported foods. As the number of agencies and levels of

organizations across jurisdictions increases, the need for special efforts to maintain effective communication and coordination increases as well. (See Chapter 5 for general approaches to investigating clusters and outbreaks of foodborne illnesses.)

7.1 Categories and Frequency of Multijurisdictional Outbreaks

A multijurisdictional outbreak of foodborne illness requires the resources of more than one local, state, territorial, tribal, or federal public health or food regulatory agency to detect, investigate, or control the pathogen in question (Box 7.1). For some, such as multistate outbreaks identified through PulseNet surveillance, the multijurisdictional nature of the outbreak may be readily apparent. For others, it may emerge during the investigation. Special efforts may be needed to help agencies recognize a multijurisdictional outbreak and then to identify and engage key partners in the investigation.

The passage of the Food Safety Modernization Act (1) in 2011 gave new authorities to the Food and Drug Administration (FDA) and provided a mandate to enhance surveillance and response capacity at local, state, territorial, tribal, and federal levels. Combined with the development and implementation of whole-

genome sequencing (WGS), these investments in foodborne disease surveillance have increased the number of outbreaks recognized as multijurisdictional (Table 7.1). For example, during 2006–2010, 1.7% of all foodborne illness outbreaks reported to the Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System [NORS] involved multistate exposures and many more affected residents of multiple states or counties (2). During 2011–2016 the percentage of outbreaks with multistate exposures doubled to 3.4% (3). Overall, during 2009–2018, 27.1% of *Escherichia coli* O157:H7 outbreaks and 14.1% of *Salmonella* outbreaks involved multistate exposures, discovered largely through PulseNet (3). Thus, for these most important foodborne pathogens, the need for multijurisdictional coordination should be anticipated during the earliest stages of an investigation.

Box 7.1. Categories of Multijurisdictional Outbreaks

- Outbreaks affecting multiple local health jurisdictions (e.g., city, county, town) within the same state.
- Outbreaks involving multiple states.
- Outbreaks involving multiple countries.
- Outbreaks affecting multiple distinct agencies (e.g., public health, food regulatory, emergency management).
- Outbreaks, regardless of jurisdiction, caused by highly pathogenic or unusual agents (e.g., *Clostridium botulinum*) that require specialized laboratory testing, investigation procedures, or treatment.
- Outbreaks in which the suspected or implicated vehicle is a commercially distributed, processed, or ready-to-eat food contaminated before the point of service.
- Outbreaks involving large numbers of cases that may require additional resources to investigate.
- Outbreaks in which intentional contamination is suspected.

7.1 Categories and Frequency of Multijurisdictional Outbreaks

Table 7.1. Number of foodborne outbreaks with multistate exposure, multistate residency, multicounty exposure, and multicounty residency, by etiology, United States, 2009–2018 (3)

ETIOLOGY AND AGENT	NO. TOTAL OUTBREAKS	MULTISTATE EXPOSURE	MULTISTATE RESIDENCY, SINGLE STATE EXPOSURE	MULTICOUNTY EXPOSURE	MULTICOUNTY RESIDENCY, SINGLE COUNTY EXPOSURE
Confirmed Etiology	4,239	317	228	239	1,075
<i>Escherichia coli</i> O157:H7	192	52	5	32	42
<i>Salmonella</i>	1,291	182	76	121	347
<i>Clostridium perfringens</i>	165	0	3	0	49
<i>Staphylococcus aureus</i>	47	0	2	1	14
Hepatitis A virus	27	2	2	4	7
Norovirus	1,532	3	89	22	437
Other	985	78	51	59	179
Suspected Etiology	1,962	5	101	18	385
Unknown Etiology	2,184	2	101	36	357
Multiple Etiologies	146	1	6	3	36
TOTAL	8,531	325	436	296	1,853

Specifically related to multijurisdictional outbreaks, recent investments have been made to

- Improve coordination and data-sharing between public health partners and the public.
- Increase state and local participation in national surveillance networks.
- Expand and integrate national surveillance systems.
- Enhance laboratory and epidemiologic methods for agent identification and outbreak detection and investigation.

Coordinating offices for foodborne illness investigations in the three primary federal agencies include

- CDC: Outbreak Response and Prevention Branch (Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases).
- FDA: Coordinated Outbreak Response and Evaluation Network (CORE).
- U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS): Applied Epidemiology Staff.

