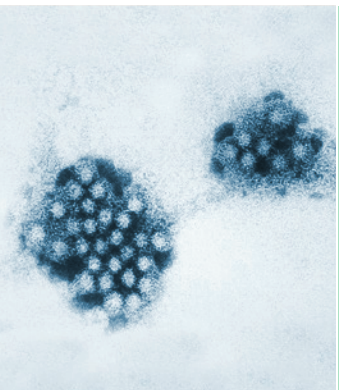
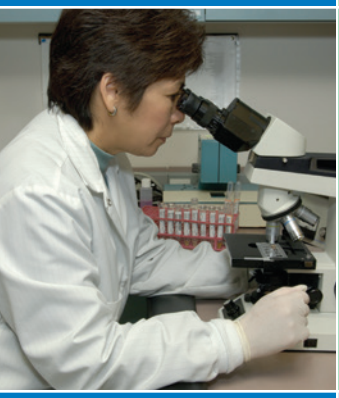
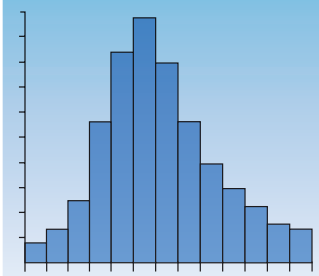
SECOND EDITION

GUIDELINES FOR FOODBORNE DISEASE OUTBREAK RESPONSE







CIFOR
Council to Improve Foodborne Outbreak Response
Detect • Investigate • Control • Prevent

Dedication

This second edition of the CIFOR *Guidelines for Foodborne Disease Outbreak Response* is dedicated to the memory of Dr. William (Bill) E. Keene, who passed away unexpectedly on December 1, 2013, after a short illness. Bill was a charter member of CIFOR in 2006 and a driving force in the organization until his death. He played a monumental role in writing and editing the original, as well as this new (second), edition of the CIFOR Guidelines.

Bill joined the Oregon Public Health Division in 1990 and worked there for 23 years as a foodborne disease epidemiologist. During that time he became known nationally and internationally as a leading expert on foodborne disease surveillance and outbreak investigation. Bill was well known for his passion for public health and dogged determination in solving foodborne outbreaks, often working around the clock to do so. He was a strong, vocal leader during investigations of multistate foodborne outbreaks and solved many, frequently documenting new outbreak vehicles or pathogen–vehicle associations.

Bill profoundly influenced virtually all recent national efforts to improve response to foodborne disease outbreaks in this country (such as CIFOR). His innovations were at the cutting edge of new surveillance and outbreak investigation methods.
Bill's passion for foodborne outbreak investigations was reflected in his office's additional role as a national museum of foodborne illness outbreaks. Bill's office memorialized famous outbreaks from the last 2 decades with shelves containing the packages of the implicated food vehicles. His personal license plate was Oregon O157H7.

The following words or phrases have been used to describe Bill: energetic, zealous, dedicated, diligent, food safety hero, public health jewel, superior intelligence, brilliant, hard-working, dry wit, uncompromising candor, innovative, pioneer, inimitable, passionate, high standards, exemplified determination and stamina when investigating outbreaks, tireless, tremendously personable, freely shared his expertise, ever-available, warm, gregarious, and generous. We agree—but to many of his colleagues on CIFOR and throughout the public health community, Bill was most of all an admired, respected, and cherished colleague and friend. He will be missed terribly.
Those of you who are familiar with Bill's work will recognize some of the outbreak investigation examples in these Guidelines as his investigations. In addition, the conversational tone, dry humor, and almost poetic nature of the writing in innumerable places throughout these Guidelines can unmistakably be recognized as Bill's work. It follows, then, that these Guidelines serve as one small way to memorialize Bill's incredible contributions to the field of foodborne disease epidemiology.

Foreword

We congratulate the Council to Improve Foodborne Outbreak Response (CIFOR) for issuing this second edition of the *Guidelines to Improve Foodborne Outbreak Response*. This new edition incorporates lessons learned over the past few years, along with new and improved techniques for surveillance, detection, investigation, and response to foodborne disease outbreaks.

CIFOR was conceived in 2005 by a small group of forward-looking leaders at the Council of State and Territorial Epidemiologists, Association of Public Health Laboratories, and the Centers for Disease Control and Prevention. They recognized the need to improve the way local, state, and federal government agencies coordinate their respective roles in the surveillance, detection, and investigation of and response to outbreaks of foodborne illness. One of the first projects the newly formed CIFOR took on was to develop guidelines to help government agencies improve their foodborne disease outbreak response activities.

The first edition of the *Guidelines to Improve Foodborne Outbreak Response,* published in 2009, and the *Guidelines to Improve Foodborne Outbreak Response Toolkit*, published in 2011, made a major contribution to improving government's response to foodborne disease outbreaks. The Guidelines and Toolkit are now referenced in many documents that address foodborne disease response. They have been used as criteria for measuring the effectiveness of programs, as key references in training courses, and as tools by government workgroups who have been meeting to identify and prioritize tasks for improving joint responses to foodborne disease outbreaks. A 2013 RAND Health survey of intended users found that 80% of respondents reported being familiar with the Guidelines and 65% with the Toolkit.

Since their issuance, the CIFOR *Guidelines* have influenced the way multiagency outbreak responses are conducted by epidemiologists, laboratorians, and environmental health/food regulatory agencies at the local, state, and federal levels. Agencies are communicating better, they better understand their respective roles and responsibilities, and they are responding quicker and more effectively because of the implementation of the CIFOR Guidelines.

CIFOR also has established a close working relationship with the food industry, the sector that bears primary responsibility for the safety of the food supply. The standing CIFOR Industry Workgroup led to development of the recently published *Foodborne Illness Response Guidelines for Owners, Operators and Managers of Food Establishments* to facilitate the food industry's response to outbreaks of foodborne illness.

We are confident that this second edition will lead to further improvement in response to foodborne disease outbreaks by the thousands of dedicated local, state, and federal employees who are working together toward that goal.

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Acknowledgements for the First and Second Editions

The original development of the CIFOR *Guidelines for Foodborne Disease Outbreak Response* took thousands of hours of work by dozens of individuals over a 3-year period. Each of these individuals had a full-time job, and many of them were repeatedly pulled to investigate foodborne disease outbreaks over the course of the project. They gave their time, energy, and expertise because of a strong commitment to improving the quality of foodborne disease outbreak response.

Because of the solid foundation established in the first edition of the Guidelines, no major changes were needed in the second edition. Most of the original chapter authors and many of the original members of CIFOR and its workgroups stepped up to make necessary revisions to ensure the Guidelines stay current. Many other individuals who were not involved in the first round gave their time and expertise to help CIFOR reach this goal. We express our deep gratitude to everyone who participated.

Among the many individuals involved in the first edition, we particularly acknowledge John Besser, Craig Hedberg, Patrick McConnon, Donald Sharp, and Jeanette Stehr-Green, who repeatedly stepped up to provide extra guidance and support whenever the need arose. Jac Davies, the editor and lead author, had a particularly large role in creating this document and was committed to giving her time and effort to this project. We would like to especially acknowledge her involvement.

For the second edition, Jeanette Stehr-Green played a major role, not only taking the lead on two chapters but also repeatedly reviewing the entire document and providing many helpful suggestions for improvements. We are grateful for her engagement in this effort. Craig Hedberg, John Besser, Donald Sharp, Dhara Patel, and Jac Davies also contributed significantly to the second edition, which would not have been possible without their ongoing commitment and support.

The following organizations and agencies participate in CIFOR, and their representatives participated in the development of these Guidelines:

- Association of Food and Drug Officials (AFDO)
- Association of Public Health Laboratories (APHL)
- Association of State and Territorial Health Officials (ASTHO)

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- Centers for Disease Control and Prevention (CDC)
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- Food and Drug Administration (FDA)
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- National Association of State Departments of Agriculture (NASDA)
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CHAPTER

1

Overview of CIFOR Guidelines

Although a variety of steps for investigating an outbreak exist in the training literature, no agreed-upon standard approach exists for response to an outbreak. Why is this? Simply put, no one set of steps is appropriate for all outbreaks. Response varies by outbreak and surrounding circumstances (e.g., etiologic agent, number of cases, and likely source of exposure). Response also varies by the agencies involved, available resources, and expertise of investigators.

To add to the possible range of responses to an outbreak, certain activities might be required by local ordinance or state statute in some jurisdictions but not in others. In addition, some activities considered part of an outbreak response are routinely undertaken in some jurisdictions before an outbreak is ever recognized (e.g., follow-up of cases to collect detailed information about exposures).

Overview of CIFOR Guidelines

The challenge of developing standard steps for an outbreak response is amplified by the fact that investigation activities are rarely undertaken sequentially or linearly. Some activities can take place concurrently with other activities, while others must wait for the results of earlier activities. Furthermore, some activities, such as communication or implementation of control measures, occur repeatedly throughout an investigation.

The CIFOR Guidelines for Foodborne Disease Outbreak Response describe the overarching functions and related activities that are common to most outbreak investigations. These functions include:

- **Planning and Preparation (Chapter 3);**
- **Surveillance and Outbreak Detection (Chapter 4);**
- **Investigation of Complaints, Clusters, and Outbreaks (Chapter 5); and**
- **Control Measures (Chapter 6).**

The CIFOR Guidelines are not limited to one approach to performing these functions but provide a range of approaches with the rationale behind them. In this way, the Guidelines enable users to make practical decisions about their (or their agencies') response to an outbreak, including the order, magnitude, or necessity of the associated activities.

Because investigations that involve multiple agencies in different geographic locations or from different sectors are complex, the CIFOR Guidelines provide special considerations for **Multijurisdictional Outbreaks (Chapter 7).** As a context for responding to foodborne disease outbreaks, the Guidelines also cover **Fundamental Concepts of Public Health Surveillance and Foodborne Disease (Chapter 2)** and **Legal Considerations for the Surveillance and Control of Foodborne Disease Outbreaks (Chapter 9).** Finally, to assist agencies in assessing their response to foodborne disease outbreaks, the Guidelines provide **Performance Measures for Foodborne Disease Programs (Chapter 8).**

The following sections summarize the contents of all chapters in these Guidelines. These summaries are intended to give a high-level overview of each chapter, thus making information of particular interest easier to find. The detailed information about each topic covered below can be found under the chapter and section numbers referenced in each paragraph.

Overview of Chapter 2. Fundamental Concepts of Public Health Surveillance and Foodborne Disease

Introduction (Section 2.0)

Preventing foodborne illness relies on our ability to translate the principles of food safety into the practices food production. Foodborne diseases and outbreaks reflect what we eat; how our food is cultivated or raised, processed, and distributed; and how and by whom our food is prepared; A variety of surveillance programs are necessary to track foodborne diseases and outbreaks and shed light on food vehicles, settings, pathogens, contributing factors, and environmental antecedents to develop effective control and prevention measures.

Trends in Diet and the Food Industry (Section 2.1)

Dietary Changes (2.1.1)

The American diet has transformed significantly in recent years with the consumption of a broader variety of foods and

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increasing amounts of fruit, vegetables, and seafood. The food industry has accommodated Americans' dietary demands by moving from locally grown and raised products to routine importation of foods from other countries. The safety of imported food products depends largely on the public health and food-safety systems of other countries and contributes to trends in foodborne diseases and outbreaks.

Culinary practices that use undercooked or raw foods have become popular and might also contribute to increased infections and outbreaks caused by the microorganisms associated with these foods.

Changes in Food Production and Preparation (2.1.2)

Changes in food-production technology and improved growing, harvesting, packaging, and transportation practices contribute to trends in foodborne disease. The industrialization of food production has led to concentrated animal feeding operations and increasingly intense agricultural practices that can facilitate spread of disease and contamination of food products. Changes in agricultural processing or packaging can facilitate bacterial contamination or growth, and routine use of antibiotics to promote the growth of livestock and poultry most likely has contributed to increased human infections caused by drug-resistant bacteria. The broadening distribution of foods has contributed to outbreaks of foodborne disease involving larger numbers of people, multiple states, and even multiple countries.

Recent interest in eating locally produced foods has resulted in increased numbers of small food producers and direct-to-consumer marketing. The effect on foodborne disease trends is yet to be determined, but implementation of improved food-safety measures could be more challenging among an increased number of more widespread smaller food producers, many of which are exempted from food-safety regulations that pertain to other retail food establishments.

In addition, an increasing number of Americans eat their meals away from home. Analyses of foodborne disease outbreaks and special studies suggest that commercial food-service establishments, such as restaurants, play an important role in foodborne disease in the United States.

Trends in Food-Safety Problems (Section 2.2)

Food-Product Recalls (2.2.1)

Food recalls are one indication of food-safety problems. During 2012, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) reported more than 258 recalls of food associated with microbial contamination. Recalled products were distributed locally, nationally, or internationally and were sold in a variety of retail settings. The most commonly identified contaminating pathogens were *Listeria monocytogenes,* Shiga toxin–producing *Escherichia coli,* and *Salmonella* species; the latter two were associated most frequently with recalls resulting from the investigation of human illness.

Foodborne Disease and Outbreaks (2.2.2)

The occurrence of foodborne disease and outbreaks is another indicator of food-safety problems but also reflects surveillance efforts. In the United States, recent years have seen an increase in outbreaks associated with commercial products contaminated before the point of sale rather than associated with a localized endpoint contamination event.

The traditional foodborne disease outbreak scenario involves a highly local outbreak, resulting from a localized endpoint contamination event that occurred shortly

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before consumption of the implicated food. Localized event outbreaks are usually investigated and addressed by local public health agencies and constitute more than 95% of outbreaks reported to the Centers for Disease Control and Prevention (CDC) (2.2.2.1).

Another kind of outbreak involves commercial food products that are contaminated upstream of the point of sale. Cases are typically exposed in multiple locations that reflect the distribution of the product. Commercial food-product outbreaks involve a variety of investigators from local, state, and federal agencies and can highlight food-safety problems in national (or multinational) corporations with industrywide implications with regard to control measures. Although probably undercounted, commercial food-product outbreaks account for only a small proportion (2%) of all foodborne disease outbreaks reported to CDC. Such outbreaks, however, constitute a disproportionate number of reported outbreak-related illnesses (7%), hospitalizations (31%), and deaths (34%) (2.2.2.2).

Local public health agencies play an important role in the investigation of contaminated commercial food-product outbreaks by searching for local cases, participating in hypothesis generation, and performing other agreed-upon tasks, such as case interviews in an expedient manner. Because a seemingly localized outbreak might herald a more widespread and diffuse food-safety problem affecting multiple jurisdictions, local investigators should always watch for indicators of a commercial food-safety problem when investigating an apparent local outbreak (2.2.2.3).

Trends in Surveillance (Section 2.3)

Overview (2.3.1)

Public health surveillance is an active process of collecting, analyzing, interpreting, and disseminating data about selected diseases with the purpose of initiating action to improve the health of the community. It is the foundation of communicable disease epidemiology and an essential component of a food-safety program.

Selected Surveillance Systems of Relevance to Foodborne Diseases (2.3.2)

Many surveillance systems are used in the United States to provide information about foodborne disease, outbreaks, and conditions contributing to their occurrence. Some focus on specific enteric pathogens likely to be transmitted through food and have been used extensively for decades. More recently, new surveillance methods have emerged (e.g., contributing factor surveillance, sentinel surveillance, and national laboratory networks). Each surveillance system plays a critical role in detecting and preventing foodborne disease and outbreaks.

Notifiable disease surveillance (2.3.2.1)

In notifiable disease surveillance, health-care providers and laboratorians are required by law to report individual cases of disease when selected pathogens are identified in patient specimens or specific clinical syndromes are recognized. Local public health agencies report these diseases to the state or territorial public health agency. States and territories (or sometimes local public health agencies) voluntarily share selected information with CDC through the National Notifiable Diseases Surveillance System (NNDSS), which CDC oversees. Combining the information in these individual reports enables investigators to detect illness clusters that might be outbreaks caused by contaminated food.

Foodborne illness complaints (2.3.2.2)

Foodborne illness complaint systems enable public health agencies to receive, triage, and respond to reports from the public about possible foodborne illnesses. The processing of complaints varies by agency. Most agencies collect some exposure information and

Overview of Chapter 2. Fundamental Concepts of Public Health Surveillance and Foodborne Disease

record the complaint in a log book or on a standardized form; a growing number of health departments enter this information into an electronic database for easy review and analysis. Regular review of these reports for trends or commonalities can identify foodborne illnesses in the community and possibly clusters of foodborne diseases. A large proportion of foodborne disease outbreaks are detected through complaint systems.

Contributing factor and environmental antecedent surveillance (2.3.2.3)

Contributing factors are a listing of factors that increase the risk of foodborne diseases and repeatedly contribute to foodborne disease outbreaks. Contributing factors are factors that lead to contamination of food with microorganisms or toxins, enable survival and growth of microorganisms in food, or prevent inactivation of toxins present in food. Environmental antecedents—root causes—are the underlying reasons for the contributing factors. Environmental antecedents must be identified and addressed for the contributing factors to be prevented in the future.

Investigators from state and local public health agencies gather information about contributing factors and environmental antecedents in foodborne disease outbreaks through environmental health assessments conducted by food-control officials and/or their own staff and report the results to CDC. Contributing factors cannot be identified through general inspections of operating procedures or sanitary conditions like those used for licensing or the routine inspection of a restaurant but require a systematic description of what happened and how events most likely unfolded in an outbreak. Because many investigators fail to adjust their day-to-day regulatory inspection process to conduct an environmental health assessment, contributing factors and environmental antecedents in outbreaks often are not adequately assessed.

CDC's Environmental Health Specialists Network (EHS-Net) was established in 2000 to address the environmental causes of foodborne disease. Current participants include environmental health specialists and epidemiologists from eight state and local health departments, FDA, USDA, and CDC. Improving environmental health assessments in foodborne disease outbreak investigations and reporting contributing factor and environmental antecedent data to CDC is one of EHS-Net's primary research activities. Through EHS-Net, CDC has developed the National Voluntary Environmental Assessment Information System (NVEAIS), a surveillance system that routinely and systematically monitors and evaluates environmental causes of foodborne disease outbreaks including contributing factors and environmental antecedents.

Hazard surveillance during routine inspections (2.3.2.4)

Contributing factors are used to develop prevention and control measures at food-production and food-service facilities before a food-safety problem occurs. Inspections of these facilities, often referred to as Hazard Analysis Critical Control Point (HACCP) inspections, are targeted at the implementation of these measures. Results of these inspections form the basis for hazard surveillance. No national hazard surveillance system exists.

Foodborne Diseases Active Surveillance System (FoodNet) (2.3.2.5)

FoodNet is a sentinel surveillance system at 10 participating sites in the United States, undertaken in collaboration with CDC, USDA, and FDA. FoodNet concentrates on foodborne disease documented by laboratory testing and is an active surveillance system (i.e., investigators regularly contact laboratories to enhance reporting). FoodNet serves as a platform for a variety of epidemiologic studies that provide insights into the incidence of and trends in foodborne and diarrheal diseases.

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FoodNet sites periodically conduct surveys of the population to estimate background rates of consumption of a variety of food items in the community. The results, distributed in the FoodNet Atlas of Exposures, can be compared to rates of exposure to certain food items among cases in a foodborne disease outbreak investigation for hypothesis generation.

Behavioral Risk Factor Surveillance System (BRFSS) (2.3.2.6)

BRFSS is a state-based telephone survey established by CDC that collects information about health risk behaviors, preventive health practices, and health-care access. BRFSS is not an appropriate system for detecting foodborne illness, but it can be used to identify behaviors (e.g., food-handling practices and eating meals away from home) that can inform foodborne illness prevention efforts.

National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet) (2.3.2.7)

PulseNet is a national network of local, state, territorial, and federal laboratories coordinated by CDC that perform pulsed-field gel electrophoresis (PFGE) on selected enteric pathogens by using standardized methods. PulseNet enables investigators from participating sites to upload PFGE patterns to an electronic database and compare them with patterns of other pathogens isolated from humans, animals, and foods to identify matches and possible linkages between pathogens (e.g., outbreaks). PulseNet has vastly improved rapid detection of even relatively small foodborne disease outbreaks that occur in multiple sites across the country.

National Antimicrobial Resistance Monitoring System—Enteric Bacteria (NARMS) (2.3.2.8)

NARMS was developed to monitor antibiotic resistance patterns in selected bacteria found in humans, animals, and meat and poultry products. NARMS data enable investigators to better understand the interaction between antibiotic use in livestock and antibiotic resistance in pathogens from animals and humans who ingest animal food products.

Foodborne Disease Outbreak Surveillance System (FDOSS) (2.3.2.9)

CDC collects voluntary reports from public health agencies summarizing the results of foodborne disease outbreak investigations. This system has been modified and expanded over time. In 2009, the system was expanded to include reporting of waterborne outbreaks and enteric disease outbreaks caused by person-to-person contact, direct contact with animals, and contact with contaminated environments. The expanded system is called the National Outbreak Reporting System (NORS). CDC, USDA/FSIS, FDA, and other investigators analyze the data to improve the understanding of the human health impact of foodborne disease outbreaks and the pathogens, foods, and settings involved in these outbreaks.

National Electronic Norovirus Outbreak Network (CaliciNet) (2.3.2.10)

CaliciNet is a network of public health and food-regulatory laboratories that submit norovirus sequences identified from outbreaks to a national database. CaliciNet participants use standardized laboratory protocols. The information is used to link norovirus outbreaks that may be caused by common sources (such as food), monitor trends, and identify emerging norovirus strains.

Surveillance of the food supply (2.3.2.11)

Testing of the food supply and associated environments is performed by local, state, and federal regulatory officials and the food industry. FDA is leading an effort to bring state manufactured food regulatory microbiological and chemical food-testing laboratories under ISO 17025 accreditation, the international standard for laboratory quality systems. Data generated by accredited laboratories will be used to support FDA enforcement actions, for

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surveillance, and during response to foodborne disease outbreaks.

Quality and Usefulness of Surveillance Data (2.3.3)

Although surveillance data are of great utility, they are far short of perfect, and their shortcomings often compromise their utility. Surveillance statistics reflect only a fraction of cases that occur in the community. Incomplete diagnosis and reporting of foodborne illnesses (2.3.3.1) and use of culture-independent diagnostic tests (2.3.3.2) inhibit surveillance and the detection of foodborne disease outbreaks. The specific data elements collected through surveillance and the validity and accuracy of the information collected further impact the usefulness of surveillance information (2.3.3.3). Nonetheless, it should still be appreciated that even with the capture of only a fraction of foodborne illnesses through surveillance, these intensely investigated events shed light on food vehicles, settings, pathogens, contributing factors, and environmental antecedents and provide extremely valuable information.

Etiologic Agents Associated with Foodborne Diseases (Section 2.4)

Overview (2.4.1)

Foodborne illnesses have myriad causes including microorganisms (e.g., bacteria, viruses, parasites, and marine algae) and their toxins, mushroom toxins, fish toxins, heavy metals, pesticides, and other chemical contaminants. Human illness caused by these agents is often categorized into those caused by toxins present in food before it is ingested (preformed toxins) or those caused by multiplication of the pathogen in the host and damage from toxins produced within the host or invasion of host cells (infection).

Patterns in Etiologic Agents Associated with Foodborne Disease Outbreaks (2.4.2)

On the basis of reports to CDC's Foodborne Disease Outbreak Surveillance System (FDOSS) in 2009–2010, bacteria (including their toxins) accounted for 46% of reported outbreaks that had an identified cause. Viruses constituted 47% of identified causes of foodborne disease outbreaks, increasing from 16% in 1998; the increase largely reflects the increased availability of methods to diagnose viral agents. Marine algae and fish toxins, mushroom toxins, and chemicals accounted for 4% of outbreaks with an identified cause.

Because no etiologic agent is identified for a large proportion of foodborne disease outbreaks and not all outbreaks are detected, investigated, and reported through FDOSS, the relative frequency of various etiologic agents based on these or similar data should be interpreted with caution.

Determining the Etiologic Agent in an Outbreak (2.4.3)

Laboratory testing of clinical specimens from patients is critical in determining the etiology of a foodborne disease outbreak. For most foodborne diseases, stool is the specimen of choice. In an outbreak, specimens are collected as soon as possible after onset of symptoms. The number of specimens collected depends on the suspected agent and capacity of the testing laboratory; ideally, specimens from 5-10 persons are collected and tested (2.4.3.1).

Isolation of the etiologic agent from food is challenging because certain pathogens require special collection and testing techniques. In addition, food samples collected during the investigation might not reflect foods eaten at the time of the outbreak. As a result, food testing results should be interpreted with caution (2.4.3.1).

Predominant signs and symptoms, and the average incubation period, can provide insights into the etiologic agent before laboratory test results are available. Illnesses resulting

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from preformed toxins manifest rapidly, often in a matter of minutes or hours; the most common symptom is vomiting, although other symptoms occur depending on the agent. Illnesses caused by infections take longer to manifest, ranging from hours to days or weeks. Symptoms usually include diarrhea, nausea, vomiting, and abdominal cramps. Fever and an elevated white blood cell count also can occur (2.4.3.2.1).

Because certain pathogens are commonly associated with certain foods, the suspected food in an outbreak can occasionally suggest a particular disease agent. However, most foods can be associated with a variety of pathogens and new vehicles emerge each year, so care must be taken in inferring an etiologic agent on the basis of a suspected food (2.4.3.2.2).

Mode of Transmission (2.4.4)

Many agents responsible for foodborne illness can be transmitted by other routes (e.g., water, person to person, and animal to person). Early in the investigation of a potential foodborne disease outbreak, investigators should consider all potential sources of transmission.

Although in-depth case interviews and epidemiologic, environmental health, and laboratory studies are necessary to confirm suspicions about the mode of transmission in an outbreak, characteristics among cases or timing of illness onset might provide clues that suggest one mode of transmission over others.

- Foodborne transmission is suggested by cases who have shared a common meal or food and have onset of illness consistent with eating of the shared meal or food; cases with distinctive demographic characteristics (i.e., age group, sex, and ethnicity) which could reflect unique food preferences or exposures; and cases with a geographic distribution similar to the distribution of food products (2.4.4.1). Of note, outbreaks that appear to be foodborne are occasionally linked to nonfood environmental sources (i.e., fomites) (2.4.4.4).
- Waterborne transmission should be considered if illness is widespread, persons of both sexes and all age groups are affected, the geographic distribution of cases is consistent with public water distribution; cases are not reported among breast-fed babies or persons who drink only bottled water or beverages from boiled water; complaints about water quality in the affected community have been reported; or multiple pathogens are involved (2.4.4.2).
- Person-to-person transmission should be suspected when cases cluster in social units (e.g., families, schools, dorms or dorm rooms) and when cases occur in waves separated by approximately one incubation period of the disease agent (2.4.4.3).

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Good planning and preparation will help investigators identify the source of an outbreak more quickly and implement control measures more efficiently and effectively. Planning and preparation activities are far-reaching and include:

- Identification of the agencies likely to be involved in an outbreak investigation and their available resources (Section 3.1);
- Establishment and training of a core outbreak investigation and control team (Section 3.2);
- Identification of necessary resources (Section 3.3);
- Development of standard processes for receiving foodborne illness complaints from the public (Section 3.4), managing records (Section 3.5), communication (Section 3.6), escalation to involve other agencies (Section 3.9), and recovery and follow-up after an outbreak (Section 3.7); and
- Assurance of legal preparedness (Section 3.8).

Agencies likely to be involved in an outbreak response also should decide in advance whether and how to apply an Incident Command System in the event of an outbreak (Section 3.10).

Agency Roles (Section 3.1)

A foodborne disease outbreak can be managed solely by a single local health agency or become the shared responsibility of multiple local, state, and federal agencies. The agencies involved will depend on the nature of the outbreak (e.g., type of pathogen, suspected or implicated vehicle, number of persons affected), the roles and responsibilities of the various agencies, and their available resources.

The following local, state, and federal agencies have access to different resources and can contribute to outbreak response efforts in different ways:

- Local health agencies (3.1.2.1);
- State health departments (3.1.2.2);
- State environmental health agencies (3.1.2.3);
- State food-safety regulatory authorities (3.1.2.4);
- CDC (3.1.2.5);
- FDA (3.1.2.6); and
- USDA/FSIS (3.1.2.7).

In addition to these individual agencies, several cross-agency programs have been developed to improve outbreak response including the state-based Rapid Response Teams (RRT) (3.1.2.8); the Food Emergency Response Network (FERN) of local, state, and federal laboratories (3.1.2.9); and the Federal Multi-Agency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO) (3.1.2.10).

In some communities, academic centers are available to partner with agencies before or during an outbreak investigation to provide technical assistance and training; conduct special laboratory analyses or food-safety research; or provide additional resources to conduct interviews or implement control measures (3.1.5).

In addition, food manufacturers, distributors, retailers, and trade associations can provide knowledge and information about product identities, formulations, processing practices, and distribution patterns and are key to outbreak investigation and implementation of control measures (3.1.4).

If an outbreak occurs in a facility or community managed by an agency that has some level of autonomy or operates its own public health program, other agencies might be involved in an investigation or take the lead, such as a tribal organization (3.1.3.1), the military (3.1.3.2), or National Park Service unit (3.1.3.3). Some investigations may take place

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on other federal lands (3.1.3.4) or may require the involvement of law enforcement (3.1.3.5).

Outbreak Investigation and Control Team—Model Practices (Section 3.2)

Typically, the responsibility for conducting a foodborne disease outbreak investigation, recommending control measures, and monitoring their implementation falls on a core team of individuals. Depending on the size and scope of the investigation, the team's size varies from one or two to hundreds. In smaller investigations, individuals may fulfill multiple roles concurrently.

The composition of the core team should be determined before an outbreak occurs and should include individuals with knowledge and skills to address the responsibilities common to most outbreaks, such as:

- Team leader (3.2.2.1);
- Epidemiologic investigator (3.2.2.2);
- Environmental investigator (3.2.2.3);
- Laboratory investigator (3.2.2.4); and
- Public information officer (3.2.2.5).

Depending on the unique characteristics of the disease or the outbreak, individuals with other expertise might be needed in an outbreak investigation. Such persons might include public health nurses, statisticians, health-care providers, and health educators; however, those specific needs probably cannot be anticipated before an outbreak (3.2.2.6).

Outbreak Investigation and Control Teams—Model Practices (3.2.3)

Outbreak response team members should work closely together, not in isolation. Because the work of one team member often builds on that of another team member, good communication among team members and timely sharing of pertinent information is critical. Implementation of the following practices will improve the effectiveness of the team:

Emergency response unit (3.2.3.1)
If population size and number of outbreaks warrants it, an emergency response unit consisting of senior epidemiologists, environmental scientists, and laboratorians that train and work together in response to all outbreaks should be established. In states with a Rapid Response Team (RRT), the RRT will assume this role.

Additional support for large-scale outbreaks (3.2.3.2)
Because some outbreaks are too large for a single agency to manage, health departments should identify and train individuals outside the agency who would be willing and able to provide support during a large-scale outbreak (e.g., staff from other branches of government, university students, and Medical Reserve Corp volunteers).

Agency-specific response protocol and other resources (3.2.3.3)
The outbreak response team should have pre-identified protocols for outbreak investigation and access to resources that enable them to answer questions and make decisions during an outbreak, such as a reference library or list of resource persons with expertise in specific disease agents and investigation methods. A list of people inside and outside the agency who should be contacted in the event of an outbreak should be prepared and updated regularly.

Training for the team (3.2.3.4)
Team members should be trained in the agency's outbreak response protocols and their role on the team. Training can be provided through established classroom and self-study courses but is likely to be more effective when interesting and provided through team and interagency exercises, on-the-job training during a real-life investigation, and debriefings after each outbreak investigation.

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Collaboration with representatives of the food industry during training exercises can streamline actual outbreak investigations through improved understanding and communications with this partner.

Resources (Section 3.3)

To ensure a rapid response to an outbreak, health departments should assemble (and learn to use) resources necessary for an investigation before an outbreak occurs. Recommended resources include:

- Support personnel to make phone calls, answer calls, and enter data (3.3.2.1);
- Legal counsel (3.3.2.2);
- Equipment (3.3.2.3);
- Supplies (3.3.2.4);
- Outbreak investigation documents (3.3.2.5); and
- Reference materials (3.3.2.6).

Procedures for routinely reviewing and replacing missing or outdated supplies, equipment, and reference materials should be part of an agency's outbreak response protocol.

Foodborne Illness Complaint Processing (Section 3.4)

A process, including a standard data collection form, should be established to receive complaints of possible foodborne illnesses from the public. If the complaint is likely to be related to food, a detailed food history should be collected from the complainant. Use of an enteric illness log or database to track all illness complaints and designation of one person to process or review all complaints will increase the likelihood of identifying patterns and possible outbreaks.

Records Management (Section 3.5)

Before an outbreak, procedures for records management should be established, including use of standardized forms for collecting and organizing outbreak information, development of database templates, and identification of tools to analyze outbreak data to speed analysis of investigation results. Staff should be trained in the use of these items. Policies for sharing information between members of the investigation team (and their associated agencies) and facilities implicated in an outbreak also should be established.

Communication (Section 3.6)

Good communication is critical throughout the investigation of a foodborne disease outbreak. Before an outbreak, agencies should develop methods for communicating with individuals and organizations key to an investigation (3.6.2.1). Key individuals and organizations include the following:

- The outbreak investigation and control team and involved agencies (3.6.2.2);
- Other local, state, and federal authorities (3.6.2.3);
- Local organizations, food industry, and other professional groups (3.6.2.4);
- The public (3.6.2.5);
- Cases and family members (3.6.2.6; and
- The media (3.6.2.7).

Processes for communicating with these individuals and organizations should include routinely updating contact lists and developing standard channels of communication so that all involved know who to communicate with and where the information will come from during an outbreak.

Planning for Recovery and Follow-up (Section 3.7)

Agencies should establish protocols for actions that must be taken or results that must be achieved before an implicated facility or food source can return to normal operations and

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develop methods to monitor those facilities. Agencies should establish a process for creating after-action reports following investigations, with lessons learned and action items for follow-up and quality improvement.

Legal Preparedness (Section 3.8)

Legal preparedness is the foundation for effective outbreak response. The following items will ensure legal preparedness: a) laws and legal authorities needed to support surveillance, detection, investigation, and control activities; b) professional staff who understand and are competent in using their legal authorities; c) memoranda of agreement and other legal agreements for coordinated implementation of laws across jurisdictions and sectors; and d) information about best practices in using law for outbreak response.

Escalation (Section 3.9)

If an outbreak affects multiple jurisdictions or is likely to exceed the resources or expertise of a particular agency, investigators should escalate the investigation and involve other agencies as soon as the need is suspected. Investigators from local health departments should notify their State Epidemiologist. Investigators from the state health department should notify CDC and the appropriate food-regulatory agency. Investigators requesting help should be prepared to share as much information about the outbreak as possible, including the setting of the outbreak, population at risk, suspected etiologic agent, suspected source, and agencies involved.

Incident Command System (ICS) (Section 3.10)

ICS, as an integral part of the Federal Emergency Management Agency's National Incident Management System (NIMS), is a widely applicable management system designed to enable effective and efficient incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. The ICS organizational structure is scalable and develops in a modular fashion according to the size and complexity of the incident, as well as the specifics of the hazard environment created by the incident.

The role of ICS in a foodborne disease outbreak investigation varies; some agencies use an ICS structure, and others do not. Agencies involved in foodborne disease outbreak investigation and response should decide in advance whether and how to apply an ICS and, if applicable, incorporate the ICS structure into their response planning and training. If someone claims to have tampered with food or intentional contamination is suspected, law enforcement officials should be notified, and the credibility of the threat should be assessed. If the threat is credible, the outbreak will move into a law enforcement realm with activation of the ICS.

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Overview (Section 4.1)

Foodborne disease surveillance generally refers to the routine monitoring of enteric diseases potentially transmitted through food. When a possible foodborne disease or outbreak is first detected or reported, investigators will not know whether the disease is foodborne, waterborne, or attributable to other causes. Investigators must keep an open mind in the early stages of the investigation to ensure that possible causes are not prematurely ruled out.

Foodborne disease surveillance serves many functions, including detection of disease clusters and problems in food production or delivery. Broader goals include defining the magnitude and burden of foodborne disease in the community, monitoring trends, measuring the effectiveness of control programs, attributing disease to specific food vehicles, providing a platform for applied research, and facilitating understanding of the epidemiology of foodborne diseases.

Three general surveillance methods are used to detect foodborne disease outbreaks:

- Pathogen-specific surveillance (Section 4.2);
- Complaint systems (Section 4.3); and
- Syndromic surveillance (Section 4.4).

Pathogen-Specific Surveillance (Section 4.2)

In pathogen-specific surveillance, medical and clinical laboratory staff report individual cases of disease to the designated public health agency when certain pathogens are identified in patient specimens or specific clinical syndromes are recognized (e.g., hemolytic uremic syndrome and botulism). In addition, clinical laboratories forward selected patient isolates—specimens that were positive for a reportable enteric pathogen—to the public health laboratory.

Staff from the public health agency may interview persons with reported cases one or more times to collect clinical, demographic, and exposure information. The scope of these interviews varies by jurisdiction and can include routine collection of detailed exposure information at the time of initial report. The causative agent, onset of illness, location of the case, and exposures are examined to identify disease trends and clusters. Clusters are examined as a group and, if a common exposure seems likely, investigated as a possible outbreak (4.2.4).

If a patient isolate is forwarded, staff from the public health laboratory confirm the disease agent and conduct tests to further characterize the agent (e.g., serotyping, virulence assays, molecular subtyping, or antimicrobial susceptibility testing). Laboratory data are uploaded to national systems, such as PulseNet (4.2.5).

Microbiological screening of food or other environmental specimens may be useful for an individual case of botulism and for certain high-risk exposures reported by cases of other diseases. Unfocused microbiological screening of foods is generally unproductive (4.2.5.2).

Strengths of Pathogen-Specific Surveillance for Outbreak Detection (4.2.7)

Strengths of pathogen-specific surveillance in outbreak detection largely relate to the specificity with which disease agents are classified and include the;

- Ability to detect widespread disease clusters initially linked only by a common agent; and
- High sensitivity for detecting unforeseen problems in food and water supply systems.

Limitations of Pathogen-Specific Surveillance (4.2.8)

The limitations of pathogen-specific surveillance include:

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- Inclusion of only diseases detected by routine laboratory testing and reported to the public health agency; and
- Delay in cluster detection and follow-up resulting from events that must occur between the time a person is infected and the time his or her illness is recognized as part of a cluster.

Key Determinants of Successful Pathogen-Specific Surveillance (4.2.9)

The completeness of the reporting and isolate submission processes affects the representativeness of the reported cases and the possible number and size of outbreaks detected. If the percentage of cases detected through pathogen-specific surveillance is low (i.e., low sensitivity), small outbreaks or outbreaks spread over space and time are more likely to be missed. In addition, reported cases might differ significantly from those not reported. This bias is more likely to influence descriptions of clinical illness or the magnitude and severity of illness rather than associations with any particular vehicle (4.2.9.1).

The more common the agent, the more difficult it is to identify outbreaks and the more likely sporadic (unrelated) cases are to be misclassified with outbreak cases. Increasing the specificity of the case definition by including more specific agent classifications (e.g., inclusion of subtyping results) or restricting cases by using certain time, place, or person characteristics can minimize this impact. Because increasing the specificity of the case definition has drawbacks, use of several different levels of agent specificity during analysis of surveillance data and during investigation of a cluster might be helpful (4.2.9.2).

In pathogen-specific surveillance, the interview must cover a broader range of possible exposures than interviews for event-driven investigations. For cases detected through pathogen-specific surveillance, consider possible exposures within the usual incubation period of the disease. Interviews to detect these exposures should be undertaken as soon possible and include a mixture of questions that:

- Ask about specific exposures previously (or plausibly) associated with the pathogen;
- Prompt cases to describe common exposures in greater detail (e.g., provide brand information and place of purchase); and
- Enable cases to identify unanticipated exposures (i.e., exposures not previously associated with the pathogen) (4.2.9.3).

Use of a standardized interview form, with which the interviewer is familiar, will decrease time spent on staff training and decrease errors in data collection.

The usefulness of pathogen-specific surveillance in preventing ongoing transmission of disease from contaminated food is directly related to the speed of the surveillance and investigation process. Processes that decrease the time between infection of the patient and determination that the patient is part of a disease cluster increase the success of pathogen-specific surveillance (4.2.9.4).

Routine Pathogen-Specific Surveillance—Model Practices (4.2.10)

Practices used by an agency vary and depend on a host of factors (e.g., circumstances specific to a specific cluster or outbreak, staff expertise, agency structure, and resources). The following model practices should be considered to improve pathogen-specific surveillance:

- Encourage health-care providers to test patient specimens as part of the routine diagnostic process for possible foodborne diseases (4.2.10.1).

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- Increase reporting and isolate submission by clinical laboratories and health-care providers through education, modification of reporting rules, laboratory audits, and simplification of the reporting process (4.2.10.1).
- Amend reporting rules to expand the definition of required clinical materials for submission to include patient specimens (e.g., stools, urine, blood), because isolates, currently specified in most reporting rules, may not be available due to culture-independent diagnostics (4.2.10.2).
- Undertake subtyping of isolates as specimens are submitted, and post results to national databases as quickly as possible (4.2.10.2).
- Interview cases by using a standardized questionnaire for exposure information (consistent with the incubation period of the pathogen) as soon as possible, when patient recall and motivation to cooperate is the greatest.
- Construct the interview to include a mix of question types (i.e., specific close-ended questions, broad open-ended questions, questions that elicit additional details) to collect the desired exposure information (4.2.10.3).
- Collection of detailed exposure information as cases are reported can help evaluate clusters in real time but is resource intensive. At a minimum, collect information about limited high-risk exposures specific to the pathogen at the time of the initial report and re-interview cases with a detailed exposure questionnaire if a cluster becomes apparent (4.2.10.3).
- To identify clusters, use daily, automated reporting and analysis systems to compare disease agent frequencies at multiple levels of specificity with historical frequencies and national trends (4.2.10.4).
- Establish and use routine procedures for communicating among epidemiology, laboratory, and environmental health branches within an agency and among local, state, and federal agencies (4.2.10.5).

Complaint Systems (Section 4.3)

In complaint systems, public health agencies receive, triage, and respond to reports from the community about possible foodborne disease events. Reporting is passive and falls into two basic categories:

- Reports from an individual or group who observes a pattern of illness affecting a group of people, usually after a common exposure (e.g., event or venue); and
- Multiple independent reports about illness in single individuals (4.3.3).

Health-care provider reports and reports from other community members of unusual disease clusters are triaged; occurrence of the same disease is confirmed; cases are interviewed; data are analyzed; and investigations are initiated.

For complaints of group illness associated with an event or venue, the investigation generally involves obtaining lists of attendees, confirming ill persons have the same disease, obtaining menus from the event (and other possible group exposures), interviewing cases, performing a cohort or case–control study, and collecting food and patient specimens.

With independent complaints, individuals are interviewed about their illness and exposures at the time of the report. Exposure information generally is limited and biased toward exposures shortly before onset of symptoms. Two or more persons with a common exposure identified through interview of independent complaints are used to identify clusters of illness in much the same manner as

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common agents are used in pathogen-specific surveillance. In the absence of common, suspicious exposures shared by two or more cases, independent complaints of illness with nonspecific symptoms (e.g., diarrhea or vomiting) generally are not worth pursuing unless required by local or state statute. Routine interviews are needed for this process to be robust (4.3.4).

Complaint systems do not require identification of a specific agent or syndrome or contact with the health-care system. Complaint systems lead to identification of most localized foodborne disease outbreaks.

Strengths of Complaint Systems for Outbreak Detection (4.3.6)

The primary strengths of complaint systems derive from their lack of dependence on health-care system contact and laboratory testing. These strengths include:

- Ability to detect outbreaks from any cause, known or unknown; and
- Increased speed of detection resulting in, among other things, higher quality exposure information.

For event-related complaints, another strength is that exposures associated with the event can usually be determined and recall of exposures among attendees is usually good. Because of the relatively limited number of exposures to consider, investigations of event-related complaints can be pivotal to solving widespread outbreaks detected through pathogen-specific surveillance.

Limitations of Complaint Systems (4.3.7)

Lack of detailed exposure information and specific agent or disease information limits complaint systems, resulting in the following:

- Inability to detect widespread low-level contamination events;
- Inability to link related cases and exclude unrelated cases, leading to misclassification and increased difficulty in detecting associations between exposures and disease; and
- Detection primarily of outbreaks resulting from illnesses of short incubation (i.e., chemical or toxin-mediated) or with unique symptoms.

Key Determinants of Successful Complaint Systems (4.3.8)

Detection of outbreaks by notification of group illness is limited by the severity of the illness, public awareness of where to report the illness, ease and availability of the reporting process, and investigation resources. Detection of outbreaks from independent complaints is influenced by these factors and by the number of cases reported, the interview process, the uniqueness of the illness or reported exposure, and methods used to evaluate reports (4.3.8.1).

When an outbreak associated with a group event is reported, some group members may be ill for reasons other than a group exposure. Inclusion of these cases in the analyses hinders detection of associations between exposures and disease. The likelihood of this occurring depends on the nature of the symptoms and their background prevalence. Identification of a specific disease agent or increasing the specificity of symptom information (e.g., bloody diarrhea or specific duration of illness) can minimize this problem (4.3.8.2).

Because exposures associated with group events are limited and can be described specifically, patient recall and timing are less of an issue than with pathogen-specific surveillance or independent complaints. Nonetheless, the more specific exposure-related questions are during case interviews, the better recall will be. Interviewing food-preparation staff or event organizers before cases can help (4.3.8.3).

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When individual exposure histories are collected for independent complaints or group illnesses, potential exposures are broad-ranging and difficult to recall. The problem may be even greater than in pathogen-specific surveillance because no causative agent has been identified that would enable investigators to focus on exposures previously associated with that pathogen. Hence, interviews must be conducted promptly and systematically to be effective (4.3.8.3).

Complaint Systems—Model Practices (4.3.9)

Multiple factors influence an agency's response to a complaint. The following model practices should be considered to improve complaint systems:

- For individual complaints, collect a detailed 5-day exposure history (unless otherwise indicated by the incubation period of the illness) by using a standardized form that covers both food and nonfood exposures, and record exposure information in a way that facilitates comparisons with histories reported by other persons. As more information about the likely etiologic agent is collected, the timeframe can be modified (4.3.9.1).
- To decide whether investigation of a commercial food establishment named in a complaint is likely to be beneficial, consider details of the complainant's illness and the foods eaten at the establishment. A follow-up investigation may be warranted if the confirmed diagnosis and/or clinical symptoms are consistent with the foods eaten and the timing of illness onset, a specific food-safety problem was observed, or two or more persons with a similar illness or diagnosis implicate an establishment and have no other shared food history or evident source of exposure (4.3.9.2).
- For group illnesses associated with an event, focus interviews on shared exposures with the realization that persons within the group might have more than one event in common (4.3.9.3).
- For group illnesses, obtain clinical and food specimens. Collect and store food samples, but generally test food only after epidemiologic implication (4.3.9.4).
- For group illnesses, establish an etiologic agent to enable implementation of rational interventions and linkages with other outbreaks or sporadic cases (4.3.9.5).
- Compile interview data in a single database and examine daily for exposure clustering. Compare with exposure information obtained through pathogen-specific surveillance (4.3.9.6).
- Improve interagency cooperation and communication among agencies that receive illness complaints (4.3.9.7).
- Check complaint information against national databases (e.g., USDA/FSIS Consumer Complaint Monitoring System) (4.3.9.8).
- Improve reporting from the public by simplifying the reporting process (4.3.9.9) and increasing public awareness to report (4.3.9.10). 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.
- To increase the likelihood that patterns are detected, set up the reporting process so all reports go through one person, or one person routinely reviews reports (4.3.9.11).

Syndromic Surveillance (Section 4.4)

Syndromic surveillance involves the systematic (usually automated) gathering of data on nonspecific health indicators that may reflect increased disease occurrence. Syndromic surveillance typically relies on the following types of information:

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- Preclinical information, which does not depend on access to health-care (e.g., school and work absenteeism, sales of over-the-counter drugs, calls to poison control centers);
- Clinical prediagnostic information, which requires contact with the health-care system but not definitive diagnosis or reporting (e.g., emergency department chief complaints, ambulance dispatches, and lab test orders); and
- Postdiagnostic data, which requires contact with the health-care system and some degree of diagnosis (e.g., hospital discharge codes).

In syndromic surveillance, increases in specific indicator signals are evaluated. If the increase is determined likely to represent a true outbreak, exposure information is collected through interviews of individual cases (4.4.4).

Strengths of Syndromic Surveillance (4.4.6)

In theory, syndromic surveillance offers increased speed in outbreak detection; the ability to detect outbreaks from any cause, known or unknown, diagnosed or not; and reduced dependence on individuals because of automated reporting. In addition, the infrastructure needed for the automated electronic data transfer in syndromic surveillance is likely to be useful for other types of surveillance and public health activities.

Limitations of Syndromic Surveillance (4.4.7)

Syndromic surveillance has serious limitations, including ability to detect only large events, numerous false-positive signals caused by the lack of specificity of indicators, reliance on routine surveillance to evaluate signals, lack of exposure information, and substantial costs for system development.

Key Determinants of Successful Syndromic Surveillance Systems (4.4.8)

The key determinants of successful syndromic surveillance are the specificity of the indicators and speed of detection, factors that are inversely proportional. Less specific indicators mean that more cases are needed to overcome background noise and that false-positive alerts are likely. More specific signals decrease these problems but do not offer any time advantage over other forms of surveillance. The collection of deidentified data due to personal information privacy issues slows investigations of positive signals.

Practices for Improving Syndromic Surveillance (4.4.9)

Because the usefulness of syndromic surveillance for detecting foodborne disease events has not been demonstrated, the need for additional investment is not clear, especially if these systems compete for resources with under-resourced standard surveillance systems. To improve a syndromic surveillance system, however, it might be useful to integrate the system with standard surveillance systems and corroborate findings using data from multiple sources. Fine-tuning algorithms used to signal an alert also might reduce false-positive signals.

Overview of Chapter 5. Investigation of Clusters and Outbreaks

Introduction (Section 5.0)

Foodborne disease outbreaks are detected by recognition of similar illnesses among persons with a common exposure that leads to a complaint or notification of health officials, or by identification of case clusters through pathogen-specific surveillance. Outbreaks identified through pathogen-specific surveillance are initially recognized as clusters of cases defined by pathogen subtype characteristics. The distribution of these cases by time, space, and personal characteristics provide clues about whether the cases are likely to represent an outbreak from a common source of exposure. Only a systematic investigation can confirm whether the cluster actually is an outbreak.

Because many agents transmitted by food also can be transmitted by water and from person to person, animal to person, or other mechanisms, when a potential foodborne disease outbreak is detected, investigators must keep an open mind and not rule out other causes prematurely.

Characteristics of Outbreak Investigations (Section 5.1)

Importance of Speed and Accuracy (5.1.1)

Speed and accuracy are the two key qualities of all outbreak investigations. One cannot be sacrificed for the other. Speed and accuracy can help public health officials:

- Stop an outbreak quickly and prevent additional illnesses;
- Prevent future outbreaks by identifying the circumstances that led to the current outbreak;
- Identify new hazards, including new agents, new food vehicles, new agent–food interactions, and other unsuspected gaps in the food-safety system;
- Maintain the public's confidence in the food supply and in the public health system; and
- Empower the public to protect itself from food-safety problems.

Principles of Investigation (5.1.2)

After a suspicious foodborne illness complaint associated with a particular event or establishment is received or an unusual cluster of isolates is detected through pathogen-specific surveillance, a preliminary investigation should be conducted to determine whether the reported illnesses may be part of an outbreak (5.1.2.1).

During an investigation, the focus of activities may shift between laboratory studies; epidemiologic studies; regulatory investigations of food-production sources and distribution chains; environmental health assessments of food-production, -processing, and -service facilities; and communication of investigation findings to support control and prevention measures. Leadership of an investigation should reflect the focus of investigation activities (5.1.2.2).

Maintaining close communication and coordination among epidemiologic, environmental health, and laboratory investigators is the best way to ensure that concurrent activities do not interfere with each other and important investigation steps are not forgotten. A consistent point of contact for each investigation will help to avoid mixed messages and incomplete or misinformation (5.1.2.3).

Hypothesis generation should begin early in an outbreak investigation to narrow the focus of the investigation and use time and resources most effectively. As more information is obtained, hypotheses can be modified. Key steps in hypothesis generation include the following:

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- Reviewing previously identified risk factors and exposures for the disease;
- Examining the descriptive epidemiology of cases to identify person, place, or time characteristics that might suggest particularly likely exposures; and
- Interviewing in detail the affected persons or a sample of affected persons to identify unusual exposures or commonalities among them (5.1.2.4).

Interviews can be conducted by one or by multiple interviewers. Multiple interviewers regularly need to compare notes to recognize uncommon exposures mentioned by multiple cases. The use of standardized forms for collecting information (e.g., exposure histories from cases, environmental health assessment information) ensures that pertinent information is not overlooked and enables investigators to become proficient with the forms, saving time during an investigation (5.1.2.5). The use of standardized "core" questions and data elements facilitates data sharing and comparisons across jurisdictions.

All outbreak investigations involve collection of private information that must be protected from public disclosure to the extent allowed by law. Investigators need to be familiar with relevant state and federal laws and practices, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (5.1.2.6).

Complaint, Cluster, and Outbreak Investigation Procedures (Section 5.2)

Conduct a Preliminary Investigation (5.2.1)

After illnesses are detected through complaints or case clusters through pathogen-specific surveillance, a preliminary investigation should be undertaken to determine whether the reported illnesses may be part of an outbreak.

- For complaints of group illness attributed to a particular event or establishment, multiple cases with similar symptoms and an incubation period consistent with the timing of the reported exposure are suggestive of an outbreak (5.2.1.1).
- For case clusters identified through pathogen-specific surveillance, cases (defined by subtype characteristics) clearly in excess of the expected number and demographic features or known exposures of cases suggestive of a common source are clues that the cluster might represent an outbreak (5.2.1.2).

Assemble the Outbreak Investigation and Control Team (5.2.2)

Outbreak investigation and control team leaders should be alerted as soon as a possible outbreak is identified (5.2.2.1). After reviewing the descriptive features of the outbreak and relevant background information, team leaders should assess the priority of investigating the outbreak. Highest priority typically is given to outbreaks that have a high public health impact; are ongoing; or appear to be associated with a food-service establishment in which ill food workers provide a continuing source of infection or commercially distributed food product that is still being consumed (5.2.2.2).

Team leaders then should assess the availability of sufficient staff to conduct the investigation, particularly to interview cases quickly and solicit controls, as needed. If sufficient staff are not available, team leaders should request external assistance (5.2.2.3).

The outbreak investigation and control team should be assembled and briefed about the outbreak, the members of the team, and their individual roles in the investigation. For outbreaks involving multiple jurisdictions, the outbreak investigation and control team should include members from all agencies participating in the investigation (5.2.2.3).

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Establish Goals and Objectives for the Investigation (5.2.3)

The outbreak investigation and control team should establish goals and objectives for the investigation. The primary goals of most investigations are to implement interventions to stop the outbreak and prevent similar outbreaks. To achieve these goals, the outbreak investigation and control team will need to;

- Identify the etiologic agent;
- Identify persons at risk and size and scope of outbreak;
- Identify mode of transmission and vehicle;
- Identify the source of contamination;
- Identify contributing factors and environmental antecedents; and
- Determine potential for ongoing transmission and need for abatement procedures.

Select and Assign Investigation Activities (5.2.4)

Epidemiologic, environmental health, and public health laboratory activities that support these objectives should be assigned to outbreak investigation and control team members. These activities will differ depending on the specifics of the outbreak and whether the outbreak is associated with an event (or an establishment) or was identified through pathogen-specific surveillance.

Cluster investigation—model practices (5.2.4.1)

The practices used by an agency to investigate a cluster vary on the basis of a host of factors. The following practices should be considered to improve cluster investigation:

- Interview cases involved in a cluster as soon as possible, and use interview techniques (e.g., review of cash register receipts or use of a calendar to reconstruct recent events) that encourage recall of exposures. Trained interviewers who have demonstrated proficiency in conducting exposure interviews should conduct the interviews (5.2.4.1.1).
- Use a dynamic cluster investigation process to generate hypotheses (5.2.4.1.2). In this model, initial cases in a recognized cluster are interviewed with a detailed exposure history questionnaire. As novel exposures are suggested during the interviews (i.e., are commonly reported among the first 5-10 cases), initial cases are systematically re-interviewed to uniformly assess their exposure, and the exposures are added to the interview of subsequently identified cases.
  - For agencies that routinely interview ALL cases with a detailed exposure questionnaire when illness is first reported, dynamic cluster investigation can be initiated as soon as a cluster is recognized. Such an approach results in improved recall of exposures by cases and allows for the possibility of case–case analytic studies (i.e., case–control studies in which cases with microbial agents other than the agent under investigation, but who have been interviewed using the same form, are used as "controls" to identify risk factor differences). Because of the compressed time frame of the investigation, the dynamic cluster investigation approach is more likely to result in a meaningful intervention (5.2.4.1.2.1).
  - For agencies that do not have sufficient resources to conduct detailed exposure history interviews for every case, a two-step interviewing process may be the best alternative. All cases are interviewed at the time of initial report to collect information about a limited set of "high-risk" exposures specific to the pathogen. When a cluster becomes apparent, all cases in the cluster are then interviewed by using a detailed exposure questionnaire following the "dynamic cluster investigation" approach (5.2.4.1.2.2).

