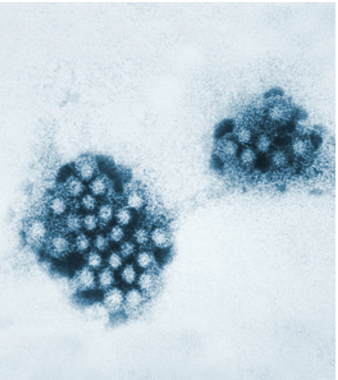
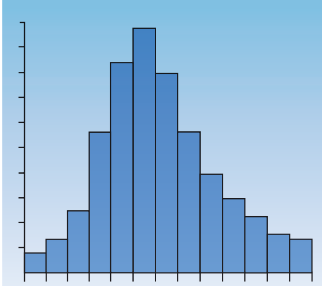
GUIDELINES FOR FOODBORNE DISEASE OUTBREAK RESPONSE





CIFOR
Council to Improve Foodborne Outbreak Response

Detect • Investigate • Control • Prevent

Foreword

We are pleased and honored to join in congratulating the Council to Improve Foodborne Outbreak Response (CIFOR) on the landmark publication of its *Guidelines for Foodborne Disease Outbreak Response*, which address some of the most critical elements of a more effective, prevention-oriented food safety system.

The *Guidelines* is the culmination of a three-year process that brought together public health and food safety practitioners and experts from all levels of government to improve our response to foodborne outbreaks and create a common framework for evaluating foodborne disease surveillance. The CIFOR process alone provides a model for the kind of collaboration across professional, agency, and geographic boundaries that is essential to tackling a problem—in this instance, foodborne illness—that defies boundaries.

Publication of the *Guidelines* is significant also for the commitment it reflects to harmonize and integrate as fully as possible how health officials and regulators detect, investigate, and control outbreaks so that fewer people get sick. By harmonizing data collection, improving data sharing, and fostering new levels and modes of collaboration, we have the opportunity not only to contain outbreaks more promptly but also to learn more robustly the lessons they can teach for future prevention.

Like any guideline, the *Guidelines for Foodborne Disease Outbreak Response* will be, in the end, only as good as their implementation by our many colleagues in local, state, and federal agencies, for whom it provide both a flexible, forward-looking framework and a call to action. The call to action is important in the policy arena, too. Implementation of the *Guidelines* requires the commitment of policymakers and elected officials, who as surrogates for the public, rightfully demand improved foodborne disease surveillance and outbreak response and must provide the legal authorities, financial resources, and organizational capacities to achieve .

The CIFOR *Guidelines* points the way toward a better system of outbreak response. It is now incumbent on all of us to go there.

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Preface

The Council to Improve Foodborne Outbreak Response (CIFOR) *Guidelines for Foodborne Disease Outbreak Response* were developed to aid government agencies responsible for preventing and managing foodborne disease. The *Guidelines* focuses on local and state agencies, including public health, environmental health, agriculture, and other agencies responsible for food safety, because they investigate most of the outbreaks of foodborne disease in the United States. However, the *Guidelines* also supports the federal public health and regulatory agencies critical to the U.S. food-safety infrastructure.

The *Guidelines* describes the overall approach to outbreaks of foodborne diseases, including preparation, detection, investigation, control, and follow-up. The *Guidelines* also describes the roles of all key organizations involved in these outbreaks, provides recommendations for processes to improve communication and coordination among multiple agencies during multijurisdictional outbreaks, and identifies indicators that different organizations can use to gauge their performance in responding to foodborne disease outbreaks. Even though the *Guidelines* document provides comprehensive information for individuals and organizations involved in foodborne disease, it is not intended to replace existing procedure manuals. Agencies and individuals should use the *Guidelines* to compare existing procedures, fill gaps in and update site-specific procedures, create procedures where they do not exist, and train program staff.

CIFOR intends the *Guidelines* to serve as a foundation for epidemiologists, laboratorians, environmental health specialists, and others involved in food-safety programs. Many local, state, and federal government agencies work to solve outbreaks of foodborne diseases, and CIFOR hopes this document will standardize foodborne disease investigation across all those agencies.