7.2 Multijurisdictional Outbreak Detection

7.2.1 Multijurisdictional outbreaks may be detected at local, state, territorial, tribal, or federal levels. Outbreaks detected at the local level through investigations of consumer complaints, individual cases, or case clusters of reportable foodborne illnesses (Chapter 4) may identify common-source outbreaks or multiple subclusters of illnesses that implicate or suggest likely contamination of food before the point of service.

Detection of multijurisdictional outbreaks at a state level may result from an increase of sporadic infections with common subtype characteristics identified, investigation of subclusters of illnesses that identify a possible association with multiple food service establishments, or the linking of multiple, discrete common-source outbreaks by common agent, food, or water.

Similarly, national increases of infections with common subtype characteristics identified; identification of subclusters of illnesses associated with multiple restaurants or food service establishments in multiple states; and linkage of multiple, discrete common-source outbreaks in multiple states would lead to a multijurisdictional outbreak investigation.

Detection of a pathogen, such as *Listeria monocytogenes*, Shiga toxin-producing *E. coli*, or *Salmonella*, from a food item that resulted from testing by a federal or state food regulatory agency would lead to a search for human illnesses caused by the same organism with common subtype characteristics. Multijurisdictional investigation of infections with common subtype characteristics would be conducted to determine whether they were part of an outbreak.

7.2.2 When findings indicate that multiple jurisdictions might be involved in an investigation, additional communication and coordination are needed (Table 7.2). With initiation of an investigation of a

potential multijurisdictional outbreak, a local agency should ensure notification of the state health department and other local agencies, as appropriate, and provide subsequent updates in accordance with state procedures to ensure coordination between epidemiology, environmental health, and the public health laboratory.

Detection of multijurisdictional outbreaks at a state level requires notification of affected county and city health departments. CDC and state and federal food regulatory agencies need to be notified of subclusters or linked common-source outbreaks. For example, FDA has established its CORE Network to respond to outbreaks. USDA-FSIS has developed a template for including their agency in foodborne illness outbreak response procedures (4). Notify USDA-FSIS of outbreaks potentially associated with USDA-FSIS-regulated products by sending an email to FoodborneDiseaseReports@usda.gov and to the appropriate regional contact in the USDA-FSIS Office of Enforcement, Investigation, and Audit (<https://www.fsis.usda.gov/wps/portal/informational/districtoffices#oica>).

Detection of multijurisdictional outbreaks at a national level requires notification of appropriate state and federal food regulatory agencies and state health departments of an increase in apparently sporadic infections, subclusters, or linked common-source outbreaks. In these events, states typically notify local agencies of the outbreak and the need for their assistance in conducting the investigation. Of particular importance are requests to interview case-patients as soon as possible using a detailed exposure questionnaire to obtain detailed food and environmental exposure histories, including product brand and retail source.

7.2.3 Assemble and brief the outbreak and investigation control team. Open communication between investigation team members to plan, conduct, and evaluate

7.2 Multijurisdictional Outbreak Detection

Table 7.2. Multijurisdictional Outbreak Identification Methods and Required Notification steps, by Agency Level

OUTBREAK IDENTIFICATION METHOD	REQUIRED NOTIFICATION STEPS
LOCAL LEVEL	
<ul style="list-style-type: none"> • Common-source outbreak identified with cases among persons who reside in other local jurisdictions. • Common-source outbreak identified with exposures in another jurisdiction. • Common-source outbreak identified in one jurisdiction, investigation implicates food item contaminated before the point of service. • Subcluster of illnesses associated with restaurants or food service establishments. 	<ul style="list-style-type: none"> • Notify affected jurisdictions to request assistance to contact and interview case-patients in other jurisdictions. • Notify the affected jurisdiction immediately. • Notify appropriate state and federal food regulatory agencies about probable contaminated food vehicle, or subcluster. • Notify affected county and city health departments, state health department, and Centers for Disease Control and Prevention (CDC).
STATE LEVEL	
<ul style="list-style-type: none"> • Statewide increase identified in infections with common subtype characteristics. • Subclusters of illnesses associated with multiple restaurants or food service establishments. • Common-source outbreaks in multiple local jurisdictions linked by common agent, food, or water. 	<ul style="list-style-type: none"> • Notify affected county and city health departments and CDC. • Notify appropriate state and federal food regulatory agencies of subclusters or linked common-source outbreaks.
FEDERAL LEVEL	
<ul style="list-style-type: none"> • National increase identified in infections with common subtype characteristics. • Subclusters of illnesses associated with multiple restaurants or food service establishments in multiple states. • Common-source outbreaks in multiple states linked by common agent, food, or water. • Food item tested positive by federal or state food regulatory agency linked to apparently sporadic infections with common subtype characteristics. 	<ul style="list-style-type: none"> • Notify appropriate state and federal food regulatory agencies, and state health departments of increase in infections, subclusters, or linked common-source outbreaks. • Notify CDC, affected state health departments, and other state and federal food regulatory agencies.