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- Judgment is required in the interpretation of hypothesis-generating interviews. Previously identified risk factors for the pathogen in an outbreak should not be ruled out just because fewer than half of cases reported the exposure, particularly if the exposure is unusual or difficult to recognize. For testing hypotheses, the specificity of exposure source information is critical (e.g., brand and product identity, purchase dates, distribution information) in implicating a food item and facilitates traceback studies (5.2.4.1.3).

- Cross-reference case interviews with foodborne illness complaints to identify undiagnosed cases that could be linked to an outbreak. Common exposures reported in interviews related to foodborne illness complaints could be the key to identifying the source of the outbreak (5.2.4.1.4).
- To evaluate shared exposures among cases, use the FoodNet Atlas of Exposures for crude estimates of the background rate of consumption of different foods in the community. The observed consumption rate among cases can be tested against the estimated rates by using a binomial distribution probability model. In the absence of survey data, common-sense estimates of the prevalence of a given exposure can help identify exposures of interest (5.2.4.1.5).
- Conduct an environmental health assessment of implicated facilities. An environmental health assessment differs from a general, routine inspection used for licensing a restaurant or food-production facility. It focuses on the problem at hand and considers how the disease agent, host factors, and environmental conditions interacted to cause the problem (5.2.4.1.6). The goals of an environmental health assessment are to identify:
  - Possible points of contamination of the implicated food with the disease agent;
  - Whether the causative agent could have survived (or, in the case of a toxin, not been inactivated);
  - Whether conditions were conducive for subsequent growth or toxin production by the disease agent; and
  - Antecedents, circumstances behind the problem, which resulted in the conditions allowing the outbreak to happen.

  Only by identifying the antecedents can investigators develop effective interventions to prevent the problem in the future.

  The specific activities in an environmental health assessment will differ on the basis of the causative agent, the suspected vehicle, and the setting but usually include the following:
  - Describing the implicated food;
  - Observing procedures to make the implicated food;
  - Talking with food workers and managers;
  - Taking measurements (e.g., temperatures);
  - Developing a flow chart or flow diagram for the food item or ingredient implicated to capture detailed information about each step in the food-handling process, including storage, preparation, cooking, cooling, reheating, and service;
  - Collecting food specimens and, occasionally, clinical specimens from people in contact with the suspected food vehicle or the environment in which it was produced or used; and
  - Collecting and reviewing documents on source of food.
- Conduct investigational tracebacks/traceforwards of food items under investigation. Tracing the source of food items or ingredients from the point of purchase/consumption back through

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distribution to the source of production can be critical to identifying epidemiologic links among cases or ruling them out. The convergence of food items eaten by multiple cases along a distribution pathway can help identify the source of contamination. Conversely, failure to identify common suppliers among suspected foods eaten by different cases might indicate that the food item is not the vehicle for the outbreak. Formal regulatory tracebacks may be subsequently needed to confirm the distribution of implicated products. (5.2.4.1.7).

Coordinate Investigation Activities (5.2.5)

The outbreak investigation and control team should meet daily and regularly update others involved in the investigation. If the outbreak has gained public attention, the public information officer needs to prepare a daily update for the media.

Close communication and collaboration among epidemiology, environmental health, and public health laboratory staff are necessary to ensure concurrent activities do not interfere with each other and to guide the activities of individual investigators. The public health laboratory needs to immediately forward new case information to epidemiologists. As epidemiologists interview cases about exposures in restaurants and other licensed facilities, they should rapidly forward that information to environmental health specialists. Environmental health specialists should share results of interviews with food workers and reviews of food preparation that indicate important differences in exposure potential that should be distinguished in interviews of cases.

Compile Results and Reevaluate Goals for Investigation (5.2.6)

Document and compile results of each outbreak investigation in a manner that enables comparison with the original goals for the investigation. Demonstrate how each goal was achieved or, if the goal was not achieved, explain why. Novel questions or opportunities to address fundamental questions about foodborne disease transmission can develop during an investigation. The opportunity to address these questions might require reevaluation of the investigation's goals.

Development of an epidemic curve that is regularly updated can help depict the course of an outbreak and provide insight to disease transmission and relationships to notable events.

Interpret Results (5.2.7)

The outbreak investigator must use *all* available information to construct a coherent narrative of what happened and why. Results of epidemiologic studies must be integrated with results of informational product tracebacks, interviews of food workers, environmental health assessments, and food-product and environmental testing. When all of these data elements support and explain the primary hypothesis, strong conclusions can be drawn.

In this process, investigators should consider their data critically. Statistical associations between exposure and illness may reflect a causal link but may also reflect confounding, bias, chance, and other factors. Conversely, failure to achieve a statistically significant association between illness and exposure may result from small sample size, contamination of multiple vehicles or unrecognized ingredients, or high background rates of exposure.

Investigators should be wary of explanations that depend upon implausible scenarios. Minor inconsistencies are common and may be ignored, but large numbers of inconsistencies might indicate that alternate hypotheses need to be considered.

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Conduct a Debriefing at End of Investigation (5.2.8)

Encourage a post-outbreak meeting among investigators to assess lessons learned and compare notes on final findings. Such meetings are particularly important for multiagency investigations, but they also are important for single-agency investigations. The post-outbreak meeting should take place as soon as possible after the investigation ends to capture this information while recall is still fresh.

Summarize Investigation Findings, Conclusions, and Recommendations (5.2.9)

At a minimum, every outbreak investigation should be documented by using a standardized form (e.g., CDC's form 52.13 or its equivalent) to facilitate inclusion in state and national outbreak databases. Investigators are encouraged to submit preliminary reports while the investigation is ongoing to help link outbreaks occurring simultaneously in multiple places and facilitate further investigation. Larger or more complex investigations or investigations with significance for public health and food-safety practice demand a more complete report and, possibly, publication in a peer-reviewed journal. Written reports should include:

- Background;
- Methods;
- Results;
- Conclusions;
- Recommendations; and
- Epi-curve with outbreak investigation timeline.

Distribute Report (5.2.10)

Copies of the report should be shared with all persons involved with the investigation (e.g., investigation team members, health department officials and press officers, health-care providers who reported cases) and distributed to persons responsible for implementing control measures (e.g., owners and managers of establishments identified as the source of the outbreak and program staff who might oversee implementation of control measures or provide technical assistance). The report is a public record and should be made available to members of the public who request it.

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Introduction (Section 6.0)

The purpose of outbreak investigations is to stop the current outbreak, determine how the contamination occurred, and implement prevention-based approaches to minimize the risk for future outbreaks. Rapid response is key. The two major types of foodborne disease outbreaks—those originating from retail food establishments (which sell to the consumer) or home preparation of food and those originating from commercial processors/producers—require two different types of control measures.

Information-Based Decision-Making (Section 6.1)

To prevent further illness in an outbreak, control measures should be initiated as soon as possible, even concurrently with ongoing investigations. Sometimes nonspecific control measures can be implemented immediately to prevent further transmission of disease, regardless of the type of disease or source (6.1.1). If any possibility exists that an outbreak might be due to intentional contamination, then law enforcement agencies will need to be notified immediately.

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The quality of information on which control measures are based, as well as the possible positive and negative consequences of undertaking (or not undertaking) the control measures, should be kept in mind and can add confidence to decision-making (6.1.2).

Control measures can be categorized as actions to control the source (i.e., prevent continued exposure to the original source of the foodborne illness) (Section 6.2), actions to take when intentional contamination is suspected (Section 6.3), and measures that prevent secondary transmission (i.e., transmission from persons infected through the original source to others through food, water, or person-to-person transmission) (Section 6.4). Additional measures might be necessary to prevent future outbreaks (Section 6.9).

Control of the Source (Section 6.2)

Nonspecific Control Measures (6.2.1)

If the pathogen causing an outbreak is known, limited control measures might be possible even before the mode of transmission is clear or a food or facility have been implicated. Control measures, at this point, will be nonspecific (i.e., not aimed at the definitive source of the outbreak) and focus on prevention of secondary spread among known cases and communications with health-care providers and the public (6.2.1.1).

If the facility has been implicated, nonspecific control measures can be implemented, even though a specific food or causative agent has not yet been identified. Nonspecific control measures (e.g., stopping bare-hand contact with food, emphasizing hand-washing, excluding ill employees) are good public health practice and are generally effective, regardless of the disease. Suspicions about the type of agent involved (e.g., viral, bacterial, chemical) can assist in identifying and prioritizing control measures (6.2.1.2).

While these first actions are under way, appropriate food samples need to be collected for laboratory analyses and chain-of-custody practices need to be maintained and documented. Samples should be stored and analyzed when more information is available to implicate certain food items.

Specific Control Measures (6.2.2)

When a food has been implicated, control measures directed at the specific cause can be implemented. Desirable control measures vary depending on whether the implicated food is associated with a food-service establishment or is home prepared (6.2.2.1) or is processor/producer-based (6.2.2.2).

Foods associated with food-service establishments or home preparation (6.2.2.1)

Specific control measures include:

- Removing the implicated food from sale or preventing consumption (6.2.2.1.1);
- Cleaning and sanitizing of the implicated facility and equipment, followed by microbial verification of the effectiveness of the cleaning and sanitizing processes (6.2.2.1.2);
- Training staff on general safe food-preparation practices and practices specific to controlling the causative agent (6.2.2.1.3);
- Modifying food-production or preparation processes at the facility to prevent further contamination of food or survival and growth of microbes already present in food with follow-up monitoring to ensure that processes have been implemented (6.2.2.1.4);
- Eliminating the implicated foods from the menu until it is certain that control measures are in place (6.2.2.1.5);
- Removal of infected food workers or restriction from food-preparation activities (6.2.2.1.6);
- Closure of the facility and an outline of actions necessary for the facility to reopen (6.2.2.1.7); and

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- Communication with the public about the outbreak if medical treatment is needed for persons exposed to the etiologic agent, reporting of suspected cases is necessary for investigation purposes, or the risk for exposure still exists (6.2.2.1.8).

Foods associated with a processor/producer (6.2.2.2)
Implication of multiple food-service establishments in an outbreak or receipt of multiple, seemingly unrelated, reports of illness from consumers eating the same type of food suggests an outbreak caused by food contaminated at the processor/producer level. Depending on the scope of the outbreak and probable point of contamination, most of the specific control measures listed above will still be appropriate once the point of contamination is identified; however, efforts also might be needed to recall the implicated food from the market. The decision to recall a food is based on the strength of the evidence linking the food to illness and the ongoing risk for exposure among consumers (i.e., the likelihood that the food is still on the market or is in the homes of consumers).

Recall of food at the processor/producer level generally requires federal and/or state action. Contact the federal or state regulatory agency that has jurisdiction over the product. FDA regulates the safety of most foods, except meat, poultry, and most out-of-shell egg products that are regulated by USDA. The appropriate regulatory authority will contact the manufacturer immediately and get its cooperation. The regulatory authority may recommend that the manufacturer issue a food recall. In addition, the regulatory authority and/or the manufacturer may ask retailers to remove the product from their shelves and for distributors to withhold the product from distribution.

Procedures for removing food from the market (6.2.2.2.1)
Once a decision is made to remove food from the market, the goal is to remove it as quickly and efficiently as possible. Food is removed from the market more smoothly if certain steps are undertaken by industry, retail establishments, and public health agencies before a food-safety problem occurs. Industry and retail establishments should routinely maintain product source and shipping information for quick access in conducting tracebacks and trace-forwards and develop methods to rapidly notify customers (e.g., blast e-mail/fax). Public health agencies should establish relationships with industry and retail establishments before a food-safety problem occurs. They should also develop a list of control measures to immediately put in place when a recall has been issued, and be aware of common errors that lead to recalled food being put back into commerce. Regulatory agencies responsible for retail food facilities need a means to immediately notify all food facilities in their jurisdiction through e-mail, blast fax, or phone calls of a recall.

The agency/jurisdiction should monitor to ensure the recall is effective in stopping illnesses and food is completely removed. Assuring the effectiveness of recalls often requires close cooperation among local, state, and federal agencies on audits for recall effectiveness checks.

Communication with the public (6.2.2.2.2)
Notify the public if the outbreak involves distributed product. Messages to the public should follow good risk communication practices. Provide information about how to handle the suspected product (discard, special preparation instructions, or return to place of purchase). Means of notification depend on the public health risk and the target population and might include press releases, radio, television, fax, telephone, e-mail, Web posting, social media, or letters. Attempt to reach all members of the population at risk, including non–English–speaking and low-literacy populations.

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Post-recall reporting by the food business or manufacturer (6.2.2.2.3)

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.

Intentional Contamination (Section 6.3)

Indicators of Intentional Contamination of Food (6.3.1)

Even though intentional contamination of food is very rare, a number of such instances have been reported. Agencies responding to outbreaks should always keep in mind the possibility that an outbreak might be due to a criminal act and look for indicators of intentional contamination (e.g., presence of unusual microorganisms in host food, an unusually high inoculum, a disease found outside the normal transmission season).

Actions to Take When Intentional Contamination is Suspected (6.3.2)

Each agency should establish a process for actions to take if intentional contamination is suspected. Organizations responsible for outbreak investigations should determine in advance of any outbreak which law enforcement agencies will be notified if intentional contamination is suspected and how that notification will occur. Any criminal investigation will need to be coordinated with the foodborne disease outbreak investigation.

Control of Secondary Spread (Section 6.4)

Education (6.4.1, 6.4.2, 6.4.4)

Education is key to preventing the spread of infection from persons exposed to the original outbreak source to others through food, water, and person-to-person contact. Health-care providers should be encouraged to collect appropriate patient specimens and report cases of notifiable disease to the health department (6.4.1) and be reminded about infection control precautions for hospitalized and institutionalized persons with infectious diarrhea (6.4.4). The public should be reminded of basic food-safety precautions, as well as means to decrease risk for infection through the current outbreak (6.4.2). The operator of the implicated facility should be notified of the steps needed to control the situation and to prevent further outbreaks. Food workers at the implicated facility should be educated about the disease (e.g., symptoms, mode of transmission, and prevention) and general infection control precautions including thorough hand-washing, not working when ill, and use of gloves and utensils when handling ready-to-eat foods (6.4.4).

Exclusion and Restriction of Infected Persons from Settings Where Transmission Can Occur (including food-preparation, health-care, and child-care) (6.4.3)

A person who has been ill with vomiting and diarrhea should be excluded from the facility. For norovirus outbreaks, exclusion should be until the person is free of symptoms for 72 hours. In *Salmonella* and *Shigella* outbreaks, all employees should be cultured whether ill or not, and restricted until culture negative as infected, asymptomatic food workers could transmit infection to others. Conversely there is little evidence for an important role of infected food handlers in transmission of *E. coli* O157:H7. Local ordinances or state statutes should be used to determine requirements for returning to work. However, if the outbreak investigation and control team believes a public health threat exists, the team should strongly recommend exclusions of food workers.

Prophylaxis (6.4.5)

For some diseases, prophylaxis might be appropriate, and the public health agency should work with area hospitals, physicians, local health departments, specialty clinics, or other health-care providers to provide vaccination, immune globulin, or antibiotics to exposed persons. Special attention should

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be given to prophylaxis of groups at higher risk for severe illness and poor outcomes from foodborne disease, including infants, pregnant women, elderly persons, and immune-compromised persons.

Communication (Section 6.5)

Communication is critical in determining what control measures to implement and when to change an intervention's focus.

Outbreak Investigation and Control Team and Related Agencies (6.5.1 and 6.5.2)

Information should be shared routinely with all members of the outbreak investigation and control team, including actions taken and updates on the outbreak (6.5.1). Agency heads should routinely receive information about the status of the investigation (6.5.2). If the outbreak is potentially multijurisdictional, other relevant agencies and organizations should also routinely receive status reports. Messages and information need to be coordinated with other agencies so that consumers are not confused.

The Public (6.5.3)

If the public has been informed about an outbreak, periodically issue updates so that the public can make good decisions to protect themselves. Use all available sources to disseminate information—the Internet, television, radio, social media, and newspapers. Adopt a standardized format or script for reporting risk information, complex procedural or technical information, or recommended actions. Emphasize safe food-preparation practices and handwashing to groups at higher risk than others for severe illness and poor outcomes from foodborne disease.

Industry (6.5.4)

Contact the food establishments(s) directly linked to an outbreak as soon as possible, and tell them as much as possible. Share the findings that have implicated their product or facility, and seek their help in the investigation. Provide them with the CIFOR Industry Guidelines to assist them in response. Because enforcement action may result from the investigation, the local legal framework needs to be understood before any interactions with facilities that may be linked to an outbreak.

At the time of an outbreak, outreach by government agencies to the appropriate trade associations with information about the outbreak and actions members should take can help prevent spread of the current problem or similar problems in their firms. Interactions with the food industry and related trade associations can help dispel misconceptions about the outbreak and take advantage of a teachable moment. However, state, local, and federal agencies need to have working relationships with industry *before* an outbreak occurs.

End of the Outbreak (Section 6.6)

Most outbreaks can be considered over when two or more incubation periods have passed without new cases (6.6.1). Remove restrictions when no further risk to the public exists (6.6.2). Post-outbreak monitoring is necessary to ensure the outbreak has ended and the source has been eliminated (6.6.3). Efforts should be made to monitor the population at risk for disease, the implicated foods for contamination, and the implicated facilities to make sure they are complying with all required procedures. The latter requires continued communication with the implicated food establishment and may require increased inspections and customized training.

After-Action Meetings and Reports (Section 6.7)

The outbreak investigation and control team should meet and review all aspects of the investigation including the root cause of the outbreak, long-term and structural control

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measures, effectiveness of outbreak control measures, problems with the response effort and needed changes, and need for further study. The complexity of the review depends on the size of the outbreak.

Outbreak Report (Section 6.8)

Summary reports should be prepared for all outbreaks to document activities, educate staff, and look for trends across outbreaks that can be useful in future investigations. For a large outbreak, the final report should be more comprehensive, with information provided by all team members. Such a report should be disseminated to all participating organizations and investigators. Given that outbreak reports are likely to be subject to Freedom of Information Act requests, reports should not identify individuals or share other legally nonpublic information, unless absolutely necessary, nor should they include inappropriate language.

Other Follow-Up Activities (Section 6.9)

The outbreak investigation findings might identify the need for new measures to detect, control, or eliminate pathogenic microorganisms (or their toxins) from food requiring future studies or research (6.9.1). If something unusual characterized the outbreak (e.g., unusual exposure, presence of a pathogen in a food where it had not previously been seen) the results of the investigation should be disseminated more widely (e.g., through peer-reviewed journals) (6.9.2). Investigation findings might identify the need for broad education efforts of the public, food workers and processors, or health-care providers (6.9.3). They might also identify the need for new public health or regulatory policies at the local, state, or federal level, such as changes in inspection practices, source controls, or surveillance procedures or increased control over the recall process (6.9.4).

Introduction (Section 7.0)

A multijurisdictional foodborne disease event (e.g., foodborne disease outbreak or contaminated food-product recall) requires the resources of more than one local, state, territorial, tribal, or federal public health or food-regulatory agency to detect, investigate, or control. Categories of multijurisdictional outbreaks include:

- Outbreaks affecting multiple local health jurisdictions 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 agent;
- 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; and
- Outbreaks in which intentional contamination is suspected.

Overview of Chapter 7. Special Considerations for Multijurisdictional Outbreaks

Background (Section 7.1)

In February 2001, the National Food Safety System (NFSS) Project, Outbreak Coordination and Investigation Workgroup, published guidelines for improving coordination and communication in multistate foodborne disease outbreak investigations. The audience for these guidelines was local, state, and federal agencies, including public health, epidemiology, environmental, laboratory, and agriculture representatives; industry; and professional organizations.

Terrorist attacks on September 11, 2001, raised concerns about the potential for intentional contamination of food at all levels of the food system, which would require interaction among agencies that previously had not worked together. Subsequent large multistate case clusters and foodborne disease outbreaks, largely detected through PulseNet, underscored the need for multijurisdictional coordination during foodborne disease events.

The Council to Improve Foodborne Outbreak Response (CIFOR) was created in 2006 to help develop model programs and processes to facilitate the investigation and control of foodborne disease outbreaks and guidelines for the investigation of multijurisdictional outbreaks, including those affecting multiple states, multiple localities within a state, and multiple agencies. These guidelines were included in the 2009 CIFOR Guidelines for Foodborne Disease Outbreak Response.

The passage of the Food Safety Modernization Act in 2011 gave CDC and FDA greater responsibility in the coordination of multijurisdictional outbreaks. Coordinating offices for foodborne illness investigations in the three primary federal agencies include:

- CDC: Outbreak Response and Prevention Branch;
- FDA: Coordinated Outbreak Response and Evaluation Network (CORE); and
- USDA/FSIS: Applied Epidemiology Staff, Office of Public Health Science.

Major Indicators of a Multijurisdictional Outbreak and Notification Steps (Section 7.2)

Certain outbreak characteristics are indicators of a multijurisdictional outbreak and include the implication of a fresh produce item contaminated before the point of service; isolation of *E. coli* serotypes O26, O45, O103, O111, O121, and O145 as the etiologic agent; and multiple common-source outbreaks linked by common agent, food, or water. Depending on the indicator, a variety of agencies might be affected by the event or need to participate in the investigation and need to be notified immediately (Table 7.3).

Coordination of Multijurisdictional Investigations (Section 7.3)

Investigating a multijurisdictional foodborne disease event represents a collaborative process among local, state, and federal agencies and industry and may 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 may be located at a local or state public health or food-regulatory agency or at CDC, FDA, or USDA/FSIS. Several principles guide the decision about where to locate the coordinating office for a given multijurisdictional investigation:

- If possible, investigations should be coordinated at the level at which the outbreak originally was detected and investigated.
- The coordinating office must have sufficient resources, expertise, and legal authority to collect, organize, and disseminate data from the investigation.

Overview of Chapter 7. Special Considerations for Multijurisdictional Outbreaks

- As outbreak investigations progress through phases of activity, coordination should reflect the focus of the investigation at the time.

Multistate outbreaks and outbreaks associated with regionally or nationally distributed food products may require regional or national resources. Although they require active participation from multiple local agencies and state response coordination, consultation, and information sharing, they also may require federal agency leadership, depending on the capabilities and willingness of the states involved (7.4.2).

Sharing of information between public health and food-regulatory agencies is critical to the effectiveness of multijurisdictional investigations and often requires information-sharing protocols. 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.

Individual food companies and trade associations should be engaged early in an outbreak investigation because they can provide important product information, help with traceback investigations, assist in hypothesis generation, and facilitate implementation of control measures.

Releasing public information about an outbreak should be coordinated with the lead coordinating agency when feasible. 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 needed for the public to protect themselves.

Most health departments have incident command systems (ICS) that guide outbreak responses within the public health agencies. Historically multijurisdictional foodborne disease outbreak investigations have not required formal activation of ICS. However federal agencies are now mandated to use ICS for response to outbreak incidents. The Department of Homeland Security released the National Incident Management System (NIMS) and requires all federal agencies to incorporate and use NIMS for incident response. NIMS is a comprehensive, standardized, scalable, and flexible system used by all levels of government to manage and coordinate emergencies and other significant incidents.

Outbreak Detection and Investigation by Level (Section 7.4)

Outbreaks can be detected at the local level (7.4.1), state level (7.4.2), and federal level (7.4.3). Means of detection will vary depending on the level.

Investigation actions depend on the nature of the outbreak, how it was identified, and its state and national significance. Actions may include:

- Notification of jurisdictions or agencies that might also be affected by the problem, might be investigating the problem simultaneously, or might need to be involved in the investigation (e.g., appropriate food-regulatory agency);
- Distribution of summary data about the outbreak and periodic updates to these identified jurisdictions or agencies;
- Interview of cases locally (or provision of support to ensure timely conduct of interviews);
- Efforts to subtype agents and upload patterns to PulseNet; and
- Establishment of a coordinating office to collect, organize, and disseminate collective data.

Overview of Chapter 7. Special Considerations for Multijurisdictional Outbreaks

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

The organizations involved in a multijurisdictional outbreak should hold a conference call 1–3 months after the initial investigation ends to review lessons learned and to update participants on findings, conclusions, and actions taken. The lead agency(ies) coordinating the investigation should prepare an after-action report after the conference call. The report should summarize the effectiveness of communication and coordination among jurisdictions and identify specific gaps or problems that arose during the investigation. All multijurisdictional investigations should be reported by individual states to NORS. The multijurisdictional nature of the investigation should be indicated by completion of appropriate data fields in the NORS report form.

Overview of Chapter 8. Performance Measures for Foodborne Disease Programs

Introduction (Section 8.0)

Progress is being made toward the development of comprehensive national performance standards, measures, and models that public health agencies can follow to ensure foodborne illness surveillance and outbreak detection and response systems work at maximum efficiency. CDC's Public Health Emergency Preparedness Goals established a general framework and a few specific performance measures relevant to foodborne disease surveillance. CDC's

Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) program has developed a series of performance metrics that cover a range of outbreak detection and response activities. These are designed to demonstrate successes and identify gaps in the detection, investigation, and control of enteric disease outbreaks.

Because the evidence base for establishing performance measures has increased greatly since the original publication of the CIFOR Guidelines, the performance measures included in this chapter have been modified, and some have been selected for the development of target ranges.

Purpose and Intended Use (Section 8.1)

The First Edition of the Guidelines included measurable indicators of effective surveillance for enteric diseases and of response to outbreaks by state and local public health officials. The performance indicators were intended to be used by agencies to evaluate the performance of their foodborne disease surveillance and control programs. However, the original Guidelines stopped short of providing specific targets for individual metrics.

Since the development of the Guidelines, performance, accountability, and transparency by public health agencies have received more emphasis. Therefore, target values need to be developed that will help state and local public health agencies demonstrate their performance and effectiveness for foodborne disease surveillance and outbreak control activities. Given a public health system that involves multiple independent jurisdictions, having performance criteria and metrics along

Overview of Chapter 8. Performance Measures for Foodborne Disease Programs

with target values will provide a framework for communicating model practices for surveillance activities; facilitate training for staff; enable aggregation of data at the state, regional, and national level to evaluate program effectiveness and identify needs for improvement; and create clear expectations for performance.

Performance Indicators (Section 8.2)

Major performance indicators are organized in multiple tables by program function. The roles and responsibilities of foodborne disease surveillance and control programs vary by state in accordance with state law. Individual agencies that wish to evaluate their programs by using these indicators should select indicators and metrics that best reflect their activities, regardless of where they fall in the document's table structure.

The first four tables focus on foodborne disease program objectives and indicators:

- Table 8.1. Objectives of foodborne disease surveillance program
- Table 8.2. Short-term objectives, indicators, subindicators, and metrics
- Table 8.3. Intermediate objectives, indicators, subindicators, and metrics
- Table 8.4. Long-term objectives, indicators, subindicators, and metrics

A fifth table, Table 8.5, covers 16 performance indicators that have been selected for the development of target ranges on the basis of their importance and feasibility of implementation. These include metrics for epidemiology, laboratory, and environmental health programs. Target ranges for these performance measures are being developed under direction of the CIFOR Performance Indicators Work Group and will be maintained separately on the CIFOR website. This will allow target ranges to be modified as needed on the basis of the availability of resources and the performance of the system.

Overview of Chapter 9. Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

Introduction (Section 9.0)

Public health legal preparedness has four core elements: a) laws and legal authorities needed to conduct functions essential to effective surveillance and disease control, b) staff competency in understanding and using those laws, c) coordination across sectors and jurisdictions in the implementation of law, and d) information about best practices in using law for public health purposes (9.0.1). State and local public health officials should ensure their agencies and jurisdictions are legally prepared for foodborne disease surveillance and control. As part of ensuring their jurisdictions' legal preparedness, they should consult with their legal counsel and with counterparts in other government agencies and private organizations that have legal authorities or legal duties relevant to surveillance and control of foodborne disease outbreaks (9.0.2).

Public health agencies, as part of the executive branch of government, are broadly charged to implement laws enacted by the legislature and interpreted by the courts. They also possess inherent police powers to protect the health and safety of the public. The U.S. Constitution as well as state constitutions, statutory and regulatory law, ordinances, and court rulings,

Overview of Chapter 9. Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

provide protections to local, state, and federal governments in the conduct of surveillance and control of foodborne disease (9.0.3) (9.0.4).

CDC operates under congressionally enacted statutory law and provisions of the Public Health Service Act to gather data on nationally notifiable diseases and perform laboratory tests on specimens received from state and local governments. CDC is not authorized to mandate reporting or methods of reporting and partners with state and local public health agencies and the Council of State and Territorial Epidemiologists (CSTE) to receive voluntary reports. CDC does not collect personal identifiers on routine surveillance data that it receives (9.0.5.).

Legal Framework for Mandatory Disease Reporting (Section 9.1)

Statutes and Regulations (9.1.1)

State health departments have broad statutory authority to collect information and require reports of conditions of public health importance, as well as specific legal authority to conduct surveillance and control for certain diseases (e.g., tuberculosis, HIV infection, vaccine-preventable diseases). All states have statutes addressing response to bioterrorism incidents (9.1.1.1).

Epidemiologists and health officers in state and local agencies maintain and update the list of reportable diseases and conditions and laboratory findings in their jurisdiction after public input and approval by an oversight body (typically a board of health established by statute). Required reporting of specific laboratory test results generally means the list must be regularly updated as new laboratory tests are developed (9.1.1.2).

Reporting Processes (9.1.2)

State and local statutes and regulations usually specify the time frame for reporting, means of reporting, and information to be reported (9.1.2.1), as well as the entities that are required to report (9.1.2.2). Specifics vary from one locale to another (9.1.2.3). Some public health agencies have adopted regulations that require hospital and clinical laboratories to submit isolates of specific pathogens to a public health laboratory to improve surveillance of foodborne diseases and outbreak detection (9.1.2.4).

Accessing Medical and Laboratory Records (9.1.3)

Typically, 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.

Enforcement (9.1.4)

Failure to comply with reporting regulations is punishable by law but is rarely enforced because penalizing a health-care provider may be counterproductive to the success of a surveillance program. In most cases of nonreporting, the public health agency explains the regulatory requirement and its rationale and asks for future compliance, rather than seeking penalties or sanctions. Reporting is difficult to enforce with a laboratory or health-care provider outside the agency's jurisdiction. Arrangements and ongoing communication should be established with out-of-state clinical laboratories and hospitals to ensure reporting.

Protection of Confidentiality (9.1.5)

Personally identifying information in disease reports and investigation records is confidential and exempt from disclosure in response to Freedom of Information Act requests. Descriptors such as age, sex, race/ethnicity, and residence, and date of diagnosis might enable identification of an ill person and need to be treated as personally

Overview of Chapter 9. Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

identifying information. The public health agency generally is restricted from sharing personally identifying information with other government agencies without the consent of the reported person, with a few exceptions (e.g., in a bioterrorism incident or when it is deemed necessary to protect the public health). Reporting statutes typically provide for punishment of government employees for a breach of confidential information held by the public health agency.

Health information protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may be disclosed by the reporting source (e.g., physician) without individual authorization to a public health agency authorized by law to collect or receive such information. The legal requirement to report relieves the reporting source (e.g., physician) of concern that reporting breaches the privacy of the doctor–patient relationship.

Cross-Jurisdiction and Cross-Sector Coordination (9.1.6)

State and local 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.

Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases (Section 9.2)

Sources of Surveillance Information (9.2.1)

Reports of food-related illness may come to the attention of the state or local health agency in a variety of ways (e.g., surveillance reports, foodborne illness complaints from the public, syndromic surveillance).

Statutes and Regulations Governing Surveillance and Investigation (9.2.2)

Voluntary, unconfirmed disease reports (e.g., complaints of food-safety problems by the general public) or diagnoses for which names of patients are not collected (e.g., syndromic surveillance) generally do not have as strong a level of legal protection as do reports in which patients are named (e.g., surveillance reports or foodborne illness complaints).

Routine investigation of reports to confirm the diagnosis and determine the source of exposure, risk factors for infection, and contacts is usually considered part of surveillance and disease control activities authorized by state and local statutes.

The legal authorities to conduct outbreak detection activities are the same regardless of the intentionality of the contamination. However, once intentional contamination is suspected, additional state criminal, antiterrorism, and emergency response laws most likely will enhance or control the course of the outbreak investigation and response.

Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks (Section 9.3)

Because of improvements in surveillance and outbreak detection and globalization of the food supply, more multistate and international foodborne disease outbreaks are being discovered (9.3.1). As a result several federal agencies have played an increasingly direct, leading role in the control of foodborne diseases (9.3.2) including CDC; FDA; USDA/FSIS; USDA/Animal and Plant Health Inspection Service; U.S. Environmental Protection Agency; and when bioterrorism is suspected, U.S. Department of Justice and U.S. Department of Homeland Security. The primary legislation by which FDA exercises authority over food is the Federal Food, Drug, and Cosmetic Act (FFDCA) (9.3.2.1). The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011,

Overview of Chapter 9. Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

amended the FFDCA to enhance the federal government's ability to prevent and respond to contamination in the food supply (9.3.2.2). FSMA addresses prevention, inspection, compliance, and response activities. It also adds authorities to ensure that imported products are as safe as domestically produced food. USDA/FSIS operates under the authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA) (9.3.2.3).

In instances in which improper food preparation at the local level results in foodborne disease, the broad authority of public health agencies to control epidemics and end nuisances, as well as specific authority they have to inspect restaurants and ensure proper food safety, is used to close food-service establishments; remove contaminated food from possible consumption; require changes in food preparation; and temporarily remove infectious persons from the workplace. These actions are taken through agency authority granted by rule or through administrative orders. If necessary, agencies may seek enforcement through court orders (9.3.3).

Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution (Section 9.4)

Because of the need to link epidemiologic data with product information to take regulatory action (e.g., product recall), the roles of state and local public health agencies and CDC must be coordinated with the roles of federal regulatory agencies (9.4.1)

In the event of a possible criminal act, joint investigation by regulatory and nonregulatory public health and law enforcement agencies may be hindered by the different legal powers and investigatory practices of each agency. State and local public health officials, in collaboration with counterparts in law enforcement agencies, should periodically assess the need for memoranda of understanding to clarify the roles of public health and law enforcement agencies in conducting joint investigations. Regulatory and nonregulatory public health and law enforcement officials all must conform to constitutional standards about collection of evidence such as chain of custody procedures (9.4.2).

CIFOR Legal Preparedness Resources (Section 9.5)

CIFOR has created several resource documents to help state and local public health agencies improve their legal preparedness to conduct surveillance for foodborne diseases and respond to outbreaks within their jurisdictions and across jurisdictional boundaries, including

- Analysis of State Legal Authorities for Foodborne Disease Detection and Outbreak Response.
- Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response.
- Menu of Legal Options for Foodborne Disease Detection and Outbreak Response.

These documents are available through the CIFOR website at www.cifor.us.

CHAPTER

2

Fundamental Concepts of Public Health Surveillance and Foodborne Disease

During the past century, the American diet transformed significantly in what food we eat, how we grow or raise that food, and how that food arrives to our tables. Factors contributing to these changes included industry consolidation and globalization, health concerns and dietary recommendations, and culinary trends and dining habits. What we eat; how our food is cultivated or raised, processed, and distributed; and how and by whom our food is prepared relate directly to the foodborne diseases we experience.

Preventing foodborne disease relies on our ability to translate knowledge of the principles of food safety to the practices of food production and preparation at each level of the food system and in home kitchens. Foodborne disease outbreaks represent important sentinel events that signal a failure of this process. Determining whether this failure resulted from the emergence of a new hazard or failure to control a known hazard is critical to developing strategies to prevent future outbreaks and evaluating the success of those strategies.

2.0. Introduction

A variety of surveillance programs are required to accomplish this complex task. Some focus on specific enteric pathogens likely to be transmitted through food and have been used extensively for decades. More recently, new surveillance methods have emerged that shed light on food vehicles, settings, pathogens, contributing factors, and environmental antecedents.

This chapter provides an overview of fundamental concepts in public health surveillance and foodborne disease in the United States and outlines some factors responsible for recent trends and challenges.

2.1. Trends in Diet, the Food Industry, and Foodborne Disease Outbreaks

2.1.1. Dietary Changes

That we no longer are a nation of meat and potato eaters is evidenced by the most recent dietary recommendations of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA), which emphasize the importance of eating a variety of fruit, vegetables, and protein.[1] From 1985 through 2005, the annual per capita consumption of fruit and vegetables rose from 89 to 101 pounds and from 123 to 174 pounds, respectively.[2] In 2011, the annual per capita consumption of seafood (fish and shellfish) was 15.0 pounds, compared with 12.4 in 1980.[3,4]

Changes in diets and food preferences have resulted in a greater demand for a broader variety of fruits, vegetables, and other foods. The food industry has accommodated this demand by moving from locally grown and raised products to routine importation of items once considered out of season or too exotic. According to a report by the USDA's Economic Research Service (ERS), U.S. food imports grew from $41 billion in 1999 to $103 billion in 2011.[5] Much of that growth occurred in fruit and vegetables, seafood, and processed food products. In 2011, an estimated 15%–20% of all food consumed in the United States originated from other countries, including over 70% of seafood and about 35% of fresh produce. In some seasons, as much as 60% of fresh produce consumed by Americans is imported.[6]

The safety of imported food products depends largely on the public health and food safety systems of other countries and is not always guaranteed. The existence of food safety problems in other countries is supported by recent analyses of foodborne disease outbreaks reported to the Centers for Disease Control and Prevention (CDC). During 2005–2010, 39 outbreaks (0.7% of outbreaks where the country of origin of the contaminated food item or ingredient was reported) were linked to imported items from 15 countries. Of those outbreaks, nearly half (17) occurred in 2009 and 2010. Overall, fish was the most commonly implicated food in these outbreaks, followed by spices (including fresh and dried peppers). Nearly 45% of the imported foods causing outbreaks came from Asia.[7]

Culinary preferences that use undercooked or raw foods—particularly dairy, fish, or shellfish—might also be contributing to more frequent infections and outbreaks caused by the microorganisms associated with these foods.[8, 9, 10, 11, 12, 13, 14] For example, among

2.1. Trends in Diet, the Food Industry, and Foodborne Disease Outbreaks

foodborne disease outbreaks reported to CDC during 1993–2006, unpasteurized dairy products caused a disproportionate number of outbreaks and outbreak-associated illnesses compared with pasteurized dairy products, on the basis of estimated units of product consumed. Outbreaks resulting from unpasteurized dairy products also disproportionately affected persons <20 years of age.[15] Similarly, among the 36 dairy-associated outbreaks reported to CDC during 2009–2010 for which pasteurization information was reported, 26 (81%) involved unpasteurized products.[16]

2.1.2. Changes in Food Production and Preparation

Changes in what we eat and drink are not the only contributors to trends in foodborne disease. How our food is cultivated or raised, processed, and distributed and where, how, and by whom our food is prepared also are factors. Food can be contaminated anywhere along the supply chain from farm to fork.

The demand for processed and ready-to-eat foods has led to the industrialization of food production, with concentrated animal feeding operations, increasingly intense agricultural practices, and broadening distribution of food products. Changes in agricultural, processing, or packaging methods might facilitate bacterial contamination or growth,[17, 18, 19, 20, 21, 22,23, 24, 25, 26.27, 28, 29] and use of antibiotics in livestock and poultry most likely has contributed to increased human infections caused by drug-resistant bacteria.[30, 31, 32, 33] In addition, the broadening distribution of food products has contributed to outbreaks of foodborne disease involving larger numbers of people, multiple states, and even multiple countries.[34]

In seeming contradiction to the growing industrialization of food production and mass distribution of foods nationally and internationally, interest in eating locally produced foods also has grown in many communities because of concerns about nutrition, the environment, and local economy. As a result of this increased interest in eating locally (sometimes termed the "locavore movement"), the number of small food producers and direct-to-consumer marketing avenues (e.g., farmers markets, farm stands, farm-to-school programs, and "pick-your-own operations") has also risen. According to census data, from 1997 to 2007, direct sales of agricultural products to the public increased by 105%, compared with an increase of 48% for all agricultural sales. Over the same period, the number of farms selling directly to consumers increased by 24%, compared with a 0.5% reduction in the total number of farms.[35]

The effect of increased consumption of locally produced foods is yet to be determined. It would seem that the consequences of consuming unsafe food differ marginally between small and large producers, although fewer people might be adversely affected by a limited distribution system, as is probably the case for smaller producers. On the other hand, implementation of improved food safety measures could be more challenging among an increased number of more widespread, smaller food producers. In addition, farm direct sales (i.e., farmers selling produce, eggs, and other foods that 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[36] and, in some states and local jurisdictions, have been exempted from food safety regulations that pertain to other food facilities.

By whom and where our food is prepared probably also plays a role in foodborne diseases occurrence and outbreaks. Increasingly more Americans eat their meals away from home. According to the National Restaurant

2.1. Trends in Diet, the Food Industry, and Foodborne Disease Outbreaks

Association's 2012 industry overview, 970,000 restaurant locations will have more than 70 billion meal and snack occasions.[37] Forty-nine percent of all food spending in 2011 was on food prepared away from home, up from 33% in 1970.[38]

The increased number of meals eaten away from home most likely has influenced the occurrence of foodborne disease. In an analysis of foodborne disease outbreaks reported to CDC during 2009–2010, 48% were associated with restaurants or delicatessens (including cafeterias and hotels).[38] In addition, studies of both sporadic and outbreak-associated foodborne illness, including infection with Shiga toxin–producing *Escherichia coli* (STEC) O157:H7, *Salmonella enterica* serotype Enteritidis, *S. enterica* serotype Typhimurium, and *Campylobacter jejuni*, suggest that commercial food-service establishments, such as restaurants, play an important role in foodborne disease in the United States.[40]

2.2. Trends in Food-Safety Problems

2.2.1. Food Product Recalls

Food recalls indicate both food safety problems and demonstrations of control measures in response to those problems. Distributors or manufacturers recall their food products for either of two reasons: (a) a regulatory authority or the food industry identifies a food-safety problem during production, processing or distribution or (b) suspicion or identification of the product as the cause of human disease. During 2012, the U.S. Food and Drug Administration (FDA) and the USDA Food Safety and Inspection Service (USDA-FSIS) reported more than 258 recalls of food associated with microbial contamination. Imported food products were also among the list of recalled foods. These recalls demonstrate the breadth of products and pathogens responsible for foodborne diseases in the United States.[41, 42]

During that period, manufacturers and distributors recalled shellfish and smoked, dried, frozen, and uneviscerated fish; fresh fruit, herbs, and vegetables; cheese, ice cream, and other dairy products; ready-to-eat prepared foods such as peanut butter and peanut butter products, vegetarian meatloaf, and salsa; pistachios, cashews, and other nuts; ready-to-eat meat and poultry products; raw ground beef and various types of raw beef; and food ingredients, such as flour, oat fiber, starter yeast, seasonings, and flavor concentrate. The products were distributed locally, nationally, or internationally and were sold not only by national chain retail stores and food services but also at farm stands and small health food stores carrying organic and "natural" products.[41,42]

Most of these recalls followed identification of bacterial contamination of a food or beverage, but in some instances, the contamination was associated with reported human illnesses.

The contaminating pathogens most commonly identified in food recalls were *Listeria monocytogenes*, STEC, and *Salmonella*; the latter two were associated most frequently with recalls resulting from the investigation of human illness. Additional products were recalled because of contamination (or potential contamination) with *Cronobacter sakazakii* and bacterial toxins (e.g., *Clostridium botulinum* neurotoxin, *Staphylococcus aureus* enterotoxin, and *Bacillus cereus* toxin).[41,42]

2.2. Trends in Food-Safety Problems

2.2.2 Foodborne Disease and Outbreaks

The occurrence of foodborne disease and outbreaks indicates both food-safety problems and surveillance efforts. In 2011, CDC estimated that foodborne diseases were responsible for 48 million illnesses each year, resulting in 128,000 hospitalizations and 3,000 deaths.[43] During 2009–2010, 1,527 foodborne disease outbreaks were reported to CDC, resulting in at least 29,444 individual illnesses and 23 deaths.[44] In recent years, the nature of foodborne disease outbreaks detected in the United States has shifted.

2.2.2.1. Localized "event" outbreaks

The traditional foodborne disease outbreak scenario involves an acute and highly local outbreak, resulting from an endpoint contamination event in a small kitchen that occurred shortly before consumption of the implicated food (i.e., terminal food-handling error). These localized outbreaks often follow a local event, such as a church supper, family picnic, wedding reception, or other social event. The inoculum dose and attack rate among exposed persons can be high, making the outbreak quickly apparent to those in the group that attended the social event. Affected persons commonly notify public health authorities through foodborne disease complaint systems (see below). The solution is typically local, necessitating education of food workers and changes in individual food-service establishment policies and operating procedures.

Localized event outbreaks, including those for which the exposure occurs at a single event but the population affected covers multiple counties or states, comprise more than 95% of outbreaks reported to CDC (CDC, unpublished data, 2006–2010).

2.2.2.2. Contaminated commercial product outbreaks

Another kind of outbreak involves food products that are contaminated upstream of the point of sale. Exposure typically occurs in multiple locations that reflect the distribution and subsequent handling of the product. Victims may be scattered across different counties, states, or even countries. The attack rate in these outbreaks may be very low, resulting in no readily apparent clustering of cases absent laboratory subtyping of ostensibly "sporadic" case isolates.

Investigation of commercial product outbreaks often requires the coordinated efforts of a multidisciplinary team to clarify the extent of the outbreak, implicate a specific food, and determine the source of contamination. Often, no obvious terminal food-handling error is found.[45, 46]

Although likely undercounted, commercial product outbreaks account for only a small proportion (2%) of all foodborne disease outbreaks reported to CDC. Such outbreaks, however, comprise a disproportionate number of reported outbreak-related illnesses (7%), hospitalizations (31%), and deaths (34%) (CDC, unpublished data, 2006–2010). The larger number and more serious illnesses associated with commercial product outbreaks most likely result in part from the efforts of PulseNet in helping to recognize these outbreaks. PulseNet, the national molecular subtyping network that analyzes bacterial isolates from human clinical specimens and food samples for their genetic relatedness, focuses on more serious foodborne pathogens, including *E. coli* O157:H7, *Salmonella*, and *Listeria*, and is better able than other means of detecting outbreaks by linking related cases, thus associating larger numbers of cases with each outbreak. Nonetheless, case counts in these outbreaks are likely to be severely undercounted.

Commercial product outbreaks involve a variety of investigators from local, state, and federal agencies and can highlight food safety problems in national (or multinational)

2.2. Trends in Food-Safety Problems

corporations with industrywide implications with regards to control measures. As a result, these outbreaks have been more publicly visible and most likely have received more investigation resources than the more prevalent localized outbreaks. Further studies are needed to better understand the occurrence of localized outbreaks and commercial product outbreaks and their impact on the health of the community.

2.2.2.3. Local investigator role in contaminated commercial product outbreaks

Because a seemingly localized outbreak might herald a more widespread and diffuse food-safety problem affecting multiple jurisdictions, local investigators need to watch for indicators of a commercial food safety problem (see Chapter 7) and alert others immediately when a multijurisdictional outbreak is suspected. Local investigators play an important role in the investigation of multijurisdictional outbreaks by searching for local cases, participating in hypothesis generation, and performing other agreed-upon tasks, such as case interviews, in an expedient manner.

Each and every case interview in a multijurisdictional outbreak is critical, as was illustrated in an outbreak of *E. coli* O157:H7 infection in 2003 that was associated with blade-tenderized frozen steaks. Information from three persons with culture-confirmed cases in Minnesota and from single confirmed cases in two other states enabled officials to identify the source of the steaks and recall 739,000 pounds of beef in a timely manner.[47]

2.3. Trends in Surveillance

Our ability to use public health surveillance to track cases of foodborne disease and outbreaks, as well as behaviors and conditions that contribute to foodborne disease, is critical to our understanding and control of these diseases.

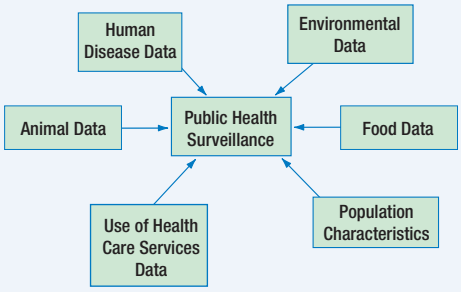
2.3.1. Overview

Public health surveillance is an active process of collecting, analyzing, interpreting, and disseminating data about selected diseases with the purpose of initiating action to improve the health of the community. It is the foundation of communicable disease epidemiology and an essential component of a food-safety program.[48] Surveillance data can reveal the burden of a particular disease in the community or the presence and scale of a possible outbreak. Surveillance data also can provide clues to the source of and contributing factors to disease outbreaks. Over time, surveillance data can identify disease and behavioral trends and enable investigators to learn more about the diseases being tracked and ways to prevent them (referred to as preventive controls in the Food Safety and Modernization Act).

Surveillance programs conducted by public health and other health-related agencies are much broader than those focused on detecting foodborne diseases. Surveillance also is conducted to identify waterborne diseases and diseases transmissible from person to person; breakdowns in infection control in health-care facilities; animal-based diseases that may affect humans; food contaminated by human pathogens; patterns of behavior that increase risk for poor health; and many other health-related events. Furthermore, surveillance programs typically use a variety of data sources to provide a complete understanding of a particular disease in the community and insight into its control (Figure 2.1).

2.3. Trends in Surveillance

Figure 2.1 Sources of information for public health surveillance



2.3.2. Selected Surveillance Systems of Relevance to Foodborne Diseases

Multiple types of surveillance systems related to foodborne disease are used in the United States. Some of them, including notifiable disease surveillance, complaints from consumers about potential illness, and reports of outbreaks, focus on the detection of specific enteric diseases likely to be transmitted by food and have been used extensively by health-related agencies for decades. More recently, new surveillance methods have emerged including hazard surveillance, sentinel surveillance systems, and national laboratory networks for comparing pathogen subtypes, which are particularly applicable to foodborne disease.[49]

Many surveillance systems play a critical role in detecting and preventing foodborne disease and possible outbreaks in the United States, helping to ensure food is safe as it moves through the food chain to the tables of consumers.

2.3.2.1. Notifiable disease surveillance

One of the oldest public health surveillance systems in the country is notifiable disease surveillance. Notifiable disease surveillance begins with an ill person who seeks medical attention. The health-care provider sends a specimen (for foodborne illness, this usually is a stool specimen) to the laboratory for the appropriate tests, and the laboratory identifies the agent responsible for the patient's illness so the patient can be treated. Next, the laboratory or health-care provider notifies local public health officials of the illness. Once the patient's information goes to a public health agency, the illness is compared with other similar reports. Combining the information in these separate reports allows investigators to detect illness clusters that might be outbreaks caused by contaminated food.

All states and territories have legal requirements for the reporting of certain diseases and conditions, including enteric diseases likely to be foodborne, by health-care providers and laboratories to the local or state public health agency. In most states and territories, the law usually requires local public health agencies to report these diseases to the state or territorial public health agency. What to report and with what urgency vary by state and by disease. In the past, disease reports usually arrived by mail, telephone, or fax, but many agencies now have developed electronic laboratory reporting systems.

States and territories (or sometimes local public health agencies) voluntarily share notifiable disease surveillance information with CDC through the National Notifiable Disease Surveillance System (NNDSS), which CDC oversees. No personal identifiers are forwarded, and only minimal information is available about cases (e.g., date of onset and patient age, sex, race/ethnicity, county of residence). National data are used to monitor disease trends and to target research, prevention, and control efforts.

State public health laboratories also participate in national notifiable disease surveillance through programs such as PulseNet (see below)[50] and the Laboratory-based Enteric Diseases Surveillance (LEDS) system, an electronic reporting system for laboratory-

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confirmed isolates, including *Salmonella*, *Shigella*, and STEC.[51,,52, 53]

2.3.2.2. Foodborne illness complaints

Receiving and responding to complaints of disease from the public is a basic function of many public health and other health-related agencies and can lead to the identification of foodborne illnesses in the community and clusters of persons with suspected foodborne disease.

With foodborne disease complaints, affected members of the community report illness they suspect to be foodborne to the health department. Sometimes the reports are made by a third party who recognizes a pattern of illness in the community (e.g., a physician who has seen multiple ill patients with a common exposure, a staff member from a nursing home reporting multiple diarrheal illnesses among residents, or a pharmacist who notes increased sales of antidiarrheal medications). Other agencies sometime receive these reports (e.g., agriculture food safety offices and poison control centers) and forward them to the health department.

The processing of foodborne illness complaints varies by agency on the basis of the suspected pathogen and agency resources. Some health departments are expected to investigate all commercial food establishments named by sick persons. Most health departments record complaints in a log book or on a standardized form. A growing number of health departments enter this information into an electronic database for easy review and analysis, a practice associated with the detection of more outbreaks per complaint reported.[54]

Some complaint systems are more well publicized and involve community members more heavily. A Web-based system in Michigan (RUsick2) piloted in the early 2000s enabled ill persons to share information about their illness and recent exposures and helped the health department identify clusters of persons with unsuspected foodborne disease. During the pilot test, the system resulted in an estimated fourfold increase in the reporting of foodborne illness complaints. Two foodborne disease outbreaks were identified that most likely would not have been identified through other means.[55]

Use of Web-based reporting systems has increased over time. In a 2010 survey of local health departments, 40% of responding agencies reported that they received illness complaints, at least in part, from Web-based reporting.[54]

The value of illness complaint systems was underscored in the 2010 survey of local health departments in which responding agencies reported that 69% of foodborne disease outbreaks in their jurisdiction were detected through complaint systems. Furthermore, agencies serving a population of one million or more reported that 85% of foodborne disease outbreaks were found through a consumer complaint surveillance system.[54]

FDA and USDA-FSIS also maintain complaint systems and interact with local, state, and federal public health agencies during complaint investigations.

More details on consumer complaint systems can be found in Chapter 4.

2.3.2.3. Contributing factor and environmental antecedent surveillance

Contributing factors are environmental factors that increase the risk for foodborne diseases and repeatedly contribute to foodborne disease outbreaks. The list includes factors that lead to contamination of food with microorganisms or toxins, allow survival and growth of microorganisms in food, or prevent inactivation of toxins present in food. Contributing factors are based on

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known microbiological characteristics of and symptoms produced by specific pathogens, toxins, or chemicals and historical associations between known etiologic agents, specific food vehicles, and the setting of production.

Environmental antecedents—root causes—are the underlying reasons for the contributing factors. Environmental antecedents must be identified and addressed for the contributing factors to be prevented.

Communicable disease control officials or foodborne disease outbreak surveillance officials from state and local health departments gather information about contributing factors and environmental antecedents in outbreaks from environmental health assessments conducted by food-control officials from their own environmental health assessments or through some combination of the two and report it to CDC. Factors contributing to an outbreak and their environmental antecedents usually cannot be identified through a regulatory inspection of a food-service or food-production establishment as conducted day to day by food-control authorities. The process of identifying contributing factors and environmental antecedents associated with an outbreak must be driven first by describing what and how events probably unfolded, focusing on the etiologic agent and the implicated food that was prepared or served during the outbreak, rather than on identification of regulation violations. Failures to implement regulatory requirements will come to light during the course of this process but are not the focus of the environmental health assessment. Unfortunately, many food-control authorities fail to adjust their day-to-day regulatory inspection process to adequately conduct an environmental health assessment during the investigation of an outbreak of foodborne illness; therefore, contributing factors and environmental antecedents often are not adequately assessed and reported.

In 2000, CDC established the Environmental Health Specialists Network (EHS-Net) to better provide information about environmental causes of foodborne disease. Current participants include environmental health specialists and epidemiologists from eight state and local health departments and from FDA, USDA-FSIS, USDA's Food and Nutrition Service, and CDC. Improving environmental health assessments in foodborne outbreak investigations and reporting contributing factors and antecedent data to CDC is one of EHS-Net's primary activities.