Technical experts from different government and academic organizations across the country, representing a wide variety of disciplines, have compiled the information in the *Guidelines*. The *Guidelines* have undergone a comprehensive public review process. CIFOR considers these *Guidelines* a consensus document that captures best practices and identifies emerging new practices in outbreak response to foodborne diseases.

Acknowledgements

The development of the *CIFOR Guidelines for Foodborne Disease Outbreak Response* took thousands of hours of work by dozens of individuals over a 3-year period. Every one of these individuals had a full-time job, and many of them were repeatedly distracted by foodborne disease outbreaks over the course of the project. They gave of their time, energy, and expertise because of a strong commitment to improving the quality of foodborne disease outbreak response. CIFOR expresses its deep gratitude to everyone who participated.

We particularly acknowledge John Besser, Craig Hedberg, Pat McConnon, Don Sharp, and Jeanette Stehr-Green, who repeatedly stepped up to provide extra guidance and support whenever the need arose. Jac Davies, the editor and lead author, had a particularly large role in the creation of this document and was committed to giving her time and effort to this project. We would like to especially acknowledge her involvement.

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

- Association of Food and Drug Officials
- Association of Public Health Laboratories
- Association of State and Territorial Health Officials
- Centers for Disease Control and Prevention (CDC)
- Council of State and Territorial Epidemiologists
- Food and Drug Administration (FDA)
- National Association of County and City Health Officials
- National Association of State Departments of Agriculture
- National Environmental Health Association
- U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS)

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Table of Contents

Table of Contents

Table of Contents

Table of Contents

Table of Contents

Table of Contents

Table of Contents

Table of Contents

CHAPTER 1

Overview of CIFOR Guidelines

Although a variety of steps for investigating an outbreak exist in the training literature, there is no agreed upon, standard approach for response to an outbreak. Why is this? Simply put, no one set of steps is appropriate for all outbreaks. The response varies with the outbreak and surrounding circumstances (e.g., etiologic agent, number of cases, and likely source of exposure). The response also varies depending on the agencies involved, available resources, and the 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 others. In addition, some activities that are considered part of an outbreak response are routinely undertaken in some jurisdictions before an outbreak is ever recognized (e.g., follow-up of cases to collect detailed information about exposures).

Overview of CIFOR Guidelines

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

Nonetheless, a description of the steps involved in the response to an outbreak is instructive. Such a portrayal, although not an accurate depiction of reality, is more easily understood by the novice who needs to learn about outbreak investigation. A description also emphasizes the need to work systematically through each outbreak investigation, allowing activities to consciously be omitted or rearranged, but not overlooked in the urgency of the moment.

The CIFOR Guidelines for Foodborne Disease Outbreak Response describes 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 Clusters and Outbreaks** (**Chapter 5**), and
- **Control Measures** (**Chapter 6**).

The CIFOR Guidelines is 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 allows users to make practical decisions about their (or their agency's) 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 more complex, the CIFOR Guidelines provides special considerations for **Multijurisdictional Outbreaks** (**Chapter 7**). As a context for responding to foodborne outbreaks, the Guidelines also covers **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 provides **Performance Indicators for Foodborne Disease Programs** (**Chapter 8**).

The following sections summarize the contents of Chapters 2 through 6, which provide key background information and cover all of the critical steps in detecting and responding to foodborne disease outbreaks. These summaries are intended to give a high level overview of each chapter, thus making it easier to find information of particular interest. 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 that occur at each step in the production of food. Foodborne illnesses and disease outbreaks, detected through public health surveillance, reflect what and how we eat

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

and represent important sentinel events that signal a failure in the food-safety process.

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 increasing amounts of fruit, vegetables, and seafood. Culinary practices that use undercooked or raw foods have become popular. In addition, an increasing number of Americans eat their meals away from home.

Changes in Food Production (2.1.2)

The food industry has accommodated Americans' dietary demands by moving from locally grown and raised products to routine importation of out-of-season or exotic foods from other countries. Changes in technology and improved growing, harvesting, packaging, and transportation practices facilitate the importation of distantly grown, fragile foods.