outbreak investigation activities is critical to the success of the investigation (Chapter 5). For multijurisdictional investigations, the outbreak investigation and control team should include members from all agencies participating in the investigation (Chapter 3, Tables 3.1 and 3.2). Agency preparedness plans should be in place to facilitate rapid identification and notification

of these key partners. In addition, many health departments have an incident command system (ICS) that guide outbreak response (Box 7.2). Historically, investigations of multijurisdictional foodborne illness outbreaks have not required formal activation of ICS. However, federal regulatory agencies use ICS for their response to outbreak incidents.

7.2 Multijurisdictional Outbreak Detection

Box 7.2. Use of Incident Command Systems

An incident command system (ICS) is the nationally recognized way that diverse individuals, agencies, and the private sector plan to work together to command, coordinate, and communicate during emergencies. Agencies responding to a public health emergency or foodborne outbreak can use ICS principles to help manage responses. ICS principles provide the flexibility needed to manage a wide range of foodborne illness outbreak responses, including single agency and multiagency outbreak investigation and control teams.

ICS provides for internal communications among primary event responders, public information officers, and security/safety officers and for external liaison with various organizations. Key features for foodborne outbreak investigation and control teams include the following:

- Standardized but flexible organizational structure.
- Clearly defined and standardized roles and responsibilities.
- Formal and systematic planning approach.
- Coordinated response team, stakeholder, and public communications.
- Formal mechanisms for managing transitions from routine to nonroutine responses by expanding and contracting response team structure and resources as needed.

These features provide a predictable framework that can bring order to potentially chaotic situations when standard agency operating procedures and routine chain of command are inadequate to address the needs of an incident.

Because outbreak investigation staff may be physically located in different agencies in several different cities or states, briefings may need to be conducted by teleconference or webinar. All members of the of the investigation team—epidemiologists,

environmental health specialists, laboratorians, and food regulators—need to be familiar with and follow relevant state and federal laws, terms of any memorandum of understanding between agencies, and data-handling practices.

7.3 Identifying and Investigating Subclusters

Subclusters are groups of cases within a larger defined cluster for which exposure to the same individual points of service, such as a restaurant, cafeteria, grocery store, or institution, is identified. Subcluster investigations provide an invaluable opportunity to solve an outbreak because the outbreak vehicle was most likely served by the common establishment (Chapter 5). Although subclusters have traditionally been identified within clusters of cases defined by a common serotype, pulsed-field gel electrophoresis pattern, or closely related genomic sequence, successful subcluster investigations also have been conducted during

Cyclospora outbreaks, where no subtyping of the outbreak strain characteristics was possible.

In multijurisdictional investigations, make special efforts to identify potential subclusters across the geographic distribution of outbreak cases and to prioritize the coordination of subcluster investigations and tracing of common food exposures associated with the subclusters. If not previously established, a coordinating office (or individual) for subcluster investigations should be empowered to prioritize collection, organization, and dissemination of subcluster data.

7.4 Coordinating Multijurisdictional Investigations

Coordinating a multijurisdictional investigation might require establishment of a coordinating office to collect, organize, and disseminate data from the investigation. Depending on the scope and nature of the multijurisdictional event, the coordinating office might be located at a local or state public health or food regulatory agency or at CDC, FDA, or FSIS.

Several principles guide decision about where to locate the coordinating office for a given multijurisdictional investigation. The primary goal is to avoid interagency conflict about coordination that might distract from prompt conduct of the investigation and to present unified, consistent messages to the public.