Through EHS-Net, CDC has developed the National Voluntary Environmental Assessment Information System (NVEAIS), a surveillance system that routinely and systematically monitors and evaluates environmental causes of foodborne disease outbreaks, including contributing factors and environmental antecedents. This system links with the existing surveillance system for reporting foodborne disease outbreaks to CDC (see below).[56]

The information collected through NVEAIS and similar surveillance systems can inform hypothesis generation regarding antecedents to foodborne disease outbreaks and strengthen the ability of food-control authorities to formulate and evaluate the effectiveness of food-safety actions. For example, Delea et al., in an analysis of contributing factors from 154 foodborne disease outbreaks during June 2006–September 2007, identified lack of paid sick leave, language barriers between management and workers, and inadequate hand sink availability as environmental antecedents for food workers working while ill and poor hand-washing practices.[57]

2.3.2.4. Hazard surveillance during routine inspections

Approximately 75 state and territorial agencies and approximately 3000 local agencies assume the primary responsibility for licensing and inspecting retail food-service establishments.[58] Many of these same agencies oversee other

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aspects of the domestic food supply chain. The retail food -service industry alone consists of more than one million establishments and 16 million employees.[56]

Contributing factors are used to develop prevention and control measures at food production and food-service establishments before a foodborne disease outbreak occurs. Inspections of these facilities, often referred to as Hazard Analysis Critical Control Point (HACCP) inspections, are targeted at the implementation of these prevention and control measures. Results of these inspections form the basis for hazard surveillance.

No national hazard surveillance system is available to food-control authorities, although work being conducted through the Conference for Food Protection may evolve into a national system.

2.3.2.5. Foodborne Diseases Active Surveillance Network

The Foodborne Diseases Active Surveillance Network (FoodNet) conducts active, population-based surveillance for laboratory-confirmed infections caused by nine pathogens and one syndrome commonly transmitted through food. FoodNet is a sentinel surveillance system, covering 15% of the U.S population (48 million in 2011) and is a collaboration of CDC, USDA-FSIS, FDA, and 10 state health departments. FoodNet site investigators regularly contact area laboratories to ascertain all infections with the pathogens under surveillance (i.e., active surveillance).

FoodNet sites also have conducted surveys of the frequency of enteric illness and food consumption in the population. The results of these surveys, distributed as the FoodNet Atlas of Exposures, provide crude estimates of the background rate of consumption of a variety of food items in the community and are useful in hypothesis generation during investigation of a foodborne disease outbreak.[59] FoodNet sites also have conducted surveys of practices for diagnosing enteric infections in clinical laboratories.[60]

Surveillance and special studies undertaken by FoodNet sites provide valuable insight into the national incidence of, and trends in, foodborne and diarrheal diseases [61, 62, 63, 64, 65, 66, 67, 68] and have identified previously unrecognized sources of foodborne infection, such as chicken as a risk factor for infection with *Salmonella* Enteritidis,[67, 69] hummus and melon as risk factors for infection with *Listeria monocytogenes,*[70] and riding in a shopping cart next to raw meat or poultry as a risk factor for infection with *Salmonella* and *Campylobacter* in infants.[71, 72] FoodNet also provides information for evaluating new strategies for conducting epidemiologic investigations, including investigations of outbreaks.[73]

2.3.2.6. Behavioral Risk Factor Surveillance System

The Behavioral Risk Factor Surveillance System (BRFSS) is a state-based system of surveys established by CDC in 1984 that provides information about the prevalence of health risk behaviors, preventive health practices, and health-care access. BRFSS data are collected by random-digit–dialed telephone interviews in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam. A set of core questions is asked of all BRFSS respondents across the country; other questions can be selected for use by individual state and local health agencies, including questions related to food safety.

BRFSS is not appropriate for detecting foodborne illness, but it can be used to identify behaviors (e.g., food-preparation practices and eating meals away from home) that can inform foodborne illness prevention efforts. For example, in an analysis of 1995–1996 BRFSS food-safety questions from Colorado, Florida, Missouri, New York, Tennessee, Indiana, New Jersey, and South Dakota, several high-risk food-handling, preparation, and consumption

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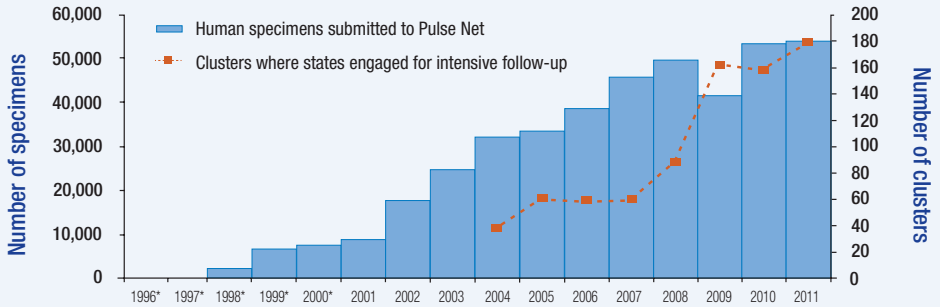
behaviors were common among respondents, and some were particular to specific population groups.[74]

2.3.2.7. National Molecular Subtyping Network for Foodborne Disease Surveillance

National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet) is a national network of local, state or territorial, and federal laboratories coordinated by CDC that enables comparison of subtypes of pathogens isolated from humans, foods, animals, and environments across local, state, and national jurisdictions. The name derives from pulsed-field gel electrophoresis (PFGE), a laboratory method used to determine the molecular fingerprints of bacteria. This method, developed and refined during the 1980s and implemented for widespread use during the 1990s, revolutionized the investigation of foodborne disease outbreaks by identifying unique strains within a bacterial species. For example, each of the many strains of *Salmonella* has a unique PFGE pattern or fingerprint. Because foodborne disease outbreaks usually are caused by a single bacterial strain, investigators can identify illnesses in the subgroup of persons infected with the same strain of *Salmonella* as a cluster of possibly related cases, to be considered separately from persons infected with other strains of *Salmonella*. By focusing on the correct group of cases, investigators can more quickly determine whether a cluster of cases represents an outbreak and identify the source of the outbreak. PFGE also can be used to characterize bacterial strains in food or the environment to determine whether those strains match the pattern responsible for an outbreak.[75, 76, 77, 78, 79, 80]

PulseNet has standardized the PFGE methods used by participating laboratories to distinguish strains of STEC, *Salmonella*, *Shigella*, *Listeria*, and *Campylobacter*. In addition, PulseNet maintains a centralized electronic database of PFGE patterns at CDC. Participating laboratories can upload their pattern(s) into the national database and review their current and historical patterns. CDC compares uploaded PFGE patterns with patterns of bacterial strains circulating nationally. This capability has improved investigators' ability to rapidly detect even relatively small clusters of possibly related illnesses in a small geographic area or dispersed across the country. As the number of participating laboratories and popularity of PulseNet have grown, the number of patterns from human isolates uploaded to the system and clusters detected through the system have steadily increased over time (Figure 2.2).[81, 82]

Figure 2.2 Bacterial isolates from humans uploaded to PulseNet USA, and identified clusters, 1996–2011†



*For 1996–2000, data may not be complete. †For 2011, data are preliminary and subject to change.

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2.3.2.8. National Antimicrobial Resistance Monitoring System—Enteric Bacteria

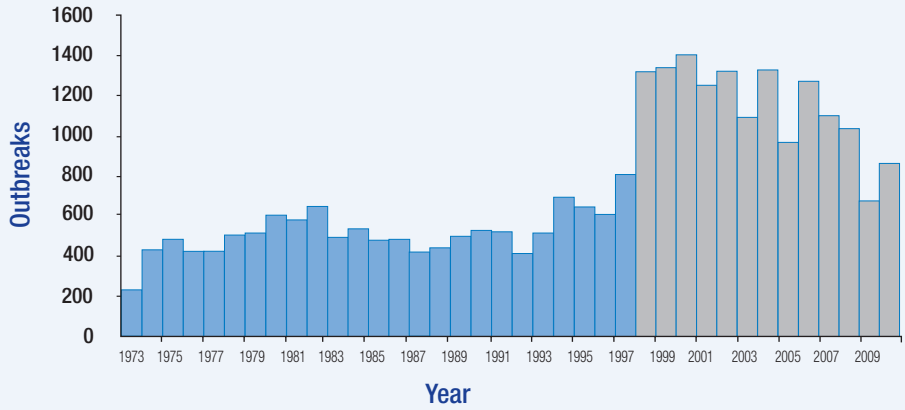
The National Antimicrobial Resistance Monitoring System—Enteric Bacteria (NARMS) was developed to monitor antibiotic resistance patterns in selected enteric bacteria found in humans, animals, and meat and poultry products. Bacterial isolates are forwarded to reference laboratories at CDC, USDA, or FDA and are tested against a panel of antimicrobial drugs important in human and animal medicine. Data collected by NARMS enable investigators to better understand the patterns of antibiotic resistance in microbes infecting animals and humans who ingest foods of animal origin. [83, 84, 85, 86, 87, 88, 89, 90]

2.3.2.9. Foodborne Disease Outbreak Reporting System

The Foodborne Outbreak Reporting System was initiated by CDC in the 1960s to collect voluntary reports from public health agencies summarizing the results of foodborne disease outbreak investigations. In 1973, the database for the system was computerized. In 1998, CDC increased communication with state, local, and territorial health departments about foodborne disease outbreaks and formalized procedures to finalize reports from each state each year. The system also became Web-based through the electronic Foodborne Disease Outbreak Reporting System (eFORS). These changes led to a substantial increase in the number of outbreaks reported, resulting in a discontinuity in trends during 1997–1998 (Figure 2.3).[91]

In 2009, the system was expanded to include reporting of waterborne outbreaks and enteric disease outbreaks caused by person-to-person contact, direct contact with animals, and contact with contaminated environments. The expanded system is called the National Outbreak Reporting System (NORS). CDC, USDA-FSIS, FDA, and other investigating agencies analyze these data to improve the understanding of the human health impact of foodborne disease outbreaks and the pathogens, foods, and settings involved in these outbreaks. Data are also available to the public online at http://wwwn.cdc.gov/foodborneoutbreaks/.

Figure 2.3 Number of reported foodborne disease outbreaks, United States, 1973–2010



Lighter gray bars starting in 1998 illustrate the change in number of outbreaks reported due to changes in the Foodborne Disease Outbreak Surveillance System.

Source: CDC Foodborne Disease Outbreak Surveillance System (2012).

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2.3.2.10. National Electronic Norovirus Outbreak Network

The National Electronic Norovirus Outbreak Network (CaliciNet) is a network of public health and food regulatory laboratories that submit norovirus sequences identified from outbreaks to a national database. CaliciNet participants perform molecular typing of norovirus strains by using standardized laboratory protocols. The information is used to link norovirus outbreaks that may be caused by common sources (such as food), monitor trends, and identify emerging norovirus strains. As of February 2012, public health laboratories in 25 states have been certified by CDC to participate in CaliciNet.[92]

2.3.2.11. Surveillance of the Food Supply

Testing of the food supply and associated environments is performed by local, state, and federal regulatory officials and the food industry. Food testing is a tool used to validate that 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 PFGE 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 that are caused by specific food sources, to assess changes in food contamination over time, and to assess the success of regulatory measures.

USDA-FSIS food laboratories maintain ISO 17025 accreditation, the international standard for laboratory quality systems. FDA is leading an effort to bring state manufactured food regulatory microbiological and chemical food-testing laboratories under ISO 17025 accreditation to enhance efforts to protect the food supply. Data generated by accredited laboratories will be made available for consideration during FDA enforcement actions as well as for surveillance purposes and during response to foodborne disease outbreaks through the Electronic Laboratory Exchange Network (eLEXNET). Laboratory accreditation will also assist state manufactured food regulatory programs in achieving conformance with the Manufactured Food Regulatory Program Standards (MFRPS).[93]

2.3.3. Quality and Usefulness of Surveillance Data

Surveillance plays a critical role in detecting and controlling foodborne diseases and outbreaks. Surveillance data can be used to examine long-term patterns of specific foodborne diseases, to characterize groups at greatest risk for these diseases, and to identify sudden changes in disease occurrence that suggest an outbreak or environmental hazard that needs investigation. Surveillance data can provide the basis for an understanding of foodborne illness in the community and how best to use limited resources to address problems associated with foodborne illness. Surveillance data can help generate hypotheses about specific foodborne diseases and provide clues about the problem for exploration through in-depth studies. Surveillance data can identify contributing factors and environmental antecedents to foodborne disease outbreaks, which in turn can be used to develop preventive controls and thereby reduce the burden of foodborne disease. Surveillance data also can be used to evaluate the effectiveness of interventions by the food industry and public health and regulatory agencies. Although surveillance data are of great utility, they are far short of perfect, and their shortcomings often compromise their utility.

2.3.3.1. Completeness of detection and reporting of foodborne diseases

Although national capacity for detection and surveillance of foodborne disease has improved considerably in the past 20 years,[94] for a number of reasons, surveillance statistics reflect only a fraction of cases: (a) some people do not seek medical attention for vomiting or diarrhea of limited duration or do not seek care because

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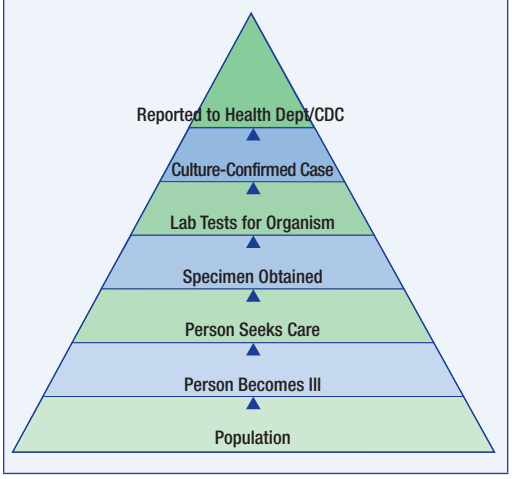
they lack health-care coverage; (b) health-care providers frequently do not obtain diagnostic tests for illnesses likely to be self-limited; (c) not all types of infections can be diagnosed with routine laboratory testing; and (d) laboratories and health-care providers may fail to report the illness to a public health agency.[95, 96, 97, 98] For example, according to a population-based survey undertaken in 1996–97 in selected states, only 12% of persons who had a diarrheal illness (14.6% of those with bloody diarrhea and 11.6% of those with nonbloody diarrhea) sought medical care. Among those who sought medical care, 21% were asked by their physician to provide a stool specimen for culture, and 89% of these complied with this request.[99]

As a result, cases of foodborne illness are lost at each step in the diagnosis and reporting process and thus are not included in national statistics. As little as 5% of bacterial foodborne illness might be reported to CDC through notifiable disease surveillance.[100] Some investigators portray this disparity between the occurrence of foodborne illness and the reporting of cases to the health department by using a burden of illness pyramid (Figure 2.4).[100]

Figure 2.4 Burden of illness pyramid reflecting the proportion of foodborne illnesses that make it through each step of the diagnosis and reporting process.[100]



With dozens—or even hundreds—of possible etiologies for foodborne disease, and most of them with similar or at least overlapping clinical manifestations, laboratory-confirmation of the agent is often essential for public health action. However, because most diarrheal illnesses are self-limited and laboratory test results often are not used to guide the initial course of treatment for a patient, health-care providers often do not request stool cultures. Physicians are more likely to request a culture for persons with acquired immunodeficiency syndrome, history of travel to a developing country, bloody stools, diarrhea of >3 days' duration, or fever, or who require intravenous rehydration.[101]

Lack of laboratory confirmation can hinder appropriate management and treatment of an individual patient with acute diarrhea and inhibit surveillance and other public health actions.[101, 102] For the individual patient, identification of the specific agent can:

- Help with the appropriate selection of antimicrobial therapy, shortening the patient's illness and reducing morbidity;
- Support the decision not to treat, if the patient would not benefit from antimicrobial therapy or would even be harmed by the use of antibiotics (e.g., prolongation of the carrier state with salmonellosis); and
- Guide the use of invasive diagnostic techniques (e.g., avoid colonoscopy if an infectious etiology is identified).

From a public health perspective, a pathogen-specific diagnosis with subtyping and prompt notification of public health authorities can:[100,101]

- Enhance actions to prevent the spread of infection to others through patient education and exclusion of ill persons from food preparation or care of individuals at increased risk for poor outcomes from foodborne diseases;

2.3. Trends in Surveillance

- Allow tracking of trends in foodborne diseases through surveillance;
- Enhance the detection and control of outbreaks, particularly outbreaks caused by low-level contamination of food or exposures over a wide geographic area;
- Provide antimicrobial sensitivity data for the community;
- Prevent the emergence of drug resistance through the more judicious use of antibiotics and avoidance of broad-spectrum antibiotics; and
- Support studies of sporadic, non-outbreak–associated illnesses to describe changing epidemiology and identification of new risk factors.

Improved disease detection and completeness of reporting would facilitate the above patient care and public health goals. Nonetheless, it should still be appreciated that even with the capture of only a fraction of foodborne illnesses through surveillance, these intensely investigated events shed light on food vehicles, settings, pathogens, contributing factors, and environmental antecedents, and provide extremely valuable information.

2.3.3.2. Culture-independent diagnostic tests

Culture-independent diagnostic tests are also threatening surveillance and outbreak detection efforts. These tests, largely based on enzyme immunoassays and similar procedures, are becoming available for some foodborne illnesses. These methods allow for a quick identification of a pathogen and rapid initiation of treatment. However, they usually do not result in a culture that can be forwarded to the public health laboratory for further characterization (e.g., subtyping and antimicrobial susceptibility testing), limiting the identification of clusters, and tracking of antimicrobial resistance. Furthermore, the accuracy of culture-independent diagnostic tests differs from that of cultures, making it difficult to include the results of such tests in the definitions used in notifiable disease surveillance.[103, 104]

To address the impact of culture-independent diagnostic tests on foodborne disease surveillance and outbreak detection in the short term, steps need to be taken to maintain pathogen isolates for characterization at public health laboratories. This includes working with the medical device industry and the FDA to ensure that specimens collected for culture-independent diagnostic tests are adequate for subsequent culture and building capacity at public health laboratories that will be increasingly charged with isolating foodborne pathogens from patient samples. In the long term, new tests for determining pathogen subtype, virulence, and antimicrobial susceptibility need to be developed that are themselves culture-independent.

2.3.3.3. Quality and usefulness of information collected

Many factors influence decisions about which surveillance data to collect and how to collect them, both of which affect the quality and usefulness of the data. The contributing factor category of data reported to CDC through the Foodborne Disease Outbreak Surveillance System is a good example of how these decisions are made and how surveillance systems evolve over time to balance user needs, identification of data to collect, willingness of officials to report, and accuracy of officials' reports.

Before October 1999, contributing factor data were reported and summarized into five broad categories: improper storage or holding temperature; inadequate cooking; contaminated equipment or working surfaces; food acquisition from unsafe source; poor personal hygiene of food handler; and other. Food-control authorities used the information, but the broad categories were not detailed enough and did not fully meet their needs. Articles by Bryan et

2.3. Trends in Surveillance

al., Guzewich et al., and Todd et al. [105, 106, 107, 108] framed information gleaned from foodborne disease surveillance systems in terms of the key end user of the data—those charged with foodborne disease prevention. Specifically, Bryan et al. described the value and limitations of existing food vehicle and contributing factor data and recommended a list of specific contributing factors to be reported.[108]

To meet the needs of data users, CDC incorporated the contributing factors suggested by Bryan et al. into the new foodborne outbreak reporting form in October 1999. Another factor, glove-handed contact by handler/worker/preparer, was also added.

The change, however, is not without controversy among those who report and use this information. Some question whether food-control authorities have the expertise to accurately identify the most likely contributing factors from among the now complicated list of factors. Consistent identification of these factors is also an issue. Some believe the contributing factor list is too complex for a surveillance system and should be removed entirely or returned to the pre-1999 abbreviated list. Still others believe without a context for the factors reported—even the pre-1999 abbreviated list of factors has limited, if any, value.

As new information becomes available about the value of specific data elements, the contributing factor surveillance system, like all surveillance systems, will continue to evolve. CDC's EHS-Net program has been addressing these problems through the National Voluntary Environmental Assessment Information System (NEVAIS) and related training programs (see above).

2.4. Etiologic Agents Associated with Foodborne Diseases

2.4.1. Overview

Foodborne illnesses have myriad causes, including microorganisms (e.g., bacteria, viruses, parasites, and marine algae) and their toxisns, mushroom toxins, fish toxins, heavy metals, pesticides, and other chemical contaminants (Table 2.1). These agents cause human disease through a number of mechanisms and are often categorized into those caused by toxins present in food before it is ingested (preformed toxins) and those caused by multiplication of the pathogen in the host and damage resulting from toxins produced within the host (enterotoxins) or adherence to or invasion of host cells (infection).

Details about the most common foodborne disease–causing agents, including signs and symptoms, incubation periods, modes of transmission, common food vehicles, and control measures, can be found in:

- American Public Health Association. *Control of Communicable Diseases Manual* (latest edition) Washington, DC: APHA;
- CDC. CDC A–Z Index. www.cdc.gov/az/a.html;
- U.S. Food and Drug Administration. The Bad Bug Book, 2nd edition. www.fda.gov/downloads/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/UCM297627.pdf;
- International Association of Milk, Food and Environmental Sanitarians. *Procedures to Investigate Foodborne Illness*. 6th edition. Des Moines, Iowa: IAMFES (reprinted 2007); and
- CDC. Diagnosis and management of foodborne illnesses: a primer for physicians and other health-care professionals. MMWR Recomm Rep 2004:53(RR-4). (www.cdc.gov/mmwr/pdf/rr/rr5304.pdf)

2.4. Etiologic Agents Associated with Foodborne Diseases

Table 2.1. Examples of agents that commonly cause foodborne illness, by agent type and mechanism of action

TYPE OF AGENT	GENERAL MECHANISM OF ACTION	EXAMPLE
Bacteria	Preformed toxin	*Bacillus cereus* *Clostridium botulinum* *Staphylococcus aureus*
	Infection and production of enterotoxins	*Bacillus cereus* *Clostridium botulinum* *Clostridium perfringens* *Enterohemorrhagic Escherichia coli* Enterotoxigenic *E. coli (STEC)* *Vibrio cholerae*
	Infection	*Bacillus anthracis* *Brucella spp. (B. melitensis, B. abortus, B. suis)* *Campylobacter jejuni* Enteroinvasive *E. coli* *Listeria monocytogenes* *Plesiomonas shigelloides* *Salmonella spp.* *Shigella spp.* *Streptococcus pyogenes* *Vibrio parahaemolyticus* *V. vulnificus* *Yersinia enterocolytica and Y. pseudotuberculosis*
Virus	Infection	Hepatitis A virus Norovirus (and other caliciviruses) Rotavirus Astroviruses, adenoviruses, parvoviruses
Parasite	Infection	*Cryptosporidium* *Cyclospora cayetanensis* *Diphyllobothrium latum* *Entamoeba histolytica* *Giardia intestinalis* *Taenia saginata* *Taenia solium* *Toxoplasma gondii* *Trichinella spiralis*
Marine algae toxins	Preformed toxin	Brevetoxin (neurotoxic shellfish poisoning) Ciguatoxin (ciguatera) Domoic acid (amnestic shellfish poisoning) Saxitoxin (paralytic shellfish poisoning)
Fungal toxins	Preformed toxin	Aflatoxin Mushroom toxins (amanitin, ibotenic acid, muscinol, muscarine, and psilocybin)

2.4. Etiologic Agents Associated with Foodborne Diseases

Table 2.1. Examples of agents that commonly cause foodborne illness, by agent type and mechanism of action *Continued*

TYPE OF AGENT	GENERAL MECHANISM OF ACTION	EXAMPLE
Fish toxins	Preformed toxin	Gempylotoxin (escolar) Scombrotoxin (histamine fish poisoning) Tetrodotoxin (puffer fish)
Chemicals	Preformed toxin (hazardous at certain levels)	Antimony Arsenic Cadmium Copper Fluoride Lead Mercury Nitrites Pesticides (e.g., organophosphates, carbamate) Thallium Tin Zinc

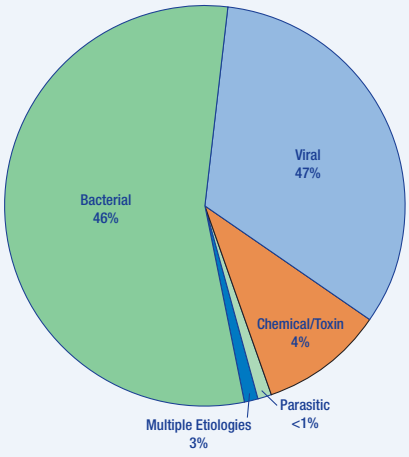
2.4.2. Patterns in Etiologic Agents Associated with Foodborne Disease Outbreaks

Patterns in the agents causing foodborne disease outbreaks have been identified through the voluntary reporting of outbreaks to CDC through the Foodborne Disease Outbreak Surveillance System.

In the most recent CDC surveillance summary of U.S. foodborne disease outbreaks (covering 2009–2010), bacteria (including their toxins) accounted for 46% of reported outbreaks that had an identified cause (Figure 2.5). The most common bacteria implicated in outbreaks were *Salmonella*, STEC, *Clostridium perfringens, Campylobacter, Bacillus cereus, Staphylococcus aureus, Shigella, Listeria monocytogenes,* and *Vibrio* spp. (Figure 2.6). Clostridium botulinum also was reported but was a less common bacterial cause of foodborne disease.[109]

During the same surveillance period, viruses constituted 47% of identified causes of foodborne disease outbreaks, increasing from 16% in 1998. The increase in proportion of outbreaks from viral pathogens over time reflects the increased availability of methods to diagnose viral agents in recent years.[109] During 2009–2010, noroviruses accounted for 99% of

Figure 2.5 Foodborne disease outbreaks by confirmed etiology, United States, 2009-2010*



* Includes only outbreaks for which an etiology was determined. For 31% of outbreaks, no etiologic agent was identified.

Source: CDC Foodborne Disease Outbreak Surveillance System (2012)

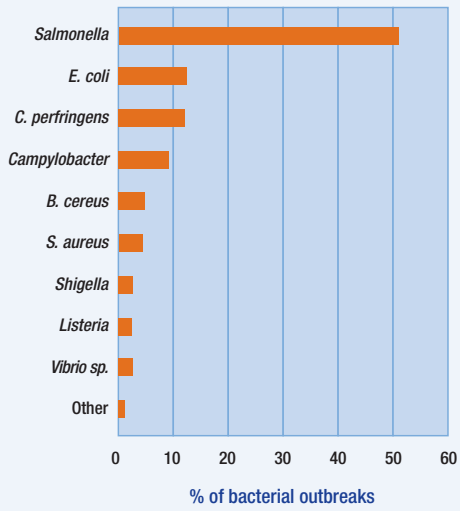
2.4. Etiologic Agents Associated with Foodborne Diseases

viral outbreaks. Hepatitis A virus and rotaviruses played a minor role in foodborne disease outbreaks during these years.

During 2009–2010, parasites accounted for <1% of outbreaks with identified etiologies. Marine algae and fish toxins, mushroom toxins, and chemicals accounted for 4% of outbreaks with an identified cause. The most commonly reported chemical/toxin causes were scombrotoxin (42%) and ciguatoxin (35%).[109]

For a large proportion (31%) of outbreaks reported during 2009–2010, no etiologic agent was identified. Reasons include inadequate collection of stool specimens, delay in outbreak detection and specimen collection, and inappropriate testing of specimens.[110,111] Because laboratory methods for confirming viral diseases are less available than tests for bacterial diseases, many outbreaks of foodborne illness from viruses probably fall into the "unknown etiologic agent" category.[110]

Figure 2.6 Distribution of bacterial foodborne disease outbreaks by etiologic agent, United States, 2009-2010



Source: CDC Foodborne Disease Outbreak Surveillance System (2012)

In addition, not all outbreaks are detected, investigated, and reported to CDC. Outbreaks most likely to be brought to the attention of public health authorities are those that can cause serious illness, hospitalization, or death.[109] Furthermore, outbreaks of diseases characterized by short incubation periods, such as those caused by chemical agents or staphylococcal enterotoxin, might be more likely to be recognized than diseases with longer incubation periods, such as hepatitis A.[110]

2.4.3. Determining the Etiologic Agent in an Outbreak

2.4.3.1. Laboratory confirmation of etiologic agent

Laboratory testing of clinical specimens from ill persons is critical in determining the etiology of a suspected foodborne disease outbreak and implementing appropriate control measures. For most foodborne diseases, stool is the specimen of choice; however, samples of blood, vomitus, or other tissues or body fluids are occasionally indicated. Specimens are collected as soon as possible after onset of illness from persons who manifest illness typical of the outbreak and who have not undergone antibiotic treatment. The number of specimens collected depends on the suspected agent and capacity of the testing laboratory; ideally, specimens from 5–10 persons are collected and tested. Methods for collection, storage, and transport vary depending on the suspected agent (e.g., bacterium, virus, or parasite).[109, 112, 113]

Isolation of the causative agent from a suspected food item can provide some of the most convincing evidence of the source of a foodborne disease outbreak and can obviate the need for more time-consuming analytic epidemiologic approaches. Food testing, however, has inherent limitations. Specific contaminants or foods might require special collection and testing techniques, and demonstration of an agent in food is not always possible. Because contaminants

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in food change with time, samples collected during an investigation might not represent those ingested when the outbreak occurred. Subsequent handling or processing of food might result in the death of microorganisms, multiplication of microorganisms originally present at low levels, or introduction of new contaminants. If contamination of the food is not uniform, the sample collected or portion analyzed might miss the contaminated portion. Finally, because food is usually not sterile, microorganisms can be isolated from samples but not be responsible for the illness under investigation. False-negative results are more likely than false-positive results and are of little significance. In other words, a negative result does not rule out a food item as the source of an outbreak.

Food testing can be an important adjunct to many investigations of commercial products, but testing without a specific focus can be prohibitively expensive. As a result, food testing should not be undertaken routinely but should be based on meaningful associations, such as reports of ill persons eating the same food product or an environmental health investigation that identifies specific food safety problems.

2.4.3.2. Other clues to the etiologic agent

During the wait for laboratory confirmation, the following information can help shorten the list of likely agents causing an outbreak:

- Predominant signs and symptoms among ill persons;
- Incubation period, if known;
- Duration of illness; and
- Food history leading to suspected food, if known.

An example of how predominant signs and symptoms and incubation period can be used to help determine the etiologic agent in an outbreak is provided in Appendix 2.

In determining the clinical characteristics of ill persons in an outbreak, most investigators question ill persons specifically about the occurrence of a standard set of signs and symptoms often associated with foodborne diseases. A commonly used set of signs and symptoms includes headache, nausea, vomiting, myalgia (muscle aches), abdominal (stomach, belly) cramps, unusual fatigue (feeling tired), fever (and whether temperature was measured), chills, any diarrhea or loose stools, three or more loose stools within a 24-hour period, and any blood in the stool. Negative findings can be as pertinent as positive findings and should be recorded.

The incubation period is the time from exposure to the etiologic agent to development of symptoms. Determining the incubation period for an illness is influenced by whether the calculation is based on onset of the prodromal symptoms (e.g., general feeling of being unwell) or specific signs and symptoms of enteric disease (e.g., vomiting or diarrhea) that may occur later. Because ill persons typically recall onset of the latter more clearly, some investigators consistently use onset of these "hard" symptoms to calculate the incubation period. Many investigators, however, collect information from both times (where applicable), generally using onset of hard symptoms as the default. For most etiologies it is important to collect both the date and the specific time of symptom onset.

2.4.3.2.1. Signs, symptoms, incubation period, and duration of illness

In identifying the likely etiologic agent in an outbreak on the basis of signs, symptoms, incubation period, and duration of illness, it is often helpful to first categorize a suspected foodborne illness as resulting from a preformed toxin, enterotoxin, or infection.

Illnesses from preformed toxins are caused by ingestion of food already contaminated by toxins. Sources of preformed toxin include

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certain bacteria, poisonous chemicals, heavy metals, and toxins found naturally in animals, plants, or fungi. Preformed toxins most often result from bacteria, such as *Staphylococcus aureus*, *Bacillus cereus*, and *Clostridium botulinum*, that release toxins into food during growth in the food. The preformed toxin is ingested; thus live bacteria do not need to be consumed to cause illness.

Illness from a preformed toxin manifests more rapidly than does illness from an enterotoxin or infection because time for growth and invasion of the intestinal lining or production of enterotoxin is not required. The incubation period for illnesses from a preformed toxin is often minutes or hours.

Signs and symptoms depend on the toxin ingested but commonly include vomiting. Other symptoms can range from nausea and diarrhea to interference with sensory and motor functions, such as double vision, weakness, respiratory failure, numbness, tingling of the face, and disorientation. Fever is rarely present.

Infections result from growth of a microorganism in the body. Illness results from two mechanisms:

- Viruses, bacteria, or parasites invade the intestinal mucosa and/or other tissues, multiply, and directly damage surrounding tissues; or
- Bacteria and certain viruses invade and multiply in the intestinal tract and then release toxins that damage surrounding tissues or interfere with normal organ or tissue function (enterotoxins).

The necessary growth of the microorganism, damage of tissues, and production and release of toxins takes time. Thus, the incubation periods for infections are relatively long, often days, compared with minutes or hours as with preformed toxins.

Symptoms of infection usually include diarrhea, nausea, vomiting, and abdominal cramps. Fever and an elevated white blood cell count can also occur. If an infectious agent spreads from the gut to the bloodstream, other organs (e.g., liver, spleen, gallbladder, bones, and meninges) can be affected, resulting in an illness of longer duration, increased severity, and signs and symptoms associated with the particular organ affected.

2.4.3.2.2. Suspected food

Certain microorganisms are associated with certain food items because the food derives from an animal reservoir of the microorganism or the food provides conditions necessary for the survival and growth of the organism. As a result, the food item suspected in an outbreak, if known, can occasionally provide insight into the etiologic agent (Table 2.2). However, most foods can be associated with a variety

Table 2.2. Examples of food items and commonly associated microorganisms *(based on Chamberlain 2008)*[116]

ITEM	COMMONLY ASSOCIATED MICROORGANISM
Raw seafood	*Vibrio* spp., hepatitis A virus, noroviruses
Raw eggs	*Salmonella* (particurlarly serotype Enteritidis)
Undercooked meat or poultry	*Salmonella* and *Campylobacter* spp., Shiga toxin-producing *Escherichia coli* (STEC), *Clostridium perfringens*
Unpasteurized milk or juice	*Salmonella*, *Campylobacter*, and *Yersinia* spp., STEC
Unpasteurized soft cheeses	*Salmonella*, *Campylobacter*, *Yersinia Listeria monocytogenes*, STEC
Home-made canned goods	*Clostridium botulinum*
Raw hot dogs, deli meat	*Listeria* monocytogenes.

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of etiologic agents, and new vehicles for transmission emerge each year. Therefore, care must be taken in inferring the etiologic agent from the suspected food item.

2.4.4. Mode of Transmission

Many agents responsible for foodborne illness also can be transmitted by other routes, such as drinking water, recreational water, and person-to-person and animal-to-person transmission. For example, only an estimated 31% of shigellosis cases, 8% of cryptosporidiosis cases, and 26% of norovirus infections result from foodborne transmission.[114] Consequently, early in the investigation of a possible foodborne disease outbreak, investigators should consider all possible sources of transmission and collect information from ill persons about sources of drinking water, exposure to other ill persons and child care settings, exposure to recreational water, and contact with animals and their environments, as well as about food and other environmental exposures.

Although in-depth interviews of persons with suspected cases and epidemiologic, environmental health, and laboratory studies are necessary to confirm suspicions about the mode of transmission in an outbreak, characteristics among cases or timing of illness onset might provide clues that suggest one mode of transmission over others and enable investigators to focus on investigating that source.

2.4.4.1. Transmission by food

Illness among persons with the following characteristics might suggest transmission of an agent by food:

- Persons who have shared a common meal or food, and onset of illness is consistent with when the shared meal or food was consumed;
- Persons with distinctive demographic characteristics (i.e., age group, sex, and ethnicity) and possibly unique food preferences; or
- Persons with a geographic distribution similar to the geographic distribution of food products.

2.4.4.2. Transmission by water

The following clues might suggest transmission of an agent by drinking water:

- Widespread illness affecting persons of both sexes and all age groups;
- Geographic distribution of cases consistent with public water distribution but not food distribution patterns (e.g., limited to persons residing within city limits or a clustering of cases adjacent to cattle ranches or farms served by well water);
- Absence of cases among breast-fed babies or persons who drink only bottled water or beverages from boiled water;
- Dose-response with increasing attack rates among persons drinking more water;
- Concurrent complaints about water quality in the affected community; or
- Involvement of multiple pathogens.

A clustering of cases among children, particularly children who have shared a common recreational water exposure, such as a water park, community pool, or lake, might suggest transmission by recreational water.

2.4.4.3. Transmission from person-to-person

Person-to-person transmission should be suspected when

- Cases are clustered in social units such as families, schools (and classes within schools), nursing homes, dorms or dorm rooms, and sororities/fraternities; and
- Cases occur in waves separated by approximately one incubation period of the etiologic agent.

2.4.4.4. Transmission from fomites

The importance of nonfood environmental sources in transmission is poorly understood,

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but outbreaks that initially appear to be foodborne are occasionally linked to other sources. For example, a norovirus outbreak after a business luncheon was eventually linked to environmental contamination from a child with diarrhea.[115] In another instance, a protracted outbreak of salmonellosis was originally linked to consumption of pasteurized milk, but the vehicle was ultimately shown to be externally contaminated milk cartons (i.e., not the milk itself). [*Salmonella* Braenderup in Oregon, B. Keene, unpublished data, 2013].

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CHAPTER

3

Planning and Preparation

The primary goal of a foodborne disease outbreak investigation is to implement control measures as quickly as possible to halt transmission of illness. Another important goal is to understand the processes that led to food contamination or pathogen transmission well enough to prevent similar outbreaks. Good planning and preparation, bringing the right expertise to the investigation, communicating quickly with all organizations that should be involved, and rapidly sharing investigation findings can accomplish these goals.

The early days of an investigation are critical. Ideally an agency should always be prepared for an investigation so it will spend as little time as possible getting organized once an outbreak is identified. This chapter describes the roles of the major agencies involved in foodborne disease outbreak response and highlights the resources, processes, and relationships that should be in place before an outbreak. The chapter also provides links to related topics and more detailed information about outbreak investigation and response throughout these Guidelines.

3.0. Introduction

When a possible foodborne disease outbreak is first detected or reported, investigators will not know whether the disease is foodborne, waterborne, or attributable to other causes. Investigators must keep an open mind in the early stages of the investigation to ensure that possible causes are not prematurely ruled out. Although these Guidelines focus on foodborne disease, the agency roles and responsibilities described in this chapter, and many of the surveillance and outbreak detection methods described in Chapter 4 and the outbreak investigation methods described in Chapter 5 apply to a variety of enteric and other illnesses, regardless of the source of contamination.

3.1. Agency Roles

3.1.1. Overview

A foodborne disease outbreak may be managed solely by one local agency or may become the shared responsibility of multiple local, state, and federal agencies. The nature of the outbreak, including the type of pathogen, suspected or implicated vehicle, number and location of affected persons, geographic jurisdictions involved, and local and state food-safety rules and laws, will determine the types of agencies that need to be involved. Section 7.2 in these Guidelines provides detailed information about the major indicators that an outbreak requires a multijurisdictional response (i.e., response by multiple agencies and agencies at different levels of government).

Outbreak response will also be influenced by agencies' roles and responsibilities and typically available resources. Each agency's response plan should include its likely role in a foodborne disease 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.

3.1.2. Local, State, and Federal Agencies

Across the country, state and local agencies differ widely in their organizational structure, responsibilities, and relationships. The sections below summarize typical responsibilities for agencies at the local and state levels. However, assignment of those responsibilities will vary depending on a particular state's organizational, legal, and regulatory structure; the distribution of responsibilities across different types of state and local agencies; and the size and capacity of the local agencies.

3.1.2.1. Local health agencies

Throughout the United States, local health agencies vary extensively—from those in small rural communities serving a population of 20,000 or less to those in large metropolitan areas serving populations of eight million or more. Consequently, the size, complexity of function, and availability of resources differ significantly among agencies. However, all local health agencies conduct the following roles and responsibilities to greater or lesser degrees.

- Roles and responsibilities

  Conduct surveillance; receive complaints about possible foodborne illnesses; maintain and routinely review complaints of possible foodborne illnesses; routinely communicate with local health-care professionals; conduct interviews and gather information from ill persons in local or multijurisdictional outbreaks; regulate food-service operations; routinely inspect food-service operations; investigate complaints about food-service operations; implement control measures to stop outbreaks; educate food workers about preventing outbreaks of foodborne disease; inform the public and the media;

3.1. Agency Roles

serve as liaison with local food industry representatives and with the state and federal public health and food-safety regulatory agencies. May also provide advanced laboratory testing, including subtyping, such as molecular fingerprinting in the National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet).

- Resources
  Vary by agency but may include expertise in epidemiologic and environmental outbreak investigation and response and health education and promotion information for dissemination to the public. Extensive knowledge of local populations and community businesses, health-care providers and organizations, and other resources.

- Contribution to outbreak investigation and response
  Detect foodborne diseases; identify local outbreaks; know about suspected facilities (e.g., facility inspection reports, previous complaints); support recall efforts; know affected communities; know local health-care professionals and diagnostic practices.

3.1.2.2. State agencies—health department

- Roles and responsibilities
  Conduct surveillance; identify local and statewide outbreaks; coordinate multijurisdictional outbreaks; provide advanced laboratory testing, including molecular fingerprinting in PulseNet; support or direct environmental, laboratory, and epidemiologic investigations with advanced expertise; investigate outbreaks associated with commercially distributed products; provide health education and promotion materials; maintain tools for collecting and analyzing outbreak-associated information; provide public information; provide legal support for outbreak investigation and control; promote statewide policies to increase food safety; serve as liaison, and coordinate communication with other state, local, and federal agencies and (in some instances) with food corporations; disseminate information to local agencies. May conduct investigations in local areas where there is no local health agency with jurisdiction.

- Resources
  Expertise in epidemiologic and environmental outbreak investigation and response (including traceback investigations); expertise in specific disease agents; advanced laboratory testing with expertise in microbial analyses and identification through state laboratories; tools for collecting and analyzing outbreak-associated information; health education and promotion information (often in multiple languages) for dissemination to the public; additional staff to aid in outbreak investigations.

- Contribution to outbreak investigation and response
  Epidemiologic, environmental, and laboratory support for local health agencies; coordination of multijurisdictional outbreaks.

3.1.2.3. State agencies—environmental health

Note: these roles may be carried out by agencies with different names, including environmental conservation or quality.

- Roles and responsibilities
  Support or direct environmental testing; provide advanced laboratory testing of food or environmental samples; provide educational materials to public about food and environmental safety; maintain tools for collecting and analyzing outbreak-associated information; promote statewide policies to increase food and environmental safety; serve as liaison with other state, local, and federal agencies; disseminate information to local agencies.

3.1. Agency Roles

- Resources
  Expertise in foodborne and environmental outbreak investigation and response, as well as regulatory food inspections; advanced laboratory testing of food and environmental samples with expertise in microbial analyses and identification.

- Contribution to outbreak investigation and response
  Environmental investigation and laboratory support for local health agencies, sometimes takes the lead in foodborne disease outbreak investigation.

3.1.2.4. State agencies—food-safety regulatory authorities

Note: these roles may be carried out by agencies with different names, including Department of Agriculture, Food Protection, Health or Environmental Health.

- Roles and responsibilities
  Ensure good manufacturing practices in commercial food operations; test dairy, meat, and food products for microbial contamination; inspect plant(s) after they are implicated in an outbreak; coordinate food recalls conducted by industry; and stop sales of adulterated product within their jurisdictions. Conduct regulatory sanitation inspections at commercial food operations, retail establishments, such as grocery stores, supermarkets, and warehouses. Consult with health departments in outbreak investigations (e.g., support through knowledge of food production and distribution and information provided by industry that may contribute to the success of investigations). Conduct investigational tracebacks as part of exposure assessments in epidemiologic studies. Conduct environmental health assessments at locations where food may have been contaminated.

- Resources
  Expertise in food manufacturing and distribution; staff to conduct plant inspections and specialized testing of dairy, meat, and food products; expertise in regulatory tracebacks. Laboratory support, usually involving surveillance for food adulterants, including chemical, physical, and microbiological adulterants and contaminants.

- Contribution to outbreak investigation and response
  Support investigations that involve commercially distributed food products through consultation with health department investigators, plant inspections, traceback investigations, and food recalls.

3.1.2.5. Federal agencies—Centers for Disease Control and Prevention

- Roles and responsibilities
  Conducts or coordinates national surveillance for illnesses caused by pathogens commonly transmitted through food and for outbreaks of foodborne diseases of any cause; leads and supports national surveillance and communication networks, including Laboratory-based Enteric Diseases Surveillance system (LEDS), Foodborne Diseases Active Surveillance Network (FoodNet), PulseNet, Environmental Health Specialists Network (EHS-Net), and Foodborne Disease Outbreak Surveillance System (FDOSS); maintains clinical, epidemiologic, and laboratory expertise in pathogens of public health importance; develops and implements better tools for public health surveillance; provides consultation, assistance, and leadership in outbreak investigations; improves and standardizes laboratory testing methods for foodborne disease pathogens; provides advanced laboratory testing; facilitates coordination among jurisdictions within multijurisdictional outbreaks, where appropriate; coordinates communication with other federal agencies; provides training in investigation and laboratory methods;

3.1. Agency Roles

under the Food Safety Modernization Act (FSMA), coordinates Integrated Food Safety Centers of Excellence, partnerships between state health departments and academic centers to provide technical assistance and training on epidemiologic, laboratory, and environmental investigations of foodborne illness outbreaks and associated analyses (www.cdc.gov/foodsafety/fsma.html#section399); coordinates and collaborates with international surveillance, communication, and training methods; works to prevent and control outbreaks on cruise ships.

- Resources
  Experts (or trainees) in clinical, epidemiologic, and environmental health aspects to assist with cluster evaluation and outbreak investigations; advanced laboratory capacity (including resources to develop new testing methods); surge capacity to assist in large outbreaks; tools for collecting and analyzing outbreak-associated information; training programs; health education and promotion materials for the public; resources through the Foodborne Disease Centers for Outbreak Response Enhancement (FoodCore) program, centers based in health departments around the country that work together to develop model practices for outbreak response so that others can learn from their experiences and replicate what works best (www.cdc.gov/foodcore/index.html).

- Contribution to outbreak investigation and response
  Assistance in single-jurisdiction outbreaks upon request of the jurisdiction; leadership, coordination, and logistics support and coordination for multijurisdictional outbreaks; centralized data collection and analysis for large multistate outbreaks; assistance in outbreaks from new or rare disease agents or from new modes of transmission of known disease agents; advanced laboratory testing; availability of additional personnel and other resources to aid local and state health agencies; conduit to other federal agencies.

3.1.2.6. Federal agencies—Food and Drug Administration

- Roles and responsibilities
  Named as lead agency for food safety under the Food Safety Modernization Act (FSMA) with a focus on preventing outbreaks through requirements placed on food-production facilities to implement contamination prevention plans, ability to regularly monitor those facilities, and ability to issue product recalls if necessary. Oversight of imported food, with ability to conduct inspections and refuse admission of imported food products. Regulates the safety of most foods (except meat, poultry, and pasteurized egg products, which are regulated by USDA's Food Safety and Inspection Service [USDA-FSIS]). Regulates dietary supplements, food additives, and food labeling for FDA-regulated foods, and oversees seafood and juice regulations for Hazard Analysis and Critical Control Points. Conducts research into foodborne contaminants. Conducts post-market surveillance and compliance of food industry. Oversees regulatory traceback investigations and recalls of food products. Publishes the FDA Food Code. Regulates ships that travel interstate, such as on rivers and intercoastal waters, as well as trains and buses that travel interstate. Improves and standardizes laboratory testing methods for foodborne disease pathogens; provides advanced laboratory testing; assists non–federal, governmental food laboratories in becoming accredited to the ISO/IEC 17025:2005 standard. Facilitates coordination among jurisdictions within multijurisdictional outbreaks, where appropriate; coordinates communication with states and other federal agencies;

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provides training in investigation and testing methods; coordinates and collaborates with international food regulatory agencies, communication, and training methods.

- Resources

  The Coordinated Outbreak Response and Evaluation network (CORE) is a dedicated multidisciplinary team of expert epidemiologists, microbiologists, environmental health specialists, consumer safety officers, and communications specialists who coordinate FDA's response to foodborne disease outbreak events. CORE coordinates the efforts of 20 District Offices located in five regions (www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm135269.htm) that provide field investigators, laboratory support, technical consultation, regulatory support, media relations and liaison with states and Rapid Response Teams (RRTs; See section 3.1.2.8). CORE is supported by subject-matter experts from FDA's Center for Food Safety and Applied Nutrition and the Office of Regulatory Affairs, who provide policy, technical, and scientific support to foodborne disease outbreak investigations and education materials for the public.

- Contribution to outbreak investigation and response

  Assistance in identification of the food product(s) associated with an outbreak, the source, and the extent of distribution; testing of product(s) obtained from commerce or production; traceback and environmental health assessments, including investigational tracebacks as part of exposure assessments in epidemiologic studies; prevention of further exposure to contaminated product(s); initiation of regulatory action, including mandating recalls, if appropriate; and assistance to the Federal Bureau of Investigation (FBI) when deliberate contamination of food is suspected.

3.1.2.7. Federal agencies—U.S. Department of Agriculture, Food Safety and Inspection Service

- Roles and responsibilities

  Ensures the nation's commercial supply of meat, poultry, and pasteurized egg products is safe, wholesome, and correctly labeled and packaged through a national program of inspection, investigation, and enforcement; provides data analysis, advice, and recommendations on food safety; conducts microbiological testing of meat and poultry products; responds to foodborne illnesses, intentional food contamination, and major threats to FSIS-regulated products, including overseeing recalls for contaminated meat and poultry products; conducts audits to determine the equivalency of foreign food-safety systems and re-inspecting imported meat, poultry, and egg products; develops public information and education programs for consumers.

- Resources

  Approximately 7600 inspection program personnel who provide daily regulatory oversight at more than 6000 FSIS-regulated establishments nationwide coordinated by 10 district offices; three field laboratories, including the Outbreaks Section of Eastern Laboratory in Athens, Georgia; field investigators with expertise in inspection, traceback, and enforcement; personnel with expertise in food safety and public health science and in performing environmental health assessments; educational materials and guidance for consumers.

- Contribution to outbreak investigation and response

  Assistance, traceback coordination, and epidemiologic consultation during investigations involving FSIS-regulated meat, poultry, and egg products; conducting investigational traceback investigations as part of exposure assessments in epidemiologic studies; testing of product

3.1. Agency Roles

from commerce or production; ability to take enforcement and regulatory control actions against food manufacturers and distributors; assistance in working with international food manufacturers and distributors; consultation to public health and state agriculture agencies.

3.1.2.8. Cross-agency program—Rapid Response Teams

The FDA Rapid Response Team (RRT) Project is an FDA initiative that partners with state programs to build food-safety infrastructure and integrated rapid response for all-hazards food emergencies. FDA works with 19 pilot RRTs through cooperative agreements to improve food program infrastructure; strengthen collaboration among local, state, and federal partners; and create fully integrated and sustained response capabilities for food emergencies. The knowledge gained from this initiative is being captured in the RRT Best Practices Manual (www.afdo.org/Resources/Documents/6-resources/TheRRT Manual_2013_FINAL.pdf). In states where they exist, the RRT assumes the role of the Outbreak Investigation and Control Team, as described in section 3.2 below, for multijurisdictional and/or state-level outbreaks.

3.1.2.9. Cross-agency program—Food Emergency Response Network (FERN)

USDA-FSIS and FDA co-lead the Food Emergency Response Network (FERN), 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. FERN has four primary responsibilities: prevention, preparedness, response, and recovery. Although FERN was begun with terrorism in mind, the network has played a crucial role during large-scale foodborne disease outbreaks, including the 2011 multistate outbreak of listeriosis linked to cantaloupes. FERN laboratories have the capability to detect and identify biological, chemical, and radiologic agents in food and provide food-testing surge capacity during national emergencies. More information about FERN is available at www.fernlab.org.

3.1.2.10. Cross-agency program—Federal Multi-Agency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO)

The Federal Multi-Agency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO) was established to ensure a rapid and coordinated response by federal agencies to large-scale and/or complex foodborne illness outbreaks, including outbreaks caused by intentional food contamination. When activated MAC-FIO will meet regularly to provide policy direction and prioritize resources applied to the response, as appropriate. MAC-FIO also coordinates and collaborates with local, state, and tribal government officials. MAC-FIO, co-chaired by the Director of the USDA Office of Homeland Security and Emergency Coordination and the Health and Human Services Assistant Secretary for Preparedness and Response, includes officials from supporting agencies with decision-making authority.

3.1.3. Other Agencies

Outbreaks can occur in facilities or communities managed by agencies that have some level of autonomy and operate their own public health programs. Such agencies include tribes, the military, and the U.S. Department of the Interior (National Park Service [NPS]). The FBI or other law enforcement agency may assume leadership of the outbreak investigation when intentional contamination of a food is suspected or confirmed, with the initial lead agency shifting to a supporting role. Local, state, and federal public health agencies need to understand the jurisdictional issues in outbreaks involving these settings and available resources, and establish relationships with these agencies before any outbreaks.

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3.1.3.1. Tribes

- Jurisdiction
  Varies by tribal organization, but in general the tribes have complete sovereignty and are completely autonomous. Investigations may be conducted by tribal health staff, Indian Health Service (IHS) staff, or state or local health departments, but nontribal entities can become involved in an investigation only at the tribe's request. No legal requirement exists for reporting a foodborne disease outbreak to any public health officials, although memoranda of understanding between tribal governments and local or state agencies may establish lines of communication and reciprocal support during public health emergencies. Control measures typically are implemented by IHS staff in cooperation with tribal government but can be implemented only when authorized by tribal government.

- Relationships
  Outbreaks may be detected by IHS staff or by tribal members and reported to IHS. IHS notifies the appropriate state and local health departments. Some tribes also may notify the local or state health department or CDC. State and local health department staff need to develop relationships with IHS public health staff, tribal health staff (if any), and tribal leadership in tribal areas within or adjacent to the public health agency's jurisdiction. During an outbreak, communication should be ongoing, not only between state or local health department and IHS, but also directly with tribal government. Regional tribal epidemiology centers, run by tribal boards, provide epidemiology capacity for multiple tribes and focus on health issues selected by the boards. They may become involved in outbreak investigations and are a good place to promote routine communication. IHS is a good source of information about coordinating public health issues with tribes.

- Resources for outbreak investigation and response
  IHS has many public health staff, including sanitarians and public health nurses, at clinics on many tribal lands. These staff most likely would handle an outbreak and would request help from IHS, the state, or CDC, if needed. Some tribes have public health staff, but most do not have public health laws or the capacity to respond to outbreaks.

3.1.3.2. Military

- Jurisdiction
  Autonomous authority over all military bases, facilities (including food-production and food-service facilities and health-care facilities), and vehicles. Jurisdiction depends on the particular branch of the military involved and whether the U.S. Department of Defense maintains public health responsibility.

- Relationships
  Military public health personnel communicate with local and state health agencies for outbreaks that might involve civilians. Local and state health agencies should establish communication with the public health staff of any military facilities within or adjacent to their jurisdiction before any outbreaks. Other branches of the military and other federal agencies communicate through the Multi-Agency Coordination Group for Foodborne Illness Outbreaks (established by the U.S. Department of Health and Human Services and USDA) which is activated in response to large-scale and/or complex foodborne illness outbreaks (see 3.1.2.10).

- Resources for outbreak investigation and response
  Military agencies conduct training in food safety and epidemiology; inspect and test food-production and food-processing facilities and delivered food products; and coordinate these programs with other military and

3.1. Agency Roles

federal agencies. Preventive medicine and environmental health officers in each branch direct and conduct epidemiologic investigations of foodborne disease outbreaks and make recommendations. Veterinary officers conduct traceback investigations. The Department of Defense has officers trained in public health, environmental health, epidemiology, microbiology, toxicology, pathology, and food technology who can coordinate and support outbreak investigations.

3.1.3.3. National Park Service

- Jurisdiction

  Jurisdiction in National Parks is a function of the legislation designating the specific park. Three types of jurisdiction exist: a) exclusive federal jurisdiction; b) concurrent jurisdiction with state and local agencies; and c) proprietary (owned by the federal government but sometimes operated by a local entity and dependent on support from local police, fire departments, and others for services).

- Relationships

  Notifies relevant local and state health departments of suspected outbreaks. Notifies appropriate federal agency if commercial product is suspected. Works closely with CDC. Relies on CDC or state health departments for laboratory testing. Local and state health agencies whose jurisdiction contains or is adjacent to a national park should establish communication with the NPS Office of Public Health before any outbreaks. Where appropriate, local and state health departments should include questions about visiting parks when they conduct interviews during an investigation and notify NPS if a park might be involved.

- Resources for outbreak investigation and response

  Epidemiologic expertise, including a medical epidemiologist in the NPS Office of Public Health; U.S. Public Health Service staff assigned to NPS to conduct investigations (including regional public health consultants based around the country); park rangers who have extensive knowledge of their jurisdiction and the population that visits that jurisdiction; scientists in the NPS system with a wide range of expertise (e.g., veterinarians, water specialists, environmental health); contractors who run park operations on behalf of NPS including health clinics in selected sites.