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 has 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.

Trends in Food Product Recalls (2.1.3)

Food recalls are one indication of food-safety problems. During February 2007 through February 2008, the U.S. Department of Agriculture (USDA) and the federal Food and Drug Administration (FDA) reported more than 90 voluntary recalls of food associated with microbial contamination. Recalled products were distributed locally, nationally, or internationally and were sold in a variety of retail settings. Many recalls were for contaminated meat; however, other foods also were recalled. The contaminating pathogens most commonly identified in food recalls were *Listeria monocytogenes*, Shiga toxin-producing *Escherichia coli*, and *Salmonella* species, but products also were recalled that were contaminated with viruses, parasites, and toxins.

Trends in Surveillance (Section 2.2)

Overview (2.2.1)

Many surveillance systems are used in the United States to provide information about the occurrence of foodborne disease. 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., hazard surveillance, sentinel surveillance systems, and national laboratory networks). Each surveillance system plays a role in detecting and preventing foodborne disease and outbreaks.

Selected Surveillance Systems of Relevance to Foodborne Diseases (2.2.2)

Notifiable disease surveillance (2.2.2.1)

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, which in turn submits the information to the National Notifiable Disease Surveillance System, which the Centers for Disease Control and Prevention (CDC) oversees.

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

Notifiable disease surveillance is "passive" (i.e., the investigator waits for disease reports from those required to report) and is susceptible to diagnosis and reporting problems.

Foodborne disease complaints/notifications (2.2.2.2)
Foodborne Disease Complaint/Notification systems allow 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 record the complaint in a log book or on a standardized form. Regular review of these reports for trends or commonalities can identify foodborne illnesses in the community and possibly clusters of foodborne diseases.

Behavioral Risk Factor Surveillance System (2.2.2.3)
The Behavioral Risk Factor Surveillance System (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.

Hazard surveillance (2.2.2.4)
Factors that lead to the contamination of food with microorganisms or toxins or allow survival and growth of microorganisms in food (i.e., contributing factors) are used to develop control and intervention measures at food production and service facilities. 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. Currently no national hazard surveillance system exists.

Contributing factor surveillance (2.2.2.5)
Investigators from state and local public health agencies gather information about contributing factors in foodborne outbreaks through environmental 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 routine inspection of a restaurant but require a systematic description of what happened and how events most likely unfolded in an outbreak. Because many food control officials fail to adjust their day-to-day regulatory inspection process to conduct an environmental assessment, contributing factor data in outbreak investigations 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. Participants include environmental health specialists and epidemiologists from nine states, the FDA, USDA, and CDC. Improving environmental assessments in foodborne outbreak investigations and reporting contributing factor and antecedent data to CDC is one of EHS-Net's primary research activities. CDC is exploring development of a surveillance system for contributing factors and antecedents from investigations of foodborne disease outbreaks.

Foodborne Diseases Active Surveillance System (FoodNet) (2.2.2.6)
FoodNet is a sentinel surveillance system undertaken at 10 participating sites in the United States 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

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

platform for a variety of epidemiologic studies and provides insights into the incidence of and trends in foodborne and diarrheal diseases.

National Molecular Subtyping Network for Foodborne Disease Surveillance (Pulse Net) (2.2.2.7)
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 using standardized methods. PulseNet allows 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 occurring in multiple sites across the country.

National Antimicrobial Resistance Monitoring System–Enteric Bacteria (NARMS) (2.2.2.8)
NARMS was developed to monitor antibiotic resistance patterns in selected bacteria found in people, animals, and meat 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 Outbreak Reporting System (2.2.2.9)
CDC's Foodborne Outbreak Reporting System collects voluntary reports from public health agencies summarizing the results of foodborne outbreak investigations. This system has been modified and expanded over time. In 2001, reporting became Web-based in a system called the electronic Foodborne Outbreak Reporting System (eFORS). Starting in 2009, the system includes modules for reporting waterborne outbreaks and enteric disease outbreaks caused by person-to-person contact and by direct contact with animals and will be called the National Outbreak Reporting System.