- Outbreaks are most efficiently investigated as close to the source as possible. In general, investigations should be coordinated at the level at which the outbreak originally was detected and investigated. This is likely to be where most relevant investigation materials will reside, which can facilitate organization and analysis of data. An outbreak involving several local health agencies might best be coordinated by a lead local agency. Similarly, investigation of a multistate outbreak with most cases in one or a few adjacent states might best be coordinated by a lead state agency. Investigations of outbreaks of more widely dispersed cases identified through pathogen-specific surveillance might best be coordinated by CDC.
- The coordinating office must have sufficient resources, expertise, and legal authority to collect, organize, and disseminate data from the investigation. Local agencies might not have sufficient resources to effectively coordinate a multijurisdictional investigation, or state rules might assign jurisdiction over multicounty investigations to the state health department. In these situations, the coordinating office should be located at the state level. In multistate investigations, the coordinating office should be located at

CDC if no individual state is prepared to do so. In multistate investigations led by an individual state, CDC should support the investigation in coordination with the lead agency.

- Investigations of the food contamination phase should be coordinated within food regulatory agencies. In addition to food regulatory agencies' greater expertise and experience with these investigations, rules governing the collection of product manufacturing and distribution information might dictate that authorized food regulatory agencies not share that information with outbreak investigators in other agencies.

7.4.1 Outbreak investigations progress through phases of activity, and leadership of the investigation should reflect the focus of the investigation at the time.

Investigations initiated at a local level are handled in accordance with routine policies and procedures under local agency leadership unless otherwise specified by state procedures. The level of state involvement depends on local or state protocols.

During investigations that require active participation from multiple local agencies and state agencies, a state agency needs to coordinate among the epidemiology, environmental health, and laboratory components of the investigation at the state level and ensure that state epidemiology, environmental health, and laboratory programs communicate and coordinate activities with counterparts at the local and federal levels. Typically, epidemiologic efforts to characterize the outbreak by person, place, and time dominate the early stages of an investigation. Efforts to identify the mode of transmission and food vehicle begin to incorporate environmental health specialists and food regulators. Determining contributing factors and environmental antecedents, conducting regulatory tracebacks, and

7.4 Coordinating Multijurisdictional Investigations

implementing control measures move the investigation into the food regulatory realm. Transition of leadership within the outbreak control team should be planned in advance by consensus and communicated to the entire team.

During investigations of national significance, federal agencies need to coordinate the epidemiology, environmental health, and laboratory components of the investigation at the federal level and ensure that federal epidemiology, environmental health, and laboratory programs are communicating and coordinating activities with their counterparts at the state and local levels.

7.4.2 Communication and coordination plans should reflect the focus of the investigation at the time. Investigations initiated at a local level require information sharing and coordination among multiple local agencies under local agency leadership unless otherwise specified by state procedures. The state receives information and provides consultation.

When the resources of one or more local jurisdictions cannot adequately respond to events by following routine procedures, the state should provide response coordination, consultation, and information sharing. On the basis of established procedures, emergency management systems, possibly including ICS, might be activated at the local—or possibly state—level. Federal agencies are notified and involved depending on product type and distribution.

Multistate outbreaks and outbreaks associated with regionally or nationally distributed food products involve a transition from state to national significance. These outbreaks might require regional or national resources. Although they require active participation from multiple local agencies and state response coordination, consultation, and information

sharing, they also might require federal agency leadership, depending on the capabilities and willingness of the states involved.

Sharing of information between public health and food regulatory agencies is critical to the effectiveness of multijurisdictional investigations. Ensuring the facilitation of rapid and open information sharing can greatly enhance the efficiency and effectiveness of multijurisdictional investigations. Because these activities build on each other, establishing information-sharing protocols during the earliest stages of the investigation is critical. State, local, and federal public health officials should ensure that their agencies have the legal authorities needed to share information and that their professional staff understand those authorities (Chapter 2). Unless state and local public health officials have been commissioned to receive confidential information from FDA, they might need to work directly with the establishment implicated in the outbreak to obtain those data (Chapters 2 and 3). FDA's Office of Partnerships has a commissioning and credentialing program that enables the sharing of commercial confidential information to Commissioned Officials and/or signatories of Confidentiality Agreements (Chapter 2.3.4).

