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).

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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

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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).

Overview of Chapter 3. Planning and Preparation

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.

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

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

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

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).

Overview of Chapter 5. Investigation of Clusters and Outbreaks

- 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.

Overview of Chapter 5. Investigation of Clusters and Outbreaks

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.

Overview of Chapter 6. Control Measures

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.

Overview of Chapter 6. Control Measures

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

Overview of Chapter 6. Control Measures

- 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.

Overview of Chapter 6. Control Measures

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

Overview of Chapter 6. Control Measures

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

Overview of Chapter 6. Control Measures

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.