Quality and Usefulness of Surveillance Data (2.2.3)
Surveillance statistics reflect only a fraction of cases that occur in the community. Incomplete diagnosis and reporting of foodborne illnesses inhibits surveillance and the detection of foodborne disease outbreaks (2.2.3.1). The specific data elements collected through surveillance and the validity and accuracy of the information collected further impact the usefulness of surveillance information (2.2.3.2).

Etiologic Agents Associated with Foodborne Diseases (Section 2.3)

Overview (2.3.1)
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 (2.3.2)
On the basis of reports to eFORS from 1998 to 2002, bacteria (including their toxins) accounted for 55% of foodborne disease outbreaks for which an etiologic agent was determined. Viruses accounted for 33% of these outbreaks but increased from 16% in 1998 to 42% in 2002 probably because of the increased availability of methods to diagnose viral agents. Marine algae, fish, and mushroom toxins and other chemicals accounted for 10% of outbreaks for which a cause was known.

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

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

Determining the Etiologic Agent in an Outbreak (2.3.3)

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 from at least 10 individuals who manifest illness typical of the outbreak and have not received antibiotics.

Isolation of the etiologic agent from food is more 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 (2.3.3.1).

Predominant signs and symptoms, and the average incubation period, can provide insights into the etiologic agent. Illnesses resulting 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.

Because certain pathogens are commonly associated with certain foods, the suspected food in an outbreak can 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 (2.3.3.2.2).

Mode of Transmission (2.3.4)

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.

Occasionally case characteristics suggest one mode of transmission over others in an outbreak.

- Foodborne transmission is suggested by cases with distinctive demographic characteristics (i.e., age group, sex, and ethnicity) that could reflect unique food preferences or exposures and cases with a geographic distribution similar to the distribution of food products.
- Waterborne transmission should be considered if illness is widespread, both sexes and all age groups are affected, the geographic distribution of cases is consistent with public water distribution, complaints about water quality in the affected community have been reported, or multiple pathogens are involved.
- 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.

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 response team (Section 3.2),
- Identification of necessary resources (Section 3.3);
- Development of standard processes for receiving foodborne illness complaints (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 individuals affected) and the resources necessary to address it.

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 conservation or quality agencies (3.1.2.3),
- State agriculture departments (3.1.2.4),
- CDC (3.1.2.5),
- FDA (3.1.2.6), and
- USDA/FSIS (3.1.2.7).

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), military agency (3.1.3.2), or National Park Service unit (3.1.3.3). 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).

Outbreak Investigation and Control Team (Section 3.2)

Typically, the responsibility for conducting a foodborne outbreak investigation, recommending control measures, and monitoring their implementation falls on a core team of individuals.

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).

Overview of Chapter 3. Planning and Preparation

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

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 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 allow them to answer questions and make decisions during an outbreak. 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.

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.

Complaint Processing (Section 3.4)

A process, including a standard data collection form, should be established to receive complaints of potential foodborne illnesses from the public. 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.

Overview of Chapter 3. Planning and Preparation

Records Management (Section 3.5)

Before an outbreak occurs, procedures for records management should be established, including use of standard forms for collecting and organizing outbreak information, development of database templates, and identification of tools to analyze outbreak data to ensure speedy 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. Agencies should develop methods for communication with individuals and organizations key to an investigation before an outbreak occurs (3.6.2.1). Key individuals and organizations include the following:

- The outbreak investigation 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 updated contact lists (where appropriate) and standard channels of communication so that each knows who to communicate with and where the information will come from during an outbreak.

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 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 an effective outbreak response effort. 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 program. Investigators from the state health department should notify CDC and the appropriate food-regulatory agency.

Incident Command System (Section 3.10)

An Incident Command System (ICS) is a structure that provides for internal communications within a government system among primary event responders, public information officers, and security and safety officers and for external liaison with various

Overview of Chapter 3. Planning and Preparation

organizations. ICS is designed to enable effective, efficient incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. The role of an ICS response in an outbreak investigation varies and is not without controversy, with some agencies using an ICS structure while others do not. Agencies involved in foodborne 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.