Identifying the source of a multijurisdictional outbreak is a collaborative process among local, state, and federal agencies and industry. Individual food companies and trade associations should be engaged early on to help with the investigation. Industry collaborators might be able to provide important information about food product identities, formulations, and distribution patterns that can improve hypothesis generation and assist in informational tracebacks to aid hypothesis testing. Early engagement of industry also can facilitate control measures by enabling affected industries to implement orderly product withdrawal or recall procedures.

7.4 Coordinating Multijurisdictional Investigations

Release of public information about the outbreak should be coordinated with the lead investigating agency when feasible. Although the public and news media are not aware of most outbreak investigations, the results of investigations are public information. In addition, responding to media attention is important to address public concerns about the outbreak. Although individual agencies participating in the investigation might be obligated to provide the perspective of their own leadership when responding to media inquiries, a coordinated communications plan can help provide a consistent, unified message about the progress of the investigation, the source of the outbreak, or any prevention activities that the public can do to protect itself. Coordinating communications with the media is particularly important when media attention is needed for public action to avoid exposure to a specific contamination source, such as a recalled food product.

7.4.3 Use standardized data-collection forms and centralize compilation of data from case-patient interviews. The National Hypothesis Generating Questionnaire (NHGQ) can be used to collect information on a broad range of food and nonfood exposures (http://cifor.us/downloads/clearinghouse/NHGQ_v2_OMB0920_0997.pdf) during the early stages of an outbreak investigation (Chapter 5). As hypotheses develop and are refined, an outbreak-specific questionnaire can be developed to systematically collect data from the various states or local jurisdictions contributing to the investigation. Collecting detailed information on both the food item and its source as early in the process as possible is key to identifying the source of an outbreak. Thus, ensuring that all agencies participating in the investigation use the same outbreak-specific questionnaire is important. In addition, if sufficient staff are not available to rapidly conduct interviews, agencies should request external assistance to conduct interviews.

Compiling data from case-patient interviews in a central location where they can be reviewed in aggregate will facilitate recognition of suspected food items, particularly when an unusual or new food item may be involved.

7.4.4 Coordinate informational tracebacks to identify suspected vehicles and guide sampling activities. Tracing the source of food items or ingredients through distribution to source of production can be critical to identifying epidemiologic links among cases or ruling them out (Chapter 5).

Multijurisdictional investigations increase the importance of product tracing because they can triangulate among multiple distribution pathways that may link geographically dispersed cases. Thus, coordinating traceback investigation across the outbreak should be prioritized. The coordinating office (or individual) for traceback investigations should be empowered to prioritize collection, organization, and dissemination of traceback data to determine whether it converges on a common source or supplier. Because this information can be critical to identifying epidemiologic links, results should be shared, as they develop, with epidemiologists, which will enable epidemiologists to have meaningful input in exposure selection and interpretation to help guide future directions for the investigation (5).

Identification of a common source or supplier can facilitate sampling activities to confirm contamination of the product and the potential source of the contamination.

7.5 Multijurisdictional Outbreak Investigation After-Action Reports and Reporting to NORS

The lead agency(ies) coordinating the investigation should hold a conference call 1–3 months after the initial investigation ends to review lessons learned and to update participants about findings, conclusions, and actions taken (Chapter 6). After the conference call, they should prepare an after-action report to summarize the effectiveness of communication and coordination among jurisdictions, identify specific gaps or problems that arose during the investigation, and communicate lessons learned regarding root cause and contributing factors (6).

All participating agencies should have the opportunity to review and comment on the

report before it is more widely distributed.

The lead agency(ies) should review after-action reports periodically to determine whether common problems regarding investigation, response, or root cause are recurring over time; this review can help with an agency’s quality improvement and prevention efforts.

Individual states should report all multijurisdictional investigations to NORS. The lead investigating agency, whether a state or local health department or CDC, should collate information from all involved jurisdictions and submit one outbreak report to NORS (<https://www.cdc.gov/nors/downloads/appendix-b.pdf>).

References

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Performance Metrics for Foodborne Illness Programs

CHAPTER SUMMARY POINTS

- Evaluating the timeliness and effectiveness of surveillance, investigation, and control of foodborne illnesses and outbreaks is critical to improving these activities at the local, state, territorial, tribal, and national levels.
- Numerous programs involved in foodborne illness outbreak detection, investigation, and response have developed and routinely use metrics to assess their work and measure performance.
- The aggregation of data at state, regional, or national levels could provide a comprehensive overview of foodborne illness surveillance and control programs, rather than a system for ranking them.