3.1.3.4. Other federal lands

- Jurisdiction

  NPS jurisdiction is described above. Public health jurisdiction on other types of federal land is not always easy to determine. On many federal lands (e.g., national forests, Bureau of Land Management land), state laws apply, but federal agencies may have overlapping jurisdiction. State laws generally do not apply to federal prisons. Each public health agency that contains federal lands within its jurisdiction should identify the responsible local, state, and federal agencies before an outbreak.

3.1.3.5. Law enforcement

If intentional contamination of food or other criminal activity is suspected, law enforcement agencies at the local, state, and federal levels will become involved in the investigation and may assume leadership of the outbreak investigation, with the initial lead agency shifting to a supporting role. Agencies responsible for controlling foodborne disease outbreaks should establish relationships and communication pathways with law enforcement agencies before any outbreak. Any suspicion of intentional contamination should be reported immediately to law enforcement agencies.

3.1. Agency Roles

3.1.4. Industry—Food Manufacturers, Distributors, Retailers, and Trade Associations

- Roles and responsibilities
  Growing, raising, processing, manufacturing, packaging, distributing, storing, and selling food by using practices that protect the public's health; withdrawing or recalling products from the marketplace when they have been identified as the source of a foodborne disease outbreak; communicating with the public about outbreaks associated with food products.

- Resources
  Knowledge of and information about product brands, formulations, possible food-safety hazards, processing practices, and distribution patterns to assist with outbreak hypothesis generation and testing and product/ingredient tracing. Some industry members have expertise in microbiology and food-safety research.

- Contribution to outbreak investigation and response
  Source of information about the products and practices under investigation, including product characteristics, formulations, distribution patterns, market share, and customers that have purchased the products; working collaboratively to establish a framework for rapid communication and information sharing with the public; outbreak hypothesis generation and testing; mechanisms for withdrawing/recalling products from the marketplace.

3.1.5. Academic Centers

In some communities, academic centers are available to partner with agencies during investigations by conducting special laboratory analyses or providing additional resources, conducting interviews, or implementing control measures. In particular, CDC has designated five Integrated Food Safety Centers of Excellence across the country where academic centers have partnered with state health departments to provide technical assistance and training on epidemiologic, laboratory, and environmental investigations of foodborne illness outbreaks and associated analyses (www.cdc.gov/foodsafety/fsma.html#section399). Academic centers also can conduct applied food-safety research to expand results of investigations, including work that might identify additional causal factors for outbreaks, and test alternative control measures. USDA's National Institute of Food and Agriculture (USDA-NIFA) Food Virology Collaborative for Outreach, Research, and Education (NoroCORE) includes academic institutions that are working to strengthen food safety by studying human noroviruses across the food supply chain in an effort to design effective control measures and prevent viral foodborne illness. The published results from research can help inform future outbreak investigations and those implementing control measures. Relationships with academic centers and expectations for their role in outbreak response should be established before any outbreak.

3.1. Agency Roles

CIFOR Keys to Success: Focus Area 1—Relationship with relevant agencies and organizations

Roles and Responsibilities

- Agency/jurisdiction has procedures for working with other agencies and organizations during an outbreak response. Procedures are written and easily accessible by staff.
- Agency/jurisdiction determines in advance the role of the local incident command system (ICS) in the response to an outbreak.
- Staff understand the likely roles/responsibilities of key agencies and organizations during an outbreak response, the resources they have available, and the contributions they can make to an outbreak response.
- Agency/jurisdiction cross-trains with other key agencies and organizations to better understand its roles and responsibilities during an outbreak response.

Communication

- Staff know how to contact key local, state, and federal agencies likely to be involved in foodborne disease outbreak response.
- Agency/jurisdiction has procedures for communication between members of the outbreak investigation and control team and their agencies and with other agencies and organizations involved in foodborne disease outbreak response.
- Staff undertake routine communication with key agencies and organizations before an outbreak occurs.

Multijurisdictional Outbreaks

- Staff readily recognize signs suggestive of a multijurisdictional foodborne disease outbreak.
- Staff rapidly notify agencies that might need to participate in a multijurisdictional outbreak response or will be affected by the event.

Making Changes

- Agency/jurisdiction debriefs investigators after each outbreak response, and refines outbreak response planning based on lessons learned.
- Agency/jurisdiction has performance indicators related to relationships with other agencies and routinely evaluates its performance in this Focus Area.

3.2. Outbreak Investigation and Control Team

3.2.1. Overview

The responsibility for investigating foodborne disease outbreaks and implementing control measures falls 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 one or two to hundreds. In smaller investigations, individuals may fulfill multiple roles concurrently. A team is more likely to effectively and efficiently respond to an outbreak if team members combine their strengths and collaborate.

Team members' assigned tasks and their knowledge and skills define their roles. Job titles alone might not accurately indicate who does what. Members may come from different programs within an agency or

3.2. Outbreak Investigation and Control Team

from different agencies. Membership in the outbreak investigation and control team can vary depending on the specifics of the outbreak—for example, different disease pathogens or different outbreak settings require different skills or agency associations. 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 (NIMS) which federal agencies are now mandated to utilize (see Section 3.10 for more specifics about NIMS and Incident Command Systems).

The composition of foodborne disease outbreak investigation and control teams should be determined before any outbreaks. Team members should be pre-assigned specific tasks and should receive training if necessary to ensure they know how to carry out those tasks. They also should understand the roles of the other team members.

Most importantly, team members should work closely together. Their roles are not mutually exclusive; for example, epidemiologists can help laboratorians; environmental health specialists can help epidemiologists. Furthermore, the work of one team member often builds on the work of others. The team cannot succeed without a strong working relationship and ongoing, effective communication among its members. Key principles of outbreak investigation, including leadership and communication among team members, are covered in Section 5.1.2. The process for activating the outbreak investigation and control team is described in Section 5.2.2.

3.2.2. Roles of Core Team Members

The same person(s) may play many of these roles, depending on the size of the investigation.

3.2.2.1. Team leader

- **Responsibilities**
  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.

- **Desirable skills**
  Organization of investigation information; general knowledge of all elements of an outbreak investigation and the roles of each team member; specific expertise with outbreak investigation methods and with foodborne infections; understanding of roles of all agencies involved in investigation; ability to communicate; leadership skills.

3.2.2.2. Epidemiologic investigator

- **Responsibilities**
  Identifies and interviews cases; develops hypotheses and strategies to test them; interviews both cases and healthy controls; plans epidemiologic studies; 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.

- **Desirable skills**
  Ability to rapidly assess a situation; interpret surveillance information; design epidemiologic studies (e.g., case–control studies, cohort studies, and surveys) and develop questionnaires; conduct epidemiologic studies; conduct interviews, including hypothesis-generating interviews;

3.2. Outbreak Investigation and Control Team

with assistance from the laboratory investigator, identify appropriate clinical tests for suspected pathogens; and analyze and interpret data using standard epidemiologic methods as defined in the Applied Epidemiology Competencies, including measures of association and tests of statistical significance (www.cste.org/group/CSTECDCAEC).

3.2.2.3. Environmental investigator

- Responsibilities

  Investigates food preparation sites, including sites involved with growing, raising, processing, manufacturing, packaging, storing, and preparing food; collects environmental and food samples, and documents and maintains adequate chain of custody of the samples through their delivery to the testing laboratory; arranges for testing of samples; coordinates food sampling, management, and testing procedures with laboratory investigator; reports results; interviews food workers and managers; reviews food-preparation and food-handling records; reviews food-inventory and food-distribution records, food flow, contributing factors, and environmental antecedents; consults with epidemiologic and laboratory investigators; conducts environmental health assessments to determine contributing factors and environmental antecedents/root causes; may conduct investigational traceback investigations as part of exposure assessments in epidemiologic studies; assesses industry food-safety systems following Hazard Analysis and Critical Control Point principles, where required; may also interview cases and collect stool samples; and identifies measures to prevent future outbreaks of foodborne illness.

- Desirable skills

  Ability to think critically while investigating food-production and food-preparation processes; conduct interviews; collect food and environmental samples, and document and maintain adequate chain of custody; with assistance from the laboratory investigator, identify appropriate tests for suspected pathogens. Knowledge about causative agent (e.g., likely sources, optimum growth conditions, inhibitory substances, means of inactivation), factors necessary to cause illness (e.g., infectious dose, portal of entry), and implicated vehicle (e.g., physical and chemical characteristics of the vehicle that might facilitate or inhibit growth, methods of production, processing, and preparation).

3.2.2.4. Laboratory investigator

- Responsibilities

  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 laboratory testing, including collection, handling, storage, and transport of specimens; communicates laboratory testing methods and results and the maintenance of chain of custody to USDA-FSIS and FDA investigators or other food-regulatory agency gathering evidence of food-product adulteration. USDA-FSIS and FDA recommend food-testing laboratories work to obtain accreditation under ISO standard 17025.

- Desirable skills

  Varies with the suspected outbreak agent(s) but may include knowledge of classical or molecular microbiology and organic or inorganic chemistry or radiochemistry. Whether testing food and environmental samples, clinical specimens, or both, the laboratory investigator should be familiar

3.2. Outbreak Investigation and Control Team

with optimal specimen or sample types and with transport and storage conditions, including documenting and maintaining adequate chain of custody, testing methods, and relevant laboratory-based networks (e.g., PulseNet).

3.2.2.5. Public information officer

- Responsibilities

  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.

- Desirable skills

  Ability to prepare health education messages and press releases using best practices in health education and risk communications; and speaking and presentation skills. Understands mechanisms and protocol for relating to the news media, including press, radio, and television. Ability to communicate with a diverse audience that has limited scientific knowledge.

3.2.2.6 Additional team members

Additional team members with other expertise may be needed, depending on the unique characteristics of the disease or outbreak. Such persons might include public health nurses to assist in conducting interviews or collecting clinical samples; statisticians to assist in designing investigation studies and in analyzing data for large or complex outbreaks; health-care providers to discuss laboratory results with patients and to administer treatment and prophylactic medications; and health educators to help craft communications for the public.

3.2.3. Outbreak Investigation and Control Teams—Model Practices

These model practices are all recommended; however, full implementation of all of these practices might not be possible in many jurisdictions because of resource limitations and competing priorities. Implementing as many as possible and as completely as possible will improve the effectiveness of outbreak investigation and control teams.

3.2.3.1. Emergency response unit

All agencies that are responsible for responding to outbreaks should establish a dedicated emergency response unit. In small agencies with limited outbreaks, this might be a single person who receives advanced training. In large agencies, this might be a team of senior epidemiologists, environmental scientists, and laboratorians who can train and work together. The dedicated unit should respond to all outbreaks, giving consistency to investigations and enabling development of advanced expertise. In states with an RRT, the RRT will assume this role for the state agencies.

3.2.3.2. Additional support for large-scale outbreaks

An agency's ability to conduct interviews during outbreaks will directly affect the speed of response to the outbreak. Some outbreaks are too large for one agency to conduct the necessary interviews quickly enough with available resources. Advance preparations can help mitigate the impact of a large-scale outbreak and ensure effective response.

- Identify persons within the agency or from other organizations—such as other branches of government, university students, volunteers (e.g., Medical Reserve Corps)—who would have minimal skills or knowledge and would be willing to help conduct interviews or provide other support during a large-scale outbreak.
- Develop a contact list and protocol for contacting these individuals when needed. Ensure the list includes after-hours and

3.2. Outbreak Investigation and Control Team

weekend contact information, and assign an individual or group to update it regularly.

- Develop training and job description(s) for these individuals. If possible, provide on-the-job training specific to their assigned tasks and their roles in the overall investigation. Such training could occur shortly before performance of the necessary task.
- Outbreak investigations themselves provide the best opportunity to develop outbreak investigation skills. Mentored participation in an outbreak should be a priority for training.

3.2.3.3. Agency-specific response protocol and other resources

At a minimum, the outbreak investigation and control team should have been trained in specific pre-identified protocols. The team also needs access to additional resources that can help answer questions and provide information for decision-making during an outbreak. These protocols and resources should be assembled before an outbreak.

- Prepare a response protocol based on the CIFOR guidelines but also customized to the agency's needs with specific information relevant to the agency.
- 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 (state, adjacent local health, and federal agencies). Ensure the list includes after-hours and weekend contact information, and update it regularly.
- Assemble a reference library (including online resources) with information about foodborne diseases, enteric illnesses, and control measures. Where possible include electronic resources that can be accessed by laptop computers during field investigations. Regularly review and update the contents of this reference library.
- Assemble a list of resource persons who have expertise in specific disease agents and investigation methods and contact information for these persons.
- Develop field investigation or "go" kits for environmental health investigators, including sampling utensils, thermometers, stool collection kits, and appropriate forms. Ensure that relevant field investigators have access to these kits and are aware of where they are located. Detailed information about kits and sample lists are included at the CIFOR Clearinghouse at www.cifor.us/clearinghouse/keywordsearch.cfm and in the International Association for Food Protection *Procedures to Investigate Foodborne Illness* (http://www.foodprotection.org/publications/other-publications/).

3.2.3.4. Training for the team

Ongoing training is critical for all members of the outbreak investigation and control team to ensure they are proficient at performing the duties assigned to them. 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 team role. Training also should be provided for additional tasks outside of a team member's regular role that they might be required to perform. For example, in a large outbreak, public health nurses, environmental health specialists, or other staff might be required to interview ill persons for epidemiologic studies and consequently should receive training specifically in how to conduct interviews. For a larger agency that investigates a large number of outbreaks, this may be on-the-job training. For a smaller agency with a limited number of outbreak investigations, special training opportunities should be arranged. Consider the use of webinar technology where there is little or no opportunity for travel.

- Ensure all team members have a common understanding of the primary goal for outbreak response, which is to implement

3.2. Outbreak Investigation and Control Team

control measures as quickly as possible to prevent illness.

- Provide team members with continuing education and training opportunities, including cross-training/joint training.
- Exercise teams together to ensure each team member understands and can perform his or her role according to agency-specific protocols and legal authorities and understands the roles and responsibilities of other team members. These exercises also can identify likely problem areas and gaps in resources.
- Conduct regional training with multiple agencies, including table-top exercises. Such training can help identify problems that might arise during a multijurisdictional outbreak.
- Make training interesting, covering not just methods and statistics but also outcomes of the people in the outbreak and the investigation.
- 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.
- Outbreaks themselves provide training opportunities. If an agency does not frequently have outbreaks, team members might be able to assist in responses to outbreaks in other jurisdictions. This can help promote learning and provide valuable insights an agency can use to refine its own protocols.
- Conduct a debriefing after each outbreak to identify lessons learned and refine the agency's response protocols.
- Foodborne disease outbreaks provide a good training ground for any epidemiologic investigation. Involving other agency staff in investigations, even if their regular job is not related to food safety, can both support the current investigation and render these staff better prepared to assist in future investigations.

CIFOR Keys to Success: Focus Area 2—Necessary Resources

Outbreak Investigation and Control Team

- Agency/jurisdiction has access to staff with knowledge and experience in epidemiology, environmental health, the laboratory, health education, and communications to help in the response to an outbreak.
- Agency/jurisdiction has a designated outbreak investigation and control team with expertise in epidemiology, environmental health, and the laboratory.
- Staff have access to and familiarity with standardized documents used in an outbreak response, including reporting forms, questionnaires, and disease-specific information sheets.

Surge Capacity

- Available resources enable agency/jurisdiction to continue other necessary (core) functions during an outbreak response.
- Agency/jurisdiction anticipates gaps in resources and identifies sources to fill those gaps before an outbreak occurs (e.g., obtaining epidemiologic support from the state public health agency, identifying outside laboratories to provide support in large outbreaks).

Making Changes

- Agency/jurisdiction conducts a debriefing among investigators after each outbreak response and refines outbreak response planning based on lessons learned.
- Agency/jurisdiction has performance indicators related to the resources necessary for outbreak response, and routinely evaluates its performance in this focus area.

3.3. Resources

3.3.1. Overview

Part of preparing to investigate a foodborne disease outbreak is assembling the necessary resources—supplies, equipment, and people—to support the outbreak investigation and control team and ensure that everything needed in the investigation and response is quickly available. Having a complete set of supplies and equipment at hand enables the outbreak investigation and control team to move rapidly into the field. Having support personnel available ensures that phone calls can be answered and data can be entered quickly into databases for analysis, reducing wasted time. Procedures for routinely reviewing and replacing missing or outdated supplies and equipment should be part of an agency's outbreak response protocol.

3.3.2. Recommended Resources

3.3.2.1. Administrative staff

Support personnel to make phone calls, answer incoming calls from concerned members of the public, enter data into a database, copy paperwork, and other administrative work.

3.3.2.2. Legal counsel

Legal counsel to prepare public health orders, review and recommend revisions in agency procedures and control measures, ensure confidentiality of health data, and address legal issues.

3.3.2.3. Equipment

- Sterilization equipment for sample collection tools and temperature probes.
- Temperature-checking probes and backups.
- Equipment to determine food characteristics (e.g., pH, water activity, sugar content).
- Capabilities and equipment for conference calls.
- Multiple phone lines.
- Computers, laptops, software (e.g., data entry, statistical), portable printers, paper, graph paper, pens, clipboards.
- Camera.

3.3.2.4. Supplies

Keep food-sample containers and investigation equipment and clinical specimen kits, including stool specimens and blood drawing kits, available at all times (Box 3.1). Foodborne disease outbreak investigation kits should be maintained in ready-to-use condition, with sampling containers and implements kept sterile. Establish, maintain, and review or verify inventory regularly (at least twice a year and preferably quarterly), particularly during and after an incident. Replace missing and expired materials and resterilize existing equipment. Detailed information about kits and sample lists are included at the CIFOR Clearinghouse at

Box 3.1. Example supplies for food and water sampling kits

- Sterile sample containers (e.g., plastic bags, wide-mouth plastic and glass jars with screw caps, bottles, whirlpack bags) and mailing instructions.
- SSterile and wrapped sample-collection implements (e.g., spoons, scoops, tongue-depressor blades, spatulas, spongesticks, swabs, knives).
- SSterile stool sample kits for food workers or cases.
- SSterilizing and sanitizing agents (e.g., 95% ethyl alcohol, sodium or calcium hypochlorite, alcohol swabs), hand sanitizers, and sanitizer test strips.
- SRefrigerants (e.g., ice packs), thermometer (0°–220°F), insulated containers.
- SLabeling and sealing equipment (e.g., fine-point felt-tip marking pen, roll of adhesive or masking tape, waterproof labels or tags, custody tape).
- SForms, including sample collection and blank laboratory submission forms, chain-of-custody and other forms for documenting activities.

3.3. Resources

www.cifor.us/clearinghouse/keywordsearch.cfm and in the International Association for Food Protection *Procedures to Investigate Foodborne Illness* (http://www.foodprotection.org/publications/other-publications/).

3.3.2.5. Outbreak investigation documents

Note: These and other sample documents are available from the CIFOR Clearinghouse at www.cifor.us/clearinghouse/keywordsearch.cfm.

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

3.3.2.6. Reference materials

- 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*.
- *Procedures to Investigate Foodborne Illness*, by the International Association for Food Protection.
- FDA's *Investigations Operations Manual* available at www.fda.gov/iceci/inspections/iom/default.htm.

3.4. Foodborne Illness Complaint Processing

As discussed in Section 4.3.9, having an organized, formal process for receiving and reviewing foodborne illness complaints from the public is a model practice. The complaint processing system should be able to cross-reference information from follow-up of cases identified through pathogen-specific surveillance. Use a standard process to collect information, including a standard intake form. Collect as much information as possible at the initial call. If the complaint is likely to be related to food, obtain an extended, detailed food history from the complainant.

The food history is important because most complainants do not accurately identify the relevant source of exposure. If possible, a single person should receive or process all foodborne illness complaints so patterns can be identified quickly. Alternatively multiple staff could take the calls using standardized data collection forms, which are then reviewed by one person. Staff receiving calls and backup staff should be trained to give appropriate instructions to callers about prevention of secondary spread and seeking health-care services.

3.5. Records Management

3.5.1. Overview

Records management is an important element of successful outbreak investigation and response. Appropriately managed records support the outbreak investigation and control team by giving all team members quick access to needed information. Requiring team members to use standard protocols for collecting and organizing information associated with an outbreak can serve a quality-assurance role and help ensure that important investigation and response steps are followed. Finally, maintaining good records for

3.5. Records Management

each outbreak can help staff identify what went wrong or worked well during the outbreak and can provide valuable information for improving outbreak investigation and response protocols. All information collected about an outbreak should be organized in an electronic database to allow easy searching and analysis.

3.5.2. Records Management—Model Practices

3.5.2.1. Information collection and sharing

- Identify standardized forms, including illness complaint forms, disease-specific report forms, and trawling interview questionnaires, for recording information about possible cases (examples of such forms are available through the CIFOR Clearinghouse at www.cifor.us/clearinghouse/keywordsearch.cfm). These forms may need to be modified in response to the specifics of the current outbreak.
- Train staff in the use of standardized forms to ensure proper completion by all members of the investigation team.
- Determine how and what information from forms and questionnaires can be properly and efficiently shared within the investigation team.
- Ensure that data are entered as soon as possible to enhance the ability to analyze as quickly as possible.
- Determine when and how to share outbreak information with the person or organization in charge of the facility implicated in an outbreak.

3.5.2.2. Data tracking and analysis

- Establish an enteric illness log or database to track all illness complaints. A database with templates for rapid data entry and analysis will streamline the data-management process.
- Identify tools used to analyze outbreak data (e.g., Epi Info, SAS). Ensure staff are trained to use these tools.
- Ensure that appropriate electronic records-management procedures are in place, including routine data backups, off-site redundant storage, and disaster recovery procedures.

3.6. Communication

3.6.1. Overview

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 good communication, 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, the time before and between outbreaks should be used to lay the groundwork for communication. This includes developing and updating contact lists, defining communication processes, and establishing relationships with key persons both internal and external to the agency.

3.6.2. Communication—Model Practices

Although these model practices for communication are all recommended, full implementation of all of these practices may not be possible in many jurisdictions because of resource limitations and competing priorities. Implementing as many and as completely as possible will improve the effectiveness of communication.

3.6. Communication

3.6.2.1. Contact lists

Establish and frequently update a contact list (primary phone numbers and alternates, cell phone numbers, 24-hour numbers, home numbers, pagers, e-mail, 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, and the agency director;
- Critical contacts in other government agencies;
- Important food industry contacts, including trade associations;
- Key health-care provider contacts; and
- Primary media contacts.

Ensure the contact list is updated at least twice yearly and, when feasible, made available to all stakeholders by electronic (e.g., e-mail updates, shared and secure website) and hard copy (e.g., laminated contact card) formats. This is usually much more difficult than expected and requires tenacity but is critical for mobilizing resources in emergencies.

3.6.2.2. Communication among the agencies and units of the outbreak investigation and control team (e.g., among epidemiology, environmental health, and laboratory)

- Ensure everyone who may be involved in outbreak response knows the other team members.
- Decide on the basis of roles who will be notified when an outbreak is suspected, including any changes in notification according to the nature of the outbreak (e.g., pathogen type, involvement of commercial product) and timing (weekends and holidays versus weekdays).
- Identify the persons who will be responsible for communication on behalf of their organizational unit (epidemiology, environmental health, laboratory) and for the outbreak investigation and control team.
- Determine how confidential information will be stored and whether and how it can be shared.
- Determine who will receive copies of written reports.
- Establish routine communication among the outbreak investigation and control team members before an outbreak.

Define a formal communication process for agencies of the outbreak investigation and control team for use during outbreaks. Options include daily phone calls and routine e-mail alerts. Developing a consistent approach to internal communications during an outbreak helps everyone on the team know what to expect.

3.6.2.3. Communication with other local, state, and federal authorities

- Identify an agency lead on interactions with local, state, and federal authorities, ideally the lead investigator. Establish procedures for coordinating communication with these entities to provide consistent messaging and accurate information flow.
- Distribute a list of your agency's contacts to other agencies, and obtain their contacts.
- Develop standardized templates and processes (including notification triggers and timelines) for sharing information with other agencies, including who will be responsible for notifying the next level of public health agency.
- Commit to notifying collaborating agencies very early in the outbreak investigation process. Most outbreaks have real or potential multijurisdictional dimensions because they may involve food in interstate commerce or persons living or traveling in multiple counties or states or because the

3.6. Communication

complexity of the investigation requires a multidisciplinary approach.

- Foster working relationships with other agencies, holding joint meetings and planning sessions before any outbreaks.
- Establish processes for participating in multiagency, multijurisdictional conference calls, and train staff in appropriate conference call etiquette.
- Determine how confidential information will be stored and whether and how it can be shared.

3.6.2.4. Communication with local organizations, food industry, and other professional groups (including health-care providers)

- Identify an agency lead on interactions with local organizations and food industry, ideally someone trained as a public information officer and who has appropriate background to answer questions. Establish procedures for coordinating communication with these groups to provide consistent messaging and accurate information flow.
- Create templates for communications with each group (e.g., press releases, fact sheets), focusing on the most common foodborne diseases and customizing by group (e.g., health-care providers, school officials, restaurant managers). Sample materials are available at the CIFOR Clearinghouse at www.cifor.us/clearinghouse/keywordsearch.cfm.
- Create and test tools for rapid communication with each group (e.g., blast e-mails, blast faxes, web-based survey instruments).
- Establish routine communications with each group (e.g., newsletters, e-mails, phone conversations), ensuring they will know with whom to communicate, triggers for reporting, and source of information during a foodborne disease outbreak. Be aware that recipients may ignore such communications, so try to make the communications interesting, relevant, succinct, and infrequent.
- Determine who will communicate with which groups during an outbreak.

3.6.2.5. Communication with the public

- Identify an agency lead on interactions with the public, ideally someone trained in communications. Establish procedures for coordinating communication with the public to provide consistent messaging and accurate information flow.
- Create templates for communications with the public (e.g., press releases, fact sheets), focusing on the most common foodborne diseases. Sample materials are available at the CIFOR Clearinghouse at www.cifor.us/clearinghouse/keywordsearch.cfm.
- Create and test web-based tools for communication with the public (e.g., blast e-mails, survey instruments, social networks).
- Establish relationships with consumer and community groups that may be helpful in disseminating information about foodborne disease outbreaks and disease prevention messages.
- Periodically issue foodborne disease prevention messages or press releases to the public to reduce illness and ensure the public knows with whom to communicate (often their primary-care provider) and from where information will come during a foodborne disease outbreak.
- Establish standard channels of communication (e.g., website, telephone number), and use those same channels each time a public health issue arises about which the public may seek information. Make sure the public knows the source, or publish it where the public is likely to access it.
- Guide staff on how to respond to and communicate with angry food-service workers, managers, and members of the public.

3.6. Communication

3.6.2.6. Communication with cases and family members

- Identify persons with clinical training, such as public health nurses or medical epidemiologists, to communicate with cases about the outbreak and actions they should take to protect their health and their family's health.
- Provide these individuals with training in communication for high stress/high outrage situations.
- Establish policies for communication with cases and family members to ensure they receive consistent and appropriate messages.

3.6.2.7. Communication with the media

- Identify an agency lead on media interactions, ideally someone trained as a public information officer. Establish procedures for coordinating communication with the media to provide consistent messaging and accurate information flow.
- Obtain media training for primary agency spokespersons.
- Identify contact persons from major local media outlets.
- Periodically hold a media education event to teach new professionals in the community's media market about public health and response to foodborne disease outbreaks.
- Identify routine deadlines and time frames for reporting news through major local media outlets (e.g., the deadline for having news from a press release appear in the evening newspaper).
- Establish standard channels of communication (e.g., website, telephone number), and use those same channels each time a public health issue arises about which the public might seek information.

CIFOR Keys to Success: Focus Area 3—Communications

Contact Lists

- Agency/jurisdiction identifies key persons and organizations related to outbreak response before an outbreak occurs, including members of the outbreak investigation and control team, officials inside the agency, contacts at external agencies (i.e., other local, state, and federal agencies), and the media.
- Agency/jurisdiction establishes and frequently updates contact lists for key individuals and organizations.

Communication Practices

- Agency/jurisdiction has procedures for communicating with key individuals and organizations. Procedures are written and easily accessible by staff.
- Agency/jurisdiction has staff trained in communicating with the media and risk communications.
- Agency/jurisdiction identifies a person(s) responsible for external communications on behalf of the agency/jurisdiction during each outbreak response.

Making Changes

- Agency/jurisdiction conducts a debriefing among investigators after each outbreak response and refines outbreak response planning based on lessons learned.
- Agency/jurisdiction has performance indicators related to communications and routinely evaluates its performance in this focus area.

3.7. Planning for Recovery and Follow-Up

3.7.1. Overview

Part of preparing for outbreak response is planning for the recovery and follow-up stages. Make sure your agency's protocols include standardized processes for recovery and follow-up; these will help ensure that appropriate actions are taken after each outbreak and investigation difficulties are identified and rectified before the next outbreak.

3.7.2. Recommended Practices for Recovery and Follow-Up

- Establish standard protocols for actions that must be taken or results that must be achieved before an implicated facility or food source can resume normal operations.
- Establish standard protocols for monitoring an implicated facility or food source if post-outbreak monitoring should be deemed necessary.
- Establish a process for creating after-action reports following investigations, with lessons learned and action items for follow-up and quality improvement.
- Detailed information about model practices for recovery and follow-up is included in Chapter 6.

3.8. Legal Preparedness

Ensuring that a given state or local public health agency has developed full legal preparedness for outbreak response provides a foundation for effective response efforts. In this context, a legally prepared health department has a) the laws and legal authorities needed to support all relevant surveillance, detection, investigation, and control activities; b) professional staff who understand and are competent in using their legal authorities; c) memoranda of agreement and other legal agreements in place for coordinated implementation of laws across jurisdictions and sectors; and d) information about best practices in using law for outbreak response. The agency also should have an attorney on call to help address specific legal issues that arise during an outbreak. See Chapter 9 for details about legal preparedness and ways an agency can develop a legal framework to support its foodborne disease control activities.

3.9. Escalation

3.9.1. Overview

Even though a single agency is likely to be able to independently manage many outbreaks, in other instances the agency will need to—and should—ask for help, particularly because many outbreaks will become part of a multijurisdictional investigation.

A cardinal rule for all foodborne disease response programs: Ask for help earlier rather than later. Don't let the trail grow cold before getting help on the scene. Affected persons recover and forget details, labs destroy specimens, and food establishments discard product. As noted at the beginning of this chapter, the primary goal of investigations of foodborne disease outbreaks is implementation of control measures as quickly as possible to prevent further illness. To fulfill this goal, an investigation may need to be escalated to involve multiple agencies. Members of the outbreak investigation and control team should frequently ask themselves whether escalation is advisable and should be ready to bring in outside help quickly.

3.9. Escalation

Even an apparently local outbreak may herald part of a much larger problem. This is especially true of an outbreak that appears to be associated with a facility that is part of a regional or national chain or when the suspected food is in general commercial distribution. Other indications of multijurisdictional outbreaks are listed in Chapter 8.

3.9.2. When to Ask for Help

- Scale or complexity of outbreak seems likely to overwhelm agency resources.
- Outbreak is known or suspected to affect multiple counties, states, or countries.
- Investigation points to a commercially distributed product.
- Nature of outbreak (e.g., likely causative agent, affected population, scale) or response is beyond the experience of agency staff.
- Specific technical support is needed that requires expertise not available in the agency.

3.9.3. How to Obtain Help

- Steps in asking for help vary by agency seeking help and the purpose of the assistance.
- At the local level, call the State Epidemiologist or his/her surrogate. Most state epidemiology offices have a 24-hour number and someone on call 24/7.
- At the state level, call the most appropriate office at CDC or the CDC emergency response number, which is staffed 24/7. Emergency response staff will contact the appropriate office at CDC.
- If the suspected product falls under the jurisdiction of one of the food regulatory agencies, call that agency using its 24-hour contact number.
- Be prepared to share as much information about the outbreak as possible including setting of the outbreak, population at risk, suspected etiologic agent, suspected source and agencies involved.

3.10. Incident Command System

3.10.1. Overview

Increasingly, agencies responding to a public health emergency, occasionally including foodborne disease outbreaks, consider using an Incident Command System (ICS) to help coordinate response.[1] ICS structures provide for internal communications within a government system between primary event responders, public information officers, and security and safety officers and for external liaison with various organizations. ICS structures provide for communication and coordination among agencies involved with responding to a multijurisdictional outbreak of foodborne disease.

The role of an ICS response in outbreak investigations varies. Even within a single investigation, some agencies may use an ICS structure, whereas others do not. In some states and local jurisdictions, ICS are formal structures controlled by public safety officials with no other jurisdiction for food safety or outbreak control, which can distract from the conduct of a public health investigation. However, some public health and food-safety agencies at the local and state levels are starting to embrace ICS and adapting the ICS structure to meet their needs. Federal agencies are required by executive order to use the ICS to address foodborne disease outbreaks so that all relevant federal agencies, as well as state and local governments, are appropriately coordinated and connected with communication and decision-making during emergencies. The ICS framework is integral to the operations of the FDA's RRTs.

3.10. Incident Command System

3.10.2. Definition and History of ICS

The ICS originally was developed in the 1970s to coordinate activities to control wildfires in California. The system has been expanded and integrated into the Federal Emergency Management Agency's National Incident Management System (NIMS) to aid intra-agency and interagency coordination, especially during large-scale emergencies that involve multiple jurisdictions. The ICS features a clearly defined chain of command with common nomenclature for key management positions; defined management sections; and a modular organizational structure; and uses specifically defined emergency response function roles.

ICS, as an integral part of NIMS, is a widely applicable management system designed to enable effective, efficient incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. ICS is a fundamental form of management established in a standardized format, with the purpose of enabling incident managers to identify the key concerns associated with the incident—often under urgent conditions—without sacrificing attention to any component of the command system.

The ICS organizational structure is scalable and develops in a modular fashion according to the size and complexity of the incident, as well as the specifics of the hazard environment created by the incident. Responsibility for the establishment and expansion of the ICS modular organization ultimately rests with the Incident Commander, who bases the ICS organization on the requirements of the situation. As incident complexity increases, the organization expands from the top down as functional responsibilities are delegated.

Homeland Security Presidential Directive 5, Management of Domestic Incidents, orders the heads of all Federal Agencies to adopt the National Incident Management System (NIMS) in the response to domestic incidents. In 2010, the U.S. Department of Health and Human Services and USDA established an Incident Command System Working Group that developed protocols for the Multi-Agency Coordination Group for Foodborne Illness Outbreaks. This Coordination Group can convene quickly during an outbreak of foodborne illness involving multiple federal agencies to share information, make decisions, and leverage resources (see Section 3.1.2.10).

3.10.3. Context for Use

Agencies involved in foodborne disease outbreak investigation and response should decide in advance whether and how to apply an ICS and, if applicable, incorporate the ICS structure 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 disease outbreak investigations do not require formal activation of ICS, but outbreak investigation and control teams will benefit from training in ICS principles and methods.

If a person who claims to have tampered with food contacts an agency, or in any outbreak in which intentional contamination is suspected, notification of law enforcement officials and assessment of the credibility of the threat are essential. If the threat is credible, the outbreak would move into a law enforcement realm with activation of the ICS.

Early inclusion of ICS principles and methods can prevent problems over the long term. Trying to pick up and implement ICS after an incident has expanded creates many organizational issues for all responders involved. In recent years, federal departments and agencies have begun moving toward

3.10. Incident Command System

making adoption of NIMS by state, tribal, and local organizations a condition for federal preparedness assistance, including grants and contracts.

3.10.4. Training

Regardless of whether an agency elects to apply the ICS structure to its foodborne disease outbreak response, it should provide ICS training to the outbreak investigation and control team before any outbreaks. This is a standard requirement for all RRT members.

Ideally ICS training would use foodborne disease outbreak examples so that all team members clearly understand how to use the ICS structure in an outbreak situation. The FDA offers ICS training specifically focused on foodborne disease outbreak response. The RRT Best Practices Manual (Volume 1) includes a detailed chapter on the use of ICS by RRTs, including recommended training (www.afdo.org/Resources/Documents/6-resources/The RRT Manual_2013_Final.pdf).

3.11. Reference

Qureshi K, Gebbie KM, Gebbie EN. - Implementing ICS within public health agencies. Albany, NY: State University of New York, Albany; 2005. Available at. www.ualbanycphp.org/pinata/phics/guide/default.cfm (accessed October 3, 2013).

CHAPTER

4

Foodborne Disease Surveillance and Outbreak Detection

The term "foodborne disease surveillance" is often used to describe routine monitoring in a population for any enteric disease. The actual vehicle is usually not known during the surveillance and early stages of the investigation processes, and transmission ultimately could be caused by food, water, person-to-person spread, animal contact, or other exposures.

A primary function of foodborne disease surveillance is detection of problems in food and water production and delivery systems that might otherwise have gone unnoticed. Rapid detection and investigation of outbreaks is a critical first step to abating these active hazards and preventing their further recurrence (discussed further in Chapter 5). Broader goals of surveillance include defining the magnitude and burden of disease in the community, monitoring trends, measuring the effectiveness of control programs, attributing disease to specific food vehicles, providing a platform for applied research, and facilitating understanding of the epidemiology of foodborne diseases. This chapter focuses on outbreak detection aspects of surveillance.

4.0. Introduction

Unlike food-monitoring programs, which seek to identify problems in food production and correct them before illnesses occur, foodborne disease surveillance cannot prevent initial cases of disease. Nevertheless, surveillance is a sensitive tool available for identifying failures anywhere in food-supply systems. Food monitoring must concentrate on monitoring the effectiveness of risk-reduction procedures at critical control points during the production of certain foods. However, the range of possible food vehicles detectable through foodborne disease surveillance includes all food or other substances contaminated at any link in the chain from production to ingestion. Foodborne disease surveillance complements regulatory and commercial monitoring programs by providing primary feedback on the effectiveness of prevention programs.

Over the years, foodborne disease surveillance, coupled with outbreak investigation, has remained among the most productive public health activities, resulting in the recall of hundreds of millions of pounds of contaminated products and prompting numerous large and small changes in food-production and food-delivery systems. Many improvements in food safety during the past 100 years directly or indirectly resulted from outbreak investigations. However, current surveillance practices vary widely, are unevenly resourced, and generally exploit only a fraction of the system's potential.

When a possible foodborne disease outbreak is first detected or reported, investigators will not know whether the disease 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. Although the focus of these Guidelines is foodborne disease, many of the surveillance and detection methods described in this chapter and the investigation methods described in Chapter 5 apply to a variety of enteric and other illnesses, regardless of source of contamination.

4.1. Overview

Disease surveillance is used to identify clusters of possible foodborne illness. Investigation methods (Chapter 5) then are used to identify common exposures of ill persons in the cluster that distinguish them from healthy persons. Although, in practice, detecting individual foodborne disease outbreaks involves multiple approaches, two general methods are used in outbreak detection: 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 disease outbreaks is limited. 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, as will be described later in Chapters 4 and 5.

- Pathogen-specific surveillance: Health-care providers and laboratorians report individual cases of disease when selected pathogens, such as *Salmonella enterica* or *Escherichia coli* O157:H7, are identified in specimens from patients. This surveillance method also includes specific clinical syndromes with or without laboratory confirmation, such as hemolytic uremic syndrome and botulism, which usually indicate a particular pathogen. Exposure information is gathered by interviews with cases. Data and pathogens collected as part of food, animal, or environmental monitoring programs enhance this surveillance method. The national notifiable disease reporting system and molecular subtyping available through the National Molecular Subtyping Network

Table 4.1. Comparison of foodborne disease surveillance systems

FUNCTIONAL CHARACTERISTIC OF METHOD	SURVEILLANCE METHOD			
	PATHOGEN-SPECIFIC	COMPLAINT		SYNDROMIC
		GROUP NOTIFICATION	INDIVIDUAL COMPLAINT	
Inherent speed of outbreak detection	Relatively slow	Fast	Fast	Potentially fast*
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 periods‡	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 health-care 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 cases and collection of appropriate food history)* Even higher when combined with subtyping	High** *(after interview of cases and collection of appropriate food history)*	Low to moderate *(after interview of cases and collection of appropriate food history)*	Low¶

* An advantage in speed is limited mainly to nonspecific health indicators (preclinical and clinical prediagnostic 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.

¶ Exposure histories are not typically obtained.

** 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.

4.1. Overview

for Foodborne Disease Surveillance System (PulseNet) are examples of pathogen-specific surveillance.

- Complaint systems
  Health-care providers or the public identify and report suspected disease clusters (group notifications) or individual complaints. Exposure information is acquired by interviews with cases.
- Syndromic surveillance
  This surveillance method generally involves systematic (usually automated) gathering of data on nonspecific health indicators that might reflect increased disease occurrence, 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.

This chapter reviews major features, strengths, and limitations of each surveillance method and provides recommendations for increasing the effectiveness of each.

4.2. Pathogen-Specific Surveillance

4.2.1. Purpose

To systematically collect, analyze, and disseminate information about laboratory-confirmed illnesses or well-defined syndromes as part of prevention and control activities.

4.2.2. Background

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 public health laboratory 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), permitting individual cases of disease to be grouped with other cases most likely to share a common food source or other exposure (Box 4.1). 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 *Escherichia coli* (STEC) O157:H7, *Shigella*, *Listeria*, and *Campylobacter*.

Box 4.1. Selected nationally notifiable diseases that can be foodborne

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

In addition, the following are nationally notifiable:

- Foodborne disease outbreaks
- Waterborne disease outbreaks

From CDC. Nationally Notifiable Infectious Diseases. United States 2008. Revised. Available at www.cdc.gov/nndss/document/2012_Case%20Definitions.pdf

4.2. Pathogen-Specific Surveillance

4.2.3. Case Reporting and Laboratory Submission Process

Most diseases 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 diseases, including those that might be foodborne (Table 4.2). These criteria describe the diseases to report, to whom, how, and in what time frame. For this type of surveillance, diseases are defined by specific laboratory findings, such as isolation of *Salmonella enterica*, or by well-defined syndromes, such as hemolytic uremic syndrome. Diseases are reported primarily by laboratories, medical staff (e.g., physicians, infection-control practitioners, medical records clerks), or both. Disease 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 laboratories serving primary health-care facilities to public health laboratories for confirmation and further characterization, as required by state laws or regulations or as requested by the local jurisdiction.

States and territories (or sometimes local public health agencies) voluntarily share pathogen-specific disease surveillance information with the Centers for Disease Control and Prevention (CDC). No personal identifiers are forwarded, and only minimal information is available about cases (e.g., date of onset, age, sex, race/ethnicity, county of residence). CDC works with states to compile national surveillance data.

State-specific reporting requirements can be viewed at www.cste.org/group/SRCAQueryRes.

4.2.4. Epidemiology Process

Information received by the public health agency through multiple avenues, including basic clinical and demographic data from individual cases of specific laboratory-confirmed illness or well-defined syndromes, is reconciled and linked with case isolates or other clinical materials received in the public health laboratory. 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.

Cases are usually interviewed one or more times about potential exposures and additional clinical and demographic information. The scope of these interviews varies by jurisdiction. Interviews typically cover basic descriptive information and exposures of local importance, such as attendance at a child-care 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, more detailed exposure interviews might be collected only when clusters are investigated or outbreaks are recognized (Chapter 5). However, routine collection of detailed exposure information as soon as possible after reporting maximizes exposure recall, provides a basis for rapid cluster investigation, and is strongly recommended for high-consequence enteric pathogens, such as STEC O157:H7 and *Listeria monocytogenes*. (See Chapter 5 for further discussion.)

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

4.2. Pathogen-Specific Surveillance

clusters or trends. This is the critical first step in hypothesis generation. Clusters of unusual exposures, abnormal exposure frequencies, unusual 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, investigated further (Chapter 5). In some jurisdictions, cluster detection and triage is a laboratory function (see section 4.2.5 below).

Hypotheses to explain the cluster can be developed in several ways. If trawling questionnaires (i.e., 'hypothesis-generating" or "shotgun" questionnaires, or extensive interviews of possibly exposed persons, including food histories) are routinely administered after a case is reported, hypotheses can be generated through examination of previously obtained exposure data based on common exposures above what would be expected. This approach can be followed by an iterative follow-up interview (see below). In jurisdictions where trawling questionnaires are not used routinely, such interviews might be used only for cases suspected to be part of a common-source cluster. Unless these interviews identify an obvious exposure leading to direct public health intervention, hypotheses are tested during the ensuing investigation (see Chapter 5).

Questionnaire data are not the sole source of information available to investigators. The basic demographic profile of cases (age, sex, occasionally racial or ethnic composition) often provides important clues to the identity of commercial food sources. The geographic and temporal distribution of cases likewise can suggest (or rule out) certain kinds of exposures. Investigators should take advantage of product distribution data obtained from the food distributors or noteworthy outliers (i.e., the cases that do not fit an otherwise well-established pattern). Other potentially useful information includes routine food-monitoring test results (see section 4.2.5.2) or concurrent group or individual complaints (see section 4.3). The most successful investigators consider information from as wide a variety of sources as possible.

Finally, pathogen-specific data are ideally compared routinely with complaint data, which offer significant advantages in sensitivity and specificity over either system alone (see section 4.3.6).

4.2.5. Laboratory Process

Clinical diagnostic laboratories forward case isolates, specimens that were positive for a reportable enteric pathogen by a culture-independent test, or other clinical materials to public health laboratories as part of mandated or voluntary reporting rules. Such problems as mislabeling, broken-in-transit, or quantity-not-sufficient are resolved. Receipt of samples is recorded, and sample information is entered into the laboratory database. 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.

The agent identification is confirmed, and tests used for subtyping (such as serotyping, virulence assays, molecular subtyping, or antimicrobial susceptibility tests) are conducted to further characterize the agent. Reports are issued either singly or in groups to the epidemiology department. Reports also may be issued to submitters as permitted by local policies. Pulsed-field gel electrophoresis (PFGE) or other subtype patterns and accompanying metadata are uploaded to local and national databases. Consolidated daily reports, such as subtype frequency reports, are often used to facilitate cluster recognition. These reports may be automatically generated by

4.2. Pathogen-Specific Surveillance

laboratory or epidemiology information systems; extracted from the PulseNet database; or facilitated by software, such as the CIFOR laboratory/epidemiology reporting program (http://www.cifor.us/projelr.cfm). 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. Specimen data (including detailed subtyping results) are additionally uploaded to national surveillance systems, such as the U.S. Laboratory-based Enteric-Diseases Surveillance (LEDS [in the United States] or TESSy [in Europe]).

4.2.5.1 Cluster definition and triage

Although, in practice, the term may be used somewhat casually, a "cluster" can be defined as two or more cases of disease linked by place, time, pathogen subtype, or other characteristic. Our interest in clusters stems from the fact that some clusters represent common-source outbreaks. An ill-defined transition in use of the terms "cluster" to "outbreak" reflects the certainty that similar cases are in fact related. Sometimes transition is immediately and trivially apparent; at other times, doubts linger indefinitely.

Clusters may be more or less recognizable and more or less actionable. Although this chapter focuses on case clusters and outbreaks, it should be clear that for some high-consequence agents or syndromes (e.g., botulism or paralytic shellfish poisoning), even single cases may merit a prompt and aggressive public health response.

Clusters are common, and pursuing them all with equal vigor is not practical or productive. The cluster triage process is primarily manual. Incoming surveillance data are evaluated for unusual case counts based on historical frequencies (accounting for seasonality), the severity of disease, matches between human cases and food or animal monitoring samples, and competing demands for investigators' time. 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 the diseases. Although cluster recognition software, such as SaTScan™, cusum outbreak detection algorithms, and query algorithms in the PulseNet Web Portal 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. 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.

The subject of cluster evaluation will be covered in more detail in Chapter 5. As whole-genome sequencing becomes part of routine public health surveillance activities, new approaches will need to be developed to define and evaluate clusters (also see section 4.2.9.2). At this writing, real-time whole-genome sequencing for outbreak detection and investigation has been initiated on a pilot basis. Full transition to genome-based molecular surveillance is anticipated in the near future.

4.2.5.2. Microbiological Screening

Microbiological screening of food or other environmental specimens can be useful for an individual case of botulism and for certain high-risk exposures reported even by single cases of other diseases (e.g., pet reptiles for *Salmonella* or raw milk or ground beef for STEC). Targeted screening also might be warranted when specific foods are suspected and reasonable samples are available. Unfocused microbiological screening of multiple foods to investigate clusters is generally unproductive and always resource-intensive.

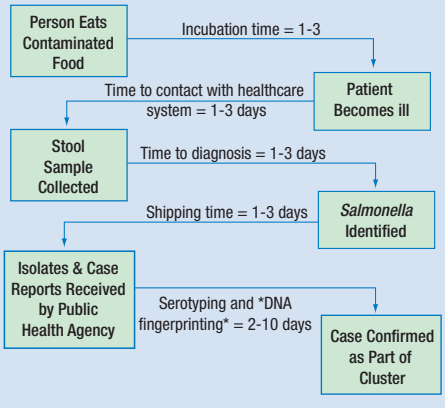
4.2. Pathogen-Specific Surveillance

Routine food screening 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. Screening information also might be available from the food industry. 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, and selected live-animal testing are co-mingled in the PulseNet database, although important product details might not be readily available.

4.2.6. Timeline for Case Reporting and Cluster Recognition

Pathogen-specific surveillance requires a series of events from the time a patient is infected through the time public health officials determine the patient is part of a disease cluster. This delay is one of the limiting factors of this type of 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 4.1.

Figure 4.1. Sample *Salmonella* case reporting timeline



1. Incubation time:
   The time from ingestion of a contaminated food to beginning of symptoms. For *Salmonella*, this typically is 1–3 days, sometimes longer.
2. Time to contact with health-care provider or doctor:
   The time from the first symptom to medical care (when a stool sample is collected for laboratory testing). This time may be an additional 1–3 days, sometimes longer.
3. Time to diagnosis:
   The time from provision of a sample to lab identification of the agent in the sample as *Salmonella*. This may be 1–3 days from the time the lab receives the sample.
4. Sample shipping time:
   The time required to ship the *Salmonella* isolate from the lab to the state public health authorities who will perform serotyping and DNA fingerprinting. This usually takes 1-3 days or longer, depending on transportation arrangements within a state and distance between the clinical lab and the public health department. Diagnostic labs are not required by law in many jurisdictions to forward *Salmonella* isolates to public health labs, and not all diagnostic labs forward any isolates unless specifically requested to do so.
5. Time to serotyping and DNA fingerprinting:
   The time required for the state public health authorities to serotype and to perform DNA fingerprinting on the *Salmonella* isolate and compare it with the outbreak pattern. Serotyping typically takes 3 working days but can take longer. DNA fingerprinting can be accomplished in 2 working days (24 hours). However, many public health labs have limited staff and space and experience multiple emergencies simultaneously. In practice, serotyping and PFGE subtyping may take several days to several weeks; faster turnarounds are highly desirable. The transition to whole genome sequencing for

4.2. Pathogen-Specific Surveillance

subtyping and serotyping will likely reduce turnaround time for this process.

The total time from onset of illness to confirmation of the case as part of an outbreak is typically 2–3 weeks.

4.2.7. Strengths of Pathogen-Specific Surveillance for Outbreak Detection

- Permits detection of widespread disease clusters initially linked only by a common agent. Most national and international foodborne disease outbreaks are detected in this manner.
- When combined with case information from clusters recognized though complaints (section 4.3), and when specific exposure information is obtained, is arguably the most sensitive single 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.

4.2.8. Limitations of Pathogen-Specific Surveillance

- Works only for diseases detected by routine testing and reported to a public health agency.
- Is relatively slow because of the many steps required, as described in figure 4.1.

4.2.9. Key Determinants of Successful Pathogen-Specific Surveillance

The following interrelated factors are critical to understanding the use of surveillance data to identify potential outbreaks and form the basis for best practices of cluster investigations (see Chapter 5).

4.2.9.1. Sensitivity of case detection

Surveillance represents a sampling of the true population of affected persons because most cases of foodborne disease are not diagnosed and reported. **The completeness of the reporting and isolate submission processes affects the representativeness of the reported cases and the potential number and size of outbreaks detected.** If the percentage of cases reported or isolates submitted is low (i.e., sensitivity is low), small outbreaks or outbreaks spread over space and time are likely to be missed. Furthermore, if sensitivity is low, reported cases might differ significantly from cases not reported. This bias is more likely to influence descriptions of clinical illness or the magnitude and severity of illness than associations with any particular vehicle, but it is worth keeping in mind as one develops hypotheses about the source (see Chapter 5).

4.2.9.2. Prevalence of the agent and specificity of agent classification

The more common the agent, the more difficult it is to identify outbreaks and the more likely sporadic (unrelated) cases will be misclassified as outbreak cases. Misclassification reduces the power of the investigation, obscuring trends and diluting outbreak measures of association (type 2 probability error or the possibility of missing an exposure–disease association when one truly exists). Consequently, a larger number of outbreak cases are needed to significantly associate illness with exposure.

Examination of subsets of cases using case definitions based on specific agent classifications (e.g., inclusion of subtyping results) or restricting cases using certain time, place, or person characteristics can minimize this impact. For example, *Salmonella* Typhimurium, a common serotype, provides the opportunity for misclassification (i.e., grouping together cases resulting from different exposures). However, *Salmonella* Typhimurium cases that are part of a common-source outbreak are more likely than

4.2. Pathogen-Specific Surveillance

cases not associated with the outbreak to share a PFGE subtype. Therefore, using the PFGE subtype in the case definition will decrease misclassification (i.e., exclude cases not related to the outbreak) and increase the chance of finding a statistically significant association between illness and exposure. This is the basic principle behind PulseNet.

Increasing the specificity of strain classification, for example by using serotypes, PFGE results, or whole-genome sequencing, is useful but has drawbacks. Some outbreaks are caused by more than one pathogen or more than one subtype of a pathogen. If the strain associated with an outbreak is defined too narrowly by investigators, truly associated cases with different subtypes (or no subtyping at all) will be eliminated from the investigation. Elimination of these cases may become problematic when the number of cases associated with an outbreak is small. It can result in overlooking an outbreak altogether, but it also can decrease study power and the likelihood of implicating a specific food as the source of the outbreak. In addition, genetic changes can occur as pathogens multiply over time in food, the human body, or the environment. Pathogens and strains differ in the rate of change. As a result, isolates deriving from the same source (e.g., a contaminated food) can have slightly different genome sequences.

For these reasons, use of several different levels of agent specificity during analysis of surveillance data and in the investigation of a cluster might be helpful. In addition, epidemiologic evaluation of whole-genome sequences usually involves clustering of pathogens with closely related genome sequences into larger groupings. Initial discussions are under way to develop international conventions for use of whole-genome sequence data.[1]

4.2.9.3. Sensitivity and specificity of interviews of cases

One reason an ill person seeks medical attention is suspicion that he or she might have been part of a foodborne disease outbreak. Routine case interviews should always identify group exposures, such as a banquet, after which other persons might have been ill. For these persons, the event itself largely (but not entirely) defines the exposures of interest, such as menu items. However, exposures that need to be considered in pathogen-specific surveillance usually are open-ended; they include all exposures in a time frame appropriate to the disease.

As noted above, many local agencies collect information about a limited set of high-risk exposures when the case is initially reported, and routine collection of detailed exposure information can provide a basis for real-time evaluation of clusters that might be justified for enteric pathogens of sufficient public health importance. Lack of a list of specific exposures, such as a menu, makes prompting cases during the interview more difficult. Furthermore, cases identified through pathogen-specific surveillance usually are interviewed later after the exposure than are those reported as part of specific events. **Thus, greater attention must be paid to interview timing and content.**

4.2.9.3.1. Timing

To decrease the time between exposure to the disease-causing agent and interview of the case, reporting of cases by health-care providers and laboratories should be as easy as possible. Case interviews should be conducted as soon as possible because recall will be better closer to the time of the exposure and cases will be more motivated to share information with investigators closer to the time of their illness. Acquiring timely interviews might entail working outside regular office hours.

4.2.9.3.2. Content

In pathogen-specific surveillance, the interview form itself must include a broader range of possible exposures than interview forms for

4.2. Pathogen-Specific Surveillance

event-driven investigations. Interview forms that use a combination of question types will increase the likelihood of detecting the desired exposure information and should be used, as appropriate to the outbreak circumstances. Interview forms can include questions that:

- Collect information about specific exposures, such as a broad range of specific food items and nonfood exposures previously (or plausibly) associated with the pathogen through closed-ended questions;
- Prompt cases to further describe exposures, such as brand information and place of purchase or consumption; and
- Enable cases to identify unanticipated exposures through open-ended questions (e.g., "At which restaurants did you eat?").

Questionnaire design involves balancing a number of competing demands; the end result is always a compromise. Questionnaires with many open-ended questions require more highly trained and skilled personnel than do interviews using more predefined lists of exposures. Longer questionnaires can cover more possible exposures but can task the patience of both case and interviewer; cases might quit the interview before it is completed. Open-ended questions generally are more difficult and time-consuming to abstract and for data entry.