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

Foodborne disease surveillance generally refers to the routine monitoring in a population of enteric diseases potentially transmitted through food. Foodborne disease surveillance serves many functions, including detection of disease clusters and problems in food production or delivery.

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

- Pathogen-specific surveillance (Section 4.2)
- Notification/complaint systems (Section 4.3)
- Syndromic surveillance (Section 4.4)

Pathogen-Specific Surveillance (Section 4.2)

In pathogen-specific surveillance, health-care providers and laboratorians report individual cases of disease to the 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 or other clinical material to public health laboratories.

Staff from the public health agency may interview 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 potential outbreak (4.2.4).

The public health laboratory confirms the disease agent and conducts tests (e.g., serotyping, molecular subtyping, or antimicrobial susceptibility assays) to further characterize the agent. Laboratory data are uploaded to national systems, such as PulseNet. Except for individual cases of botulism, and occasionally other infections, testing of food or other environmental specimens related to cases is not advised without strong epidemiologic or environmental information implicating the item (4.2.5).

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 our food and water supply systems.

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

Limitations of Pathogen-Specific Surveillance (4.2.8)

The limitations of pathogen-specific surveillance include

- Inclusion of only diseases detected by routine testing and reported to the public health agency and
- Delay in cluster detection and follow-up due to events that must occur between the time a patient is infected and the time he or she is recognized as part of a cluster.

Key Determinants of Successful Pathogen-Specific Surveillance (4.2.9)

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, resulting in a mischaracterization of an outbreak (4.2.9.1).

The more prevalent a disease is in the community, the more difficult outbreaks of that disease are to identify and the more difficult background cases are to distinguish from outbreak cases. Increasing the specificity of the case definition by including more specific agent classifications (e.g., subtype results) or certain time, place, or person characteristics among cases can minimize this problem (4.2.9.2)

For cases detected through pathogen-specific surveillance, consider potential 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, as appropriate circumstances, that

- Ask about specific exposures previously (or plausibly) associated with the pathogen,
- Specifically ask about a wide variety of potential exposures,
- 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).

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 increases the success of pathogen-specific surveillance (4.2.9.4).

Routine 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).
- 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).
- Minimize delays in processing reports and transporting specimens.
- Undertake subtyping of isolates as specimens are submitted and post results to national databases as quickly as possible (4.2.10.2).

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

- Interview cases using a standardized questionnaire for exposure information (consistent with the incubation period of the pathogen) as soon as possible. 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).

Notification/Complaint Systems (Section 4.3)

In notification/complaint systems, public health agencies receive, triage, and respond to reports from the public about possible foodborne illnesses. 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 following a common exposure (e.g., event or venue) and
- Multiple independent reports about illness in single individuals.

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

For reports 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. 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.

Strengths of Notification/Complaint Systems for Outbreak Detection (4.3.6)

The primary strengths of notification/complaint systems result 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.

For event-related notifications, another strength is that exposures associated with the event can normally be determined and recall of exposures among attendees is usually good.

Limitations of Notification/Complaint Systems (4.3.7)

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

- Inability to link related cases and exclude unrelated cases,

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

- Inability to detect widespread low-level contamination events, 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 Notification/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).

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 allow investigators to focus on exposures previously associated with that pathogen. Hence, interviews must be done promptly and systematically to be effective (4.3.8.3).

Notification/Complaint Systems — Model Practices (4.3.9)

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

- For group illnesses associated with an event, focus interviews on shared exposures with the realization that the individuals within the group might have more than one event in common (4.3.9.1).
- 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 etiology to enable implementation of rational interventions and allow linkages with other outbreaks or sporadic cases (4.3.9.5).
- For individual complaints, collect a detailed 5-day exposure history (unless otherwise indicated by the incubation period of the illness) 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 individuals (4.3.9.2).
- Review interview data regularly to look for trends or commonalities and compare with information obtained through pathogen-specific surveillance (4.3.9.6),

Overview of Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

- Improve interagency cooperation and communication among agencies that receive illness complaints (4.3.9.7 and 4.3.9.12).
- Check complaint information against national databases (e.g., USDA/FSIS Consumer Complaint Monitoring System) (4.3.9.12).
- 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.
- Centralize reporting or the process for reviewing reports to increase the likelihood that patterns are detected (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:

- 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.