URLs and email addresses in this chapter are valid as of July 9, 2019.

8.0 Introduction

Surveillance and investigation of foodborne illnesses and outbreaks are essential for controlling and preventing foodborne illnesses. Multiple entities—more than 3,000 local health departments; 50 state and numerous territorial and tribal health departments; and several federal agencies—interact in a complex system covering surveillance for, detection of, and response to enteric and other foodborne illnesses and outbreaks.

Evaluating the timeliness and effectiveness of surveillance, investigation, and control of foodborne illnesses and outbreaks is critical to improving these activities at all levels. Since the publication of the Second Edition of the CIFOR Guidelines, the use of performance metrics by various food-safety programs and agencies has increased. Performance metrics enable a program to assess processes and identify opportunities to improve processes. This Third Edition of the CIFOR Guidelines draws heavily on the experiences of other programs in developing and using performance metrics.

Performance metrics are commonly associated with quality improvement initiatives, including accreditation and capacity building. The types of performance metrics, and how they are developed and implemented, are often determined by the type of program

or initiative in which a jurisdiction is participating. Quality improvement literature and programmatic experience has shown that

- The most meaningful performance metrics are tied directly to a program’s activities;
- Metrics promote a common understanding of the key elements of foodborne illness surveillance and control activities across local, state, territorial, tribal, and federal public health agencies;
- Using a framework (like the one presented in this chapter) can save time and resources by describing what types of activities could be measured, but programs or jurisdictions will need to determine how to measure components in a way that is meaningful for their purposes;
- Process-based metrics are often easier to design and implement, whereas multifactorial outcome metrics can be more challenging;
- Evaluating performance metric data over time can enable programs or jurisdictions to evaluate the impact of changes in practice and target additional activities for ongoing improvement efforts; and
- Metrics can elucidate successes and identify gaps in the detection, investigation, prevention, and control of sporadic foodborne illnesses and outbreaks.

8.1 Purpose and Intended Use

Numerous programs involved in foodborne illness outbreak detection, investigation, and response have developed and use metrics for routine program evaluation (Table 8.1). The combined experience of these programs was used to develop the performance metrics in Table 8.2. URLs for each program’s complete list of metrics are available on the CIFOR website.

The metrics are a curated list of the most important metrics that programs can use to assess their work and measure performance in activities related to surveillance, investigation, and control of foodborne illnesses and outbreaks.

Foodborne illness and outbreak investigations are multidisciplinary, but different agencies use staff in varying disciplines or areas of

8.1 Purpose and Intended Use

expertise to perform surveillance, investigation, and control activities. Thus, categories of environmental health, laboratory, and epidemiology are used solely for the organization of the metrics, not to suggest which staff should perform the specific duties within an agency. In other words, not every metric applies to every agency; for example, some laboratory metrics may not be relevant to local public health agencies.

Users can evaluate their performance metric data over multiple time points, when those data are available. Additionally, users can

compare their data to the summary data from other programs or agencies to determine where improvements might be realistic. Neither target ranges nor participant data are intended to be used as scorecards or performance standards. Defining the level of performance expected from foodborne illness and outbreak surveillance, investigation, and control programs exceeds the scope of these Guidelines. The aggregation of data at state, regional, or national levels could provide a comprehensive overview of foodborne illness surveillance and control programs, rather than a system for ranking them.

Table 8.1. Programs with Performance Metrics

HOST AGENCY	PROGRAM	ABOUT THE PROGRAM
Centers for Disease Control and Prevention (CDC)	Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE)	FoodCORE centers collaborate to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne illness. They focus primarily on outbreaks caused by bacteria, including <i>Salmonella</i> , Shiga toxin-producing <i>Escherichia coli</i> (STEC), and <i>Listeria</i> .
CDC	OutbreakNet Enhanced	OutbreakNet Enhanced supports local and state health departments to improve their capacity to detect, investigate, control, and respond to enteric illness outbreaks. OutbreakNet Enhanced sites collaborate with each other and CDC to share experiences and insights that help improve enteric illness outbreak response. OutbreakNet Enhanced activities focus on improving detection and rapid interviewing <i>Salmonella</i> , STEC, and <i>Listeria</i> case-patients and of persons with enteric illness caused by pathogens that demonstrate antimicrobial resistance.
CDC	National Environmental Assessment Reporting System (NEARS)	NEARS is a Web-based surveillance system that local and state health departments use to report environmental assessment data from foodborne illness outbreak investigations. NEARS helps the national food-safety system by providing critical data from environmental assessments to prevent and reduce future outbreaks.
CDC	National Outbreak Reporting System (NORS)	NORS is a Web-based platform launched in 2009. It is used by local, state, and territorial health departments to report to CDC all waterborne and foodborne illness outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes.
Food and Drug Administration (FDA)	Rapid Response Teams (RRTs)	RRTs are multiagency, multidisciplinary teams that operate using Incident Command System/National Incident Management System principles and a Unified Command structure to respond to human and animal food emergencies. RRTs are housed in food-regulatory agencies.