No one questionnaire will work for all investigations or surveillance systems. Investigators should consider the specifics of the outbreak and setting, the importance of collecting the information, and the likely trade-offs before deciding on the content of the interview form.

Regardless of interview content, use of a standardized interview form with which the interviewer is familiar will decrease time spent on staff training and decrease errors in data collection. In addition, use of standardized core questions (i.e., questions that use the same wording for collecting information about certain exposures) and data elements (e.g., ask about the same high-risk exposures, such as sprouts, raw milk, ground beef, and leafy green vegetables) will enhance data sharing and enable comparisons among jurisdictions in multijurisdictional outbreaks—and possibly speed the resolution of commercial product outbreaks.

4.2.9.4. Overall speed of the surveillance and investigation processes

Delays are inherent in pathogen-specific surveillance. **The usefulness of pathogen-specific surveillance in preventing ongoing transmission of disease from contaminated food, especially perishable commodities, is directly related to the speed of the process.**

Once an outbreak investigation is under way, routine surveillance practices and work schedules must be changed to match the urgency of the investigation (see Chapter 5).

4.2.10. Routine Pathogen-Specific Surveillance—Model Practices

This section lists model practices for routine surveillance programs. Practices used in any particular situation depend on a host of factors, including circumstances specific to the outbreak (e.g., the pathogen and number and distribution of cases), staff expertise, structure of the investigating agency, and agency resources. For example, aggressive identification and investigation of STEC O157:H7 cases can identify outbreaks and enable the implementation of control measures that might minimize serious illness and death, whereas investigation of more numerous *Campylobacter* cases is not as likely to lead to public health interventions. Although a systematic evaluation of the following practices under different circumstances has not been performed, experiences from successful investigations support their value. Investigators are encouraged to use a combination of practices as appropriate to the specific outbreak.

4.2. Pathogen-Specific Surveillance

4.2.10.1. Reporting and isolate submission

Increasingly clinicians are diagnosing and treating patients without collecting and testing clinical specimens. Ongoing communication between public health agencies and clinicians is critical to reinforce the value of collecting and submitting specimens to public health laboratories for tracking and responding to diseases of public health interest.

Encourage health-care providers to test patient specimens as part of the routine diagnostic process for possible foodborne diseases. Increase reporting and isolate submission by clinical laboratories and health-care providers through: a) education about the value of testing and reporting mechanisms; b) regulatory action (such as modifying reporting rules to mandate isolate submission); c) laboratory audits; and d) provision of easier methods for compliance, such as automated or Web-based reporting, isolate-transport systems, more consistent reporting across reporting areas, and limitation of the amount of information initially requested. Educate physicians, laboratorians, and medical records clerks by workshops or conferences, newsletters, electronic health alerts, and regular feedback from public health agencies.

The medical rationale and specific recommendations for testing can be found in *Practical Guidelines for the Management of Infectious Diarrhea*[2] and "Diagnosis and management of foodborne illnesses: a primer for physicians and other health-care professionals."[3] The latter document provides a series of tables that give useful information about major foodborne pathogens, including signs and symptoms, incubation periods, and appropriate laboratory tests, and describes sample patient scenarios to help with the diagnostic process.

4.2.10.2. Isolate/specimen submission and characterization

Confer with the laboratory to determine subtyping methods available for the pathogen under study. Undertake subtyping as the isolates are submitted—do not wait for a specific number of specimens to accumulate before testing them. Tests such as PFGE and serotyping ideally are performed concurrently to reduce turnaround time. Recommended turnaround times are described in the Association of Public Health Laboratories/CIFOR "yardstick" project (http://www.aphl.org/aphlprograms/food/initiatives/Documents/FS_2012_Yardstick-Self-Assessment-Tool-for-Public-Health-Food-Safety-Testing.pdf). Post results to national databases as quickly as possible. Tests conducted on an as-needed basis during a cluster investigation, such as multilocus variable number tandem repeat analysis or whole-genome sequencing, should be initiated as soon as the need is recognized.

Use of culture-independent diagnostics in clinical laboratories is anticipated to be increasing in the coming years. Therefore:

- Jurisdictions should consider amending reporting rules to expand the definition of required clinical materials for submission to include patient specimens (e.g., stool, urine, blood) because isolates currently specified in most reporting rules might not be available in the near future.
- Protocols should be developed for rapidly isolating pathogens from patient specimens.

4.2.10.3. Case interviews

Quality exposure information usually is difficult to obtain and often is the major limiting factor of pathogen-specific surveillance. **Interview all persons with laboratory-diagnosed cases of possible foodborne disease as soon as case reports or laboratory isolates are received, when patient recall and motivation to cooperate with investigators is the greatest.**

Obtain an exposure history consistent with the incubation period of the pathogen

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identified (see http://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html for a table of incubation for the most common foodborne agents).

As appropriate to circumstances, construct the interview to include a mix of question types that will collect the desired exposure information, including:

- Specific closed-ended questions about exposures as *a priori* hypotheses to be tested (including specific food items that have been linked to previous outbreaks or that could plausibly be associated with the specific pathogen);
- Broad open-ended questions to capture exposures that might not have been considered; and
- Questions that elicit additional details, such as brand and place of purchase or consumption, for some of the highest likelihood exposures.

When possible, use standardized core questions and data elements used by other investigators to enhance data sharing and comparisons across jurisdictions. Experience can make one a better and more efficient interviewer. If investigations are infrequent, achieving and maintaining proficiency can be difficult; centralizing the interview process reduces these problems and makes questionnaires easier to modify on the fly.

Entering, tabulating, and analyzing questionnaire data is an essential part of effective interviewing. Questionnaires should be designed with rapid and accurate data entry in mind. The CIFOR Clearinghouse (www.cifor.us/clearinghouse/keywordsearch.cfm) provides examples of questionnaires used by various health departments to collect exposure information for different pathogens. Questions with a yes/no check-box format are efficient for collecting information about variables for which expected frequency of exposure is low. For example, because less than 20% of the population is expected to eat raw spinach, asking only whether a case ate raw spinach should be sufficient to identify raw spinach as a possible vehicle. However, because more than 75% of the population is expected to eat chicken, additional brand or source information is needed. Thus, using a hybrid approach for collecting basic exposure information about low-frequency exposures and more specific information about high-frequency exposures may be the most effective approach. The use of open-ended questions complicates electronic data entry and analysis. For jurisdictions that rely on electronic data entry at the local public health level for rapid communication with the state, answers to open-ended questions may need to be captured as text fields that can be reviewed as needed.

Routine collection of detailed exposure information enables evaluation of clusters in real time. However, most public health agencies do not have sufficient resources to conduct such interviews of every case. Given the reality of these resource limitations, a two-step interviewing process might be the best alternative approach. **When first reported, all cases should be interviewed with a standardized questionnaire to collect exposure information about limited high-risk exposures specific to the pathogen. Interviewees should be informed that investigations may require additional information and that they might be contacted again. When the novelty of the subtype pattern, geographic distribution of cases, or ongoing accumulation of new cases indicate the cluster represents an outbreak possibly associated with a commercially distributed food product, all cases in the cluster should be interviewed using a detailed exposure questionnaire as part of a dynamic cluster investigation (see Chapter 5).**

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4.2.10.4. Data analysis

Use daily laboratory reporting and analysis systems, where possible, to more easily recognize and evaluate clusters. Automated reports can be developed for laboratory information management systems or epidemiology systems or by using the CIFOR Epi/Lab reporting software.

Analyses should be able to handle various agents (e.g., species, serotype or other subtype, more stringent subtype), enabling differing types of available information, and should include basic demographic information, such as location, sex, and age. Compare possible clusters to historical frequencies and national trends. Clusters are triaged on the basis of the novelty of a subtype pattern or increased occurrence of a relatively common subtype, geographic or temporal clustering or lack thereof, or unexpected demographic distribution (also see Chapter 5).

4.2.10.5. Communication

Establish and use routine procedures for communicating among epidemiology, laboratory, and environmental health branches within an agency and between local and state agencies. Rapidly post subtyping results to PulseNet, and note the detection of clusters to PulseNet and foodborne outbreak electronic mailing lists to improve communication and cooperation within and among local, state, and federal public health agencies. **Poor coordination within and among agencies limits the effectiveness of pathogen-specific surveillance.**

CIFOR Keys to Success: Focus Area 5—Pathogen-specific surveillance

Reporting/submission of isolates

- State has mandatory reporting of diseases and submission of patient isolates that were likely to have been foodborne.
- Staff actively solicit case reports and submission of specimens/isolates to improve completeness of reporting.
- Agency/jurisdiction has system to rapidly transport specimens and isolates from clinical laboratories to the public health laboratory.

Testing of specimens

- Public health laboratory has the capacity to quickly process and test specimens submitted by clinical laboratories, including pathogen confirmation and subtyping.

Collection of exposure information

- Staff collect sufficient demographic and exposure information from patients to recognize possible patterns and associations between cases in a timely fashion.

Detection of clusters/outbreaks

- Staff analyze case information (e.g., demographics, exposure information, agent information including species, serotype, subtype) on a frequent basis to rapidly identify possible clusters or outbreaks.

Communication

- Public health laboratory shares test results with epidemiology staff in a timely fashion.
- Public health laboratory reports test results to national databases in a timely fashion.

Making changes

- Agency/jurisdiction has performance indicators related to pathogen-specific surveillance and routinely evaluates its performance in this Focus Area.

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4.2.11. Multijurisdictional Considerations for Pathogen-Specific Surveillance

Because pathogen-specific surveillance does not depend on geographic clustering, it is more sensitive to detection of widespread, low-level contamination events than surveillance through complaint systems. Outbreaks detected by pathogen-specific surveillance are more likely to span multiple jurisdictions. See Chapter 7 for Multijurisdictional Investigation Guidelines.

4.2.12. Indicators/Measures for Pathogen-Specific Surveillance

The success of pathogen-specific surveillance at detecting and resolving common-source outbreaks depends on multiple interrelated processes. Indicators for assessing and improving surveillance programs can be found in Chapter 8.

4.3. Complaint Systems

4.3.1. Purpose

Notification or complaint systems are intended to receive, triage, and respond to reports from the community about possible foodborne disease events to conduct prevention and control activities. Programs range from *ad hoc* response to unsolicited phone reports to systematic solicitation and interview of and response to community reports.

4.3.2. Background

Receiving and responding to reports of disease in the community has been a basic function of public health agencies since their inception. Whereas reports of diseases caused by specific pathogens generally follow specific disease reporting rules, complaints of illnesses by consumers associated with specific events or food establishments generally have been referred to the agency responsible for licensing the establishment. These consumer complaints lead to the identification of most localized foodborne disease outbreaks and are the only method for detecting outbreaks caused by agents, such as norovirus, for which there is rarely pathogen-specific surveillance. Unlike pathogen-specific surveillance (described above) notification and complaint systems do not depend on ill persons seeking medical attention. Therefore, it is not necessary for laboratory tests to be ordered and performed, cases reported, isolates sent to public health agencies, and subtyping or further laboratory testing (see section 4.2.6). Although pathogen-specific surveillance and complaint systems are treated separately in this chapter, these two systems are synergistic when used together.

4.3.3. Group Illness and Independent Complaints

Complaint reporting involves passive collection of reports of possible foodborne illness from individuals or groups. Reporting is of two basic types, each with its own dynamics and requirements:

- 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 wedding and reports from health-care 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 may be used together and linked with data obtained through pathogen-specific surveillance. In contrast to pathogen-specific surveillance,

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complaint reporting does not require identification of a specific agent or syndrome or contact with the health-care system.

4.3.4. Epidemiology Process

Notification of group illnesses or independent complaints can occur at the local, regional, state, or national level. Some jurisdictions mandate reporting of unusual clusters of disease. Reports from health-care providers or other community members of unusual clusters are triaged; occurrence of the same disease is confirmed; data are analyzed; investigations are initiated; and control measures are implemented as appropriate. For reports of group illness associated with an event or venue, investigation generally involves obtaining lists of attendees, confirming ill persons have the same disease, obtaining menus, interviewing cases, performing a cohort or case–control study, and collecting food and patient specimens (see Chapter 5). Outbreaks detected in this manner can be linked to other outbreaks or to other cases in the community by a variety of processes, such as PulseNet or the Foodborne Disease Outbreak Surveillance System, and communication conducted through Epi-X or the U.S. national network of epidemiologists.

Two or more persons with a common exposure identified through interview of independent complaints are used to identify clusters of illness in much the same manner as common agents are used in pathogen-specific surveillance. Exposure information captured in the initial complaint generally is limited and biased toward exposures shortly before onset of symptoms. Therefore, routine interviews are needed for this process to be robust. In the absence of common, suspicious exposures shared by two or more cases, complaints of individual illness with nonspecific symptoms—such as diarrhea or vomiting—generally are not worth pursuing. This underscores the need to collect and record sufficient exposure information on each and every independent complaint as reported exposures might become more significant when also reported by subsequent complainants.

4.3.5. Public Health Laboratory Process

Laboratory activities are not essential for primary detection of outbreaks by this process but are essential for determining etiology, linking separate events during the investigation, and monitoring the efficacy of control measures (see Chapters 5 and 6). 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 connection of this outbreak with other outbreaks from a contaminated commodity.

4.3.6. Strengths of Complaint Systems for Outbreak Detection

- Because detection does not depend on identification of an agent, this system can 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[4] and identification of *Arcobacter butzleri* as the likely agent in an outbreak of gastroenteritis at an event.[5] In one study, consumer complaint surveillance alone led to detection of 79% of confirmed foodborne outbreaks, including most norovirus outbreaks.[4]

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- For event-related complaints only: recall of food items eaten and other exposures by cases usually is good for reported events 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 (section 4.1.6). 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 (see 4.3.8.2 below), investigations of event-related notifications can be pivotal to solving widespread outbreaks detected through pathogen-specific surveillance. Recent examples include an international outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga infections associated with a raw scraped ground tuna product[6] and a large outbreak of *Salmonella* Typhimurium infections associated with peanut products.[7]

4.3.7. Limitations of Complaint Systems

- 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 cases by a health-care provider or member of the community is required.
- The value of complaints about single possible cases of foodborne disease in detecting outbreaks is limited by the exposure information used to link 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. For any true outbreak, the absence of an agent makes misclassification of cases more likely. Misclassification of cases makes identification of an association between an outbreak and an exposure more difficult.
- 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 persons associate illness with the last meal eaten before onset of symptoms – and are thus likely to be correct only for exposures with short incubation times. This is not a limitation if full interviews are conducted.

4.3.8. Key Determinants of Successful Complaint Systems

The following factors drive interpretation of complaint surveillance data, affect the success of investigations, and form the basis for best practices.

4.3.8.1. Sensitivity of case or event detection

The dynamics of outbreak detection differ somewhat for notification involving groups of illnesses and collection of independent complaints. **Detection of outbreaks by notification of group illness is limited only by the severity of the illness, public awareness of where to report the illness, ease and availability of the reporting process, and investigation resources (to determine whether the clusters are in fact outbreaks). In contrast, detection of clusters of illnesses from independent complaints relies on analysis by the public health agency of an entire group of complaints collected over time.** As with pathogen-specific surveillance, the size and number of outbreaks detectable using independent complaints as primary surveillance data are driven by the number of individual cases reported, uniqueness of the illness or reported exposure, sensitivity and

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specificity of the interview process to detect common exposures, and methods used to evaluate exposure data.

4.3.8.2. Background prevalence of disease—group complaints

When a group illness is reported, some of the cases may be ill for a reason other than a common group exposure. The likelihood of this depends on the background prevalence of the disease or complaint. For example, unrelated diarrhea cases may inadvertently be grouped with true outbreak-related cases because annually approximately 48 million persons in the United States—or one of six—"normally" experience diarrhea.[8] **Inclusion of misclassified cases (i.e., cases not associated with the outbreak) hinders the detection of associations between exposures and disease, thus decreasing the likelihood of discovery of a common source.** When reported clusters are small, the possibility must be considered that the reported cluster results from coincidence rather than causal association (type I probability error—i.e., detection of an association between an exposure and a disease where one does not exist). With unusual syndromes, such as neurologic symptoms associated with botulism or ciguatera fish poisoning, the likelihood of misclassification and type 1 probability error is low. The system specificity can be increased by identifying a specific agent or disease marker or by increasing the specificity of the symptom information (e.g., bloody diarrhea or specific mean duration of illness) or by obtaining exposure information.

4.3.8.3. Sensitivity and specificity of case interviews—group complaints

Interviews of cases for group complaints capture two types of information:

- Specific exposures associated with the reported event and
- Individual food histories of cases to rule out alternate hypotheses and exclude misclassified cases.

Because exposures associated with group events are relatively few and can be described specifically, recall tends to be good and timing is less an issue than with pathogen-specific surveillance or independent complaints. In studies of food recall accuracy, the positive predictive value of individual food items ranged from 73% to 97%.[9,10] The negative predictive value ranged from 79% to 98%. Highly distinctive foods tended to be more accurately reported. Nonetheless, the more specific exposure-related questions are, the better recall will be. For example, cases asked whether they "ate German potato salad" at a particular event are more likely to remember than if they were asked whether they ate "salad" or asked to list the foods they ate. Interviews of food-preparation staff additionally provide valuable information because they can list ingredients that cases are not likely to recall or even know about and that a standardized questionnaire might not include. A good example is the 2011 international outbreak of STEC O104:H4 infections associated with fenugreek sprouts.[11]

The second type of information gathered in the investigation of group complaints, individual food histories, presents the same challenges as information collected for outbreaks detected through pathogen-specific surveillance (i.e., includes a broad range of possible exposures among cases and is associated with difficulties in recall). The problems may be even greater because no causative agent has been identified that would enable investigators to focus on exposures previously associated with that pathogen. Hence, cases should be interviewed promptly for this aspect of the interview to be effective.

4.3.9. Complaint Systems—Model Practices

This section lists model practices for notification and complaint systems. The practices used in any particular situation

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depend on a host of factors, including the circumstances specific to the outbreak (e.g., the pathogen and number and distribution of cases), staff expertise, structure of the investigating agency, and agency resources. For example, reports of bloody diarrhea may warrant aggressive case identification and investigation to minimize serious illness and death. A cluster of possible norovirus infections might be investigated less aggressively or not investigated at all. Although these practices have not been systematically evaluated under different circumstances, experiences from successful investigations support their value. Investigators are encouraged to use a combination of these practices as appropriate to the specific outbreak.

4.3.9.1. Interviews related to individual complaints

Detection of outbreaks based on multiple individual complaints requires a system for recording complaints and comparing food histories and other exposures reported by individuals.

A detailed 5-day exposure history is recommended for individual complaints because common exposures are the sole mechanism to link cases. Although outbreaks caused by agents with short incubation periods may be able to be identified on the basis of information provided during initial complaints only, the signal-to-noise ratio would be low, and investigations would tend to be nonproductive. Therefore, a detailed interview, using a standardized form that includes both food and nonfood exposures, is preferred.

Collection of a 5-day exposure history is also recommended when an investigation begins that is based on multiple individual complaints. Given the ubiquity of norovirus infections, the investigator should pay particular attention to 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).

Health departments may choose to collect specimens from independent complaints or encourage patients to seek health care.

4.3.9.2. Follow-up of food establishments named in individual complaints of possible foodborne illness

In jurisdictions where visits are not required to every restaurant named in illness complaints, health department staff must decide whether investigation of a commercial food establishment is likely to be beneficial. To make this decision, investigators should consider details of the complainant's illness and the foods eaten at the 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 poorly 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.

As noted below (section 4.3.9.6), regular review of individual complaints is critical in 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:

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- 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.
- Repeated complaints by the same person(s) for which prior investigations revealed no significant findings.

4.3.9.3. Interviews related to reported illnesses in groups

"Complaints" of illness among groups often are tantamount to outbreak reports. A report of illness among 8–12 people who ate together merits a different response than an isolated report of diarrhea.

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. For example, an outbreak associated with a wedding reception might actually result from the rehearsal dinner, which involves many of the same people. Interviews should ask about other possible exposures either for the interviewee or for others he or she might have contacted, such as child-care attendance, employment as a food worker, or ill family members.

4.3.9.4. Clinical specimens and food samples related to group illness

Obtain clinical specimens from members of the ill group. If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. All sampling must be conducted using legally defensible procedures (e.g., chain-of-custody) and using protocols as guided by the laboratory that will do the analysis. Store the food appropriately, but generally test the food only after epidemiologic implication or identification of specific food-safety problems through an environmental health assessment. Food samples that are frozen when collected should remain frozen until examined. Samples should be analyzed within 48 hours after receipt. If sample analysis is not possible within 48 hours, then perishable foods should be frozen (−40°C to −80°C). 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. Food samples can be collected as part of the process of removing suspected food from service.

Note: Food testing has inherent limitations because most testing is agent-specific, and demonstration of an agent in food, especially viruses, 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, results of testing are often difficult to interpret. Because contaminants in food change with time, 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

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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. As a result, food testing should not be routinely undertaken but should instead be based on meaningful associations identified through data analysis of interviews with suspected cases or during environmental health assessments at the implicated food-service establishment.

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).

4.3.9.5. Establishment of etiology through laboratory testing

Even though the etiology is not essential for primary linkage of cases, as it is for pathogen-specific surveillance, **information about agents is important for understanding the outbreak and for implementing rational intervention and facilitates establishing links to other outbreaks or sporadic cases by PulseNet and the Foodborne Disease Outbreak Surveillance System.** Further information about investigation methods and establishing etiology is available in Chapter 5.

4.3.9.6. Regular review of interview data

Review interview data regularly to look for trends or commonalities. **Compile interview data in a single database, and examine daily for exposure clustering.** Comparison with exposure data obtained through pathogen-specific surveillance interviews might reveal a possible connection among cases and increase the sensitivity of both surveillance systems for detecting outbreaks.

4.3.9.7. Improvement of interagency cooperation and communication

Consumers may submit complaints to multiple organizations and agencies, such as poison control centers, agricultural agencies, facility-licensing agencies, and grocery stores. **Identify the agencies/organizations in the community that are likely to receive complaints.**

Improve communication and cooperation among agencies that receive illness complaints. Regular communication should be established between agencies that receive illness complaints, epidemiology staff, and laboratory staff. Contact information should be kept current at all times. 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.

4.3.9.8. Other potentially useful tools

Check complaint information against national databases, such as the USDA/Food Safety and Inspection Service (FSIS) Consumer Complaint Monitoring System (CCMS). Recognizing that consumers are one of the many important resources for complaint information possibly linked to its products, FSIS released a new online tool, the Electronic Consumer Complaint Form (eCCF) to enhance its current surveillance of the food supply. Before eCCF, consumer complaints were reported to FSIS through its field offices or through calls to the USDA's Meat and Poultry Hotline. The eCCF now offers all consumers, including state and local health departments and schools receiving USDA-inspected products through the National School Lunch Program, an additional channel to report complaints to FSIS that is available 24 hours a day. Increased consumer reporting through the eCCF will enhance FSIS surveillance activities to characterize, prevent, and respond rapidly to potential threats from FSIS-regulated products.

4.3.9.9. Simplification of reporting process

To increase surveillance sensitivity, remove barriers to reporting by making the reporting process as simple as possible for

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the public. For example, provide one 24/7 toll-free telephone number or one website. Such systems enable callers to leave information that public health staff can follow up.

4.3.9.10. Increased public awareness of reporting process

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 in the telephone directory. 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. Communicate the value of such reporting, not just to protect public health, but also to protect food establishments from unfounded allegations of foodborne illness.

4.3.9.11. Centralized reporting or report review process

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.

4.3.10. Multijurisdictional Considerations for Complaint Systems

Outbreaks discovered through complaints might span multiple jurisdictions, as evidenced by the 1998 parsley-associated shigellosis outbreak and the 2006 multistate lettuce-associated *E. coli* O157:H7 outbreak in taco restaurants[12]. See Chapter 7 for Multijurisdictional Investigation Guidelines.

CIFOR Keys to Success: Focus Area 4—Complaint systems

Soliciting and receiving reports

- Agency/jurisdiction has an established process for receiving reports from the public about possible foodborne illness(es).
- Public knows how to report possible foodborne illnesses to the agency/jurisdiction.
- Agency/jurisdiction solicits reports of possible foodborne illness from other agencies and organizations likely to receive these reports (e.g., poison control center, industry) inside and outside the jurisdiction.
- Agency/jurisdiction works with the local media to solicit reports of possible foodborne illness from the public.

Detection of clusters/outbreaks

- Staff collect specified pieces of information about each foodborne illness report and record the information in an electronic data system.
- Staff regularly review reports of foodborne illness to identify cases with common characteristics or suspicious exposures that might represent a common-source outbreak.

Responding to complaints

- Staff triage and respond to complaints in a manner consistent with the likely resulting public health intervention (e.g., investigate reports of group illnesses more aggressively than isolated independent illnesses).

Making changes

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

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4.3.11. Indicators/Measures

The success of complaint-based surveillance systems at detecting and resolving common-source outbreaks depends on multiple interrelated processes. Indicators for assessing and improving surveillance programs can be found in Chapter 8.

4.4. Syndromic Surveillance

4.4.1. Overview

The utility of syndromic surveillance for non-specific health indicators has not been established for enteric disease surveillance and outbreak investigation. In theory, the electronic collection of such indicators could permit rapid detection of significant trends, including outbreaks. In practice, the right mix of sensitivity and specificity has proven difficult to find, and the utility of such systems may be marginal. Surveillance for highly specific syndromes such as HUS or botulism is a critical public health function.

4.4.2. Background

Syndromic surveillance is a relatively new concept, developed in the 1990s and expanded after the 2001 postal system anthrax attacks in an attempt to improve readiness for bioterrorism. One of the first systems implemented was in New York City in 2001.

4.4.3. Reporting

Syndromic surveillance typically relies on automated extraction of health information:

- Preclinical (i.e., not dependent on access to health care, consequently less specific and potentially less useful)—school and work absenteeism, nurse help-lines, sales of over-the-counter drugs, complaints to water companies, calls to poison control centers.
- Clinical prediagnostic (i.e., requires contact with the health-care system but does not rely on a full work-up or laboratory confirmation and, therefore, takes less time)—emergency department chief complaint, ambulance dispatch, lab test orders. . Surveillance for specific syndromes, such as symptoms and non-pathogen related laboratory findings associated with botulism or hemolytic uremic syndrome (HUS) generally fall in this category.
- Postdiagnostic data—hospital discharge codes (ICD-9, ICD-10).

4.4.4. Epidemiology Process

Epidemiology or emergency preparedness groups evaluate alerts triggered by the syndromic surveillance system. The effectiveness of syndromic surveillance using non-specific health indicators in detecting outbreaks has not been demonstrated. Presumably, cases would be interviewed and exposures determined if an alert were determined likely to represent a true outbreak.

4.4.5. Laboratory Process

Laboratories do not play a direct role in preclinical syndromic surveillance. Various types of laboratory data may be utilized for clinical pre-diagnostic and post-diagnostic data-based syndromic surveillance. Public health laboratories would be involved during epidemiologic investigations triggered by a syndromic surveillance signal.

4.4.6. Strengths of Syndromic Surveillance

- In theory, syndromic surveillance using non-specific health indicators has the potential to identify clusters of disease before definitive

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diagnosis and reporting, thus generating a faster signal than can be expected with pathogen-specific surveillance.

- As with complaint systems, outbreaks from any cause, known or unknown, potentially can be detected. Included are clusters of cases identified with discharge diagnoses that include specific agents not part of standard surveillance.
- 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, an increase in diarrheal illness among young children consistent with rotavirus, and the arrival of epidemic influenza.
- Most syndromic surveillance systems have been built with automated electronic data transfer. This infrastructure should be useful for other types of surveillance and public health activities.
- Very specific syndromes, such as botulism or HUS, are important indicators of serious public health problems. Surveillance for specific syndromes with or without identification of an agent is a critical function of health agencies, and is not subject to artifacts introduced by changes in microbiology testing methodologies.

4.4.7. Limitations of Syndromic Surveillance

- Lack of specificity for most syndromic surveillance indicators in the area of foodborne disease 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 drains an agency's resources substantially.
- Evaluating a signal usually means cross-checking it with routine surveillance reports, meaning it cannot replace routine surveillance.
- More specific signals, such as discharge diagnoses, are less timely and do not appear to offer advantage over standard surveillance methods.
- The usefulness of syndromic surveillance using non-specific health indicators has not been demonstrated for foodborne disease. After examination of 2.5 million patient records in its first year of operation, the New York City surveillance system identified 18 diarrhea or vomiting alerts during three outbreak periods. Five institutional outbreaks were identified during one of these periods, but whether the data were sufficiently specific to allow for public health intervention is not clear.[13,14,15]
- The cost of developing syndromic surveillance systems is substantial, and if development occurs at the expense of maintaining or upgrading routine surveillance, results of surveillance are degraded, rather than enhanced.

4.4.8. Key Determinants of Successful Syndromic Surveillance Systems

The following factors drive the interpretation of syndromic surveillance data, affect the success of investigations, and form the basis for best practices.

4.4.8.1. Specificity and speed

Although the potential speed of syndromic surveillance is its chief strength, speed is inversely proportional to the specificity of the indicator disease information. Preclinical information, such as sales of over-the-counter drugs is generally available sooner and is less specific than clinical, prediagnostic signals (such as laboratory test orders). Prediagnostic signals, in turn, are available sooner and are less specific than postdiagnostic signals (such as hospital discharge data).

Lack of specificity at any level results in type 1 probability error (the suggestion of an

4.4. Syndromic Surveillance

association between a signal and a significant health event when, in fact, none exists) and type 2 probability error (the lack of signal suggests a disease event is not occurring, when, in fact, it is). **Less specificity means that more cases are needed to overcome background noise and that false-positive alerts are likely.**

The most specific signals—hospital discharge data—include both nonspecific diagnoses (e.g., diarrhea of infectious origin, ICD-9 #009.3) and diagnoses based on specific agents (e.g., *Salmonella* gastroenteritis, ICD-9 #003.0). Discharge signals for reportable disease, such as salmonellosis, should not offer any time advantage over standard surveillance methods because:

- The diagnoses requires agent identification and would have the same limitations as pathogen-specific surveillance,
- Standard investigation probably would be required for public health action, and
- Identification of illness may precede discharge.

Signals from rare, specific syndromes without laboratory confirmation, such as botulism-like syndrome, should be as effective as pathogen-specific surveillance. This is the basis for the national botulism surveillance program at CDC, which provides emergency clinical, epidemiologic, and microbiologic consultation and antitoxin treatment for persons with suspected botulism because of the extremely serious nature of that illness and the possibility that one case might herald other cases from the same exposure.[8,16] (http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/botulism.PDF).

4.4.8.2. Personal information privacy issues

In a survey on implementation of syndromic surveillance systems, more than half (54.2%) of respondents reported some or substantial problems caused by real or perceived patient confidentiality concerns and the Health Insurance Portability and Accountability Act (HIPAA). Respondents noted that many health-care providers and medical staff did not understand HIPAA and so tended to give minimal patient information. Questions also were raised about whether syndromic surveillance falls under the same regulations as reports of diagnosis-related disease. For example, whether health departments have the legal authority to collect these data is not always clear. Most respondents were using current disease reporting regulations to cover syndromic surveillance. Many respondents believed more specific syndromic indicators are needed to incorporate them into regulations. **Most agencies that had implemented a syndromic surveillance system used deidentified data, which slows investigations of positive signals from the surveillance system.**[17]

4.4.9. Practices for Improving Syndromic Surveillance

Because the usefulness of syndromic surveillance for detecting foodborne disease events has not been demonstrated, the need for additional investment is not clear, especially if these systems compete for resources with underresourced standard surveillance systems. If an agency implements or seeks to improve a syndromic surveillance system, it needs to consider the following practices:

- Better electronic and process integration with standard surveillance systems might improve usefulness.
- Syndromic surveillance data are most useful when corroborated with data from multiple sources (e.g., increased sales of over-the-counter diarrheal medicines associated with a rise in emergency department chief complaints of diarrhea). As historical data accumulate, fine-tuning detection algorithms to reduce false-positive signals might be possible.

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CHAPTER

5

Investigation of Clusters and Outbreaks

Outbreaks of foodborne illness are detected by recognition of similar illnesses among persons with a common exposure that leads to a complaint or notification of health officials or by identification of case clusters through pathogen-specific surveillance. Although complaints are responsible for the detection of approximately 75% of foodborne disease outbreaks, the development of pathogen-specific surveillance through public health laboratories has enabled the detection of widely dispersed outbreaks caused by commercially distributed food products. These outbreaks are initially recognized as clusters of cases defined by subtype characteristics. Distribution of cases by time, space, and personal characteristics provides important clues about whether the cases are likely to represent an outbreak from a common source of exposure. However, only a systematic investigation of the cluster can confirm whether it actually is an outbreak and, if so, whether it is a foodborne disease outbreak. Identifying the route of transmission is critical for implementing effective control measures (see Chapter 6) but is not always possible through agent identification or clinical presentation.

5.0. Introduction

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

5.1. Characteristics of Outbreak Investigations

5.1.1. Importance of Speed and Accuracy

Speed and accuracy are the two key qualities of all outbreak investigations. The investigation team cannot afford to sacrifice one for the other. The team motto should be *Fast and Right*. The importance of speed and accuracy are illustrated below.

- "Removing the pump handle." Stopping an outbreak in its tracks and preventing illnesses are the most obvious goals of outbreak investigations. From this perspective, there are three types of outbreaks.
  - *A localized one-time event, such as a specific food-preparation error or ill food worker at a food-service establishment*. By the time these outbreaks are recognized, the event may be over. However, ensuring an ill worker does not continue to spread disease or preventing secondary spread from initial cases might be possible.
  - *Widespread distribution of a perishable commodity, such as spinach or tomatoes.* Because product may still be in the marketplace when the outbreak is detected, the faster the source can be identified, the more likely the possibility that the commodity can be recalled, preventing further illness from that source. Given the large quantities of contaminated product often involved in these events, even a limited recall could significantly benefit public health.
  - *Contamination of shelf-stable commodities, such as canned or frozen foods or peanut butter, or persistent environmental contamination at a farm, food-processing facility, or restaurant.* The speed with which the source is identified and the effectiveness of a recall are directly related to the number of people exposed to the contaminated commodity and the ultimate size of the outbreak.
- Preventing future outbreaks by identifying the circumstances that led to contamination. Without a prompt, complete, and accurate investigation, the circumstances that led to contamination may not be identified, and the opportunity to prevent future outbreaks will be lost.
- Identifying new hazards. Outbreak investigations identify new agents, new food vehicles, new agent–food interactions, and other unsuspected gaps in the food-safety system. Prompt and thorough investigations while memories are fresh and specimens are available are much more likely to successfully rule out known hazards and identify new hazards. Presenting the information to the sector of the food industry involved can be critical for encouraging changes in procedures, resulting in primary prevention of sporadic illnesses and outbreaks.
- Maintaining the public's confidence. Foodborne disease outbreaks undermine the public's confidence in the food supply and in the public health system established to ensure food safety. Rapidly identifying outbreaks, determining their source, and limiting their scope are critical to restoring

5.1. Characteristics of Outbreak Investigations

confidence in the food supply and food-safety system. On the other hand, inaccurate conclusions about the source undermine public confidence and harm food producers not involved in the cause of the outbreak. For example, strawberries from California were implicated as the source of a multistate outbreak of cyclosporiasis that actually was caused by raspberries from Guatemala. Media reports based on the erroneous conclusion led to millions of dollars in lost strawberry sales, even though the error was rapidly corrected. This situation probably could have been avoided if investigators had considered results from simultaneous investigations in other localities. Maintaining close communication and coordination among members of the investigation team and with other public health officials is the best way to avoid this type of error without delaying the investigation. Early communications with industry representatives may also help to clarify possible misconceptions in data analysis. See section 6.1 for additional discussion about the importance of collecting sufficient information before taking action.

- Empowering the public. Even though releasing premature and incorrect conclusions to the public can be disastrous, and alerting the public about food-safety concerns too often can lead to warning fatigue, withholding or delaying the release of information the public may need to protect itself is inadvisable. Public health agencies are obligated to inform the public or others who need to know as quickly as possible. Generally, ask yourself,
  - "Will the release of this information enable consumers to take steps to protect themselves?"
  - "If the wrong product is identified, what will the negative impact be on public health, as well as on the industry and consumer confidence?"

Making decisions with imperfect information in the context of an ongoing outbreak is challenging, and judgments should favor protecting the public while keeping in mind the significant negative impact the announcement of an incorrect association can have on an industry. However, as new information becomes available, recommendations must be rapidly revised and communicated. For example, in 2011, a large outbreak of hemolytic uremic syndrome caused by a novel *Escherichia coli* O104:H4 strain occurred in Germany.[1] Within a week after outbreak detection, results of preliminary investigations led German public health officials to advise consumers to not eat fresh tomatoes, cucumbers, or lettuce. However, ongoing investigations during the next 2 weeks implicated consumption of sprouts, and the previous advisory was promptly retracted.[2]

5.1.2. Principles of Investigation

5.1.2.1. Outbreak detection

Outbreaks typically are detected through two general methods: complaint systems and pathogen-specific surveillance (see Chapter 4). After receipt of a complaint about suspected foodborne illness associated with a particular event or establishment or detection of an unusual cluster of isolates through pathogen-specific surveillance, a preliminary investigation should be conducted to determine whether the reported illnesses may be part of an outbreak.

5.1.2.2. Investigation leadership

During an investigation, the focus of activities might shift between roles described below. They also might shift between levels of government in accordance with authority and the availability of resources to carry out the required tasks, as follows:

- Laboratory studies to identify an agent, including microbiological studies and applied food-safety research;

5.1. Characteristics of Outbreak Investigations

- Epidemiologic studies to identify transmission routes, exposure sources, or food vehicles and risk factors for disease;
- Regulatory investigations of food-production sources and distribution chains to identify where, during production 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; and
- Communication of investigation findings to the public and the food industry to support control and prevention measures.

Investigations initiated at a local level might be more effectively coordinated or conducted at a state level if multiple jurisdictions are involved. Similarly, federal agencies might be needed to effectively coordinate and investigate multistate outbreaks. Conversely, state or local agencies with sufficient resources to investigate clusters within their jurisdictions should be encouraged to do so, even if the cluster was recognized at the federal or state level (see Chapter 7).

5.1.2.3. Communication and coordination

Coordinate activities and set up good lines of communication between individuals and agencies involved in the investigation. To avoid mixed messages and incomplete information or misinformation, each investigation should have a consistent point of contact. Guidelines for coordinating multijurisdictional investigations are summarized in Chapter 7. Investigations are rarely linear. Although most procedures for investigating outbreaks follow a logical process—from determining whether an outbreak is occurring to identifying and controlling the source—most actual investigations feature multiple concurrent steps. In addition, the focus of the investigation may need to shift as the situation warrants. For example, a key to solving the *Salmonella* Typhimurium outbreak associated with peanut products produced by Peanut Corporation of America was the recognition that subclusters of cases had common institutional exposures. This led to an investigational shift from individual case exposures to institutional food purchases.[3] Maintaining close communication and coordination among members of the outbreak investigation team is the best way to ensure concurrent activities do not interfere with each other and important investigation steps are not forgotten.

5.1.2.4. Hypothesis generation

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. Key steps in this process include the following:

- Review previously identified risk factors and exposures for the disease;
- Examine the descriptive epidemiology of cases to identify person, place, or time characteristics that might suggest a particular exposure; and
- Interview in detail the affected persons or a sample of affected persons to identify unusual exposures or commonalities among cases.

On the basis of this information, investigators can identify possible exposures for further evaluation by epidemiologic, laboratory, or environmental studies. In practice, the generation and testing of hypotheses is an iterative process, with the hypothesis modified as more information is obtained. For example, an outbreak involving a high proportion of cases among preschool-aged children might suggest exposure to a food product marketed to young children, such as a cereal product or snack food. Identification of a specific product, such as a certain vegetable

5.1. Characteristics of Outbreak Investigations

powder–coated snack, by several cases should prompt re-interview of other cases to identify previously unrecognized exposures to the product. Concordance of exposures among a substantial proportion of cases could lead directly to recall or product testing or a focused epidemiologic study to confirm the association.

Although hypothesis generation seeks to narrow the focus of the investigation, high-risk exposures that are easy to forget should not be ruled out just because a low proportion of cases report the exposure. If reason exists to suspect that a particular food item might be the source of the outbreak, that item should be included in further epidemiologic studies, regardless of whether a majority of cases recalled it. Interviews should include questions that specifically try to identify consumption of the suspected food item, especially if it is an ingredient.

5.1.2.5. Standardized data collection forms and processes

The use of standardized forms for collecting exposure histories ensures that pertinent information is collected from all cases. Consistently asking about high-risk exposures (e.g., sprouts, raw milk, ground beef, leafy greens) makes data easier to share among jurisdictions and commercial product outbreaks easier to resolve quickly. In addition, use of a standardized interview form with which the interviewer is familiar will decrease time spent on staff training and decrease errors in data collection. Similarly, use of standardized forms for environmental investigations provides comparable data for investigations that might involve multiple establishments. Because good forms take time to develop and format, developing templates *before* a crisis is critical to their rapid deployment (see also Chapter 4, section 4.3.9). The CIFOR Clearinghouse (www.cifor.us/ clearinghouse/keywordsearch.cfm) provides examples of questionnaires used by various health departments to collect exposure information for different pathogens and might be useful in template development. The Environmental Health Specialists Network (EHS-Net) website (www.cdc.gov/nceh/ehs/EHSNet/) can be referenced for models of environmental assessment forms and consumer complaint forms.

Interviewers should be trained in the use of the standardized interview forms and techniques and have demonstrated proficiency in their use during previous investigations. Interviews can be conducted by one interviewer or by multiple interviewers. Although one interviewer might recognize uncommon exposures mentioned by multiple persons, completing these hypothesis-generating interviews might take several days. Multiple interviewers can interview cases simultaneously but need to regularly compare notes so that they can recognize uncommon exposures mentioned by multiple persons. This latter process forms the basis of the dynamic cluster investigation model described below.

5.1.2.6. Privacy of individuals, patients, and their families.

All outbreak investigations involve collection of private information, such as names and symptoms that must be protected from public disclosure to the extent allowed by law. All members of the investigation team, including epidemiologists, laboratorians, environmental health specialists, and food-safety personnel, need to be familiar with and follow relevant state and federal laws and practices.

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

5.2.1. Conduct a Preliminary Investigation

5.2.1.1. For complaints of illness attributed to a particular event or establishment

The following questions should be answered:

- Are the incubation period and symptoms (or specific agent, if one or more cases have been diagnosed) consistent with an illness resulting from the reported exposure?
- Are multiple cases being attributed to the same exposure?
- Are all of the illnesses similar (suggesting that all are the same disease)?
- Could these illnesses be reasonably explained by other common exposures?

If multiple cases of illness have the same incubation period and if multiple persons have symptoms consistent with an illness resulting from the reported exposure, the complaints might represent an outbreak and need to be investigated.

5.2.1.2. For case clusters identified through pathogen-specific surveillance

The following questions should be answered:

- Do the number of cases with the cluster characteristics exceed the number expected during this time frame and season?
- Does the demographic distribution (e.g., age, sex, and ethnicity) or geography suggest a common source of exposure?
- Do cases share any unusual exposures?
- Do new cases continue to be detected, suggesting the potential for ongoing transmission and the need for abatement procedures?

If the number of cases in a cluster or the demographic features or known exposures of cases suggest a common source, or if new cases continue to be detected, the cluster might represent an outbreak and needs to be investigated. (See model practices for cluster investigation, below).

5.2.2. Assemble the Outbreak Investigation and Control Team

(See also Chapter 3)

5.2.2.1. Alert outbreak investigation and control team

Alert outbreak investigation and control team leaders as soon as the possible outbreak is identified. Review descriptive features of the outbreak setting and relevant background information about the etiologic agent, establishment, or event.

5.2.2.2. Assess the priority of the outbreak investigation

On the basis of the outbreak setting and descriptive epidemiology, **outbreak investigation and control team leaders should assess the priority of the outbreak 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 Shiga toxin–producing *E. coli* O157:H7, hemolytic uremic syndrome, or botulism;
  - Affect populations at high risk for complications of the illness (e.g., infants or elderly or immune-compromised persons); and
  - Affect a large number of persons.
- Appear to be ongoing:
  - Outbreak might be associated with food-service establishment in which ill food workers provide a continuing source of infection.
  - Outbreak might be associated with an adulterated food product in commercial distribution that is still being consumed.

5.2.2.3. Assemble and brief the outbreak investigation and control team

On the basis of the priority given the outbreak and the nature of the outbreak, investigation

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

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 cases within 24–48 hours and solicit controls as needed.** If sufficient staff are not available, external assistance should be requested to conduct interviews.

Outbreak investigation staff should be briefed on the outbreak, the members of the outbreak investigation and control team, and their individual roles in the investigation.

For outbreaks involving multiple jurisdictions, the outbreak investigation and control team should include members from all agencies participating in the investigation (see also Chapter 7).

If an agency does not believe it can manage an outbreak (i.e., the scale or complexity is likely to overwhelm agency resources, or the nature of the outbreak is beyond the expertise of agency staff), help should be requested as soon as possible (see also Chapter 3 section 3.9).

5.2.3. Establish Goals and Objectives for the Investigation

5.2.3.1. Goals

- Obtain sufficient information to implement specific interventions that will stop the outbreak.
- Obtain sufficient information to prevent a similar outbreak in the future.
- Increase knowledge of the epidemiology and control of foodborne diseases. Unanswered questions about the etiologic agent, mode of transmission, or contributing factors should be identified and included in the investigation to add to the public health knowledge base.

5.2.3.2. Objectives

For outbreaks associated with events or establishments (Table 5.1):

- Identify the etiologic agent.
- Identify persons at risk and size and scope of outbreak.
- Identify mode of transmission and vehicle.
- Identify source of contamination.
- Identify contributing factors (specific ways that food became contaminated or capable of causing illness) and environmental antecedents.
- Determine potential for ongoing transmission and need for abatement procedures.

For outbreaks identified by pathogen-specific surveillance (Table 5.2):

- Identify mode of transmission and vehicle.
- Identify persons at risk and size and scope of outbreak.
- Identify source of contamination.
- Identify contributing factors (specific ways that food became contaminated or capable of causing illness) and environmental antecedents.
- Identify size and scope of outbreak.
- Determine potential for ongoing transmission and need for abatement procedures.

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

CIFOR Keys to Success: Focus Area 6—Initial steps in investigation of clusters and outbreaks

Initial steps

- Agency/jurisdiction has processes for responding to a possible outbreak, including who is to be notified and/or involved in the investigation and specific actions. Processes are written and easily accessible by staff.
- Agency/jurisdiction has established criteria for determining the scale of the response to a possible foodborne disease outbreak on the basis of the likely pathogen, number of cases, distribution of cases, hypothesized source, and agencies likely to be involved.
- Staff can prioritize the response to a possible outbreak on the basis of agency/jurisdiction criteria and know what outbreak circumstances require an immediate response, a more moderate response, or no response at all.
- Staff have access to historical trends or other data to determine whether case counts exceed the expected number for a particular period and population.
- Staff develop one or more hypotheses about the source of an outbreak early in the investigation to guide investigation steps.

Requests for assistance

- Local agencies notify state agencies as soon as an outbreak is suspected.
- Agency/jurisdiction asks for help as soon as it recognizes the need.

Making Changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to the initial steps of an outbreak investigation and routinely evaluates its performance in this Focus Area.

5.2.4. Select and Assign investigation Activities

Tables 5.1 and 5.2 outline objectives and investigation activities that can be conducted during epidemiologic, environmental health, and public health laboratory investigations of foodborne disease outbreaks. 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, nor do responsibilities always occur linearly. In addition, considerable overlap can exist between roles, especially in local health departments. The actual responsibilities for a staff member will vary in accordance with the practices of the jurisdiction responsible for the investigation, roles defined in the outbreak investigation and control team, and resources.

Table 5.1. Investigation activities for outbreaks associated with events or establishments reported through foodborne illness complaint systems*

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify etiologic agent.	• Contact health-care providers of cases who have sought medical attention. • Interview cases to characterize symptoms, incubation period, and duration of illness. • Obtain stool specimens from cases. • 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.	• 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/health-care staff. • Obtain stool specimens from ill or all food workers. This activity could also be conducted by nursing/health-care staff. • Obtain and store samples of implicated and suspected food items and ingredients. • Determine whether setting or food item suggests a likely pathogen.	• Contact clinical laboratories that might have performed primary cultures on cases, and obtain specimens. • Test stool samples to identify agent. • Test samples of implicated food items to identify agent. • Subtype all isolates as soon as possible after receipt.
Identify persons at risk and determine size and scope of outbreak.	• 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 health-care 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.	• Obtain list of reservations for establishment, credit card receipts, receipts for take-out orders, inventory of foods ordered at establishment, or guest lists for events. Where possible, obtain information electronically.	• Contact clinical laboratories to identify additional stool specimens being cultured.

Table 5.1. Investigation activities for outbreaks associated with events or establishments reported through foodborne illness complaint systems* *Continued*

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify mode of transmission and vehicle.	• Interview identified cases and controls or well meal companions about all common exposure sources. Calculate odds ratios for specific exposures. • Interview persons with identified exposures to determine attack rates and relative risks for specific exposures.	• 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.	• 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.
Identify source of contamination.	• Combine descriptive and analytical epidemiology results to develop a model for the outbreak.	• 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.	• Evaluate results of all outbreak-associated cultures 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.

Identify contributing factors.and antecedents	• Summarize information to identify confirmed or suspected agent. • Summarize information to identify confirmed or suspected food vehicle.	• 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.	• Summarize information about culture results from clinical, food, and environmental samples.
Determine potential for ongoing transmission and need for abatement procedures.	• On the basis of agent, incubation period, and likelihood of secondary spread, create epidemic curve, and evaluate the course of the epidemic 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.	• Implement control measures to prevent further exposures: o Verify that all food workers who pose a risk for transmission have been excluded or restricted, as needed; o Verify that potentially contaminated foods have been properly disposed; o Verify that food contact surfaces and potential environmental reservoirs have been adequately cleaned and sanitized; o Train staff in safe food-preparation practices; o Modify food-production and food-preparation processes with appropriate preventive controls; and o 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.	• Assess status of completed and pending cultures to identify gaps that suggest a potential for ongoing transmission.

* These are general categories of roles to demonstrate typical investigation activities. The roles can overlap considerably, especially in local health departments. The persons who actually conduct each of these activities will vary by agency and investigation.

Table 5.2. Investigation activities for outbreaks identified by pathogen-specific surveillance

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify mode of transmission and vehicle.	• Interview cases as soon as possible with standardized detailed exposure history questionnaire to identify possible common exposures (described in detail below). In some situations, cases are interviewed as soon as they are reported and before an outbreak has been recognized. • 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 pattern possibly associated with particular food items or diets. • Compare detailed exposure history questionnaire frequencies against known or estimated background exposure rates, such as those in FoodNet Atlas of Exposures, to identify suspected food item. • Interview non-ill community controls or non–outbreak-associated ill persons to obtain detailed exposure information to be used in a case-comparison analysis of exposures. • 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 group (e.g., non-ill controls or cases not associated with outbreak) to implicate food item or nonfood-exposure source.	• Contact restaurants, grocery stores, or other locations identified by multiple cases 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 (for example, USDA-FSIS Directive 10,000.1). This will help the regulatory authority to take appropriate regulatory action. • Conduct an investigational traceback to determine whether a suspected food vehicle from multiple cases has a distribution or other point in common. • If specific food item or ingredient is implicated, conduct formal regulatory traceback.	• Store collected food samples, pending results of epidemiologic analyses. • Culture implicated food samples to confirm presence of agent. • Conduct serotype/genotype tests, and 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.

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Identify persons at risk and determine size and scope of outbreak.	• Alert health-care 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 cases if they know of others who are similarly ill. • Depending on nature of outbreak, take additional steps as warranted. Examples include reviewing employee or school absences, reviewing death certificates, surveying population affected, or directly asking members of the public to contact the health department if they have the illness under investigation.	• 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 cases to identify employee illnesses or foodborne illness complaints from patrons.	• Contact clinical laboratories to identify additional stool specimens being cultured. • Speed up referral and subtyping of outbreak pathogen.
Identify source of contamination.	• Combine descriptive and analytical epidemiology results to develop a model for outbreak.	• 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 o Reconstruct food flow for implicated food item. o Interview food workers to determine food-preparation responsibilities and practices before exposure. o Obtain samples of implicated food or ingredients. o Obtain environmental samples from food contact surfaces or potential environmental reservoirs.	• Evaluate results of all outbreak-associated cultures 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 (for example, USDA-FSIS Directive 10,000.1). This will help the regulatory authority to take appropriate regulatory action.

Table 5.2. Investigation activities for outbreaks identified by pathogen-specific surveillance
Continued

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify contributing factors and antecedents.	• Summarize information to identify confirmed or suspected food vehicle.	• Evaluate results of environmental assessment, given identification of agent and results of epidemiologic investigation, to identify contributing factors and antecedents.	• Summarize information about culture results from clinical, food, and environmental samples. • Provide background statistics on pathogen prevalence.
Determine potential for ongoing transmission and need for abatement procedures.	• 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.	• Verify that food workers who might have been infected during outbreak and who pose a risk for transmission have been excluded or restricted, as needed. • 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.	• Assess status of completed and pending cultures to identify gaps that may suggest a potential for ongoing transmission.

* These are general categories of roles to demonstrate typical investigation activities. The roles can overlap considerably, especially in local health departments. The individuals that actually conduct each of these activities will vary by agency and investigation.

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

CIFOR Keys to Success: Focus Area 7—Epidemiologic investigation

Staff skills and expertise

- Staff have good interviewing skills and can collect complete and accurate exposure information from cases and controls, where appropriate, or have access to staff in other agencies who have this expertise.
- Staff have expertise in epidemiologic study design or have access to staff in other agencies who have this expertise.

Investigation

- Agency/jurisdiction has a written protocol outlining the steps in the epidemiologic investigation of a foodborne disease outbreak. Staff have easy access to the protocol and have been trained in its implementation.
- Staff interview cases about exposures as soon as possible after the illness is reported.
- Staff have access to standard epidemiologic questionnaires used by other investigators in similar outbreaks.

Communication

- Staff communicate in a timely fashion and coordinate activities with environmental health and laboratory staff during the investigation.

Making changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to the epidemiologic investigation and routinely evaluates its performance in this Focus Area.

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CIFOR Keys to Success: Focus Area 8—Environmental health investigation

Staff skills and expertise

- Staff have expertise in food production processes, Hazard Analysis and Critical Control Points (HACCP), and environmental health assessments.
- Staff have expertise in trace-back and traceforward investigations (or have access to staff in other agencies who have this expertise).
- Staff have good interviewing skills to solicit information from facility managers and food workers or have access to staff in other agencies who have this expertise.

Investigation

- Agency/jurisdiction has a written protocol outlining the steps in the environmental assessment of a foodborne disease outbreak. Staff have easy access to the protocol and have been trained in its implementation.
- Staff undertake environmental assessments at facilities or production sites implicated during a foodborne disease outbreak (not routine food-establishment inspections), and identify appropriate contributing factors and environmental antecedents.
- Staff undertake trace-back and traceforward investigations (or have access to staff in other agencies who undertake these investigations).

Communication

- Staff communicate in a timely fashion and coordinate activities with epidemiology and laboratory staff during the investigation.

Making changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to the environmental assessment and routinely evaluates its performance in this Focus Area.

CIFOR Keys to Success: Focus Area 9—Laboratory investigation

Staff skills and expertise

- Staff have expertise in appropriate laboratory testing methods and access to necessary equipment and reagents to perform testing.

Specimen collection and testing

- Epidemiology and environmental health staff collect appropriate clinical and environmental specimens and store and transport them properly.
- Staff link patient and specimen information.
- Staff characterize isolates (e.g., by subtyping) in a timely fashion.
- Staff use standardized (currently approved) methods to subtype isolates.

Communication

- Staff communicate in a timely fashion and coordinate activities with epidemiology and environmental health staff during the investigation.
- Staff report subtyping information to appropriate national databases in a timely fashion.

Making changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to the laboratory investigation and routinely evaluates its performance in this Focus Area.

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

5.2.4.1. Cluster investigations—model practices

This section lists model practices for cluster investigations. Actual practices used in a particular situation will depend on the circumstances specific to the outbreak (e.g., the pathogen and number and distribution of cases), staff expertise, structure of the investigating agency, and agency resources. Although a systematic evaluation under different circumstances has not been performed on these practices, experiences from successful investigations support their value. Investigators are encouraged to use these practices as appropriate to the specific outbreak.