8.1 Purpose and Intended Use

Table 8.1. Programs with Performance Metrics

HOST AGENCY	PROGRAM	ABOUT THE PROGRAM
FDA	Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards)	The Retail Program Standards define what constitutes a highly effective and responsive program for regulating food-service and retail food establishments. The Retail Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness, with the ultimate goal of reducing the occurrence of those factors.
FDA	Manufactured Foods Regulatory Program Standards (MFRPS)	The MFRPS are a critical component in establishing the national Integrated Food Safety System. The goal of the MFRPS is to implement a nationally integrated, risk-based, food-safety system focused on protecting public health. The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food-regulatory programs. Development and implementation of the standards help state and federal programs better direct their regulatory activities toward reducing foodborne illness.
U.S. Department of Agriculture–Food Safety and Inspection Service (USDA-FSIS)	Public Health Indicators (from FSIS 2017–2021 Strategic Plan)	The mission of FSIS is to protect the public’s health by ensuring the safety of meat, poultry, and processed egg products. FSIS has developed plans and resources to strengthen collaborative relationships with outbreak investigation partners.

8.2 Performance Metrics

The remainder of this chapter focuses on Table 8.2, which includes 21 metrics organized by discipline: environmental health, epidemiology, and laboratory. As noted above, the disciplines listed are for organizational purposes, not to suggest which staff should conduct certain portions of outbreak investigations. Within the epidemiology section, metrics are grouped by investigations typically initiated from laboratory surveillance data and investigations typically initiated from complaint data (see Chapter 4).

Details on calculating a particular metric are available on the websites of the programs that produced the metrics, as are other metrics from these groups that might be relevant to their

programs. The original source metrics also may provide additional instructions, summary data from implementation of the metrics, and examples of how the metrics have been used to guide planning and evaluation activities.

Agencies that frequently use metrics (Table 8.1) have extensive metrics but do not capture every component of foodborne illness surveillance and control programs. Table 8.3 presents additional metrics that are not currently available from the referenced programs but may be valuable for agencies to examine. Because these metrics are not routinely collected by programs, users may need to create standardized definitions to calculate the metrics.

8.2 Performance Metrics

Table 8.2. Foodborne Illness Performance Metrics from Existing Programs

CATEGORY	PERFORMANCE METRIC	SOURCE OF METRIC
Environmental health	The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury, or unintentional food contamination. The final disposition for each complaint is recorded in the database or log and is filed in, or linked to, the establishment record for retrieval purposes.	Voluntary National Retail Food Regulatory Program Standards, https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm
	Percentage of outbreak investigations that included an environmental assessment.	National Environmental Assessment Reporting System (NEARS), https://www.cdc.gov/nceh/ehs/nears/resources.htm
	Percentage of outbreak investigations that identified a contributing factor.	NEARS, https://www.cdc.gov/nceh/ehs/nears/resources.htm
	Average number of days between date the outbreak establishment was identified for an environmental assessment and date of the establishment observation.	NEARS, https://www.cdc.gov/nceh/ehs/nears/resources.htm
	Percentage of traceback investigations that successfully result in identification of an implicated food.	Rapid Response Teams (RRTs), https://www.fda.gov/ForFederalStateandLocalOfficials/ProgramsInitiatives/ucm475021.htm#Manual
	Percentage of outbreaks reported to NEARS.	NEARS, https://www.cdc.gov/nceh/ehs/nears/resources.htm
Epidemiology	Percentage of confirmed cases with exposure history obtained for <i>Salmonella</i> , Shiga toxin-producing <i>Escherichia coli</i> (STEC), and <i>Listeria</i> .	Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE), https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OutbreakNet Enhanced (OBNE), https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Time from case report to first interview attempt for <i>Salmonella</i> , STEC, and <i>Listeria</i> cases.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Number and percentage of <i>Salmonella</i> , STEC, and <i>Listeria</i> investigations with supplemental or targeted interviewing of case-patients.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html

8.2 Performance Metrics

Table 8.2. Foodborne Illness Performance Metrics from Existing Programs

CATEGORY	PERFORMANCE METRIC	SOURCE OF METRIC
Epidemiology	Number and percentage of <i>Salmonella</i> , STEC, and <i>Listeria</i> investigations for which an analytic epidemiologic study was conducted.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Number and percentage of <i>Salmonella</i> , STEC, and <i>Listeria</i> investigations with suspected vehicle/source identified.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Number and percentage of <i>Salmonella</i> , STEC, and <i>Listeria</i> investigations with confirmed vehicle/source identified.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Number and percentage of all investigations with clinical specimens collected and submitted to any laboratory (public health or clinical).	FoodCORE, https://www.cdc.gov/foodcore/metrics/nou-metrics.html
	Number and percentage of foodborne or point-source investigations with suspected vehicle/ source identified.	FoodCORE, https://www.cdc.gov/foodcore/metrics/nou-metrics.html
	Number and percentage of foodborne or point-source investigations with confirmed vehicle/ source identified.	FoodCORE, https://www.cdc.gov/foodcore/metrics/nou-metrics.html
	Number and percentage of outbreaks for which National Outbreak Reporting System form was completed.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
Laboratory	Time from isolation/isolate-yielding <i>Salmonella</i> , STEC, or <i>Listeria</i> specimen collection to receipt at public health laboratory.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html
	Time from <i>Salmonella</i> or STEC isolate receipt (or recovery) at public health laboratory to serotype result (not applicable for <i>Listeria</i>).	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html
	Percentage of primary <i>Salmonella</i> , STEC, and <i>Listeria</i> isolates with whole genome sequencing (WGS)* results.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html
	Time from <i>Salmonella</i> , STEC, and <i>Listeria</i> isolate receipt (or recovery) at public health laboratory to WGS* upload to PulseNet.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html

8.2 Performance Metrics

Table 8.2. Foodborne Illness Performance Metrics from Existing Programs

CATEGORY	PERFORMANCE METRIC	SOURCE OF METRIC
Laboratory	Time from <i>Salmonella</i> , STEC, and <i>Listeria</i> isolate receipt (or recovery) at public health laboratory to sharing of WGS with national database.	FoodCORE, https://www.cdc.gov/foodcore/metrics/ssl-metrics.html OBNE, https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html

*PFGE and WGS data will be compiled through 2019. Starting with 2020 data, only WGS will be measured.

Table 8.3. Additional Performance Metrics to Assess Response Effectiveness

CATEGORY	PERFORMANCE METRIC
Environmental health	<p>Program maintenance of complaint data in an electronic manner that can be queried.</p> <p>Number of complaints received and rate of complaints per 100,000 population in the jurisdiction.</p> <p>Number of outbreaks detected from complaints and rate of outbreaks per 1,000 complaints.</p> <p>Percentage of investigations reported to federal regulatory agencies within 72 hours after the suspected vehicle is identified.</p> <p>Median number of days from initiation of investigations to implementation of control measures</p>
Epidemiology	<p>Median number of days from initiation of <i>Salmonella</i>, Shiga toxin-producing <i>Escherichia coli</i> (STEC), and <i>Listeria</i> investigations to identification of source</p> <p>Foodborne illness outbreak rate: number of foodborne outbreaks reported (all agents) per 1,000,000 population.</p> <p>Number of foodborne outbreaks reported (<i>Salmonella</i>, STEC, and <i>Listeria</i>) per 1,000 cases</p> <p>Percentage of outbreaks for which etiology is identified.</p>
Laboratory	<p>Number and percentage of <i>Salmonella</i>, STEC, and <i>Listeria</i> isolates/clinical specimens submitted to the public health laboratory from cases diagnosed by culture-independent diagnostic testing at the clinical laboratory.</p> <p>Percentage recovery of <i>Salmonella</i> and STEC isolates from culture-independent diagnostic test positive specimens received at the public Health Laboratory.</p>