5.2.4.1.1. Use interview techniques to improve food recall

In general, to help improve food recall when collecting exposure information for a cluster investigation:

- Use trained interviewers who have demonstrated proficiency in conducting exposure interviews.
- Question subjects as soon as possible after illness is reported.
- Do not share information about suspected food items or working hypotheses with interviewees. However, do ask specifically about suspected item(s), as described in the dynamic cluster investigation model.
- Encourage interviewees to remember information by asking them to elaborate on where they ate, with whom they ate, and events associated with the meals. Ask interviewees to look at a calendar from the appropriate time periods to jog their memory.
- Use a structured list of venues, including restaurants, grocery stores, food pantries, farmers' markets, social events, business meetings, and other places where people might buy or eat food.
- Enlist the help of persons who prepared meals during the period of interest.
- Ask whether the interviewee keeps cash register or credit card receipts that might indicate when, where, or what he or she ate.
- If the subject uses a grocery store shopper card, ask permission to obtain purchase records for a specified time period. Some grocery chains readily cooperate with these requests.

5.2.4.1.2. Use a dynamic cluster investigation process to generate hypotheses

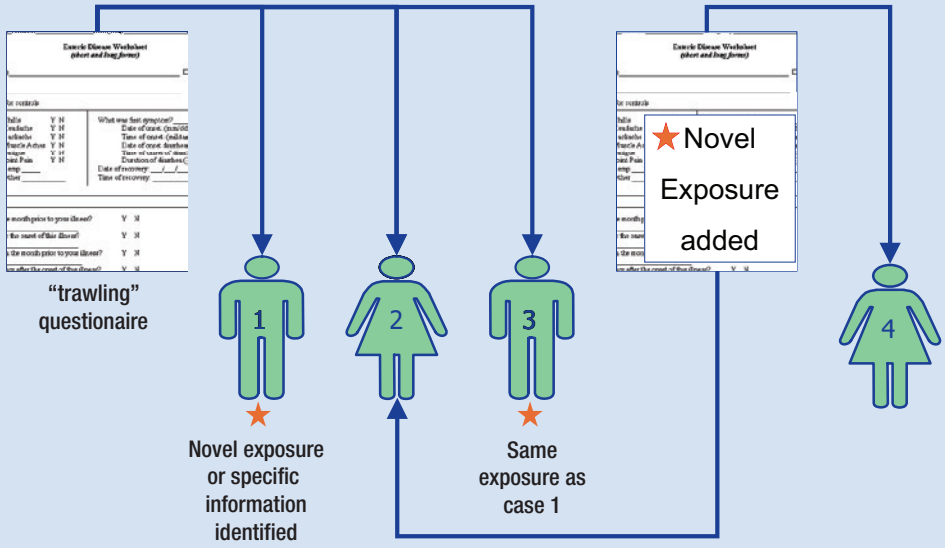
In the dynamic cluster investigation model, initial cases within a recognized cluster are interviewed with a detailed exposure history questionnaire. As new exposures are suggested during interviews, the initial cases are systematically re-interviewed to uniformly assess their exposure to the new exposures suggested by subsequent interviews. Newly reported cases also will be asked specifically about these exposures. See Figure 5.1 for a visual representation of this process.

Ideally, interviews of the first five to ten cases will produce a relatively short list of suspicious exposures—suspicious because they involve commodities that are not commonly eaten or involve specific brands of a commonly eaten food item. Because these exposures might not have been uniformly assessed on the original questionnaire, specific questions about the newly suspected exposures should be added to the questionnaire for future use. Re-interviews of initial cases, combined with interviews of new cases in the cluster, can result in rapid definition of a unique exposure shared among multiple cases. Occasionally, this evidence is so specific and so obviously unlikely to have occurred by chance alone that it can lead to direct public health intervention. More frequently, the various hypotheses will need to be tested with a case–control study, food testing, or investigational tracebacks in the ensuing investigation.

As the number of cases and jurisdictions increases, strict application of this approach

5.2. Complaint, Cluster, and Outbreak Investigation Procedures

Figure 5.1. Dynamic cluster investigation.



In this model, cases are interviewed with a detailed exposure history questionnaire. Specific exposures shared by multiple cases might surface that are suspicious because they involve commodities not commonly eaten or involve specific brands of a commonly eaten food item. Because the original questionnaire might not have captured these exposures, specific questions should be added to the questionnaire for future use and to systematically re-interview cases to assess the suspicious sources discovered during the investigation process. "Novel exposure" refers to exposure that was not specifically listed on the original detailed exposure history questionnaire.

may become infeasible. In addition, some cases might not be amenable to multiple interviews. In any event, clear and timely communications with other investigators are critical to adequately evaluate suspicious new exposures reported elsewhere.

5.2.4.1.2.1. Dynamic cluster investigation with routine interview of cases

For agencies with resources sufficient to routinely interview cases with a detailed exposure history questionnaire as illness is reported, dynamic cluster investigation can be initiated with recognition of the first cases. This increases the sensitivity and speed of outbreak identification and resolution in several ways.

- Faster interviews:
  This process increases recall and the likelihood of meaningful intervention because more interviews are conducted sooner after the onset of illness.
- Increased recall:
  Recall is also amplified by what is essentially a group dynamic. People are less likely to recall exposures when asked in general about their exposure history and more likely to remember when questioned about specific exposures that other persons have identified. For example, in the 2007 multistate outbreak of *Salmonella* Wandsworth infections associated with a vegetable powder–coated snack, cases were less likely to report its consumption when asked to list all foods eaten during the period of interest but were highly likely to remember when asked specifically whether they had eaten the particular snack. This

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same principle underlies an advantage of questionnaires with longer lists of specific exposure questions.

- Potential to conduct case–case analytical studies:
  In jurisdictions that routinely conduct interviews using detailed exposure history questionnaires, case-to-case comparison studies offer an efficient tool to evaluate exposures as part of cluster investigations. **Cases with microbial agents other than the agent under investigation or of a different subtype, ideally from the same time period, are used as "controls" to identify risk factor differences.** This requires that the persons in the cluster and persons used for comparison have been interviewed using the same form. However, because some microbial agents have common food vehicles, case-to-case comparisons might cause investigators to overlook the source of an outbreak.

5.2.4.1.2.2. Dynamic cluster investigation without routine interview of cases

Because most public health agencies do not have sufficient resources to conduct detailed exposure history interviews for every case, a two-step interviewing process might be the best alternative approach. All cases should be interviewed with a standardized questionnaire to collect exposure information about limited high-risk exposures specific to the pathogen. When, on the basis of the novelty of the subtype pattern, geographic distribution of cases, or ongoing accumulation of new cases, the cluster appears to be an outbreak associated with a commercially distributed food product, all cases in the cluster should be interviewed using a detailed exposure history questionnaire as part of a dynamic cluster investigation, as described above.

5.2.4.1.3. Interpretation of results of hypothesis-generating interviews

As noted above, detailed exposure history questionnaires are frequently used in interviews to shorten the list of exposures evaluated in a hypothesis-testing study. Good judgment is required in the interpretation of hypothesis-generating interviews. This has followed a general approach outlined below, assuming that a sufficient number of cases have been interviewed (e.g., at least eight):

- If none of the persons interviewed report a specific exposure, the hypothesis is no longer viable and most likely can be dropped from subsequent study.
- If more than 50% of persons interviewed report an exposure, that exposure should be studied further.
- If fewer than 50% of persons report an exposure, that exposure still might be of interest, particularly if it is difficult to recognize or unusual.

This approach embodies the principle that implicated food items should have been eaten by most of the cases. However, previously identified risk factors (such as sprouts for Shiga toxin–producing *E. coli*) should not be ruled out just because fewer than half of cases reported the exposure, particularly if the exposure is unusual or difficult to recognize. The practice of focusing on foods reported by more than half of cases for use in a hypothesis-testing study delayed the identification of sprouts as the actual food vehicle in the outbreak of *E. coli* O104:H4 infections in Germany in 2011.[1,2]

For testing hypotheses, the specificity of exposure source information is critical. In addition to obtaining details of brand and product identity, purchase dates and locations, and distribution information from retailers and distributors for commodity products is essential to implicate a food item. For food items that are frequently co-mingled (e.g., lettuce and tomatoes, tomatoes and hot peppers), source tracing of commodities can help disentangle

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the exposures. In addition, rapid and thorough assessment of distribution sources can identify the source with sufficient precision so that the traceback becomes the hypothesis-testing step of the investigation.[3, 4]

5.2.4.1.4. Cross-reference case interviews with foodborne illness complaints

Regardless of whether a common restaurant or event is identified in interviews of cases in a cluster, it is a good practice to review foodborne illness complaints to identify undiagnosed cases that could be linked to an outbreak. Common exposures reported in case interviews and foodborne illness complaints could be key to identifying the source of the outbreak. In Minnesota, 10% of E. coli O157:H7 outbreaks reported during 2000–2008 and 11% of *Salmonella* outbreaks reported during 2001–2007 were solved because of links between case interviews and foodborne illness complaints.[5, 6]

5.2.4.1.5. Use the FoodNet Atlas of Exposures

The observed consumption rate of a food item among case can be tested against known or estimated background consumption rates by using a binomial distribution probability model (e.g., http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Outbreaks/Gastroenteritis/Pages/Outbreak-Investigation-Tools.aspx). For food items with a relatively low expected frequency of consumption (e.g., oysters), even a small number of interviews can yield highly suggestive data. For common food items (e.g., eggs or chicken), additional and more specific product data (e.g., brand and place of purchase or consumption) are necessary.

The FoodNet Atlas of Exposures is one source of food consumption estimates, although it covers only a few dozen food items, represents only the population of FoodNet sites, and does not account for potential changes in consumption patterns since the last time the survey was performed.[7]

For example, bagged spinach was first identified as the source of a 2006 *E. coli* O157:H7 outbreak on the basis of only six structured interviews (with five persons reporting having eaten bagged, prewashed spinach). FoodNet survey data suggested that only about 17% of the U.S. population recalled eating any kind of fresh spinach within a given week. Combined with similar findings from other states conducting case investigations, these collective observations led to prompt action and further investigations, which rapidly identified the location, date, and even shift of contaminated spinach production.

The outbreak of *Salmonella* Tennessee infections associated with peanut butter highlights many of the issues discussed above. In November 2006, a widespread outbreak was detected. By December 1, 52 isolates from 25 states were linked by pulsed field gel electrophoresis pattern. Routine interviews by local officials did not identify a common food exposure. In January 2007, 31 patients were interviewed by using a standard hypothesis-generating questionnaire with over 200 items. Two food commodities (turkey and peanut butter) were identified with greater frequency of consumption than expected according to the Atlas of Exposures. However, the lack of brand information meant that cases had to be re-interviewed. Of six cases re-interviewed to assess peanut butter exposures, five reported a common brand. Had this information been systematically collected at the beginning of the investigation, a month or more may have been saved in identifying the source.[8] Thus, the practice of collecting detailed exposure information during hypothesis-generating interviews has sufficient evidence to be promoted as a standard practice. Because the Atlas of Exposures is based on surveys at selected sites at certain times, the findings must be extrapolated carefully to other populations

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and seasons. Results from the most recent FoodNet population survey are available at www.cdc.gov/foodnet/studies/population-surveys.html.

Even in the absence of survey data, common-sense estimates of the prevalence of a given exposure can be used to identify exposures of interest more quickly. For example, although not included in the FoodNet surveys, the significance of finding five of five *Salmonella* Enteritidis cases reporting consumption of shelled almonds of one brand in a 2003-2004 outbreak was readily apparent not only to epidemiologists but also to regulators and retailers, particularly because the *Salmonella* Enteritidis subtype had previously been implicated as the etiology of a large international outbreak traced to shelled almonds. If investigators have no idea of the background frequency of consumption of a food item, they can use an estimate that is very likely to be an overestimate (e.g., "I don't know how many people eat arugula each week, but I am sure it is less than 20%") for comparison with rates among cases. These what-if analyses can lead to source tracing, which can help confirm the hypothesis.

5.2.4.1.6. Conduct an environmental health assessment

When investigating a food-production, food-processing or food-service establishment implicated in an outbreak, conduct an environmental health assessment. An environmental health assessment is a systematic, detailed, science-based evaluation of environmental factors that contributed to transmission of a particular disease in an outbreak. It differs from a general inspection of operating procedures or sanitary conditions used for the licensing or routine inspection of a restaurant, food processor, or food-production facility. An environmental health assessment focuses on the problem at hand and considers how the causative agent, host factors, and environmental conditions interacted to result in the problem.

The goals of an environmental health assessment are to identify:

- Possible points of contamination of the implicated food with the disease agent;
- Whether the causative agent could have survived (or, in the case of a toxin, not been inactivated);
- Whether conditions were conducive for subsequent growth or toxin production by the disease agent; and
- Environmental antecedents that resulted in the conditions enabling the outbreak to occur.

Although a primary goal of an environmental health assessment is to identify possible points of contamination, survival, or growth of the disease agent, to be most valuable, investigators also need to identify environmental antecedents that resulted in these conditions. Environmental antecedents are the circumstances behind the problem and include inadequate worker education, behavioral risk factors, management decisions, and social and cultural beliefs. Only by identifying the problem behind the problem can investigators develop effective interventions and preventive controls.

The timing of the environmental health assessment depends largely on the specifics of the outbreak and available information but should be initiated as early as possible. 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 disease agent is likely to be viral, bacterial, toxin, or chemical, they often can begin an environmental health assessment based on

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possible factors more likely to be associated with that disease agent.

5.2.4.1.6.1. Sources of information and activities included in an environmental health assessment

Epidemiologic information is necessary to initiate an environmental health assessment and guides the assessment as it progresses. Once an investigation begins, sources of information for an environmental health assessment include product information (e.g., chemical and physical characteristics and source); written policies or procedures; direct observations and measurements; interviews with employees and managers; and lab testing of suspected foods, ingredients, or environmental surfaces.

The specific activities in an environmental health assessment differ by causative agent, suspected vehicle, and setting but usually include the following:

- Describing the implicated food;
- Observing procedures to make the implicated food;
- Talking with food workers and managers;
- Taking measurements (e.g., temperatures);
- Developing a flow chart or food flow diagram for the implicated food item or ingredient to capture detailed information about each step in the food-handling process, including storage, preparation, cooking, cooling, reheating, and service and identifying opportunities for contamination, survival, and growth (proliferation) at each step;
- Collecting food specimens and occasionally clinical specimens from people in contact with the suspected food vehicle or the environment in which it was produced or used; and
- Collecting and reviewing documents on source of food.

These activities provide information needed to develop the most likely environmental picture of the facility before the exposures that led to the outbreak. Once a complete picture has been developed, contributing factors and environmental antecedents and preventive controls can be determined.

5.2.4.1.5.2. Qualifications to conduct an environmental health assessment

To accurately relate the opportunities for contamination, survival, and growth of a disease agent in a food to a specific outbreak, the investigator needs a good understanding of:

- Agent (e.g., likely sources, optimum growth conditions, inhibitory substances, means of inactivation);
- Factors necessary to cause illness (e.g., infectious dose, portal of entry);
- Implicated vehicle (e.g., physical and chemical characteristics of the vehicle that might facilitate or inhibit growth, methods of production, processing, preparation); and
- Possible risk factors in the environment or operation that can contribute to the transmission of the disease agent.

Critical thinking skills also are needed to analyze information that evolves from an environmental health assessment, identify the likely source of the problem, and determine how the disease agent, host factors, and environmental conditions interacted to support a specific outbreak. This level of knowledge and skill requires someone with special training in this field of investigation, such as a sanitarian or environmental health specialist.

5.2.4.1.7. Conduct tracebacks/traceforwards of food items under investigation

Tracing the source of food items or ingredients from point of purchase/consumption through distribution to source of production can be critical to identifying epidemiologic links among cases or ruling them out. This

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is known as an investigational traceback, although sometimes the terms "informational traceback" or "epidemiologic traceback" also are used. When some or all of a number of conditions occur, an investigational traceback/traceforward might be warranted:

- Linked cases occur in multiple locations or jurisdictions (particularly if they occur in multiple states);
- A vehicle cannot be clearly implicated with traditional epidemiologic, laboratory, and environmental assessment methods alone; and
- More information is needed to determine whether similar food items from different establishments, stores, or firms can be linked to a distributor or processor.

The decision to conduct an investigational traceback should be based on input from public health and regulatory agencies. Because tracebacks can be intensive and complex, it is very important that the suspected food exposures are prioritized to make the best use of available resources to identify the most likely source of the problem.

For nonbranded commodities, such as produce items, the convergence of multiple cases along a distribution pathway can identify the source of contamination. In an outbreak of *E. coli* O157:H7 infections associated with hazelnuts, identification of a common supplier confirmed the hypothesis generated by case interviews.[9] Conversely, failure to identify common suppliers might indicate that the food item in question is not a likely vehicle. In the large multistate outbreak of *Salmonella* Saintpaul infections, the failure of tomato tracebacks to converge on common suppliers helped indicate that tomatoes might have been a surrogate for the actual vehicle (hot peppers) with which they were co-mingled in multiple food items. Investigational tracebacks of this type need to be conducted quickly to be incorporated into epidemiologic studies. Rather than being an outcome of epidemiologic analyses, investigational tracebacks are an integral part of the exposure assessment needed to conduct the epidemiologic analysis and should be closely coordinated with partner agencies. Subsequent formal regulatory tracebacks might be needed to confirm the distribution of implicated products.

5.2.5. Coordinate Investigation 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 Guidelines for Multijurisdictional Investigations (Chapter 7).

Update the outbreak control team daily. 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 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 stool samples from food workers or food and environmental samples from the establishment.

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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 health 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. This will ensure rapid enrollment of new cases in outbreak investigation studies. Similarly, as investigators acquire information from cases 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 investigation 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. See Chapter 7 for information about identifying and responding to multijurisdictional outbreaks.

5.2.6. Compile Results and Reevaluate Goals for Investigation (see also Chapter 6)

Compile results of outbreak investigations in a manner that enables comparisons with the original goals for the investigation. State the original goals of the investigation, and demonstrate how each goal was achieved; if the goal was not achieved, explain why. For example, in an investigation of an outbreak of vomiting and diarrhea associated with a restaurant, document the steps taken to identify the agent. These could include identifying the number of stool specimens collected, determining the intervals between onset of symptoms and collection of stool and between collection of stool and processing by the public health laboratory, identifying the methods used to culture or test the specimens, and determining the results of the tests.

Novel questions or opportunities to address fundamental questions about foodborne disease transmission can develop during the outbreak investigation. The opportunity to address these issues might require reevaluation of the investigation's goals.

Prepare epidemic curves, and update them daily to depict the beginning and end of the outbreak. Continued motion of successive epidemic curves, day by day over time, clearly indicates continuation of the outbreak (Box 5.1). Select time scales for the epidemic curve to highlight the agent, mode of transmission, and duration of the outbreak. Notable events, such as changes in food-processing methods or personnel or implementation of control measures, can be noted on the curve. Generating an accompanying timeline of the investigation's events as they happen often can be helpful.

5.2.7. Interpret Results

The outbreak investigator's job is to use all available information to construct a coherent narrative of what happened and why. This begins with the initial detection of the outbreak and formation of hypotheses on the basis of the agent's ecology, microbiology, and mechanisms of transmission in addition to the descriptive epidemiology of reported cases and interviews to identify unusual exposures or commonalities among cases. Results of subsequent analytic studies (e.g., cohort or case–control study) must

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Box 5.1. Interpretation of epidemic curves during an active outbreak

The epidemic curve (epi curve) shows progression of an 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. This delay typically is 2–3 weeks for Salmonella infections. Therefore, a person who got sick last week is unlikely to have been reported yet, and a person who got sick 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 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 interview. Sometimes an interview never occurs. If the date an ill person brought his or her specimen to the 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.
- Determining the end of an outbreak can be difficult because of the reporting delay. The curve for the most recent 3 weeks always makes the outbreak appear to be ending, even when it's ongoing. The full shape of the curve is clear only after the outbreak is over.

be integrated with results of investigational product tracebacks, interviews of food workers, environmental health assessments, and food-product and environmental testing. When all of these data elements support and explain the primary hypothesis, very strong conclusions can be drawn.

Identifying and exploiting less-obvious data sources might require some imagination. Interview questionnaires are a critical starting point but often do not provide all the answers. For example, when cases are associated with institutional settings or restaurants, it might be necessary to use the institution rather than the case as the unit of observation. Cross-referenced lists of suppliers and food items at different institutions can be more difficult to assess statistically because of their small numbers, but they can help focus commercial product-type investigations. Similarly, relevant restaurant records include much more than menu lists.

Investigators should consider their data critically and question the strength of the association, timing, dose-response, plausibility, and consistency of findings when implicating a food item (Box 5.2). Case interview data are often faulty: collected long after the fact, perhaps by proxy, and sometimes tainted by biases known and unknown. Investigators can create or compound errors during transcription, keypunching, or analysis. Records are often incomplete or unavailable. Without a systematic bias, larger data sets tend to be more robust; and minor errors may be cancelled out (or ignored), but the size of the data set is often beyond one's control. Statistical association between exposure and illness might reflect a causal link—but also might reflect confounding, bias, chance, and other factors. For example, a p value <0.05 for three food items on a questionnaire does not mean that all three (or, indeed, any of the three) are "implicated" as a vehicle, only that chance is an unlikely explanation for the observed association. Conversely, failure to achieve a p value <0.05 cannot rule out a causal role for a particular food item. As noted

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Box 5.2. Questions to consider when associating an exposure with an outbreak

Strength of association

- How strong was the association between illness and 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 of ill persons exposed to the implicated item? (This 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 to allow for a reasonable incubation period?
- Do the time windows obtained during trace-back and trace-forward 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 by involvement of additional food products).

Consistency with other studies

Studies associated with current investigation

- Do the results of trace-back and trace-forward 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 both from ill persons and the implicated item, do subtyping results (e.g., PFGE 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?

above, observed associations have to be placed in the context of the other investigation results.

Although investigators should be open to new developments and new twists to old problems, they should be wary of explanations that depend on implausible scenarios. For example, truly localized outbreaks are unlikely to result from manufacturing defects in nationally distributed products. Outbreaks that differentially affect young children are unlikely to be caused by salad items. Persons with salmonellosis are unlikely to become symptomatic within 12 hours after exposure. Minor inconsistencies are common and can be ignored, but large numbers of inconsistencies

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might indicate that alternate hypotheses need to be considered.

General principles underlie successful investigations; however, no one specific method works best in all situations. Investigators need to be flexible and innovative as circumstances demand. On one point we can agree: investigations that are never begun or that are haphazardly conducted are unlikely to yield satisfactory results. "Eighty percent of success is showing up," said Woody Allen—and that applies to outbreak investigations too. Jurisdictions that cannot commit resources to outbreak investigations themselves should do whatever they can to facilitate follow-up of their cases by other agencies (e.g., counties to states; states to other states or CDC).

Experience reminds us—again and again, unfortunately—that even seemingly well-executed investigations can be inconclusive. Small sample sizes, multivehicle situations, "cryptic" food items, 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. The decision to stop an investigation depends on the gravity and scope of the outbreak and on the likelihood that it reflects an ongoing public health threat.

5.2.8. Conduct a Debriefing at End of Investigation

Encourage a post-outbreak meeting among investigators to assess lessons learned and compare notes on ultimate findings. Debriefing should include a review of coordination and communication during the investigations, where breakdowns may have occurred, and how prior experience and training facilitated or hindered investigation efforts. The post-outbreak meeting should take place as soon as possible after the investigation ends to capture this information while it is still fresh in people's memories. This is particularly important for multiagency investigations but also is important for single-agency investigations. Another practice to consider is including industry representatives to share lessons learned, when appropriate.

5.2.9. Summarize Investigation Findings, Conclusions, and Recommendations

At a minimum, document every outbreak investigation by using a standardized form to facilitate inclusion in state and national outbreak databases (e.g., CDC's form 52.13 or its equivalent).

Summary data should be reported nationally to CDC's National Outbreak Reporting System (NORS) database. The usefulness of the reports depends on the quality and quantity of information submitted. Make every effort to complete both **Part 1: Basic Information, and Part 2: Additional Information,** and submit the information as soon as possible.

In addition, investigators are encouraged to submit preliminary reports of outbreaks while the investigation is ongoing. If submission is timely, these reports can help identify possibly related outbreaks occurring simultaneously in multiple places and facilitate further investigation of the outbreaks.

Routinely review and summarize data from these reports (e.g., in annual outbreak summaries) at state and national levels.

Larger or more complex investigations or investigations with significance for public health and food-safety practice demand a more complete narrative report and, possibly, publication in a peer-reviewed journal. Written reports should include the following:

- Background, including information about the outbreak setting, timing, and manner of detection and an explicit statement of the goals of the investigation.

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- Methods, including other agencies involved in the investigation; investigation methods; case definition; number of people exposed, interviewed, and ill; number of stool and food samples collected; pathogens tested for in stools or foods; and a high-level summary of laboratory methods used.
- Results, including percentages of cases with fever, diarrhea, vomiting, and bloody diarrhea; median and range of incubation period and duration of illness; results of stool and food testing; food items or events associated with illness and odds ratio(s) or relative risk(s) and confidence interval(s) for implicated food(s); all relevant findings from environmental investigations of establishments and food-preparation reviews; results of food-worker interviews; and food-worker stool culture results, omitting confidential or personal health information protected under the Health Insurance Portability and Accountability Act.
- Conclusions, including etiologic agent, discussion of transmission route, contributing factors, justifications for conclusions, and limitations of the study.
- Recommendations, including all specific recommendations for abatement of this outbreak and prevention of similar outbreaks.
- Epi-curve with outbreak investigation timeline that highlighted key outbreak response events.

5.2.10. Distribute Report

Make copies of the report available to all persons involved with the investigation, including:

- Investigation team members and their supervisors;
- Health department officials and press officers;
- Food-safety and regulatory agency officials and press officers;
- Health-care providers who reported cases; and
- Laboratorians who performed tests.

Also distribute copies of the report to persons responsible for implementing control measures, including:

- Owners and managers of establishments identified as the source of the outbreak;
- Program staff who might oversee implementation of control measures or provide technical assistance; and
- Organizations or regulatory agencies that might develop or implement policies and regulations for which the investigation might have implications.

The report is a public record and should be made available to members of the public who request it.

5.3. Multijurisdictional Considerations for Outbreak Investigations

Increased reliance of the United States on large-scale food-distribution systems and international food sources has increased the likelihood of outbreaks in multiple jurisdictions. Local and state health agencies always need to be sensitive to the potential for rapid escalation of any outbreak to a regional or national event (see Chapter 7).

5.4. Indicators/Measures

Key indicators and measures to assist in assessing investigation processes and the overall success of outbreak investigations can be found in Chapter 8.

5.5. References

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CHAPTER

6

Control Measures

The purpose of outbreak investigations is to stop the current outbreak, determine how the contamination occurred, and implement prevention-based approaches to minimize the risk for future outbreaks. Whereas the investigation is critical for understanding the cause, effective control measures are critical for actually stopping the outbreak and preventing reoccurrence at this and other locations.

Specifically, the objectives of control measures are to

- Prevent additional exposures; and
- If appropriate, alert the public, and tell people how to protect themselves.

In addition, investigation into the circumstances likely to have contaminated the food will lead to long-term prevention efforts. The objectives of this phase of the investigation are to:

- Prevent future outbreaks from the same source or practices; and
- Identify changes in policy or practice that will prevent future outbreaks from similar causes.

6.0. Introduction

Rapid response is key, it is important for investigators to quickly assess available information to identify suspected food or facilities, and send environmental investigators into the field as soon as possible. Contaminated food might be served at the next meal, or an ill employee might repeatedly contaminate food products. Practices or environmental conditions that led to the outbreak are likely to continue unless an intervention stops them. The source of the outbreak could be a nationally distributed food product, and a recall might be necessary to prevent additional illnesses across the country. Any time an outbreak is identified and possibly linked to a site, immediate response is critical.

The two major types of foodborne disease outbreaks—those originating from retail food establishments (which sell to the consumer) or from home preparation of food and those originating from commercial processors/producers—require two different types of control measures. Outbreaks originating from local retail food establishments, local problems at chain retail food establishments, or homes can be controlled through local food-regulatory authority actions. However, outbreaks originating from commercial processors/producers/distributors or multiple sites at chain retail food establishments typically require state and federal agency intervention.

Communication is critical in determining what control measures to implement and when to change an intervention's focus. To be effective, control measures must correlate with the likely causes of the outbreak, which are usually identified in the early phases of the epidemiologic investigation. Thus, early sharing of information from epidemiologists to environmental investigators is highly valuable. Likewise, frequent communication from environmental investigators that are implementing control measures with epidemiologists and laboratorians is critical because, as the epidemiologic investigation proceeds, different possible causes for the outbreak might be identified. Information gathered in the environmental investigation also can lead epidemiologists to identify contributing factors and environmental antecedents.

6.1. Information-Based Decision-Making

6.1.1. Concurrent Interventions and Investigations

Control measures should be implemented concurrently with investigations. Waiting for laboratory results, confirmed medical diagnosis, or results of all investigations is not necessary before initial control measures are implemented. Sometimes nonspecific control measures can be implemented immediately to prevent further transmission of disease, regardless of the type of disease or source (see section 6.2.1 below).

Sending at least two investigators to a food establishment implicated in an outbreak is best. One investigator can make certain that food about to be served is safe (e.g., no implicated leftovers are served, foods are at proper temperature, food was prepared without contact by bare hands, no ill food workers are preparing food). The second investigator conducts the investigation (e.g., obtains the menu to review everything served to cases, identifies persons who prepared suspected items, determines how the foods were prepared, determines what other groups were served the same foods). (See Chapter 5 for additional information about investigation steps.)

6.1.2. Considerations When Implementing Control Measures

Such interventions as recalling food or closing food premises can have major legal

6.1. Information-Based Decision-Making

or economic consequences, just as inaction or delayed actions can have important public health consequences. The outbreak investigation and control team must balance possible legal or economic consequences against the likelihood that any actions taken will prevent further disease. Issues to be considered when deciding whether and how quickly to implement an intervention include:

- The quality of information.
  Does evidence implicating a particular source derive from a credible analysis of available data and current knowledge? Such analyses might include a controlled study (e.g., case–control study or cohort study) or results of a dynamic cluster investigation. Controlled studies need to be well-designed and executed and of sufficient size to detect differences, with consideration given to information or selection bias and possible confounding factors. Regardless of the types of studies or methods used to implicate a source, the outbreak investigation and control team needs to consider whether the findings of different studies are consistent (e.g., several case–control studies undertaken at different sites or among epidemiologic, environmental, and microbiological studies); whether the methods for collecting data and the quality of the data collected truly support action; and whether the implicated source is biologically plausible, especially if the implicated source is new or novel.
- The outcome of the environmental health assessment.
  Do the findings from the environmental assessment support the conclusions drawn by the epidemiology or laboratory team members? Does the environmental assessment establish a picture of events that could logically support the overall epidemiologic picture of the outbreak?
- The balance between consequences of taking and not taking action.
  Is immediate intervention necessary because the outbreak is caused by a highly pathogenic microbe, easily spread and likely to be a source of secondary infections in the community, or known to cause death or serious complications? What impact will action have on the business or industry? Does taking action present a minor inconvenience or will it have resounding and lasting effects on the business or industry? Is a narrower, 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 members of the public who will need to respond on the basis of the proposed action?
- The potential for intentional contamination.
  If any possibility exists that an outbreak might be due to intentional contamination, then law enforcement agencies will need to be notified immediately. The procedures for controlling the outbreak will change significantly (see section 6.3).

These considerations can add confidence to decision-making. Precautionary control measures that have high potential for public health benefit and low impact on business operations, such as holding a specific nonperishable food from sale or excluding an ill employee, are usually not controversial and easily can be implemented in the field by the regulatory authority. However, many decisions about implementing, or waiting to implement more rigorous interventions require input from the entire investigation and control team, including epidemiology, laboratory, and environmental health specialists and legal advisors, and might need input from companies, trade associations, or other industry and academic experts.

6.2. Control of Source

6.2.1. Nonspecific Control Measures

6.2.1.1. Neither food nor facility have been implicated

If the pathogen causing an outbreak is known, limited control measures might be possible even before the mode of transmission is clear or a food or facility have been implicated. Control measures, at this point, will be nonspecific (i.e., not aimed at the definitive source of the outbreak) and will focus on preventing secondary spread by known cases and on communicating with health-care providers and the public (see information about public communication, section 6.5.3).

Communications with health-care providers might include advice about specific laboratory tests, treatment and follow-up of cases, instructions to cases about personal hygiene and ways to avoid spreading the infection, and infection control precautions for hospitalized and institutionalized patients. If communication with the public is determined to be necessary, it should include practical measures to decrease risk for illness (e.g., avoidance of known high-risk foods or special instructions for their preparation), as well as basic food-safety messages and information about how to contact public health authorities to report suspected related illnesses.

Alerting the public about an outbreak early in an investigation, when little is known or can be done about it, is not without controversy. Announcements about an outbreak (and even implication of a type of food without information about its origin) can alarm (and even panic) consumers who can do little to protect themselves and cause them to undertake unnecessary or irrational actions. Such announcements also can negatively affect industry as the public strives to avoid foods (or other products) possibly related to the outbreak.

The balance between possible harm to consumers and industry and likely benefit of such announcements must be carefully weighed. However, if such communications could prevent additional cases of the disease, they should be considered when the disease is serious, life-threatening, or widespread and/or might particularly affect persons at high risk for poor health outcomes from the disease.

Communication with other agencies (i.e., local, state, and federal) involved in the investigation also is critical at this stage. Coordinating a single public information message can help alleviate confusion among consumers and businesses. Two agencies sharing different messages on the same outbreak leads to frustration and doubt about the decisions being made.

In addition, communication with the food industry during the early stages of the investigation is important. Industry information about suppliers, storage, and handling of the food products possibly involved in an outbreak can help to identify the products on which the investigation should focus (see section 6.5).

6.2.1.2. Facility has been implicated

Nonspecific control measures can be implemented when a facility has been implicated, even though a specific food has not yet been identified. These steps are good public health practice and generally are effective, regardless of disease. These critical first actions include:

- Properly holding the leftovers and suspected ingredients for further laboratory analysis, if warranted;
- Stopping bare-hand contact with food;
- Emphasizing hand washing;
- Monitoring and recording time and temperature control of food;
- Excluding employees ill with gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea, stomach cramps) and daily monitoring of employee health to ensure that employees

6.2. Control of Source

possibly incubating the illness do not cause additional illness;

- Thorough cleaning and sanitization of the environment to eliminate possible sources of contamination; and
- If norovirus is strongly suspected, prohibiting the serving of uncooked foods until the causal pathway has been identified and remediated.

In deciding what control measures to implement, check with epidemiologists and laboratory team members to determine the type of pathogen thought to cause the outbreak, even if the specific causative agent is not yet known. For example, on the basis of symptoms, these team members often can characterize the type of agent involved, e.g., viral, bacterial, chemical. This information can help identify and prioritize control measures.

Control measures should be adjusted on the basis of knowledge of the agent, and whether a food item has been implicated. An outbreak caused by *Clostridium perfringens* has very different contributing factors and control measures than an outbreak caused by norovirus. Whereas controls for a *C. perfringens* outbreak would focus on rapid cooling, proper hot holding, and reheating, controls for norovirus would focus on exclusion of ill employees, proper hand-washing, no bare-hand contact of ready-to-eat foods, and (possibly) changes in the source of any shellfish used in the facility. Focusing on pathways commonly linked to the agent will more likely address the underlying causes of the outbreak.

Check the history of the establishment for previous outbreaks, illness complaints, or food safety problems. What is the establishment's history of correcting violations? A history of serious hazards or of not correcting violations might warrant closure.

While taking these first actions, be sure to collect appropriate samples for laboratory analyses, and document and maintain chain-of-custody practices. Discarding suspected food can help stop the outbreak, but isolating the etiologic agent from the food provides additional evidence of a particular food as the outbreak's source. Food samples need to be collected as early in the outbreak investigation as possible. Whether to analyze these samples can be decided later when more information is available. Storage capacity for samples collected for later analysis should be considered before an outbreak. Ideally, written policy guidance developed in collaboration with the public health or regulatory laboratorians on sample collection and management is already in place. If not, contact your public health or regulatory laboratory to find out how much food to collect, how to collect it, and how to store it. The guidance should cover samples that have been collected from food prepared for consumption or food that has been partially consumed, as well as samples from food for which regulatory action could readily be taken, such as unopened boxes of suspected food.

The facility from which the samples are collected should be notified and afforded the opportunity to collect companion samples.

6.2.2. Specific Control Measures

When a specific food(s) has been implicated, specific control measures can be implemented. Although all of the following control measures are recommended, full implementation of all these practices might not be possible in some jurisdictions. Implementing as many as possible and as completely as possible will improve the effectiveness of the control measures.

Control measures vary depending on whether the implicated food is associated with food-service establishments (whether single or multiple facilities) or home preparation or is processor/producer-based. The outbreak response team must determine as soon as possible whether one facility or multiple facilities are involved.

6.2. Control of Source

6.2.2.1. Foods associated with food-service establishments or home preparation

6.2.2.1.1. Removing food from sale or preventing consumption

- Collect samples of any foods discarded by the establishment or foods embargoed or placed on hold by regulatory officials.
- Most regulatory agencies have the authority to embargo, hold, or stop the sale of food suspected to be a source of an outbreak. Such action should be taken when the epidemiologic or environmental investigation supports the biological or environmental plausibility that certain foods are the outbreak's source. Contact the applicable regulatory agency as soon as it appears possible that the outbreak involves product that might have been contaminated during production.
- In investigation and enforcement matters, issuing a written hold or embargo order establishes a clear expectation and regulatory requirement for holding the food. This action will prevent the owner from serving or destroying the food before the investigation is complete.
- Fully document the information that led to the decision (whether to remove or not remove food) and the process used to make the decision.

6.2.2.1.2. Cleaning and sanitizing

- Ensure the facility is thoroughly cleaned and sanitized, followed by microbial verification of the effectiveness of the cleaning and sanitizing processes. 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 is suspected. Guidance documents targeted at industry include:
  - Guidance for the Control of *Listeria monocytogenes* Risks in Retail Food Stores, www.fmi.org/docs/food-safety/listeria-guidance.pdf?sfvrsn=4
  - FMI Listeria Action Plan for Retail Delis, www.fmi.org/docs/food-safety-best-practice-guides/listeria-action-plan-for-retail-delis.pdf?sfvrsn=9
  - Norovirus Information Guide, http://fmi.org/docs/food-safety-best-practice-guides/norovirus_info_guide-1-.pdf?sfvrsn=2

Examples of cleaning, sanitizing, and microbial verification protocols can be found in the Food and Drug Administration's (FDA's) Food Code in Annex 4 (www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm188363.htm).

6.2.2.1.3. Training

- Require training of managers, supervisors, and staff on general practices of safe food preparation, and if the specific pathogen is known, implement practices specific to control of that pathogen. Ensure that employees newly transferred to or from the involved food establishment are included in the training.
- Require the facility manager to document training of both current and newly hired staff.

6.2.2.1.4. Modifying a food-production or food-preparation process

- Ensure that food-production or food-preparation processes are appropriate and adequate to prevent further contamination of food or survival and growth of microbes already present in food.
- Modify processes if needed to reduce risk, such as changing a recipe, changing a process, reorganizing preparation processes, changing storage temperatures, or modifying instructions to consumers. Evaluate the

6.2. Control of Source

proposed times, temperatures, pH, and water activity level for controlling the pathogen of interest on the basis of sufficient scientific evidence.

- Eliminate any bare-hand contact with ready-to-eat food, and ensure that all employees are following appropriate hand-washing and food-handling practices.
- Conduct follow-up monitoring to ensure that modified processes have been implemented and are effective in addressing the food safety problem.
- Require that Active Managerial Controls, such as a Hazard Analysis and Critical Control Point (HACCP) system, be implemented, if not already in place. Such controls should be in the form of a written plan, and all staff should be trained on the plan.

6.2.2.1.5. Modifying the menu

Eliminate implicated foods from the menu until control measures are in place. 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.

6.2.2.1.6. Removing infected food workers

Ensure that infected food workers are excluded from the workplace or restricted in accordance with the Food Code or other regulatory requirements

6.2.2.1.7. Closing food premises

- If the owner is unable or unwilling to take immediate corrective action to eliminate food-safety hazards, closing the premises might be necessary. The facility must meet closure requirements as defined in local regulations, typically defined as presenting an imminent or substantial health hazard. This conclusion can be determined from observation or evidence that disease could be spread because of increased risk factors.
- If the food premises are in an institution in which residents have no alternatives, work with institution staff either to identify options for bringing in food or to leave food premises open but eliminate high-risk items from the menu.
- If the facility owner will not act voluntarily, employ other control measures, such as cease-and-desist orders, permit action, or a legal hearing.
- Follow local regulations when requiring closure of food premises. Establish a clear plan with criteria that need to be met, including appropriate environmental testing if available, for the facility to reopen. Reopen only when the criteria have been met. Provide the facility with a timely re-inspection that would qualify it for reopening.

6.2.2.1.8. Communicating with the public

- If the outbreak involves only one facility, determine whether public notification is necessary. All members of the outbreak investigation and control team (epidemiology, environmental health, and laboratory) and health department leadership should be involved in making this decision. Ask the following questions:
  - Is medical treatment necessary for persons who might have been exposed to the etiologic agent? If so, 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.
  - Is the source of the outbreak short term so no further risk exists to the public? If so, public notification generally is not necessary.
  - Does risk for exposure still exist? People take food home from restaurants, so public notification still might be appropriate.

6.2. Control of Source

- 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.

CIFOR Keys to Success: Focus Area 10—Control of source at implicated facility

Control measures

- Agency/jurisdiction works with the facility or production site, appropriate regulatory agency, and industry representatives to determine the desired control measures.
- Agency/jurisdiction has legal authority to require the desired control measures.
- Agency/jurisdiction and food-establishment management team consider a variety of control measures to address the food-safety problem (e.g., removing the vehicle from consumption, cleaning and sanitizing the environment, educating food workers, modifying food preparation, excluding ill staff, requiring no bare-hand contact of ready-to-eat foods, requiring monitoring and recording of food temperatures).
- Agency/jurisdiction implements control measures as soon as sufficient information is available to do so.

Communication

- Outbreak investigation and control team members share information from the outbreak with each other and with other appropriate health and regulatory agencies in a timely fashion. If multiple facilities across jurisdictions are implicated, response team members also communicate with officials in other jurisdictions involved in the outbreak (see Chapter 7 for Multijurisdictional Investigation Guidelines.)
- Staff effectively communicate control measures to facility manager, facility workers, and others involved in implementing control measures and provide education, as needed.
- Agency/jurisdiction engages with industry to share the significance of the findings and provide the firm with the basis for a pending recall action and/or the opportunity to present different conclusions about the source of the outbreak. This exchange enables both parties to exchange all relevant information about production practices, distribution patterns, consumer complaints, and pending information.

Monitoring

- Agency/jurisdiction monitors the implementation of control measures at the implicated facility and the effectiveness of those control measures. The inspection frequency is increased for the implicated facility to ensure that hazards do not reoccur.
- Agency/jurisdiction monitors the population at risk to ensure the outbreak has ended and the source has been eliminated.

Making changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to control of the source at the implicated facility and routinely evaluates its performance in this Focus Area.

6.2. Control of Source

6.2.2.2. Foods associated with a processor/producer

Implication of multiple food-service establishments in an outbreak or receipt of multiple, seemingly unrelated reports of illness from consumers eating the same type of food suggest an outbreak caused by food contaminated at the processor/producer-level. Trace-back investigations can help identify the point in the production and distribution process at which the implicated food most likely became contaminated and enable targeted environmental assessments to determine how the food became contaminated and to recommend specific interventions. Early engagement with the food processor/producer and the appropriate food-regulatory agency can help identify specific products that might be associated with the outbreak.

Depending on the scope of the outbreak and probable point of contamination, most of the specific control measures listed above (section 6.2.2.1) also will be appropriate once the point of contamination is identified. However, food implicated in these outbreaks might be more likely to be in distribution, at retail establishments, or in the homes of consumers. Therefore, public health and food-regulatory agencies also will need to decide whether to remove the suspected food from the market by using the procedures defined in section 6.2.2.2.1 below. If the food-regulatory agency has adequate information to implicate and accurately identify a contaminated food item, it will take the lead on recall activities.

Contact the federal or state regulatory agency that has jurisdiction over the product. FDA regulates the safety of most foods, except meat, poultry, and most out-of-shell egg products (which are regulated by the U.S. Department of Agriculture [USDA]). FDA or USDA will contact the manufacturer about the decision to remove the product from the market and will obtain the manufacturer's cooperation. The regulatory authority might recommend that the manufacturer issue a food recall. In addition, the regulatory authority and/or the manufacturer might ask retailers to remove the product from their shelves and ask distributors to withhold the product from distribution.

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, FDA can order the embargo of food for up to 30 days without a court order.

Questions to ask in considering whether to remove food from the market:

- Is risk to consumers ongoing?
- Is the product still on the market or in the distribution system?
- Is the product likely to be in the homes of consumers?
- Does the information justify removing food from the market? Remove the food if:
  - The illness and consumption of that food show a strong epidemiologic association (e.g., through a case–control or cohort study or other rigorous epidemiologic method), even if the pathogen has not been isolated from the food. Strong epidemiologic association requires a good quality analytic study that links the implicated food to the cases.

  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 the cases and has been handled properly to avoid cross-contamination.

  OR

  - Epidemiologic association is not strong, but the pathogen is so hazardous that the

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risk to the public is very high. Under these circumstances, there may be no analytic controlled studies, but if the descriptive epidemiology (e.g., demographic characteristics of cases, geographic distribution, or onset of illness) 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.

Fully document the information that led to the decision (whether to remove or not remove food) and the process used to make the decision.

6.2.2.2.1. Procedures for removing food from the market

Once a decision is made to remove food from the market, the goal is to remove it as quickly and efficiently as possible (Box 6.1). Foods with short shelf lives (e.g., fresh produce, meat, dairy products) generally are consumed or discarded within 5–10 days, depending on product, and already might have been discarded. Foods with longer shelf lives most likely will still be around. Try to prevent additional exposure by ensuring suspected food is not eaten.

To improve the effectiveness of recall measures and industry response, health and food-regulatory agencies can

- Develop a list of 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 e-mails for regulators at the local, state, and federal levels, including FDA and USDA's Food Safety and Inspection Service.
- Develop guidance for communicating with the news media.
- Develop guidelines for mitigating impact of the recall, such as providing refunds for returned product.
- Develop templates, message maps, or community information sheets for common foodborne agents for use during an outbreak.

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," which is available from the National Association of County and City Health Officials.

Regulators responsible for retail food facilities need a means to immediately notify all food facilities in their jurisdiction through e-mail, blast fax, or phone calls of a recall. 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.

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?

Ensuring the effectiveness of recalls often requires close cooperation among local,

6.2. Control of Source

Box 6.1. Recommendations for manufacturers and retail establishments to help ensure an effective food recall

Manufacturers

Recall preparedness (before an outbreak occurs):*increases with the size of the odds ratio or relative risk:*

- Maintain product source and shipping information for quick access in conducting tracebacks and traceforwards during an investigation and/or recall.
- Develop the ability to rapidly notify all customers of a recall through blast e-mail and fax, calls, text messaging, and mail to retail establishments who purchased recalled foods.
- Identify and develop procedures to prevent common errors that result in recalled food being returned to commerce (e.g., recalled food is returned and accidentally put back into distribution by workers).

After a recall is announced:

- Quickly remove recalled contaminated product from the distribution system.
- Notify customers through the regulatory agencies and news media, as needed.
- Ensure retail customers have clearly defined storage areas and handling processes for recalled products, including denaturing or other process to ensure foods are not resold.
- Put in place systems for safe handling or disposal of recalled products to avoid cross-contamination to other products, accidental redistribution, diversion, and creation of other hazards.

Retail Food Establishments

Recall preparedness (before an outbreak occurs):

- Maintain product source and shipping information for quick access in conducting tracebacks and traceforwards during an investigation and/or recall.
- When store cards are issued, obtain customers' e-mail addresses and phone numbers, and inform them they will receive notifications of any recalls of items they purchase. Inform consumers their store card information might be provided to outbreak investigators if allowed by state law.
- Develop the ability to rapidly notify all customers of a recall through blast e-mail and fax, text messaging, social media, calls, and mail to people who purchased recalled foods.
- Identify and develop procedures to prevent common errors that result in return of recalled food to commerce (e.g., recalled food is returned and accidentally put back onto shelves or into distribution by workers; product is pulled from sale from one location and not throughout the store; expanded recalls are ignored; another shipment arrives and is put onto the shelves or into distribution).

After a recall is announced:

- Quickly remove recalled product from commerce at the food facility.
- Notify customers through the regulatory agencies and news media, as needed.
- Post signs at the point of sale to advise consumers about the recall.
- Put in place fail-safe systems that do not allow sale of recalled products (e.g., cash registers that flag recalled products or that prohibit the sale of recalled products). Ensure stores have clearly defined storage areas and handling processes for recalled products, including denaturing or other process to ensure foods are not resold.
- Put in place systems for safe handling or disposal of recalled products to avoid cross-contamination to other products, accidental restocking, diversion to unsuspecting consumers, and creation of other hazards. Consider the possibility of homeless persons removing discarded product from the trash. Follow any guidance from the local health authority.
- For a highly dangerous condition, such as botulism, food seizure by the health department or regulating agency is appropriate to ensure immediate and complete removal of the suspected food from the market.

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state, and federal agencies on audits for recall effectiveness checks. 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, for example, 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.

6.2.2.2.2. Communication with the public

Messages to the public about foodborne disease outbreaks should follow good risk communication practices. Ideally, templates for public messages should be prepared before the outbreak and used consistently (see section 6.5 below and the CIFOR Clearinghouse, www.cifor.us/clearinghouse/keywordsearch.cfm, for examples of communication templates).

Notify the public if the outbreak involves distributed product. Provide information about how to handle the suspected product (discard, special preparation instructions, or return to place of purchase). Provide information about the disease, including symptoms, mode of transmission, prevention, and actions to take if illness occurs.

If the manufacturer refuses to recall the food, it should be advised promptly that public health agencies or regulators might issue their own notice to the public, and the notice could include the message that the firm declined to voluntarily recall the product. The message to the public should describe the situation and provide clear actions.

Means of notification depend on the public health risk and the target population and might include press releases, radio, television, fax, telephone, e-mail, Web posting, social media, or letters. The manufacturer, public health agencies, regulatory agencies, retail food establishment, or all four can initiate notification. These releases should be coordinated and include consistent messages to avoid confusing the public.

Attempt to reach all members of the population at risk, including non–English-speaking and low-literacy populations. Provide only objective, fact-based information about the outbreak. Do not give out preliminary, unconfirmed information. If a specific food—such as a particular brand of bagged produce—is implicated, the press releases need to inform consumers whether the local jurisdiction is interested in obtaining the product from households that still have it and, if not, the proper method of disposal.

If the outbreak is large or the etiologic agent is highly virulent, consider setting up an emergency hotline so the public can call with questions. Persons answering the phones should be trained to give consistent responses. The hotline might require having staff work after hours to answer phones after the early evening news or to respond to questions posed on social media.

If press releases are to be issued by retailers or manufacturers, relevant local, state, or federal officials should review and approve them before release. Food establishments and producers often seek guidance on the contents of their press releases, and public health and food-regulatory agencies can provide needed information and help to ensure consistent communication.

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The state or local agencies responsible for the investigation should issue their own press releases, even if the affected industry or business also is issuing a release. Local press releases often result in better coverage from the local media. If more than one agency is involved, coordination of press releases is important for alignment of messaging. If time allows, give affected industry members or businesses an opportunity to comment on your releases so that they can verify specific information, such as use-by dates; when possible, include a picture of the product label. However, avoid prolonged negotiations about wording.

6.2.2.2.3. 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;
- 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.

CIFOR Keys to Success: Focus Area 11—Food Recall

Recall Processes

- Agency/jurisdiction collaborates with state and federal agencies, as well as with the facility or production site implicated in the recall.
- Agency/jurisdiction proactively embargoes or seizes the implicated food product while awaiting official recall.
- Agency/jurisdiction has means to quickly notify retail food establishments and other sites (e.g., food banks) under its jurisdiction about the recall.
- Agency/jurisdiction has means to quickly notify public about recall.
- Agency/jurisdiction investigates new illnesses and monitors the effectiveness of the recall at all appropriate food establishments.

Making changes

- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols on the basis of lessons learned.
- Agency/jurisdiction has performance indicators related to food recall (including the number of illnesses from consuming the implicated product after the recall) and routinely evaluates performance in this Focus Area.

6.3. Intentional Contamination

6.3.1. Indicators of intentional contamination of food

Although intentional contamination of food is very rare, a number of such instances have been reported, and agencies responding to outbreaks should always keep in mind the possibility that an outbreak might be caused by a criminal act. Possible indicators of intentional contamination include:

- Unusual relationships between the individual, time, and location of the outbreak;
- The presence of unusual microorganisms in host foods;
- A shorter-than-usual incubation period that results from an unusually high inoculum or more effective exposure route;
- The presence of a large epidemic, with greater case loads than expected, especially in a discrete population;
- More severe disease than expected for a given pathogen, as well as unusual routes of exposure;
- A disease that is unusual for a given geographic area, is found outside the normal transmission season, or is impossible to transmit naturally in the absence of the normal vector for transmission;
- Multiple simultaneous epidemics of different diseases;
- Unusual strains or variants of organisms or antimicrobial resistance patterns disparate from those circulating locally;
- Claims by a perpetrator of intentional contamination;
- Knowledge that a perpetrator has access to a particular agent or agents; and/or
- Direct evidence of intentional contamination, with findings of equipment, supplies, or tampering.

Many of these indicators can be seen with naturally occurring outbreaks, so the presence of any one or even several of them should not lead to an immediate conclusion of intentional contamination. However, these indicators should cause heightened awareness, and the outbreak investigation and control team should consider the scenario of intentional contamination.

6.3.2. Actions to take when intentional contamination is suspected

Each agency should establish a process for actions to take if intentional contamination is suspected. This process might include an internal review of all evidence before notification of law enforcement agencies. Organizations responsible for outbreak investigations should determine in advance of any outbreak which law enforcement agencies will be notified in the event intentional contamination is suspected and how that notification will occur. The following state and federal organizations are likely to be involved in any investigation of intentional contamination:

- Federal Bureau of Investigation Field Offices, www.fbi.gov/contact-us/field
- FDA Office of Criminal Investigations, Field Offices, www.fda.gov/ICECI/CriminalInvestigations/ucm123034.htm
- USDA Food Safety and Inspection Service, Office of Program Evaluation, Enforcement and Review, Compliance and Investigations Division, www.fsis.usda.gov/wps/portal/informational/contactus/
- State and Local Fusion Centers, www.dhs.gov/state-and-major-urban-area-fusion-centers

Any criminal investigation will need to be coordinated with the foodborne outbreak investigation. The lead law enforcement agency should work with the outbreak investigation

6.3. Intentional Contamination

and control team to address issues such as crime scene management, documentation of chain-of-custody, and handling of procedures for environmental and human specimens, because these should be considered evidence to support a criminal investigation.

When a written or verbal threat regarding possible contaminated or tampered food is received (directly to the public health authority, through the media, or through the food industry), law enforcement authorities should be notified immediately. Such threats might be a hoax or the work of an extortionist, and release of premature information might lead to panic or play into the hands of the perpetrator.

6.4. Control of Secondary Spread

6.4.1. Information for Health-Care Providers

Communicate with health-care providers in the community to encourage them to report cases of the illness under investigation, collect appropriate specimens and conduct specific laboratory tests, and provide specific treatment and infection control guidance.

6.4.2. Information for the Public

Any outbreak is an opportunity—or "teachable moment"—to reinforce basic food safety messages to the public and to 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 at http://www.fightbac.org/. Following are specific food safety messages that are important to communicate to the public.

6.4.2.1. Personal protection from disease outbreak

- Thoroughly wash hands with soap and warm water after defecation and urination 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 health of one person or many.
- 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).

6.4.2.2. Proper food preparation

- Use best practices when handling food at home (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).

6.4.2.3. Advice on personal hygiene

- If you are ill with diarrhea or vomiting, avoid preparing food for others until at least 72 hours after you are free of diarrhea or vomiting.
- Wash hands as described above (section 6.4.2.1).
- If someone in the household has diarrhea or vomiting, clean toilet seats and flush handles, and washbasin taps and washroom door handles with disinfectant after use. If norovirus (which is highly resistant to adverse environmental conditions) is involved, promptly clean contaminated surfaces using a chlorine bleach solution with a

6.4. Control of Secondary Spread

concentration of 1000–5000 ppm (2.5–12.5 fluid ounces of household bleach [5.25%] per gallon of water) or other disinfectant registered as effective against norovirus by the Environmental Protection Agency. Wash and dry clothes, towels, and linens soiled with vomitus or stool at the highest temperature the item will allow.

6.4.3. Exclusion and Restriction of Infected Persons from Settings Where Transmission Can Occur

(including food preparation, health care, and child care)

Persons with an enteric illness can shed viruses, bacteria, or parasites for weeks after symptoms end. Infected skin lesions can be a reservoir for pathogens, which can be transmitted to food through bare-hand contact.

A person who has been ill with vomiting and diarrhea should be excluded from the facility. For norovirus outbreaks, exclusion should continue until the person is free of symptoms for 72 hours. In *Salmonella* and *Shigella* outbreaks, all employees should be cultured whether ill or not and should be restricted until cultures are determined to be negative because infected asymptomatic food workers are possible in restaurant outbreaks. Conversely, little evidence exists for an important role for infected food workers in transmission of *E. coli* O157:H7.

For more pathogen-specific guidance and other information about restricting and excluding food workers, consult the latest version of the FDA Food Code, www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm. State and local health departments may not have the legal authority to exclude food workers unless they have acute symptoms. In addition, scientific evidence supporting exclusion of food workers might not be reflected in state or local food codes or might not be available at all. However, if the outbreak investigation and control team believes a public health threat exists, the team should strongly recommend exclusions of food workers. Consult local ordinances and state statutes to understand the legal authorities under which to operate.

One issue to consider in deciding whether to exclude infected persons is the perception that employers might occasionally retaliate against workers, either by having their pay docked during or after the exclusion period or being fired. This can hamper investigations because employees might be reluctant to provide truthful health information to avoid exclusion. Strategies that can mitigate this concern include developing regulations that prohibit retaliation, helping employers identify alternate jobs that ill food workers can perform, and allowing ill employees to trade for shifts when their exclusion has been lifted.

6.4.4. Infection Control Precautions

Work with the food establishment's person-in-charge (PIC) to implement active managerial controls and create a risk-control plan or consent agreement so the PIC knows exactly what steps need to be taken and has committed to control the situation and prevent additional outbreaks. Use of active managerial controls and risk-control plans or agreements can include actions above and beyond those required by regulation (e.g., extra temperature checks and logging of temperature, mandatory glove use by all food workers, routine inquiries of staff before their shifts about whether they have had diarrhea or vomiting in the last 24 hours, additional food-safety training). Ideally, both epidemiologists and environmental health specialists are involved with the PIC in creating this plan or agreement. Important aspects of the plan are a) employee training and b) adequate oversight to ensure employees follow proper procedures.

Educate food workers about the implicated disease (symptoms, mode of transmission, and prevention) and about general infection control precautions.

6.4. Control of Secondary Spread

Reinforce the following:

- The importance of thorough hand-washing and not working when ill;
- Policy of no bare-hand contact with ready-to-eat foods;
- Proper use of gloves and utensils when handling ready-to-eat foods;
- Proper holding temperatures; and
- Proper procedures for rapid cooling and thorough cooking and reheating of foods.

Infection control precautions for hospitalized and institutionalized persons with infectious diarrhea (particularly easily transmissible infections, such as *Salmonella* serotype Typhi, *Shigella*, and norovirus) include:

- Isolation of patients (e.g., in a private room with separate toilet, if possible);
- Barrier nursing, patient care, and janitorial precautions;
- Strict control of the disposal or decontamination of contaminated clothing, surfaces, and bedding; and
- Strict observation of personal hygiene measures (see above).
- A plan for effective clean-up of diarrhea or vomitus. Appropriate guidance, references and educational materials are available at www.cdc.gov/norovirus/preventing-infection.html.

Use chlorine solutions or other approved effective sanitizers or methods (e.g., steam cleaning carpets) rather than standard cleaning chemicals to clean and disinfect all surfaces after a norovirus outbreak.

Recommended practices for infection control frequently are changed and updated. Routinely checking key sources, such as CDC, ensures organizational recommended practices are current.

6.4.5. Prophylaxis

Set up processes with area hospitals, physicians, local health departments, specialty clinics, or other health-care providers to provide prophylaxis if needed. Have tested plans in place for large-scale prophylaxis. During preparations of public communications about prophylaxis, consider the number of people likely exposed and the anticipated response to the prophylaxis offer when planning, including community medical staff, vaccine/product supply, crowd control management, and health department phone staffing.

Develop processes to identify and communicate with persons who might need prophylaxis. Depending on the organism, this might include giving special consideration to protecting high-risk groups. For example, persons with underlying chronic hepatitis B or C might need to be advised to be vaccinated against hepatitis A.

6.5. Communication

6.5.1. With Other Members of the Investigation and Control Teams

Communicate actions taken and outbreak status information to all persons involved in an outbreak investigation, including those in different agencies or different departments within the agency.

Identify and keep key personnel in the implicated food establishment informed, and notify them that they must share any new reports of illness or other new information that could affect the investigation. Illness complaints reported to food establishments about a commercial product can lead to

6.5. Communication

CIFOR Keys to Success: Focus Area 12—Control of secondary spread

Communication
- Agency/jurisdiction has means to alert health-care providers about the outbreak and provide specific information about reporting, treatment, and infection control.
- Agency/jurisdiction has ongoing communication with the public.
- Agency/jurisdiction has preexisting relationships with the media to ensure rapid and accurate communication of information to the public.
- Agency/jurisdiction has staff trained in communicating with the media and risk communications.

Control measures
- Agency/jurisdiction works with settings in which transmission easily can occur to prevent secondary spread (e.g., health care, day care).

Monitoring
- Agency/jurisdiction monitors continued spread of the disease through surveillance and other means.

Making changes
- Agency/jurisdiction debriefs investigators after each outbreak response and refines outbreak response protocols based on lessons learned.
- Agency/jurisdiction has performance indicators related to control of secondary spread from an outbreak and routinely evaluates its performance in this Focus Area.

expansion of a recall if additional product codes are associated with illness.

6.5.2. With Agency Executives and Other Agencies

Ensure that agency heads routinely receive information about the status of the outbreak investigation.

If the outbreak is potentially multijurisdictional, ensure that other relevant agencies and organizations routinely receive status reports. These might include local, state, and federal public health, agriculture, and regulatory agencies. If an outbreak potentially involves a food from a source outside the jurisdiction identifying the problem, notify all appropriate surrounding health jurisdictions, and call the manufacturer and the retail food establishment chain (if one is involved) to determine whether they also have received illness complaints. This early communication might help to identify the source quickly.

In multijurisdictional outbreaks, coordinate messages and information with other agencies so that consumers are not confused. When possible, a single spokesperson should be used to convey information and updates. Jurisdictions should attempt to release information simultaneously and take similar actions, such as recalls and consumer alerts (see Chapter 7).

6.5.3. With the Public

If the public has been informed about an outbreak, periodically issue updates. Recognize that the public obtains news from multiple sources—the Internet, television, radio, social media, and newspapers. Use all available sources to disseminate information. Know the typical deadlines for local news outlets, and try to release information within those timelines.

6.5. Communication

If the public is not receiving needed information from the public health agency, people will get it from other sources (which might not be accurate). The public health agency should be seen as, and act as, the most reliable source of information.

An agency cannot wait until all the facts are available before communicating with the public. People need enough information to be able to make good decisions to protect their health.

Important terms (e.g., risk, bacteria) might seem common but in fact often are misunderstood. Adopt a standardized format for reporting risk information. Communications about foodborne disease risks should be routine (e.g., the same process should be used each time); this helps make the process more familiar and reduces concerns about the message.

In communication planning, adopt standardized scripts for reporting complex procedural or technical information about the investigation and actions the public should take. Test messages to the public, if possible with representatives of the target population.

Certain groups are at higher risk than others for severe illness and poor outcomes from foodborne disease, including infants, pregnant women, and immune-compromised persons. Emphasize safe food-preparation practices and hand-washing to these groups. For example, pregnant women should be advised against consuming unpasteurized dairy products, uncooked lunch meats, and other products with the potential to contain *Listeria*.

6.5.4. With the Industry

Contact the food establishments(s) directly linked to an outbreak as soon as possible, and tell them as much as possible. Tell them about the findings that have implicated their product, and clearly explain the significance of the findings. Seek their help in the investigation, particularly in identifying specific products that might be associated with the outbreak. Food establishment representatives can assist with hypothesis generation and provide useful information about product formulation and distribution. Advise them about possible outbreak control measures, such as voluntary recall of an implicated product. This communication can be complicated by enforcement action that might result from the investigation.

Provide food establishments with the CIFOR Industry Guidelines to assist them in response (http://cifor.us/documents/CIFOR Industry Guidelines/CIFOR-Industry-Guidelines.pdf). These Guidelines provide owners, operators and managers of food establishments with step-by-step approaches to important aspects of outbreak response such as preparation, detection, investigation, control, and follow-up. The CIFOR Industry Guidelines also describe key information to assist industry in understanding what to expect when first notified of potential illnesses and provides tools to help guide industry through the process.

Large firms often have their own staff who understand risk communication and risk management strategies. Some medium-sized and many small firms do not have such expertise and need more guidance. Laws and policies of state and local governments differ for these situations. Understand your own legal framework so you know how to interact with food establishments possibly linked to an outbreak.

The food industry has many trade associations. Some overlap, but in general, every segment of the food industry has an association. State, local, and federal agencies need to establish working relationships with these associations *before* an outbreak. At the time of an outbreak, outreach by government agencies to the appropriate associations with information about the outbreak and about actions members should take is helpful to prevent spread of

6.5. Communication

the current problem or similar problems in their firms. Trade associations can reach large numbers of food facilities and arrange for conference calls and other communications as needed. Similarly, establishing working relationships with food manufacturing facilities in an agency's jurisdiction can help smooth the investigation and control process in an outbreak associated with those facilities.

Outbreaks are teachable moments for the food industry and for the responsible public agencies. When the news media carries stories about an outbreak, communication within the industry is lively, often with misinformation. Food-safety and public health agencies need to dispel misconceptions before they lead to other problems. These agencies also need to explain their response to the outbreak and restore public faith in the future safety of the implicated product. Furthermore, public health agencies need to learn from the food industry about information that could aid in prevention and investigation of future outbreaks.

Food-safety and public health agencies also can collaborate with industry on long-term development of training materials for members and can speak at industry meetings to clarify the prevention message.

Many food facilities and manufacturers have written emergency plans and recall procedures already in place. Regulatory officials might want to review these in advance of any actual event.

6.6. End of the Outbreak

6.6.1. Determining When an Outbreak is Over

Most outbreaks are considered over when two or more incubation periods of the etiologic agent have passed with no new cases. This arbitrary rule might not apply to clusters with low attack rates, and cases from some sources might appear intermittently for years.

6.6.2. Determining When to Remove Restrictions

Remove restrictions when no further risk to the public exists, such as when:

- Risk factors in the facility have been eliminated;
- 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;
- Employees have been taught how to avoid a problem; and
- Managers agree to provide appropriate oversight.

6.6.3. Post-Outbreak Monitoring

Monitor the population at risk for signs and symptoms of the foodborne illness to ensure the outbreak has ended and the source has been eliminated. Consider conducting active surveillance, working with health-care providers to increase their vigilance for cases, and collecting stool samples from the population at risk.

Monitor the implicated foods or food establishments to make sure no further contamination is occurring.

Maintain communication with managers of the implicated food establishment, and give them additional information if it becomes available.

Increase the number of routine inspections at the implicated food establishment to ensure they comply with all required procedures. Old, unsafe practices often are difficult to change,

6.7. After-Action Meetings and Reports

and new practices might need to be used for a substantial time before they become routine. Consider customized training to support the desired behavioral change. Determine whether behavioral change has occurred long term. Monitor the implicated firm's development and implementation of preventive controls.

The outbreak investigation and control team should meet and review all aspects of the investigation. The complexity of the review depends on the size of the outbreak. For a small outbreak associated with a single facility or event, a short written summary may be sufficient. For a large outbreak involving multiple agencies, a formal after-action meeting is appropriate.

A formal after-action meeting should:

- Identify the contributing factors and environmental antecedents of the outbreak and measures (preventive controls) to prevent additional outbreaks at this and other food establishments;
- Identify the long-term and structural control measures, and develop a plan for their implementation;
- Assess the effectiveness of outbreak control measures and difficulties in implementing them;
- Assess whether further scientific studies should be conducted;
- Clarify resource needs, structural changes, or training needs to optimize 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; and
- Discuss any legal issues that might have arisen and the need for new laws to strengthen response (see Chapter 9).

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.

6.8. Outbreak Report

Prepare reports for all outbreaks. Again, the complexity will depend on the size of the outbreak. For small outbreaks, a simple summary (following a template established by the agency) should suffice. The report can be used to educate staff and to look for trends across outbreaks that can be useful in future investigations.

Use outbreak reports as a continuous quality improvement opportunity. If all the after-action reports say the same thing, then nothing is being corrected.

The final after-action report of a large outbreak should be comprehensive, with information provided by all team participants, and should be disseminated to all participating organizations. Sample outbreak after-action reports are available at the CIFOR Clearinghouse, www.cifor.us/clearinghouse/keywordsearch.cfm.

Given that outbreak reports, especially after-action reports for large outbreaks, are likely to be subject to Freedom of Information Act requests, they should be written with public disclosure in mind. The reports should not identify individuals or other legally nonpublic information unless absolutely necessary. Proper care in writing the report will save time redacting information when the report is released to the public. Some jurisdictions

6.8. Outbreak Report

allow or mandate the inclusion of identifying information, so review state and local laws and policies.

Submit a final report of the outbreak to CDC's National Outbreak Reporting System and National Voluntary Environmental Assessment Information System databases.

6.9. Other Follow-Up Activities

6.9.1. Future Studies and Research

The outbreak investigation findings might indicate the need for future research. For example, investigators might 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. Such observations should be considered for in-depth study by the food-safety or public health agency or by research centers. Identifying issues that need follow-up research is important to improving the practice of responses to outbreaks of foodborne diseases.

6.9.2. Publication of Outbreak Results

If something unusual characterized the outbreak (e.g., unusual exposure, presence of a pathogen in a food where it had not previously been reported), the report should be disseminated more widely (e.g., Epi-X, *MMWR*, or other national forum; peer-reviewed journals).

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) should be published in an appropriate national forum.

6.9.3. Education

An outbreak can identify the need for broad education of the public; the food-service, retail, and food-processing industries; or health-care providers. Public service announcements might be necessary to remind the public about food-preparation precautions. Training for food-service workers and managers and food processors might need to be modified to address specific concerns. Managers need to oversee training of food-service workers and food processors and their use of recommended procedures. Health-care 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, and CIFOR.

6.9.4. Policy Action

Information gained during an outbreak might identify the need for new public health or regulatory policy at the local, state, or federal level. Establishment of different inspection practices, source controls, or surveillance procedures, or of increased control over the recall process might be necessary. Reports of past outbreaks should be analyzed to determine whether multiple outbreaks support the need for new policy. Other public health and environmental health agencies also should be consulted to determine whether concurrence exists on the need for new policy. If so, the issue should be presented to the appropriate jurisdictional authority by using the appropriate policy development processes.

6.10. Multijurisdictional Considerations for Control Measures

Although control measures typically are implemented at the local level, multijurisdictional outbreaks require extensive coordination among agencies to ensure control measures are implemented consistently and are effective (see Chapter 7).

6.11. Indicators/Measures

Key indicators to help assess control measures and the overall success of efforts to halt outbreaks have been developed (see Chapter 8).

6.12. Reference

1 Iowa Department of Public Health. Foodborne Outbreak Investigation Manual. Available at www.idph.state.ia.us/idph_universalhelp/Main.aspx?System=IdphFoodborneDiseaseManual&navigationType=Dynamic (accessed October 8, 2013).

CHAPTER

7

Special Considerations for Multijurisdictional Outbreaks

A multijurisdictional foodborne disease event requires the resources of more than one local, state, territorial, tribal, or federal public health or food-regulatory agency to detect, investigate, or control. A multijurisdictional investigation might involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

These guidelines are intended to help improve communication and coordination among agencies at all levels of government that are investigating multijurisdictional outbreaks. The guidelines are proposed to help agencies identify multijurisdictional outbreaks and increase the speed of investigating and controlling outbreaks.

7.0. Introduction

Specifically, the guidelines have the following objectives:

- Define when an outbreak is considered multijurisdictional;
- Establish a framework for rapidly assessing whether a given foodborne disease event affects multiple jurisdictions;
- Promote early and effective communication and coordination among agencies involved in multijurisdictional investigations;
- Detail specific actions, including conducting rapid, detailed exposure assessments of cases and investigational trace-backs of the source for suspected food items, that might be needed in a multijurisdictional outbreak;
- Provide guidance on managing the transition between the phases of an outbreak investigation during which leadership of the investigation changes; and
- Provide guidance on post-outbreak debriefing and dissemination of findings.

7.0.1. Scope

These guidelines are subject to two major limitations. First, foodborne disease outbreak investigation activities are subject to state law. Thus, these guidelines might need to be adapted to reflect the relationships between state and local agencies within a state. Second, these guidelines cannot cover all possibilities that might emerge during an outbreak investigation. However, the principles of communication and coordination established by these guidelines should help to quickly resolve problems.

For ease of reading, these guidelines focus on relationships among local, state, and federal levels. Although territories, tribal lands, military installations, and the District of Columbia are independent administrative structures with unique legal standing, the general principles of multijurisdictional investigations articulated here should be useful for health officials in these areas as well.

7.1. Background

In the United States, local or state public health or food-regulatory agencies conduct most investigations of foodborne illness following routine policies and procedures. In many local agencies, sporadic cases of specific foodborne disease are investigated by communicable disease control or public health nursing programs. Consumer complaints about foodborne illness frequently are investigated by food-regulatory programs. However, outbreak investigations usually require coordination among these programs at the local level. Thus, effective communication and coordination at all levels of an organization generally are required for successful investigations of foodborne disease outbreaks.

In 2001, the National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, published guidelines for improving coordination and communication in investigations of multistate foodborne disease outbreaks. The National Food Safety System multistate guidelines were developed specifically to address the challenges of coordinating large and complex investigations of foodborne disease outbreaks among multiple states and federal public health and food-regulatory agencies.

Since development of these guidelines, the terrorist attacks on September 11, 2001, raised concerns about the potential for intentional contamination of food at all levels of the food system, which would require interaction among agencies that previously had not worked together. In addition, large multistate case clusters and foodborne disease

7.1. Background

outbreaks have continued. For example, during 2006–2010, at least 25% of foodborne disease outbreaks reported to the Centers for Disease Control and Prevention (CDC) Electronic Foodborne Outbreak Reporting System (eFORS now renamed the National Outbreak Reporting System [NORS]) involved multistate or multicounty exposures or affected residents of multiple states or counties (Table 7.1). Furthermore, 59% of *Escherichia coli* O157:H7 outbreaks and 48% of *Salmonella* outbreaks were multijurisdictional, discovered largely through PulseNet. Because of this system, awareness has increased about the relative frequency and importance of multijurisdictional outbreaks. Thus, for these most important foodborne pathogens, the need for multijurisdictional coordination should be anticipated during the earliest stages of an investigation.

The Council to Improve Foodborne Outbreak Responses (CIFOR) was created in 2006 to help develop model programs and processes to facilitate the investigation and control of foodborne disease outbreaks. CIFOR determined that one priority would be to go beyond multistate outbreaks by also developing guidelines for multijurisdictional outbreaks. Multijurisdictional guidelines apply to multiple states but also include localities within a state and outbreaks involving multiple agencies (Table 7.2).

Recent experiences with multijurisdictional investigations have pointed to two overriding concerns with communication and coordination of multijurisdictional investigations. The first is to establish criteria by which a local health agency can recognize that a foodborne disease outbreak under

Table 7.1. Number of multistate exposure, multistate resident, multicounty exposure, and multicounty resident outbreaks, by etiology, United States, 2006–2010

	NO. OUTBREAKS					% OUTBREAKS
ETIOLOGY AND AGENT	TOTAL OUTBREAKS	MULTISTATE EXPOSURE	MULTISTATE RESIDENT	MULTICOUNTY EXPOSURE	MULTICOUNTY RESIDENT	MULTI - JURISDICTIONAL
Confirmed Etiology	2386	81	268	108	336	33
Escherichia coli O157:H7	148	28	16	21	22	59
Salmonella	591	42	81	55	106	48
Clostridium perfringens	104	0	8	0	15	22
Staphylococcus aureus	38	0	2	0	10	32
Hepatitis A	14	0	3	0	3	43
Norovirus	1093	1	12	8	98	21
Other	398	10	34	24	82	38
Suspected Etiology	881	0	58	5	79	16
Unknown Etiology	1581	0	130	29	127	18
Multiple Etiologies	141	5	4	3	12	17
TOTAL	4924	84	460	145	554	25

7.1. Background

Table 7.2. Categories of multijurisdictional outbreaks
1. Outbreaks affecting multiple local health jurisdictions (e.g., city, county, town) within the same state
2. Outbreaks involving multiple states
3. Outbreaks involving multiple countries
4. Outbreaks affecting multiple distinct agencies (e.g., public health, food-regulatory, emergency management)
5. Outbreaks, regardless of jurisdiction, caused by highly pathogenic or unusual agent (e.g., *Clostridium botulinum*) that may require specialized laboratory testing, investigation procedures, or treatment
6. Outbreaks in which the suspected or implicated vehicle is a commercially distributed, processed, or ready-to-eat food contaminated before the point of service
7. Outbreaks involving large numbers of cases that may require additional resources to investigate
8. Outbreaks in which intentional contamination is suspected

investigation is multijurisdictional and to facilitate rapid communication of that fact to all affected agencies. The second is to establish effective means of integrating local agencies into large, multistate investigations that are detected and coordinated on a national level.

The passage of the Food Safety Modernization Act (FSMA) in 2011 gave new authorities to the Food and Drug Administration (FDA) and enhanced surveillance and response capacity at local, state and federal levels. Specifically related to multijurisdictional outbreaks, the FSMA directs CDC and FDA to:

- Improve coordination and data sharing with public health partners and the public;
- Increase state and local participation in national surveillance networks;
- Expand and integrate national surveillance systems; and
- 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;
- FDA: Coordinated Outbreak Response and Evaluation Network (CORE); and
- U.S. Department of Agriculture Food Safety and Inspection Service (USDA-FSIS): Applied Epidemiology Staff, Office of Public Health Science

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

After a foodborne disease event is recognized that requires multijurisdictional investigation, agencies that might need to participate in the investigation and agencies that might be otherwise affected by the event should be immediately notified (Table 7.2). Specific examples of these indicators and required notification steps are described below (Table 7.3). In some states, functions identified as occurring at the local level might be performed at the state level. Further guidance on the role of federal agencies in food safety is available at www.foodsafety.gov/about/federal.

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

Table 7.3. Examples of major indicators and required notification steps

OUTBREAK DETECTION	MAJOR INDICATOR	NOTIFICATION STEPS
Local Level	Commercially distributed, processed, or ready-to-eat food contaminated before point of service suspected or implicated as outbreak vehicle.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA-FSIS (depending on product and on local and state reporting requirements).
	Fresh produce item contaminated before point of service is suspected or implicated as outbreak vehicle.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA, depending on state and local reporting requirements.
	Ground beef is suspected or implicated in an outbreak of Escherichia coli O157:H7 infections.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and USDA-FSIS, depending on state and local reporting requirements.
	One of the "big six", non-O157 Shiga toxin–producing E. coli is identified as the etiologic agent in an outbreak. These include E. coli serogroups O26, O45, O103, O111, O121, and O145.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA-FSIS, depending on product and state and local reporting requirements.
	Molecular subtype characteristics of etiologic agent match the pattern of an agent independently associated with other foodborne disease outbreaks.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA-FSIS, depending on product and state and local reporting requirements.
	Intentional contamination of food item is suspected or implicated.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA-FSIS (depending on product), local law enforcement, and FBI.
	Illnesses are associated with multiple restaurants or food-service establishments, especially when those establishments are part of the same chain.	Immediately notify state health department, relevant state food-regulatory agency, and CDC, depending on local and state reporting requirements.
State Level	Increase in sporadic infections with common subtype characteristics identified across multiple jurisdictions.	Immediately notify affected local agencies, CDC, and state and federal food-regulatory agencies.
	Multiple common-source outbreaks linked by common agent, food, or water.	Immediately notify affected local agencies, CDC, and relevant state and federal food-regulatory agencies.
	Microbiological food testing by state food-regulatory agency prompts recall.	Immediately notify affected state and local public health agencies, CDC, and relevant federal food-regulatory agencies.

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

Table 7.3. Examples of major indicators and required notification steps
Continued

	Illnesses are associated with multiple restaurants or food-service establishments, especially when those establishments are part of the same chain.	Immediately notify relevant state food-regulatory agency and CDC, depending on product and local and state reporting requirements.
Federal Level	Increase of sporadic infections with common subtype characteristics identified across multiple states.	Immediately notify affected state and local public health agencies and federal food-regulatory agencies.
	Multiple common-source outbreaks linked by common agent, food, or water.	Immediately notify affected state and local public health agencies, CDC, and relevant state and federal food-regulatory agencies.
	Microbiological food testing by, or reported to, FDA or USDA-FSIS prompts recall.	Immediately notify affected state and local public health agencies, CDC, and relevant state and federal food-regulatory agencies.

Abbreviations: CDC = Centers for Disease Control and Prevention; FDA = Food and Drug Administration; USDA-FSIS = U.S. Department of Agriculture Food Safety and Inspection Service; FBI = Federal Bureau of Investigation.

7.3. Coordination of Multijurisdictional Investigations

After affected agencies are notified, coordinating the 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 USDA-FSIS.

Several principles guide the 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 sporadic cases 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.** Many local agencies might not have sufficient resources to effectively coordinate a multijurisdictional investigation, or state rules might assign jurisdiction over multicounty investigations

7.3. Coordination of Multijurisdictional 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.

- **Outbreak investigations progress through phases of activity, and leadership of the investigation should reflect the focus of the investigation at the time.** 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 trace-backs, and 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. These phases might not occur independently of each other during the investigation. These phases of activity can be elaborated as follows:
  - **Investigation of the "human illness outbreaks phase" should be coordinated within the appropriate public health agencies.** In addition to public health agencies' greater expertise and experience in conducting these investigations, rules governing the reporting and collection of information about human patients require that authorized public health agencies maintain and protect that information. Although de-identified information can be shared across agencies, the redaction process can reduce the value of information available for analysis.
  - **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.
  - **When an incident involves an agricultural commodity and the bulk of the commodity is produced in a limited number of states, those state agricultural agencies should be informed of the outbreak and its progress.** They too will be receiving inquiries about the safety of their produce/product and have a legitimate interest and role in determining possible sources of the vehicle, as well as preparing for potential environmental health assessments to determine possible points of contamination, take appropriate samples, etc. Communication with those states, even where no cases occur in those states, is essential.
- **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. Unless state and local public

7.3. Coordination of Multijurisdictional Investigations

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. 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 (if you want to become a Commissioned Official or if your state can sign a 20.88 Confidentiality Agreement, see www.fda.gov/ForFederalStateandLocalOfficials/CommunicationbetweenFDAStateLocalandOfficials/Commissioning/default.htm).

- **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 investigational trace-back efforts 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.
- **Releasing 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 respond 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.
- **Most health departments have incident command systems (ICS) that guide outbreak responses within the public health agencies. Historically, investigations of multijurisdictional foodborne disease outbreaks have not required formal activation of ICS. However federal agencies are now mandated to use ICS for response to outbreak incidents.** ICS are structures that provide for internal communications within a government system among primary event responders, public information officers, and security and safety officers and for external liaison with various organizations. In concept, the ICS structures provide for communication and coordination among agencies responding to a multijurisdictional outbreak of foodborne disease. However, even though the principles of multijurisdictional investigations might be similar to ICS responses, in many states and local jurisdictions, ICS are formal structures controlled by public safety officials with no other jurisdiction for food safety or outbreak control. In these situations, activating ICS might initiate actions that distract from the prompt conduct of the investigation. Agencies involved in investigation and response to foodborne disease outbreaks should decide in advance whether and how to apply an ICS, and, if applicable, incorporate the ICS structure into their response planning. Such planning should be coordinated with all other agencies that might be drawn into the investigation and response over time.

7.3. Coordination of Multijurisdictional Investigations

Homeland Security Presidential Directive 5 (HSPD-5), Management of Domestic Incidents, called for the establishment of a comprehensive, national incident management system (www.gpo.gov/fdsys/pkg/PPP-2003-book1/pdf/PPP-2003-book1-doc-pg229.pdf). As a result, the Department of Homeland Security released the National Incident Management System (NIMS) and required all federal agencies to incorporate and use NIMS for incident response. HSPD-5 was replaced by Presidential Policy Directive 8 in 2011, which still relies on NIMS as the organizing framework for national preparedness (www.fas.org/irp/offdocs/ppd/ppd-8.pdf). NIMS is a comprehensive, standardized, scalable, and flexible system used by all levels of government to manage and coordinate emergencies and other major incidents. Some states also have mandated use of NIMS for incident response. All Rapid Response Teams are NIMS trained (see Chapter 3, section 3.1.2.8).

Except for federal agencies, most foodborne disease outbreak investigations do not require formal activation of ICS, but they might benefit from application of ICS principles and methods. **However, if a person who claims to have tampered with food contacts an agency, or in any outbreak in which intentional contamination is suspected, notification of law enforcement officials and assessment of the credibility of the threat are essential.** If the threat is credible, the outbreak will move into a law enforcement realm with activation of the ICS.

7.4. Outbreak Detection and Investigation by Level

The following sections are organized by the level at which an outbreak is recognized and the actions that should follow that recognition.

7.4.1. Outbreak Detection and Investigation at the Local Level

7.4.1.1. Detect outbreak

- Outbreaks are detected at the local level by one of the following means:
- Consumer complaint identifies group exposure with multiple illnesses;
- Multiple consumer complaints received about the same source;
- Health-care provider reports group exposure with multiple illnesses;
- Investigation of sporadic case identifies group exposure with multiple illnesses; or
- Investigation of sporadic case cluster identifies common source.

Complaints may be made to a health-care provider, public health agency, point of sale, poison control center, or the media, among others.

7.4.1.2. Ensure notification

With initiation of an outbreak investigation, a local agency should **ensure notification of the following agencies,** and provide subsequent updates as appropriate in accordance with state procedures:

- Affected and surrounding county and city health departments (i.e., epidemiology, environmental health, public health laboratory); and
- State health department (i.e., epidemiology, environmental health, laboratory).

7.4.1.3. Provide coordination

During the investigation, a local agency needs to **coordinate** the epidemiology, environmental health, regulatory, and laboratory components of the investigation.

When findings indicate that multiple jurisdictions might be involved, additional

7.4. Outbreak Detection and Investigation by Level

communication and coordination are needed:

- Referrals and requests for assistance in **incidents of local significance.**

  Incident: Local agency identifies a likely foodborne disease outbreak in another jurisdiction.

  Action: Ensure notification of the affected jurisdiction immediately.

  Incident: Common-source outbreak identified in one jurisdiction has cases among persons who reside in two or more local jurisdictions.

  Action: Request assistance to contact and interview cases in other jurisdictions.

  Incident: Local agency identifies a likely foodborne disease outbreak with exposure or food source in another jurisdiction.

  Action: Notify appropriate public health and regulatory agencies in the jurisdictions with the food source or exposure.

These investigations 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.

- Referrals and requests for assistance in incidents representing a **transition from local to state significance.**

  Incident: Common-source outbreak identified in one jurisdiction, investigation implicates processed food or fresh produce item, contaminated before the point of service, in absence of local contributing factors.

  Action: Ensure notification of appropriate food-regulatory agencies of probable contaminated food vehicle; **conduct investigational trace-back** to identify source to the point where contamination most likely occurred; or determine whether responsibility for the investigation needs to be transferred to a state or federal agency.

  Action: Ensure notification of other jurisdictions that might be investigating similar related events of the results of outbreak investigations regarding agent and vehicle.

  Action: Subtype agent; **upload patterns** to PulseNet.

Incident: Common-source outbreak identified in one jurisdiction, linked to outbreaks identified in other local jurisdictions by common agent, food, or water.

Action: Ensure notification of appropriate food-regulatory agencies and other jurisdictions, as described above.

Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

Action: Establish coordinating office (or individual) for the investigations to **collect, organize, and disseminate** all the data.

Incident: Cluster(s) of sporadic infections with common subtype characteristics identified in one local jurisdiction.

Action: Upload patterns to PulseNet.

Action: Interview cases as soon as possible using a detailed exposure questionnaire to obtain detailed food and environmental exposure histories, including product brand and retail source. Compile exposure histories and compare with expected exposure levels from Atlas of Exposures (http://www.cdc.gov/foodnet/studies/population-surveys.html), cases not associated with the cluster, or non-ill community controls.

Action: Ensure notification of appropriate food-regulatory agencies

7.4. Outbreak Detection and Investigation by Level

to initiate investigational trace-backs of suspected food items to elaborate and test hypotheses.

Action: Ensure notification of other jurisdictions likely to have additional cases, and **distribute** summary data about cases, descriptive epidemiology, investigation protocols, and standardized questionnaires to jurisdictions.

Action: Establish coordinating office (or individual) for investigation to **collect, organize, and disseminate** all the data.

These investigations 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.

7.4.2. Outbreak Detection and Investigation at the State Level

7.4.2.1. Detect outbreak

- Outbreaks typically are detected at the state level by one of the following means:
- Common-source outbreaks in multiple local jurisdictions, or multiple states linked by a common agent, food, or water.
- Cluster(s) of sporadic infections with common subtype characteristics identified across multiple local jurisdictions.
- An identified statewide increase in sporadic infections with common subtype characteristics.
- Information or alert from another public health agency, food regulatory agency, or another country.

7.4.2.2. Ensure notification

With initiation of an outbreak investigation, the state public health agency should **ensure notification of the following agencies** and provide subsequent updates as appropriate:

- All local health departments likely to be affected by the outbreak or involved in the investigation.
- The state food-regulatory agency, which often has responsibility for conducting investigational trace-backs of suspected food items.
- Other state health departments (e.g., regional counterparts, or potentially nationally through Epi-X, PulseNet, the Foodborne Outbreak email subscribers, or similar networks).
- CDC (Outbreak Response and Surveillance Team).
- Federal regulatory agency offices (e.g., USDA-FSIS, FDA, Environmental Protection Agency), depending on the nature and status of the investigation.

Agency media personnel also should be engaged as early as possible to assist with messaging and to ensure consistency of message among agencies.

7.4.2.3. Provide coordination

During the course of the investigation, 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 are communicating and coordinating** activities with counterparts at the local and federal levels.

- Referrals and requests for assistance in **incidents of state significance.**

Incident: Case clusters in multiple local jurisdictions or statewide increase of sporadic infections with common subtype characteristics identified.

Action: Upload patterns to PulseNet.

Action: Ensure notification of all local jurisdictions; **distribute** summary data about cases, descriptive epidemiology,

7.4. Outbreak Detection and Investigation by Level

investigation protocols, and standardized questionnaires.

Action: Request that local agencies **interview cases** as soon as possible using a detailed exposure questionnaire to obtain detailed food and environmental exposure histories, including product brand and retail source. **Assess** the availability and willingness of local agency staff to conduct timely interviews. **Provide support** needed to ensure **timely conduct of interviews.** As investigations heat up, priorities will need to be adjusted. Evening and weekend work commonly is required. Interviews should not be delegated to agencies or individuals unable to make the investigation a top priority.

Action: Ensure notification of appropriate food-regulatory agencies of the possible need to conduct investigational trace-backs of suspected food items to elaborate and test hypotheses.

Action: Establish coordinating office (or individual) for investigations to **collect, organize, and disseminate** all the data.

Incident: Common-source outbreaks in multiple jurisdictions or multiple states linked by common agent, food, or water. When a particular exposure is epidemiologically implicated or strongly suspected:

Action: Ensure notification of all local jurisdictions, all states, and federal agencies of the results of outbreak investigations about agent and vehicle.

Action: Ensure notification of appropriate food-regulatory agencies of the probable contaminated food vehicle in commercial distribution; **conduct investigational trace-back** to identify source to the point where contamination most likely occurred; or determine whether responsibility for regulatory action needs to be transferred to a federal agency.

Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

Action: Establish the coordinating office (or individual) for investigations to **collect, organize, and disseminate** all the data. In cooperative investigations, make raw data readily available in a common format to interested participants from all participating agencies.

The resources of one or more local jurisdictions cannot adequately respond to these events following routine procedures. These investigations **require active participation** from multiple local agencies, typically under **state agency leadership.** The state provides response coordination, consultation, and information sharing. On the basis of established procedures, emergency management systems might be activated at the local level 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 may require **federal agency leadership,** depending on the capabilities and willingness of the states involved. In a small number of events, emergency management systems might be activated at local and state levels and possibly at the federal level.

7.4. Outbreak Detection and Investigation by Level

7.4.3. Outbreak detection and investigation at the federal level

7.4.3.1. Detect outbreak

Outbreaks are detected at the federal level by one of the following means:

- Common-source outbreaks in multiple states linked by common agent, food, or water;
- Cluster(s) of sporadic infections with common subtype characteristics identified in multiple states; or
- Regional or national increase of sporadic infections with common subtype characteristics identified.

7.4.3.2. Ensure notification

When an outbreak investigation begins, the CDC Outbreak Response and Prevention Branch should **ensure notification** of and provide subsequent updates as appropriate to:

- State and local health departments (e.g., Epi-X, the Foodborne Outbreak email subscribers, PulseNet) and
- Federal regulatory agency offices (USDA-FSIS, FDA, Environmental Protection Agency).

7.4.3.3. Provide coordination

During the investigation, 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.

- Referrals and requests for assistance in **incidents of national significance.**

  Incident: Common-source outbreaks in multiple states linked by common agent, food, or water:

  Action: Ensure notification of all state and local jurisdictions, as appropriate, of results of outbreak investigations regarding agent and vehicle.

  Action: Ensure notification of appropriate food-regulatory agencies of likely contaminated food vehicle in commercial distribution; **conduct investigational trace-back** to identify source to the point where contamination most likely occurred.

  Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

  Action: Establish coordinating office (or individual) for investigations to **collect, organize, and disseminate** all the data.

  Incident: Case clusters in multiple states or regional or national increase of sporadic infections with common subtype characteristics identified.

  Action: Ensure notification of all states and local jurisdictions, as appropriate; **distribute** summary data about cases, descriptive epidemiology, investigation protocols, and standardized questionnaires.

  Action: Request that local or state agencies **interview cases** as soon as possible using a detailed exposure questionnaire to obtain detailed food-exposure histories, including product brand and retail source. **Assess** the availability and willingness of local or state agency staff to conduct interviews in a timely manner. **Provide support** needed to ensure the **timely conduct of interviews.**

  Action: Ensure notification of appropriate food-regulatory agencies of the possible need to conduct investigational trace-backs of suspected food items to elaborate and test hypotheses.

7.4. Outbreak Detection and Investigation by Level

> **Action: Establish coordinating office** (or individual) for investigations to **collect, organize, and disseminate** all the data.

These outbreaks require activation of local, state, regional, and national resources to contain disease and protect human health. They require active participation from multiple local agencies, state response coordination, consultation and information sharing, and federal agency leadership. Emergency management systems might be activated at local, state, and federal levels.

7.5. Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS

The organizations involved 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. Consider including consumer groups in this conference call or hosting a conference call specifically for consumer groups, to help them understand what happened and what is being done to prevent recurrence. Also consider including industry representatives to help disseminate lessons learned from the investigation.

The lead agency(ies) coordinating the investigation should prepare an after-action report after the conference call. The report should summarize the effectiveness of communication and coordination among jurisdictions and identify specific gaps or problems that arose during the investigation. 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 in investigation or response are occurring over time; this can help with an agency's quality improvement efforts.

All multijurisdictional investigations should be reported by individual states to NORS. The multijurisdictional nature of the investigation should be indicated by completion of appropriate data fields in the NORS report form. Individual state reports will be consolidated by CDC as part of a multistate outbreak report. In addition, FDA and USDA-FSIS write a summary report of each investigation.

CHAPTER

8

Performance Indicators for Foodborne Disease Programs

Surveillance and outbreak response are major components of states' foodborne investigation capacity and are essential for preventing and controlling foodborne illness. Multiple entities—almost 3000 local health departments, more than 50 state and territorial health departments, and several federal agencies—interact in a complex system covering surveillance to detect and respond to enteric and other foodborne diseases.

The occurrence of large and multistate foodborne disease outbreaks and concerns about bioterrorism have increased the need to rapidly detect and distinguish between outbreaks of foodborne disease and possible intentional contamination. Evaluating the timeliness and effectiveness of foodborne disease surveillance is a major step toward assessing and improving U.S. capacity for foodborne disease surveillance and outbreak response. Since the original publication of the Guidelines, there has been a great increase in the evidence base for establishing performance measures. These are reflected in the performance measures included in this chapter, for which target ranges are being developed.

8.0. Introduction

CDC's Public Health Emergency Preparedness Goals established a general framework and a few specific performance measures relevant to foodborne disease surveillance. CDC's

Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) has developed a series of performance metrics that cover a range of outbreak detection and response activities. These are designed to demonstrate successes and identify gaps in the detection, investigation, and control of enteric disease outbreaks. Thus, progress is being made towards the development of comprehensive national performance standards, measures, and models for public health agencies to follow to ensure foodborne illness surveillance and outbreak detection and response systems work at maximum efficiency.

8.1. Purpose and Intended Use

The CIFOR Guidelines for Foodborne Disease Outbreak Response were intended to serve as a comprehensive source of information on foodborne disease investigation and control for state and local health departments. The Guidelines included measurable indicators of effective surveillance for enteric diseases and for response to outbreaks by state and local public health officials. The performance indicators were intended to be used by agencies to evaluate the performance of their foodborne disease surveillance and control programs. However, the Guidelines stopped short of providing specific targets for individual metrics, to avoid their use as a score card that could be compared between agencies.

Since the development of the Guidelines, there has been more emphasis placed on performance, accountability and transparency by public health agencies. Therefore, there is a need for the development of target values that will help state and local public health agencies demonstrate their performance and effectiveness for foodborne disease surveillance and outbreak control activities. Given the distributed public health system with multiple independent jurisdictions, having performance targets will also provide a framework for communicating model practices for surveillance activities and create clear expectations for performance that will increase the likelihood of compliance.

The use of standardized performance criteria and metrics serves several functions:

- They promote a common understanding of the key elements of foodborne disease surveillance and control activities across local, state, and federal public health agencies;
- They facilitate training of food program staff in the use and interpretation of the performance criteria; and
- They allow for the aggregation of data at state, regional, or national levels to evaluate program effectiveness and to identify specific needs for improvement and additional resource investment.

The indicators were not intended as performance standards. Where specific performance standards exist (e.g., PulseNet turnaround times, Draft Voluntary National Retail Food Regulatory Program Standards), meeting the performance standard was adopted as a performance indicator. The development of performance standards depends on the availability of specific indicators such as these to provide a basis for program evaluation. Defining the level of performance expected from foodborne disease surveillance and control programs exceeds the scope of these Guidelines, However, the body of evidence needed to do so is growing, as reflected in the performance measures

8.1. Purpose and Intended Use

included in this chapter for which target ranges are being developed. Thus, this chapter increases the range of performance measures that may be useful for future public health agency evaluation and certification programs.

The aggregation of data at state, regional, or national levels is intended to provide a comprehensive overview of foodborne disease surveillance and control programs, rather than a system for ranking them.

8.2. Performance Indicators

This chapter contains tables organized to highlight major performance indicators by program function. The roles and responsibilities of foodborne disease surveillance and control programs vary by state according to state law. **Individual agencies that wish to evaluate their programs using these indicators should select indicators and metrics that best reflect their activities, regardless of where they fall in the document's table structure.**

Foodborne Disease Program Objectives and Indicators

Table 8.1. Objectives of foodborne disease surveillance program

Table 8.2. Short-term objectives, indicators, subindicators, and metrics

Table 8.3. Intermediate objectives, indicators, subindicators, and metrics

Table 8.4. Long-term objectives, indicators, subindicators, and metrics

A total of 16 performance indicators were selected for the development of target ranges based on their importance and feasibility of implementation (Table 8-5). These include metrics for epidemiology, laboratory, and environmental health programs. Most of the selected performance measures focus on the state level. Several are applicable to both state and local programs and a few are primarily focused on local agencies. For each of the performance measures, a description is provided that describes the performance measure, relevant definitions, an assessment of the feasibility of measuring performance of the metric, and detailed methods for measurement.

Target ranges for these performance measures are being developed under direction of the CIFOR Performance Indicators Work Group, and will be maintained separately on the CIFOR website. This will allow for the target ranges to be modified as needed, based on the availability of resources and the performance of the system.

Foodborne Disease Program Objectives and Indicators

Table 8.1. Objectives of foodborne disease surveillance program

SHORT-TERM OBJECTIVES	INTERMEDIATE OBJECTIVES	LONG-TERM OBJECTIVES
Detect foodborne disease events of public health importance. Respond to events in a timely manner. Intervene when appropriate to prevent illness.	Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks. Monitor trends to identify emerging foodborne diseases and food-safety problems. Increase knowledge of foodborne disease causes and abatement strategies.	Prevent future outbreaks. Reduce incidence of foodborne illness. Increase health of the general population.

Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Detect foodborne disease events of public health importance.	8.2.1. Foodborne complaints investigated	PROCESS • Program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury, or intentional food contamination. The final disposition for each complaint is recorded in the log or database and filed in or linked to the establishment record for retrieval purposes (Draft Voluntary National Retail Food Regulatory Program Standards, standard 5, part 1.d). • Demographic information obtained • Food history obtained OUTCOME • Disposition, action, or follow-up on complaint or referral report alleging food-related illness or injury within 24 hours • Outbreak detected	PROCESS • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 1.d, met, yes/no • % of complaints for which complete demographic information was available • % of complaints for which food history was obtained OUTCOME • No. complaints received. Rate of complaints received per 100,000 population in jurisdiction. • No. outbreaks detected as a result of foodborne illness complaints. Rate of outbreaks detected per 100,000 population in jurisdiction, and per 1,000 complaints received.
Detect foodborne disease events of public health importance.	8.2.2. Reported cases with specified foodborne illnesses interviewed	PROCESS • Demographic information obtained • Exposure history obtained • Case onset date obtained • Date of report documented • Case report maintained in searchable database	PROCESS • % of reported cases for which complete demographic information was available • % of reported cases with attempted interview • % of confirmed cases with exposure history obtained% of reported cases for which onset date was available • % of reported cases for which report date was available • Searchable database maintained, yes/no

Detect foodborne disease events of public health importance.	8.2.2. Reported cases with specified foodborne illnesses interviewed	OUTCOME • Interval from receipt of report to interview of case • Need for public health intervention identified (e.g., exclusion of workers, conduct of investigation)	OUTCOME • Median no. days from receipt of report to interview of case • % of cases for which an intervention was identified or ruled out
Detect foodborne disease events of public health importance.	8.2.3. Isolates or culture-independent diagnostic test (CIDT)-positive specimens of specified foodborne pathogens submitted to PHL	PROCESS • Stool collection date obtained • Date of clinical laboratory finding obtained • Date of submission to PHL documented • Date of serotyping documented • Date of subtyping by PFGE documented • Isolate/CIDT-positive specimen report maintained in searchable database OUTCOME • No. reported cases for which isolate or CIDT-positive specimen submitted to PHL • No. days from clinical laboratory finding to submission of isolate or CIDT-positive specimen to PHL • No. days from receipt of isolate by PHL to subtyping results • Subtype-clusters identified • % of pulsed field gel electrophoresis (PFGE) subtyping data results for *E. coli* O157:H7 and *Listeria* submitted to the PulseNet national database within four working days of receiving isolate at the PFGE laboratory (CDC preparedness goal)	PROCESS • % of cases for which stool collection date was available • % of investigated cases for which date of clinical laboratory finding was available • % of cases for which date of sample submission to PHL was available • % of cases for which PFGE subtyping date was available • Searchable database maintained, yes/no OUTCOME • % of cases for which isolates were submitted to PHL • Median no. days from report of clinical findings to receipt of isolate at PHL • Median no. days from receipt of specimen to serotyping or subtyping results • No. subtype clusters identified • CDC preparedness goal met, yes/no

Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics
Continued

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Respond to events in a timely manner.	8.2.4. Foodborne outbreaks investigated	PROCESS • Cases interviewed to determine illness and exposure histories • Stool samples obtained from cases • Controls (non-ill persons) interviewed to determine exposure histories • Environmental health assessment of establishment conducted, where appropriate • Food flow documented • Food workers interviewed • Stool samples obtained from food handlers • Food or environmental samples obtained OUTCOME • No. days from onset of symptoms to initiation of outbreak investigation • No. days from collection of stool samples to confirmed culture results • No. days from collection of environmental or food samples to confirmed culture result • Foodborne disease outbreak source identified	PROCESS • % of outbreak investigations with exposure assessments conducted.% of outbreak investigations with clinical specimens collected and submitted to PHL from 2 or more people% of outbreak investigations where specimens were tested for a specified set of potential agents at PHL • % of outbreak investigations with >10 ill people where an analytic study was conducted. % of investigations in which an establishment was investigated, if appropriate • % of environmental investigations that included a food flow, interviews of food workers, collection of stool samples from food handlers, collection of food or environmental samples OUTCOME • No. foodborne outbreaks reported, all agents. Rate of outbreaks reported / 100,000 population. • Median no. days from onset of symptoms of first/index case to outbreak investigation • Median no. days from submission of stool samples to receipt of results • Median no. days from submission of food or environmental samples to receipt of results • % of foodborne disease outbreaks for which a source was identified • % of outbreaks where NORS form completed

Respond to events in a timely manner.	8.2.5. Case clusters investigated	PROCESS • Cases interviewed to determine exposure histories • Analytic epidemiologic study conducted for *Salmonella* and STEC clusters with >5 cases OUTCOME • No. days from cluster recognition to completion of interviews of cases and controls • Cluster source identified	PROCESS • % of investigated clusters with routine interview of cases to determine exposure history • Once a multistate foodborne outbreak has been declared by CDC, state health departments in conjunction with their local health departments complete or closeout 80% of interviews within 48 hours using the 'outbreak designated' questionnaire% of Salmonella and STEC clusters with > 5 cases where an analytic epidemiologic study was conducted. OUTCOME • Median no. days from identification of a cluster to close out of investigation-related interviews % of clusters in which a source was identified
Intervene when appropriate to prevent illness.	8.2.7. Ill or infected food handlers identified and excluded		OUTCOME • % of outbreak investigations with exclusion of an ill person(s) from high risk setting • Median no. days from initiation of investigation to implementation of intervention
	8.2.8. Deficient food-handling practice identified and corrected		OUTCOME • % of outbreak investigations with remediation or closure of an establishment linked to illness • Median no. days from initiation of investigation to implementation of intervention
	8.2.9. Advisory issued about outbreak and implicated source		OUTCOME • Median no. days from initiation of investigation to implementation of intervention

Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics
Continued

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Intervene when appropriate to prevent illness.	8.2.10. Contaminated food recalled and removed from marketplace		OUTCOME • Median no. days from initiation of investigation to implementation of intervention
Respond to events in a timely manner, and intervene when appropriate to prevent illness.	8.2.11. After-action reviews of outbreak investigations conducted within a mean of 60 days after investigation ends (CDC preparedness goal)		PROCESS • CDC preparedness goal met, yes/no
	8.2.12. Staff trained on the agency's outbreak response protocol		PROCESS • % of staff likely to be involved in an outbreak investigation that have received training
	8.2.13. Contact lists of individuals or organizations key to foodborne disease outbreak investigations created and regularly updated		PROCESS • Contact list created, yes/no • Intervals between updates

Table 8.3. Intermediate objectives, indicators, subindicators, and metrics

INTERMEDIATE OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks.	8.3.1. Etiology of outbreak identified	PROCESS • Clinical characteristics of outbreak characterized • Stool samples collected and tested for likely agents • Food and environmental samples collected and tested for likely agents OUTCOME • Etiology of outbreak identified	PROCESS • % of outbreaks for which clinical characteristics were described • % of outbreaks for which at least 1 stool sample was tested for likely agents • % of outbreaks for which food or environmental samples were tested for likely agents OUTCOME • % of outbreaks for which etiology was identified and reported to NORS

	8.3.2. Vehicle of outbreak identified	PROCESS • Suitable epidemiologic study conducted to identify vehicle • Informational traceback conducted to subtype exposure histories • Regulatory traceback conducted to confirm production source of implicated food vehicle • Isolates from case specimens and potential vehicles subtyped OUTCOME • Vehicle of outbreak identified	PROCESS • % of outbreaks for which epidemiologic study was conducted to identify a vehicle • % of outbreaks for which informational traceback was conducted to help elucidate exposure histories • % of outbreaks for which regulatory traceback was conducted to confirm production source of implicated food vehicle • % of outbreaks for which subtyping of isolates from cases and potential vehicles was conducted OUTCOME • % of outbreaks for which a vehicle was identified and reported to NORS
Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks.	8.3.3. Contributing factors identified	PROCESS • Preparation of implicated food items reviewed • Food-preparation review guided by identification of suspected agent • Possible contributing factors to the illness, injury, or intentional food contamination identified in each on-site investigation report OUTCOME • Contributing factors identified	PROCESS • % of outbreak investigations with link to a restaurant/food establishment where an on-site environmental health assessment was conducted • % of outbreaks for which food-preparation flow was reviewed for implicated food item • % of outbreaks for which food-preparation flow was reviewed, with specific agent suspected • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 2.a, met, yes/no OUTCOME • % of outbreaks for which contributing factors were identified and reported to NORS

Foodborne Disease Program Objectives and Indicators

Table 8.3. Intermediate objectives, indicators, subindicators, and metrics
Continued

INTERMEDIATE OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Monitor trends to identify emerging foodborne diseases and food-safety problems.	PROCESS • At least annually, data in complaint log or database and illness and injury investigations reviewed to identify trends and possible contributing factors most likely to cause illness or injury. These reviews may suggest a need for further investigations and steps for illness prevention (Draft Voluntary National Retail Food Regulatory Program Standards, standard 5, part 7.a) • Routine review of cases of reported foodborne diseases for trends in emerging foodborne diseases • Routine review of outbreak investigation findings for trends		PROCESS • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a, met, yes/no • Analysis of foodborne disease case reports, yes/no • Analysis of outbreak reports, yes/no
Increase knowledge of foodborne disease causes and abatement strategies.	Incorporation of results of outbreak investigation summaries into food-safety training activities		• Training activities updated annually, yes/no • % of staff that receive training related to foodborne disease outbreak investigations

Table 8.4. Long-term objectives, indicators, subindicators, and metrics

LONG-TERM OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Prevent future outbreaks.	8.4.1. Decrease in no. outbreaks attributable to previously identified sources and contributing factors		Change in no. and % of outbreaks with specific sources and contributing factors, from baseline
Reduce incidence of foodborne illness.	8.4.2. Trends in no. confirmed foodborne outbreaks	OUTCOME • No. outbreaks reported to individual state health departments • Outbreaks per million population • Outbreaks per 1000 reported cases of specified foodborne disease agents • Outbreaks in restaurants per 1000 restaurants • No. outbreaks reported to eFORS	OUTCOME • % of outbreaks reported to state health department by year and type of agent, compared over time
Reduce incidence of foodborne illness.	8.4.3. Trends in incidence of specified foodborne illnesses	OUTCOME • Statewide annual summaries of reported foodborne diseases with trend analysis • FoodNet trend analyses	
Increase health of population.	Beyond scope of project		

8.2. Performance Indicators

Performance Measures for Program Evaluation

A total of 16 performance indicators were selected for the development of target ranges based on their importance and feasibility of implementation (Table 8-5). These include metrics for epidemiology, laboratory, and environmental health programs. Most of the selected performance measures focus on the state level. Several are applicable to both state and local programs and a few are primarily focused on local agencies. For each of the performance measures, a description is provided that describes the performance measure, relevant definitions, an assessment of the feasibility of measuring performance of the metric, and detailed methods for measurement.

Target ranges for these performance measures are being developed under direction of the CIFOR Performance Indicators Work Group, and will be maintained separately on the CIFOR website. This will allow for the target ranges to be modified as needed, based on the availability of resources and the performance of the system.

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
1. Foodborne illness complaint reporting system: Metric: Agency maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury or intentional food contamination, and routinely reviews data to identify clusters of illnesses requiring investigation. Definitions: Foodborne illness complaint: A report of illness experienced by one or more persons following exposure to a specific event or establishment. Foodborne illness complaint log: A paper registry of complaints that records information about the complaint and specific establishment. Foodborne illness complaint database: An electronic database that records information about the complaint and specific establishment in a searchable format. Feasibility: This metric is associated with CIFOR Indicator 8.2.1 "Foodborne complaints investigated." FDA's Draft Voluntary National Retail Food Regulatory Program Standards, Standard 5, Part 1.d calls for programs to maintain logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury, or intentional food contamination.	Determine if an agency has any complaint system in place and if it is used to review foodborne illness complaints. Determine if an agency has an electronic database that can be systematically reviewed to link complaints.	Complaint system is: *(select one)* Electronic database: System to log complaints: Not applicable:

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
2. Outbreaks detected from complaints: Metric: Outbreaks detected from complaints: Number outbreaks detected as a result of foodborne illness complaints. Rate of outbreaks detected per 1,000 complaints received. Definitions: Outbreak detected from a complaint: A foodborne illness outbreak that was detected as a result of a foodborne illness complaint investigation. Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. Foodborne illness complaint: A report of illness experienced by one or more persons following exposure to a specific event or establishment. Feasibility: This metric is associated with CIFOR Indicator 8.2.1 "Foodborne complaints investigated." It provides a consistent expectation for the use of complaint data system. Reporting numbers will allow simple comparisons from year to year for the agency, and reporting rates will allow for comparisons across agencies.	Determine the number of foodborne illness complaints that were received during the year. This will be the denominator for the metric. Determine the number of foodborne illness outbreaks that were detected as a result of a foodborne illness complaint investigation during the year. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 1,000. This will convert the observed numbers into a standardized rate.	Denominator (No. complaints) = _____ Numerator (No. outbreaks detected from complaints) = _____ Rate (Num./Denom. x 1000)= _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
3. Foodborne illness outbreak rate: Metric: Number foodborne outbreaks reported, all agents. Rate of outbreaks reported / 1,000,000 population. Definitions: Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. Foodborne illness outbreak rate: The number of confirmed foodborne illness outbreaks within a jurisdiction during a year, divided by the population of the jurisdiction x 1,000,000. Feasibility: This metric is associated with CIFOR Indicator 8.2.4 "Foodborne outbreaks investigated." It aggregates FoodCORE metrics for outbreak investigations across all pathogens. Reporting foodborne outbreaks is part of PHEP Performance Measure 13.3 Outbreak Investigation Reports. Reporting numbers will allow simple comparisons from year to year for the agency, and reporting rates will allow for comparisons across agencies.	Determine the population of the jurisdiction. This will be the denominator for the metric. Determine the number of foodborne illness outbreaks that were reported during the year. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 1,000,000. This will convert the observed numbers into a standardized rate.	Denominator (Population) = _____ Numerator (No. foodborne outbreaks reported) = _____ Rate (Num./Denom. x 1,000,000) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
4. Confirmed cases with exposure history obtained: Metric: Number and % of confirmed cases with exposure history obtained. Definitions: Confirmed case: Case reported to local or state health department by clinical laboratory with confirmed *Salmonella*, Shiga toxin-producing *E. coli* (STEC) or *Listeria* infection. Exposure history: An interview (of any format) that assesses exposures prior to onset of illness. The assessment should go beyond assessment of high risk settings and prevention education to ascertain food consumption/preference or other exposure data. For STEC this should include disease-specific data elements identified by CSTE and for Listeria it should include completing the *Listeria* case form. Feasibility: This metric is associated with CIFOR Indicator 8.2.2 "Reported cases with specified foodborne illness interviewed." It is consistent with FoodCORE common metrics for *Salmonella*, STEC, and *Listeria*. Reporting numbers will allow simple comparisons from year to year for the agency, and reporting rates will allow for comparisons across agencies.	Determine the number of confirmed cases reported. This will be the denominator for the metric. Determine the number of confirmed cases with exposure history obtained. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100. This will convert the observed numbers into a standardized rate. Measure and report separately for confirmed *Salmonella*, *E. coli* (STEC) and Listeria cases.	Denominator (No. confirmed cases) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Numerator (No. cases with exposure history) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Rate (Num./Denom. x 100) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria*

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
5. Isolate/CIDT-positive clinical specimen submissions to PHL: Metric: Isolate/CIDT-positive clinical specimen submissions to public health laboratory (PHL): Number and % of isolates from confirmed cases and clinical specimens from patients diagnosed by culture independent diagnostic test (CIDT), submitted to PHL. Definitions: Isolate: Primary isolates of *Salmonella*, Shiga toxin-producing *E. coli* (STEC) or Listeria, limited to first or representative isolate or sample for each case. PHL: State or local public health laboratory designated to serve as a reference laboratory for confirmation and subtyping of isolates for jurisdiction. Feasibility: This metric is associated with CIFOR Indicator 8.2.3 "Isolates of specified foodborne pathogens submitted to PHL." It is consistent with FoodCORE common metrics for *Salmonella*, STEC, and *Listeria*. Reporting numbers will allow simple comparisons from year to year for the agency, and reporting rates will allow for comparisons across agencies.	Determine the number of confirmed cases reported. This will be the denominator for the metric. Determine the number of isolates and clinical specimens from patients diagnosed by culture independent diagnostic test (CIDT), submitted to the PHL. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100. This will convert the observed numbers into a standardized rate. Measure and report separately for confirmed *Salmonella*, *E. coli* (STEC), and Listeria cases.	Denominator (No. confirmed cases) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Numerator (No. isolates/ CIDT-positive clinical specimens submitted) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Rate (Num./Denom. x 100) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria*

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
6. PFGE subtyping of isolates: Metric: Number and % of isolates with PFGE information. Definitions: Isolate: Primary isolates of *Salmonella*, Shiga toxin-producing *E. coli* (STEC), or *Listeria*, limited to first or representative isolate or sample for each case. PFGE: Pulsed-field gel electrophoresis. Feasibility: This metric is associated with CIFOR Indicator 8.2.3 "Isolates of specified foodborne pathogens submitted to PHL." It is consistent with FoodCORE common metrics for *Salmonella*, STEC, and *Listeria*. Reporting numbers will allow simple comparisons from year to year for the agency, and reporting rates will allow for comparisons across agencies.	Determine the number of isolates submitted to the PHL. This will be the denominator for the metric. Determine the number of isolates with PFGE information. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100. This will convert the observed numbers into a standardized rate. Measure and report separately for confirmed *Salmonella*, *E. coli* (STEC), and *Listeria* cases.	Denominator (No. isolates submitted) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Numerator (No. isolates with PFGE information) = A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Rate (Num./Denom. x 100)= A. *Salmonella* B. *E. coli* (STEC) C. *Listeria*

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
7. Isolate/CIDT-positive clinical specimen submission interval: Metric: Median number days from collection of clinical specimen to receipt of isolate or clinical specimen from a patient diagnosed by CIDT, at PHL. Definitions: Isolate: Primary isolates of Salmonella, Shiga toxin-producing E. coli (STEC), or Listeria, limited to first or representative isolate or sample for each case. CIDT-positive clinical specimen: Clinical specimens forwarded to PHL for confirmation and isolation from patients diagnosed with Salmonella, Shiga toxin-producing E. coli (STEC) or Listeria by culture independent diagnostic test (CIDT). Isolate/CIDT-positive clinical specimen submission interval: The number of days from collection of the clinical specimen to receipt of the isolate or clinical specimen from a patient diagnosed by CIDT, at the PHL. Feasibility: This metric is associated with CIFOR Indicator 8.2.3 "Isolates of specified foodborne pathogens submitted to PHL." It is consistent with FoodCORE common metrics for *Salmonella* and STEC. Median values likely reflect consistent general practices within the jurisdiction. Reporting median values will allow for comparisons across years within the agency and across agencies.	For each isolate or clinical specimen from a patient diagnosed by culture independent diagnostic test (CIDT), determine the date of specimen collection and the date of receipt at the PHL. Determine the number of calendar days between these dates, which is the isolate/CIDT-positive clinical specimen submission interval. Analyze the distribution of all known isolate/CIDT-positive clinical specimen submission intervals for the year. Report the median value for isolates/CIDT-positive clinical specimens with known isolate/CIDT-positive clinical specimen submission intervals. Determine the percentages of isolates/CIDT-positive clinical specimens with missing information for which an isolate submission interval cannot be determined. Measure and report separately for confirmed *Salmonella*, *E. coli* (STEC), and *Listeria* cases.	% of isolates/CIDT-positive clinical specimens with missing information: A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Median interval for isolates/CIDT-positive clinical specimens with known isolates/CIDT-positive clinical specimen submission intervals: A. *Salmonella* B. *E. coli* (STEC) C. *Listeria*

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
8. Isolate subtyping interval: Metric: Median number days from receipt of isolate to availability of PFGE subtyping results. Definitions: Isolate: Primary isolates of *Salmonella*, Shiga toxin-producing E. coli (STEC), or *Listeria*, limited to first or representative isolate or sample for each case. Isolate subtyping interval: The number of days from receipt of the isolate at the PFGE laboratory to availability of PFGE subtyping results. Feasibility: This metric is associated with CIFOR Indicator 8.2.3 "Isolates of specified foodborne pathogens submitted to PHL." It is consistent with FoodCORE common metrics for *Salmonella* and STEC. Median values likely reflect consistent general practices within the jurisdiction. Reporting median values will allow for comparisons across years within the agency and across agencies.	For each isolate, determine the date of receipt at the PFGE laboratory and the date of upload to PulseNet. Determine the number of calendar days between these dates, which is the isolate subtyping interval. Analyze the distribution of all known isolate subtyping intervals for the year. Determine the percentages of isolates with missing information for which an isolate subtyping interval cannot be determined. Report the median value for isolates with known isolate subtyping intervals. Measure and report separately for confirmed *Salmonella*, *E. coli* (STEC), and *Listeria* cases.	% of isolates with missing information: A. *Salmonella* B. *E. coli* (STEC) C. *Listeria* Median interval for isolates with known isolate subtyping intervals: A. *Salmonella* B. *E. coli* (STEC) C. *Listeria*

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
9. PHEP *E. coli* O157 and *Listeria* subtyping interval: Metric: PHEP *E. coli* O157 and *Listeria* subtyping interval: % of PFGE subtyping data results for *E. coli* O157:H7 and *Listeria* submitted to the PulseNet national database within four working days of isolate receipt at the PFGE laboratory. Definitions: PHEP: Public Health Emergency Preparedness Cooperative Agreement. PHEP specifies performance measures regarding public health surveillance and investigation of specified agents. Feasibility: This metric is associated with CIFOR Indicator 8.2.3 "Isolates of specified foodborne pathogens submitted to PHL," but entirely incorporates existing PHEP performance measures for PFGE subtyping of *E. coli* O157:H7 (PHEP 12.14) and *L. monocytogenes* (PHEP 12.15).	Determine the number of isolates submitted to the public health laboratory. Determine the number of isolates for which PFGE subtyping was performed. This will be the denominator for the metric. Determine the number of number of primary patterns from subtyped isolates uploaded to PulseNet. Determine the number of results from PFGE subtyped isolates that were submitted to PulseNet within four working days of receipt at the PFGE laboratory. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. isolates subtyped by PFGE) = _____ Numerator (No. isolates subtyped within 4 days) = _____ Rate (Num./Denom. x 100) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
10. Outbreak clinical specimen collections: Metric: Outbreak clinical specimen collections: Number and % of outbreak investigations with clinical specimens collected and submitted to PHL from two or more people. Definitions: Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. Feasibility: This metric is associated with CIFOR Indicator 8.2.4 "Foodborne outbreaks investigated." It extends FoodCORE metrics to investigations for all pathogens.	Determine the number of foodborne illness outbreaks that were investigated. This will be the denominator for the metric. Determine the number of outbreaks for which clinical specimens were collected and submitted to the PHL from two or more people. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. outbreaks) = _____ Numerator (No. outbreaks with clinical specimens collected) = _____ Rate (Num./Denom. x 100) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
11. Cluster investigation interval: Metric: Median number days from initiation of investigation to identification of source. Definitions: Cluster: Two or more isolates with a matching molecular subtype pattern identified in a period of two weeks. Cluster investigation interval: The number of days from the initiation of an investigation to the identification of source, for clusters with a source identified. Initiation of an investigation: Steps taken to investigate the possible source of a cluster of cases after it is determined that they may represent a common source outbreak. This goes beyond routine follow-up of individual cases. Feasibility: This metric is associated with CIFOR Indicator 8.2.5 "Case clusters investigated." It aggregates FoodCORE metrics for investigations across all pathogens.	Determine the number of clusters that were detected by the public health laboratory. Determine the number and % of clusters where a source was identified. For each cluster for which a source was identified, determine the date at which the investigation was initiated and the date at which the source was identified. Determine the number of calendar days between these dates, which is the cluster investigation interval. Analyze the distribution of all known cluster investigation intervals for the year. Report the median value for investigations with known cluster investigation intervals.	Percentage of clusters with source identified: _____ Median interval for cluster with known investigation intervals: _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
12. Complaint investigation interval: Metric: Median number days from initiation of investigation to implementation of intervention. Definitions: Foodborne illness complaint: A report of illness experienced by one or more persons following exposure to a specific event or establishment. Complaint investigation interval: The number of days from the initiation of an investigation to the initial intervention. Initiation of an investigation: Steps taken to investigate the possible source of a complaint after it is determined that it may represent a common source outbreak. This goes beyond routine follow-up of individual complaints. Intervention: A public health action taken to control an identified hazard. Feasibility: This metric is associated with CIFOR Indicator 8.2.1 "Foodborne complaints investigated." It aggregates FoodCORE metrics for investigations across all pathogens.	Determine the number of foodborne illness complaints that were investigated. Determine the number and percentage of foodborne complaint investigations that led to an intervention. For each complaint investigation that led to an intervention, determine the date at which the investigation was initiated and the date at which an intervention was initiated. Determine the number of calendar days between these dates, which is the complaint investigation interval. Analyze the distribution of all complaint investigation intervals for the year. Report the median value for complaint investigation intervals.	% of complaint investigations with interventions: _____ Median interval for complaints with known isolate investigation intervals: _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
13. Cluster source identification: Metric: Number and % of clusters with more than five cases in which a source was identified. Definitions: Cluster: Two or more isolates with a matching molecular subtype pattern identified in a period of two weeks. Cluster source identification: The number of identified clusters for which a specific food transmission setting, meal, food item or ingredient was identified, leading the cluster to be considered an outbreak. Feasibility: This metric is associated with CIFOR Indicator 8.2.5 "Case clusters investigated."	Determine the number of clusters that include five or more cases. This will be the denominator for the metric. Determine the number of clusters for which a source was identified that include five or more cases. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. clusters with ≥ 5 cases) = _____ Numerator (No. clusters with ≥ 5 cases with source identified) = _____ Rate (Num./Denom. x 100) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
14. Outbreak etiology reported to NORS: Metric: Number and % of outbreaks for which etiology was identified and reported to NORS. Definitions: Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. NORS form: National Outbreak Reporting System, Foodborne Disease Outbreaks and Enteric Disease Outbreaks Transmitted by Contact with Persons, Animals, or Environmental Sources, or by an Unknown Mode; NORS Form (CDC 52.13 Form). Etiology identified: For most etiologic agents CDC considers an outbreak to have a confirmed etiology if there are two or more lab-confirmed cases (*MMWR* 2000, Vol. 49/ SS-1, App. B). Etiology may be suspected based on characteristic combinations of clinical symptoms, incubation periods, and duration of illness. Feasibility: This metric is associated with CIFOR Indicator 8.3.1 "Etiology of outbreak identified." This metric will require improved investigation and documentation by many agencies.	Determine the number of foodborne outbreaks that were investigated. This will be the denominator for the metric. Determine the number of outbreaks for which an etiology was identified and reported to NORS. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. outbreaks) = _____ Numerator (No. with etiology reported to NORS) = _____ Rate (Num./Denom. x 100) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
15. Outbreak vehicle reported to NORS: Metric: Number and % of outbreaks for which a vehicle was identified and reported to NORS. Definitions: Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. NORS form: National Outbreak Reporting System, Foodborne Disease Outbreaks and Enteric Disease Outbreaks Transmitted by Contact with Persons, Animals, or Environmental Sources, or by an Unknown Mode; NORS Form (CDC 52.13 Form). Vehicle identified: A specific food item or ingredient was confirmed or suspected to be the source of the outbreak based on one of the following: (1) Statistical evidence from epidemiological investigation, (2) Laboratory evidence (e.g., identification of agent in food), (3) Compelling supportive information, (4) Other data (e.g., same phage type found on farm that supplied eggs), (5) Specific evidence lacking but prior experience makes it a likely source. Feasibility: This metric is associated with CIFOR Indicator 8.3.2 "Vehicle of outbreak identified." This metric will require improved investigation and documentation by many agencies.	Determine the number of foodborne outbreaks that were investigated. This will be the denominator for the metric. Determine the number of outbreaks for which a vehicle was identified and reported to NORS. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. outbreaks) = _____ Numerator (No. with vehicle reported to NORS) = _____ Rate (Num./Denom. x 100) = _____

8.2. Performance Indicators

Table 8.5. CIFOR performance measures chosen for target range development
Continued

CIFOR PERFORMANCE MEASURE	MEASUREMENT METHODS	PERFORMANCE
16. Outbreak contributing factor reported to NORS: Metric: Number and % of outbreaks for which contributing factors were identified and reported to NORS. Definitions: Foodborne illness outbreak: The occurrence of two or more similar illnesses resulting from ingestion of a common food. NORS form: National Outbreak Reporting System, Foodborne Disease Outbreaks and Enteric Disease Outbreaks Transmitted by Contact with Persons, Animals, or Environmental Sources, or by an Unknown Mode; NORS Form (CDC 52.13 Form). Contributing factor identified: Contributing factors (CFs) are defined as the food safety practices and behaviors which most likely contributed to a foodborne illness outbreak. A CF should be identified only if the investigator has strong evidence that it actually occurred in the investigated outbreak; just because a factor has been cited in similar outbreaks in the past does not mean it was involved in the investigated outbreak. Feasibility: This metric is associated with CIFOR Indicator 8.3.3 "Contributing factor identified." This metric will require improved investigation and documentation by many agencies.	Determine the number of foodborne outbreaks that were investigated. This will be the denominator for the metric. Determine the number of outbreaks for which a contributing factor was identified and reported to NORS. This will be the numerator for the metric. Divide the numerator by the denominator and multiply by 100.	Denominator (No. outbreaks) = _____ Numerator (No. with contributing factors reported to NORS) = _____ Rate (Num./Denom. x 100) = _____

CHAPTER

9

Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

9.0.1. Public Health Legal Preparedness

Legal preparedness is an indispensable part of comprehensive preparedness for public health threats. The Centers for Disease Control and Prevention (CDC) defines public health legal preparedness as attainment by a public health agency or system of specified legal benchmarks or standards of preparedness for specified public health concerns. Public health legal preparedness has four core elements: a) laws and legal authorities, b) competency in understanding and using law, c) coordination across sectors and jurisdictions in the implementation of law, and d) information about best practices in using law for public health purposes.

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9.0.2. Ensuring Legal Preparedness for Foodborne Disease Outbreaks

State and local public health officials should ensure their agencies and jurisdictions are legally prepared for surveillance and control of foodborne disease outbreaks. This means:

- They should have the laws and legal authorities needed to conduct all functions essential to effective surveillance and control (e.g., surveillance, reporting, enforcement, prevention, mitigation, investigation, and regulation).
- Their professional staff should be trained and demonstrate competence in applying those laws.
- They should have mutual aid agreements or memoranda of agreement in place to facilitate investigation and response across jurisdictions and jointly by public health and other agencies.
- They should have access to information about and apply best practices in using their relevant legal authorities.

The adequacy of state and local legal preparedness for foodborne disease outbreaks should be evaluated regularly through exercises and after-action reports after responses to actual outbreaks.

As part of ensuring their jurisdictions' legal preparedness, state and local health officials should consult with their legal counsel and with counterparts in other government agencies and private organizations that have legal authorities or legal duties relevant to successful surveillance and control of foodborne disease outbreaks. These include such public entities as food-regulatory and law enforcement agencies, legal counsel to municipal and state governments, and local and state courts and court administrators. Relevant private entities include private laboratories, food wholesalers, grocery retailers, and restaurants and other food vendors. Food-industry entities should be prepared to address both the regulatory requirements and the way their internal policies on sharing information might be affected by them[1]. Where possible, these entities should be included in foodborne disease exercises to test their understanding of their legal authorities and duties related to outbreaks.

9.0.3. The Constitutional Setting for Foodborne Disease Surveillance and Control

As government bodies, public health agencies operate in the context of the U.S. Constitution, the fundamental law of the land. Some of the principal constitutional features relevant to public health agencies are the three-branch system of government, federalism, and protection for civil liberties and property rights. Public health agencies belong to the executive branch and are broadly charged to implement laws enacted by the legislature and as interpreted by the courts. In the federal system, the Constitution enumerates specified powers for the federal 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. Finally, 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 disease surveillance and operations by public health agencies.

9.0.4. Legal Basis for State and Local Public Health Agencies in Surveillance and Control of Foodborne Disease

The primary role of local and state public health agencies is protection and promotion of the public's health. The legal authority supporting that role stems from statutory,

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regulatory, and case (judge-made) law, as well as from the general police powers. Important legal parameters for public health practice were articulated in the 1905 U.S. Supreme Court ruling in the case *Jacobson v. Massachusetts*:

- 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 exercised on the basis of persuasive public health and medical evidence.
- Public health agencies cannot act in an arbitrary manner nor pose unreasonable risks for harm.

In general, these parameters apply to state and local public health agencies' surveillance and control of foodborne disease 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 diseases, but in many jurisdictions, public health agencies rely on laws (state statutes and local ordinances) that authorize general infectious disease surveillance.

9.0.5. Legal Basis for CDC in Surveillance

CDC operates under congressionally enacted statutory law and, especially in the case of foodborne disease surveillance, under provisions of the Public Health Service Act (the Act). CDC is not authorized to mandate reporting of diseases and conditions either by state and local governments or by private entities.

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 (CSTE) to establish (and modify as needed) case definitions for diseases. These guidelines and case definitions, however, are not legally binding. CDC does not collect personal identifiers on routine surveillance data that it receives from public health departments.

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

By providing botulinum antiserum, CDC learns of cases of botulism and verifies that the appropriate state or local health department is aware of them.

9.1. Legal Framework for Mandatory Disease Reporting

9.1.1. Statutes and Regulations

9.1.1.1. Authorization by legislature

The legislature generally gives broad statutory authority to the state health department to collect information and require reports of conditions of public health importance, without specifying the exact diseases or infections.

In addition to broad authority, states typically have several disease-specific statutes, such as

9.1. Legal Framework for Mandatory Disease Reporting

those for human immunodeficiency virus/acquired immunodeficiency syndrome, tuberculosis, and vaccine-preventable diseases, which authorize surveillance and control activities. All states have statutes addressing response to bioterrorism incidents.

9.1.1.2. Regulatory process for maintaining and updating list of reportable diseases

Every state has an oversight body or entity authorized to promulgate reportable disease regulations (typically a board of health established by statute). The reportable disease list is revised or updated after study of, and public input on, the proposed changes.

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 oversight body. Required reporting of specific laboratory test results (rather than regulatory language of "any positive test for …") generally means the list must be regularly updated.

Reportable disease regulations are established within the context of the basic public health compact. In return for allowing the government to collect medical and personal information without consent about selected conditions, the public requires the government to maintain confidentiality of the records and to prevent or minimize public health threats.

9.1.2. Reporting Processes

9.1.2.1. Time frame and content of reports

Statutes and regulations usually specify the time frame for reporting (e.g., within 7 days of diagnosis, within 24 hours, immediately), means of reporting (e.g., electronic laboratory reporting, phone, e-mail, fax), and the information to be reported (e.g., diagnosis; personal identifying and locating information; and date of onset or diagnosis, regardless of whether the case is suspected or confirmed).

9.1.2.2. Sources of reports

Regulations specify what entities are required to report. The usual sources of mandatory reports are:

- Laboratories, including
  - Hospital-based laboratories,
  - Clinical laboratories,
  - National or regional commercial referral laboratories,
  - Local or state health department laboratories, and
  - CDC laboratories;
- Hospitals (e.g., hospitalized patients reported by infection control practitioners);
- Emergency departments;
- Office-based health-care providers;
- Long-term–care facilities or nursing homes; and
- Schools and child-care centers.

An agency also might receive reports, for example, from other state health departments.

Arrangements and ongoing communication should be established with national or regional commercial and clinical laboratories to ensure results for relevant cases are received by the investigating agencies, even when those tests are conducted out of state. The same communication channels should be established with hospitals that are out of state but that serve a population within the community affected by the outbreak.

The source of a report does not affect the legal status of the information—if it is required it is protected by statutes and regulations. Conversely, reports to the agency of illness not listed as a reportable condition might not be subject to disease surveillance regulations and confidentiality protections (see section 9.1.5. below).

9.1. Legal Framework for Mandatory Disease Reporting

9.1.2.3. Reporting methods

A state or municipality can use any of a variety of methods for reporting. Specifics vary from one locale to another. These methods include:

- Telephone;
- Hardcopy (fax or mail);
- Electronic batch reports sent by e-mail;
- Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies; and
- Automatic electronic submission through health information exchange.

9.1.2.4. Required submission of laboratory specimens

Some public health agencies have adopted regulations that require hospital and clinical laboratories to submit isolates of specific pathogens to a state or local health department laboratory for further testing. One example would be a requirement for submission of all *Escherichia coli* O157:H7 isolates for pulsed-field gel electrophoresis testing. This requirement improves surveillance for foodborne disease as common subtypes are identified. In some locales, voluntary submission of specimens to the central referral laboratory achieves the same goal.

9.1.3. Accessing Medical and Laboratory Records

Typically, 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).

9.1.4. Enforcement

Because nonreporting by health-care providers is common, redundant reporting systems have been established (e.g., *Salmonella* infection is reportable by both physicians and laboratories) to ensure a case will be reported. Nonetheless, failure to comply with reporting regulations is punishable. This is rarely enforced because penalizing a health-care provider might not result in future compliance and might reverberate throughout the clinical sector (i.e., might be counterproductive to the system).

Penalties or sanctions, however, might be imposed if lack of a report leads directly to an outbreak (for example, a food worker with hepatitis A is not reported, and immune globulin is thus not administered to restaurant customers). In most cases of nonreporting, the public health agency explains the regulatory requirement and its rationale and asks for future compliance, rather than seeking penalties or sanctions.

Reporting is difficult to enforce with a laboratory or health-care provider outside the agency's jurisdiction, such as when state X seeks reports from a referral laboratory in state Y. In this situation, lack of reporting usually results from misunderstanding of how to report.

Occasionally a laboratory will state it complies with requirements of the public health agency in which it is physically located—which might or might not require reporting of the particular disease, infection, or laboratory result.

9.1.5. Protection of Confidentiality

Personally identifying information in disease reports and investigation records is confidential and exempt from disclosure in response to freedom of information requests. If personally identifying information can be redacted and no other exemptions from disclosure apply, such records might have to be released. In redacting personally identifying information, descriptors such as age, sex, race/ethnicity, residence, and date of diagnosis can make the person identifiable. Preparing final outbreak investigation summary reports without any personally identifying information can speed

9.1. Legal Framework for Mandatory Disease Reporting

up and simplify release of those reports to attorneys or media when they are requested.

Occasionally a public health agency must respond to a media inquiry in which the media has learned the identify 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 name.

The public health agency generally is restricted from sharing personal identifying information with other government agencies without the consent of the reported person, except:

- Virtually every state has an exception for sharing information with law enforcement agencies when investigating a bioterrorism incident.
- Many state statutes contain an exception for sharing information when, in the agency's judgment, sharing is necessary to protect the public health.
- State and local public health agencies often expect that when they provide epidemiologic and laboratory data to federal agencies, such as the Food and Drug Administration FDA) or the U.S. Department of Agriculture (USDA), they will receive from those agencies results of related product investigations. However, this might not happen if the results of the investigations contain trade secrets or commercial confidential information or are part of an ongoing legal enforcement action or criminal prosecution.

Reporting statutes typically provide for punishment of government employees for a breach of confidential information held by the public health agency.

Health information protected by the Health Insurance Portability and Accountability Act of 1996 might be disclosed by the reporting source without individual authorization to a public health agency authorized by law to collect or receive such information, including a contractor (e.g., academic institutions) to which a government agency has granted authority. This disclosure without individual authorization does not include disclosure of protected health information for research purposes.

The legal requirement to report relieves the reporting source (e.g., physician) of concern that reporting breaches the privacy of the doctor–patient relationship. Explaining this to physicians often results in better compliance with reporting requirements.

9.1.6. Cross-Jurisdiction and Cross-Sector Coordination

Effective reporting of foodborne disease cases hinges on coordination of reporting across jurisdictions (e.g., local, state, tribal, and federal governments) and across sectors (e.g., health care and public health). State and local 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.[2]

9.2. Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

9.2.1. Sources of Surveillance Information

Reports of food-related illness may come to the attention of the state or local health agency in a variety of ways, such as:

A. Surveillance reports for enteric diseases, such as *Salmonella*, *Shigella*, and *Campylobacter*;

B. Request for antitoxin for botulism;

9.2. Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

C. Reports of food poisoning or gastrointestinal illness in individuals or defined groups, such as diarrhea and vomiting among residents of a nursing home or school or among attendees at a work-related meeting;

D. Reports to poison control centers;

E. Reports of enteric disease suspected of being caused intentionally;

F. Complaints of alleged contaminated, adulterated, or improperly cooked food purchased from stores or in restaurants and reported voluntarily by the general public;

G. Syndromic surveillance using deidentified emergency department or pharmacy data; and

H. Reports directly from the food industry of consumer complaints of illness or injury.

9.2.2. Statutes and Regulations Governing Surveillance and Investigation

Confirmed or probable cases identified from items 9.2.1 a–e above are subject to the reporting statute(s) and regulations of the health agency. Items 9.2.1 f and g generally do not have as strong a level of legal protection as do named case reports because they are either voluntary, unconfirmed disease reports (item f) or diagnoses for which names are not collected cannot be confirmed (item g).

Routine investigation of enteric diseases to confirm the diagnosis and determine the source of exposure, risk factors for infection, and contacts of a contagious patient is usually considered part of surveillance and disease control activities authorized by state and local statutes.

CDC may participate in an investigation of an outbreak of enteric disease within a state if invited by the state. States usually expect CDC to help coordinate large multistate outbreaks of enteric disease.

Methods for detecting a foodborne disease outbreak resulting from an unannounced intentional act of contamination are the same as those for detecting a "regular" (i.e., unintentional contamination) foodborne disease outbreak. The legal authorities to conduct outbreak detection activities are the same—at least initially—regardless of the intentionality of the contamination (e.g., disease surveillance and reporting requirements). However, once intentional contamination is suspected, additional state criminal, antiterrorism, and emergency response laws most likely will enhance or control the course of the outbreak investigation and response (see section 9.4).

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

9.3.1. General

Because of a) improvements in laboratory and communication technologies that can be used to link cases previously termed "sporadic" and b) globalization of food-production industries, more multistate and international foodborne disease outbreaks are being discovered, thus changing the locus of outbreak investigations and control measures.

9.3.2. Federal Roles and Authorizations

The changes noted above have resulted in an increasingly direct, leading role in the control of foodborne diseases by several federal agencies: U.S. Department of

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

Health and Human Services (CDC and FDA), U.S. Department of Agriculture (Food Safety Inspection Service and Animal and Plant Health Inspection Service), U.S. Environmental Protection Agency; and when bioterrorism is suspected, U.S. Department of Justice and U.S. Department of Homeland Security.[3] These agencies undertake regulatory and nonregulatory actions over food safety at various stages along the farm-to-table continuum related to:

- Safety of food, feed, and animals on the farm;
- Plant and animal health on the farm, including animal vaccines;
- Pesticide use on the farm;
- Food processing;
- Slaughter and processing of meat and poultry products and egg products;
- Labeling, transportation, storage, and retail sale of food; and
- Cruise ships, trains, buses, airplanes (i.e., all interstate transportation) and the servicing areas for these transportation vehicles (21 CFR 1240 and 1250).

These agencies also coordinate and collaborate in multistate investigations.

The following sections briefly review the authorizations that are particularly pertinent to foodborne disease outbreak investigations and control.

9.3.2.1. Federal Food, Drug, and Cosmetic Act

The primary legislation by which FDA exercises authority over food is the Federal Food, Drug, and Cosmetic Act (FFDCA). A goal of FDA is to prevent contamination of food product before distribution, but the legislation allows it 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 (i.e., continued distribution of adulterated food);
- Seizure action to remove specific lots of adulterated food;
- Mandatory recall of violative 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 (the FDA has had this authority since the Bioterrorism Act of 2002; administrative detention does not require a court order); and
- Suspension of the registration of a facility so that food from the facility cannot be introduced into commerce.

FDA's authority under the FFDCA is limited by the requirement for interstate commerce in some circumstances. However, under the Public Health Service Act, FDA can regulate intrastate commerce in some additional circumstances. State agencies might in some instances be swifter than FDA because they might require less evidence of problems before taking action than the requirements imposed on FDA by its legislation.

Amendments to the FFDCA in 2007 require FDA to establish a registry for reporting by individuals, companies, and local and state agencies of food that can cause serious adverse health consequences or death to humans or animals.

9.3.2.2. 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

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

government's ability to prevent and respond to contamination in the food supply. The law addresses prevention, inspection, compliance, and response activities. It also adds authorities to ensure that imported products are as safe as domestically produced food. FSMA also requires FDA to build an integrated national food-safety system in partnership with state and local agencies.

- Prevention. FSMA directs FDA to create minimum standards for safely producing and harvesting fruits and vegetables. FSMA requires food facilities to implement preventive and control plans that, for example, identify possible hazards, prevention measures to control hazards, and actions to be taken when hazards arise. The law also requires FDA to establish regulations to protect against intentional contamination of food.
- Inspection and Compliance. FSMA mandates inspection frequency of food facilities on the basis of risk and requires that the frequency of inspection increases as risk increases. The law gives FDA clear authority to access records, such as food-safety plans. FSMA further requires that FDA create an accreditation program for food-testing laboratories and that certain foods be tested in accredited laboratories.
- Response. FSMA gives FDA a number of new authorities to respond to food-safety events, including mandatory recall authority and suspending food-facility registration. The law also expands FDA's authority to administratively detain products, track and trace domestic and imported foods, and require additional recordkeeping for high-risk foods. FSMA directs CDC to improve surveillance for foodborne disease and to establish Integrated Food Safety Centers of Excellence in five state health departments and their partnering academic institutions.
- Partnership with Government Agencies. FSMA creates a system of collaboration among domestic and foreign government agencies. The law directs FDA to create and implement strategies to enhance the food safety capacity of state and local governments, including a new multiyear grant program. FSMA allows FDA to rely on other federal, state, and local agencies in conducting inspections required by the law.

The FDA website (www.fda.gov) provides details about the law and updates on the status of FSMA implementation.

9.3.2.3. Acts Authorizing USDA-FSIS

FSIS operates under the authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Following the provisions of these Acts, FSIS sets standards for food safety and inspects and regulates all raw and processed meat and poultry products, and egg products sold in interstate commerce, including imported products.

- FMIA. Prohibits the sale of adulterated or misbranded meat and meat products for food and ensures that animals used for meat and meat products are slaughtered and processed under sanitary conditions.
- PPIA. Ensures the inspection of domestic and imported poultry products and requires that plant facilities are sanitary and that product labels are accurate.
- EPIA. Mandates continuous inspection of the processing of liquid, frozen, and dried egg product.

9.3.3. Roles and Legal Authority of State and Local Public Health Agencies

Environmental health specialists, laboratorians, and epidemiologists should understand their respective roles and legal authorities for

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

various public health actions. In addition, they should know how and when they need to obtain expert legal counsel and upper-level management support and decision-making.

In instances in which improper food preparation at the local level results in foodborne disease, the broad authority of public health agencies to control epidemics and end nuisances, as well as specific authority they have to inspect restaurants and ensure proper food safety, is used to:

- Close restaurants;
- Embargo, seize, or destroy contaminated food or require removal of contaminated lots from retail stores;
- Require changes in food preparation; and
- Temporarily remove infectious persons from the workplace.

These actions are taken through agency authority granted by rule or through administrative orders. Such orders should contain time limits and specify the conditions for removing them. If necessary, agencies can seek enforcement through court orders.

9.4. Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution

9.4.1. Role of Data in Regulatory Action

Epidemiologic and laboratory data can provide strong evidence linking illness to consumption of a particular food, resulting in a traceback investigation. When involving multiple states, federal regulatory agencies typically lead the traceback investigation.

Because of the need to link epidemiologic data with product information to take actions that protect the public health, the roles of state and local public health agencies and CDC must be coordinated with the roles of federal regulatory agencies.

9.4.2. Joint Investigation and Collection of Evidence in Criminal Prosecutions

Some investigations are initiated by public health officials but widen to other interests and agencies when a public health event results from a potential criminal act. Joint investigation by regulatory and nonregulatory public health and law enforcement agencies may be hindered by the different legal powers and investigatory practices each agency brings to such an event. For example, officials from regulatory and nonregulatory 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. Regulatory and nonregulatory public health 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 by regulatory and nonregulatory public health and law enforcement agencies.

Laboratory specimens must be collected and submitted using procedures that ensure the chain-of-custody of the specimen, defined by one author as follows: "Everyone handling the sample [or specimen] must be able to demonstrate it is, and has been, identified as coming from the person [or item] in question to be admissible and probative in court."[4]

State and local health officials, in collaboration with counterparts in law enforcement agencies, should periodically assess the need for

9.4. Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution

memoranda of understanding to clarify the roles of public health and law enforcement agencies in conducting joint investigations. State and local health and law enforcement officials who have roles in investigating foodborne disease outbreaks should understand, and demonstrate competence in applying, their legal authorities in conducting joint investigations. Valuable resources for improving competency in joint investigations include CDC training curricula[5] and sample memoranda of understanding.[6]

9.5. CIFOR Legal Preparedness Resources

CIFOR has created several resource documents to further assist state and local public health agencies in improving their legal preparedness to conduct surveillance for foodborne diseases and respond to outbreaks within their jurisdictions and across multiple states and other jurisdictional boundaries. The CIFOR law project has the following three components, each designed to address a discrete, but related, research need and audience.

- Analysis of State Legal Authorities for Foodborne Disease Detection and Outbreak Response. This document describes and analyzes the types of state legal authorities currently available to conduct foodborne disease 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 disease surveillance and outbreak response activities.
- Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response. This document is intended as a practical guide for public health professionals who perform key roles in foodborne disease 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 disease surveillance and outbreak response actions. The menu includes legal provisions relevant to activities conducted during foodborne disease surveillance and outbreak response—outbreak detection, outbreak investigation, outbreak control, and outbreak documentation. This is intended to be a resource for states to use in filling gaps and clarifying or enhancing their legal authorities.

All of the documents are available through the CIFOR website at www.cifor.us.

9.6. References

1 Council to Improve Foodborne Outbreak Response (CIFOR). CIFOR Industry Guidelines: Foodborne Illness Guidelines for Owners, Operators, and Managers of Food Establishments. Washington, D.C.: National Association of County and City Officials, 2013.

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5 CDC. Forensic Epidemiology, v. 3.0. Available at www.cdc.gov/phlp/publications/forensicepidemiology/index.html (accessed April 8, 2014).

6 CDC. Model Memorandum of Understanding for Joint Public Health–Law Enforcement Investigations. Available at www.cdc.gov/phlp/publications/type/mmou.html (accessed April 8, 2014).

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GLOSSARY

Note: The definitions given are valid as they are used in this publication, but different definitions may be used in other contexts.

Active surveillance:
Contacting possible sources of disease reports to solicit and collect reports or specimens, rather than waiting until they are submitted to the mandated government agency. Possible sources of disease reports or specimens include laboratories, hospitals, and physicians.

Adulterated:
A legal term meaning a food product fails to meet federal or state standards. Adulteration usually refers to noncompliance with health or safety standards as determined in the United States by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

Analytic study:
In epidemiology, a study designed to examine associations, commonly putative or hypothesized causal relationships; usually concerned with identifying or measuring the effects of risk factors or with the health effects of specific exposures.

Bare-handed contact:
Contact between bare skin and food items during preparation or serving (covered under section 3-301.11 of the FDA Food Code).

Case:
In epidemiology, a countable instance in the population or study group of a particular disease, health disorder, or condition under investigation

Case–control study:
A type of observational analytic study. Enrollment into the study is based on presence ("case") or absence ("control") of disease. Characteristics such, as previous exposure, are then compared between cases and controls.

Case definition:
Standardized criteria for deciding whether a person has a particular disease or health-related condition by specifying clinical criteria and limitations on time, place, and person.

Chain-of-custody:
Standards and procedures for which evidentiary documentation and strict record keeping are indicated or required. The chain-of-custody establishes proof that the items of evidence collected during an investigation are the same as those being presented in a court of law. The chain-of-custody requires direct interviews and collection of supporting documentation (e.g., invoices, bills of lading, import documents) during the investigation. The chain-of-custody also establishes who had contact with the evidence; the date and time the evidence was handled; the circumstances under which the evidence was handled; and what changes, if any, were made in the evidence.

Cluster:
An unusual aggregation of cases grouped in time or space. The term is commonly used in pathogen-specific surveillance, when multiple infections caused by similar microbial strains are identified by a public health laboratory. The purpose of identifying clusters is to trigger further investigations to determine whether they might represent an outbreak. The number of cases needed to form a cluster cannot be absolutely defined; cluster definition can vary by type of agent, novelty of the subtype, season, and resources available for further investigation.

Cohort:
A well-defined group of people who have had a common experience or exposure and who are then followed up for the incidence of new diseases or events, as in a cohort or prospective study. A group of people born during a particular period or year is called a birth cohort.

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Cohort study:
A type of observational analytic study. Enrollment into the study is based on exposure characteristics or membership in a group. Disease, death, or other health-related outcomes are then ascertained and compared.

Contributing factors:
The food-safety practices and behaviors that most likely contributed to a foodborne illness outbreak.

Control:
In a case–control study, comparison group of persons without disease.

Denaturing:
Applying substance, such as household bleach or carbolic acid, to all portions of food products to prevent their use for food purposes.

eFORS:
Electronic Foodborne Outbreak Reporting System. A secure Web-based reporting system that enables state health departments to report foodborne disease outbreaks electronically to the Centers for Disease Control and Prevention (CDC). eFORS is being subsumed into the National Outbreak Reporting System (NORS), which will include outbreaks from all transmission routes, including water, person to person, and animal contact.

Embargo:
An order issued by a permit-issuing official or his/her designated representative at a state or local agency that prevents food from being used, sold, donated, discarded, repackaged, or otherwise disposed of until the order is lifted by the permit-issuing official, his/her designated representative, or court of competent jurisdiction.

Environmental health specialist (also called sanitarian):
A person who conducts research or performs investigations to identify, diminish, and/or eliminate sources of pollutants and hazards that affect the environment or the health of the population. He or she might collect, synthesize, study, report, and take action on the basis of data derived from measurements or observations of air, food, soil, water, and other sources.

Epidemiologist:
An investigator who studies the occurrence of disease or other health-related conditions or events in defined populations. The control of disease in populations also is often considered to be a task for the epidemiologist. Epidemiologists conduct surveillance and carry out investigations using hypothesis testing and analytic research to identify the causes of disease, including the physical, biologic, social, cultural, and behavioral factors that influence health.

Epi-X:
CDC's Web-based communications solution for public health professionals. Through Epi-X, CDC officials, state and local health departments, poison control centers, and other public health professionals can access and share preliminary health surveillance information—quickly and securely. Users also can be notified about breaking health events as they occur.

Food Code:
A reference guide published by FDA. The guide instructs retail outlets, such as restaurants and grocery stores, and institutions, such as nursing homes, how to prevent foodborne illness. It consists of a model code adopted by nearly 3000 state, local, and tribal jurisdictions as the legal basis for their food-inspection programs for safeguarding public health. It ensures that food is safe and unadulterated (free from impurities) and honestly presented to the consumer. It also provides references and public health reasons and explanations for code provisions, guidelines, and sample forms. FDA first published the Food Code in 1993 and revises it every 4 years.

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Food establishment: An operation that a) stores, prepares, packages, serves, and/or vends food directly to the consumer or otherwise provides food for human consumption, such as a restaurant; satellite or catered food location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; or institution or food bank; and b) relinquishes possession of food directly, or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food-safety regulatory agency:
Government agencies at the local, state, or federal level that are granted regulatory oversight of some aspect of the food industry. The goal of food-regulatory agencies is to ensure the public food supply is safe from disease caused by infection from human handling or by contamination from chemical or other hazardous substances.

Foodborne disease:
Any disease caused by ingestion of contaminated food. Although some agents are more likely than others to be transmitted by food, identification of foodborne, waterborne, person-to-person, or animal-to-person transmission requires investigation. Furthermore, multiple modes of transmission can be involved in any one outbreak.

Foodborne disease surveillance:
Surveillance of diseases or conditions that *might* be foodborne. Thus, all diseases of enteric origin can be tracked by this mechanism, including norovirus infection (which involves substantial person-to-person transmission), listeriosis (which can have a diarrheal stage but generally is detected by blood culture), or botulism (which presents as neurologic disease).

FoodNet Atlas of Exposures:
The results of periodic population-based surveys undertaken at selected sites in the United States. The survey collects information about exposures that might be associated with foodborne illnesses and can be used to estimate the background rates of different food exposures in the community.

HACCP (Hazard Analysis and Critical Control Point):
A science-based and systematic approach to prevent potential food-safety problems by anticipating how biologic, chemical, or physical hazards are most likely and by installing appropriate measures to prevent them.

Imminent hazard:
An important threat or danger to health that exists when evidence is sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on a) the number of possible injuries and b) the nature, severity, and duration of the anticipated injury.

Impound:
To take possession of or to seize and hold in the custody of the law.

Jurisdiction:
A government entity with the legal authority to interpret and apply the law. Also refers to the limits or territory within which that authority can be exercised.

Multijurisdictional:
Requiring the resources of more than one local, state, territorial, tribal, or federal public health or food-regulatory agency to detect, investigate, or control. A multijurisdictional investigation can involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

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Outbreak:
Two or more cases of a similar illness shown by an investigation to result from a common exposure, such as ingestion of a common food. An outbreak is a cluster with a clear association between cases, with or without a recognized common source or known disease agent. Single cases of certain rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera, elicit an outbreak-like response.

Outbreak Response Protocol:
A comprehensive document outlining the roles, responsibilities, and required actions of all individuals and organizations involved in the investigation of a foodborne disease outbreak. Outbreak response protocols can be developed for a specific organization or can encompass multiple organizations and jurisdictions.

OutbreakNet:
A national collaboration of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States. The purpose of OutbreakNet is to ensure rapid, coordinated detection and response to multistate outbreaks of enteric diseases and promote comprehensive outbreak surveillance.

Public health agency:
A government agency established at the local, state, or federal level that is responsible for developing and managing public health programs, including surveillance for infectious disease and noninfectious conditions, interventions to prevent and limit the spread of disease, and promotion of healthy behaviors and environments.

PulseNet:
An international surveillance network comprising national, state, and local public health and food-regulatory agency laboratories that conduct standardized molecular subtyping of foodborne disease pathogens (i.e., DNA fingerprinting) and maintain centrally accessible databases of patterns. PulseNet also functions as a communication hub for laboratories involved in food and foodborne disease monitoring.

Recall:
A voluntary action of removing a product from retail or distribution. The action is conducted by a manufacturer or distributor to protect the public from products that might cause health problems or possible death.

Reportable conditions (notifiable diseases):
The list of diseases based on state laws or regulations that should be reported by health-care providers (e.g., physicians and their medical staff, laboratories, and hospitals) to local or state health agencies. The list of notifiable diseases and legal obligation for reporting differ from state to state. States can report notifiable diseases to CDC, which maintains a list of nationally notifiable diseases, but compliance is voluntary. CDC reports selected diseases to the World Health Organization in compliance with the International Health Regulations.

Sporadic case:
A case not linked epidemiologically to other cases of the same illness. Single sporadic cases of extremely rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera, merit a detailed investigation as soon as possible, as though they were outbreaks, to prevent any further cases.

Surveillance:
The systematic collection, analysis, interpretation, and dissemination of data for public health action.

Traceback:
The process by which the origin or source of a cluster of contaminated food is identified.

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Traceforward:
The tracking of a recalled product from the origin or source through the distribution system.

Trawling, trolling, shotgun, or hypothesis-generating questionnaire:
A variety of interview forms designed to capture a wide range of exposures. These forms can be designed with embedded questions focused on disease-specific hypotheses (e.g., exposures previously associated with the pathogen or plausibly associated with the pathogen), as well as other food items and exposures that have not been associated with the pathogen, which can consolidate the hypothesis-generation and testing processes into a single step. For instance, the trawling questionnaire for an outbreak of *Escherichia coli* O157:H7 infection might contain standardized questions about known transmission mechanisms for this agent, such as hamburger consumption, child-care attendance, recreational pool use, animal exposures, and other exposures identified in previous outbreaks, which function as a priori hypotheses.

USDA-FSIS Consumer Complaint Monitoring System (CCMS):
An electronic database for capturing consumer complaints. Since 2001, USDA-FSIS has used this database to record, triage, and track complaints about FSIS-regulated meat, poultry, and egg products. CCMS helps to identify and trace adulterated product in commerce and enables the agency to respond and mitigate possible food-safety hazards.

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
Upper gastrointestinal tract symptoms (nausea, vomiting) occur first or predominate		
<1 hrs	Nausea, vomiting, unusual taste, burning of mouth	Metallic salts
1–2 hrs	Nausea, vomiting, cyanosis, headache, dizziness, dyspnea, trembling, weakness, loss of consciousness	Nitrites
1–6 hrs (mean 2–4 hrs)	Nausea, vomiting, retching, diarrhea, abdominal pain, prostration	*Staphylococcus aureus* and its *enterotoxins*
8–16 hrs (2–4 hrs emesis possible)	Vomiting, abdominal cramps, diarrhea, nausea	*Bacillus cereus*
6–24 hrs	Nausea, vomiting, diarrhea, thirst, dilation of pupils, collapse, coma	Amanita species mushrooms
Sore throat and respiratory symptoms occur		
12–72 hrs	Sore throat, fever, nausea, vomiting, rhinorrhea, sometimes a rash	*Streptococcus pyogenes*
2–5 days	Inflamed throat and nose, spreading grayish exudate, fever, chills, sore throat, malaise, difficulty swallowing, edema of cervical lymph node	*Corynebacterium diphtheriae*
Lower gastrointestinal tract symptoms (abdominal cramps, diarrhea) occur first or predominate		
2–36 hrs (mean 6–12 hrs)	Abdominal cramps, diarrhea, putrefactive diarrhea associated with *Clostridium perfringens*, sometimes nausea and vomiting	*Clostridium perfringens, Bacillus cereus, Streptococcus faecalis, Staphylococcus faecium*
12–74 hrs (mean 18–36 hrs)	Abdominal cramps, diarrhea, vomiting, fever, chills, malaise, nausea, headache possible. Sometimes bloody or mucoid diarrhea, cutaneous lesions associated with Vibrio vulnificus. *Yersinia enterocolitica* infection mimics flu and acute appendicitis	*Salmonella species* (including *S. arizonae), Shigella,* enteropathogenic *Escherichia coli,* other *Enterobacteriacae, Vibrio parahaemolyticus, Yersinia enterocolitica, Aeromonas hydrophila, Plesiomonas shigelloides, Campylobacter jejuni, Vibrio cholerae* (O1 and non-O1) *Vibrio vulnificus, Vibrio fluvialis*
3–5 days	Diarrhea, fever, vomiting abdominal pain, respiratory symptoms	Enteric viruses

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
1–6 wks	Mucoid diarrhea (fatty stools) abdominal pain, weight loss	*Giardia lamblia*
1 to several weeks	Abdominal pain, diarrhea, constipation, headache, drowsiness, ulcers, variable—often asymptomatic	*Entamoeba histolytica*
3–6 mos	Nervousness, insomnia, hunger pains, anorexia, weight loss, abdominal pain, sometimes gastroenteritis	*Taenia saginata, T. solium*
Neurologic symptoms (visual disturbances, vertigo, tingling, paralysis) occur		
<1 hr	*** See Gastrointestinal and/or neurologic symptoms (shellfish toxins) below	Shellfish toxin
	Gastroenteritis, nervousness, blurred vision, chest pain, cyanosis, twitching, convulsions	Organic phosphate
	Excessive salivation, perspiration, gastroenteritis, irregular pulse, pupils constricted, asthmatic breathing	Muscaria-type mushrooms
	Tingling and numbness, dizziness, pallor, gastrohemmorrhage, and desquamation of skin, fixed eyes, loss of reflexes, twitching, paralysis	Tetradon (tetrodotoxin) toxins
1–6 hrs	Tingling and numbness, gastroenteritis, dizziness, dry mouth, muscular aches, dilated pupils, blurred vision, paralysis	Ciguatera toxin
	Nausea, vomiting, tingling, dizziness, weakness, anorexia, weight loss, confusion	Chlorinated hydrocarbons
2 hrs–6 days, usually 12–36 hrs	Vertigo; double or blurred vision; loss of reflex to light; difficulty swallowing. speaking, and breathing; dry mouth; weakness; respiratory paralysis	*Clostridium botulinum* and its neurotoxins
>72 hrs	Numbness, weakness of legs, spastic paralysis, impairment of vision, blindness, coma	Organic mercury
	Gastroenteritis, leg pain, ungainly high-stepping gait, foot and wrist drop	Triorthocresyl phosphate

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
Allergic symptoms (facial flushing, itching) occur		
<1 hr	Headache, dizziness, nausea, vomiting, peppery taste, burning of throat, facial swelling and flushing, stomach pain, itching of skin.	Histamine (scombroid)
	Numbness around mouth, tingling sensation, flushing, dizziness, headache, nausea	Monosodium glutamate
	Flushing, sensation of warmth, itching, abdominal pain, puffing of face and knees	Nicotinic acid
Generalized infection symptoms (fever, chills, malaise, prostration, aches, swollen lymph nodes) occur		
4–28 days (mean 9 days)	Gastroenteritis, fever, edema about eyes, perspiration, muscle pain, chills, prostration, labored breathing	*Trichinella spiralis*
7–28 days (mean 14 days)	Malaise, headache, fever, cough, nausea, vomiting, constipation, abdominal pain, chills, rose spots, bloody stools	*Salmonella typhi*
10–13 days	Fever, headache, myalgia, rash.	*Toxoplasma gondii*
10–50 days, mean 25–30 days	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice	Etiologic agent not yet isolated—probably viral
Varying periods, depending on specific illness	Fever, chills, headache or joint ache, prostration, malaise, swollen lymph nodes, other specific symptoms of disease in question	*Bacillus anthracis, Brucella melitensis, B. abortus, B. suis, Coxiella burnetii, Francisella tularensis, Listeria monocytogenes, Mycobacterium tuberculosis, Mycobacterium* species, *Pasteurella multocida, Streptobacillus moniliformis, Campylobacter jejuni, Leptospira* species.
Gastrointestinal and/or neurologic symptoms (shellfish toxins)		
0.5–2 hrs	Tingling, burning, numbness, drowsiness, incoherent speech, respiratory paralysis	Paralytic shellfish poisoning (saxitoxins)

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
2–5 mins to 3–4 hrs	Reversal of hot and cold sensation, tingling; numbness of lips, tongue and throat; muscle aches, dizziness, diarrhea, vomiting	Neurotoxic shellfish poisoning (brevetoxins)
30 mins to 2–3 hrs	Nausea, vomiting, diarrhea, abdominal pain, chills, fever	Diarrheic shellfish poisoning (dinophysis toxin, okadaic acid, pectenotoxin, yessotoxin)
24 hrs (gastrointestinal) to 48 hrs (neurologic)	Vomiting, diarrhea, abdominal pain, confusion, memory loss, disorientation, seizure, coma	Amnesic shellfish poisoning (domoic acid)

*From FDA. Bad bug book: foodborne pathogenic microorganisms and natural toxins handbook. Available at www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ (accessed October 11, 2013).

Appendix 3

List of Key Websites and Resources Cited

Applied Epidemiology Competencies:
www.cste.org/group/CSTECDCAEC

CDC's Diseases and Conditions A–Z index:
www.cdc.gov/diseasesConditions

CIFOR Clearinghouse:
www.cifor.us/clearinghouse/keywordsearch.cfm

Control of Communicable Diseases Manual (latest edition),
American Public Health Association Press

Environmental Assessment Forms and Consumer Complaint Forms:
www.cdc.gov/nceh/ehs/EHSNet/

FDA Food Code:
www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm

FoodNet Atlas of Exposures:
www.cdc.gov/foodnet/studies/population-surveys.html

Forensic Epidemiology, v. 3.0: training curriculum, www.cdc.gov/phlp/publications/forensicepidemiology/index.html

Model Memorandum of Understanding for Joint Public Health-Law Enforcement Investigations: www.cdc.gov/phlp/publications/type/mmou.html

National Botulism Surveillance Program:
www.cdc.gov/nationalsurveillance/botulism_surveillance.html

Procedures to Investigate Foodborne Illness (latest edition),
International Association for Food Protection

Standardized Outbreak Questionnaires:
www.cdc.gov/foodsafety/outbreaks/surveillance-reporting/investigation-toolkit.html

State-Specific Notifiable Condition Reporting Requirements:
www.cste2.org/izenda/entrypage.aspx

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