Limitations of Syndromic Surveillance (4.4.7)

Syndromic surveillance has serious limitations, including 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. In addition, in response to concerns about patient confidentiality, many agencies collect only de-identified data, which slows the investigation of positive signals from the system.

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.

Practices for Improving Syndromic Surveillance (4.4.9)

Because the utility of syndromic surveillance for detecting foodborne disease events has not been established, the need for additional investment is not clear. 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)

An outbreak is the occurrence of two or more cases of a similar illness shown by an investigation to result from a common exposure. 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 ingredients 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)

Although general principles underlie successful investigations, no one specific method works best in all situations. Investigators need to be flexible and innovative and undertake activities in a thoughtful and systematic manner.

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

Investigations are rarely linear. Although most procedures for investigating outbreaks follow a logical process, most actual investigations feature multiple concurrent steps. Maintaining close communication and coordination among epidemiologic, environmental health, and laboratory investigators is the best way to ensure concurrent activities do not interfere with each other and important investigation steps are not forgotten (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:

- 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

Overview of Chapter 5. Investigation of Clusters and Outbreaks

unusual exposures or commonalities among cases (5.1.2.4).

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 (HIPAA) (5.1.2.6).

Cluster and Outbreak Investigation Procedures (Section 5.2)

Conduct a Preliminary Investigation (5.2.1)

Foodborne disease outbreaks typically are detected through three general methods: pathogen-specific surveillance, notification/complaint systems, and syndromic surveillance (5.1.2.1). After detection, 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 potential 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 is typically given to outbreaks that have a high public health impact; are ongoing; or appear to be associated with a food-service establishment, commercially distributed food product, or adulterated food *(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).

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,

Overview of Chapter 5. Investigation of Clusters and Outbreaks

- Identify persons at risk,
- Identify mode of transmission and vehicle,
- Identify the source of contamination,
- Identify contributing factors, 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 establishment) (Table 5.1) or was identified through pathogen-specific surveillance (Table 5.2).

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., reviewing cash register receipts or looking at a calendar and reconstructing recent events) that encourage recall of exposures (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 new suspicious exposures are suggested during the interviews (i.e., are reported among 5-10 cases), initial cases are systematically re-interviewed to uniformly assess their exposure and the suspicious exposure is added to the interview of subsequently identified cases.
    - For agencies that routinely interview ALL cases with a detailed exposure questionnaire, dynamic cluster investigation can be initiated as soon as a cluster is recognized. Such an approach results in improved recall because cases are more likely to remember exposures when specifically questioned about them. The approach also is more likely to result in a meaningful intervention because of the compressed time frame of the investigation (5.2.4.1.2).
    - 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 approach. All cases are interviewed 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 using a detailed exposure questionnaire following the "dynamic cluster investigation" approach (5.2.4.1.2.2).
    - For agencies that do not have sufficient resources to conduct detailed interviews with all cases in a cluster, hypothesis-generating interviews can be undertaken with a subset of cases after a cluster becomes obvious. Exposures reported by a substantial proportion of these cases can then be studied (5.2.4.1.3).
- Use the FoodNet Atlas of Exposures for an initial evaluation of shared exposures among cases. The Atlas includes information about exposures that might be associated with foodborne illnesses and can be used as a crude estimate of the background rate of different food exposures in the community. In the absence of survey data, common-sense estimates of the prevalence of a given exposure can help identify exposures of interest (5.2.4.1.4).

Overview of Chapter 5. Investigation of Clusters and Outbreaks

- 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 result in the problem (5.2.4.1.5). The specific activities included in an environmental health assessment differ by disease agent, suspected vehicle, and setting but usually include the following:
  - Describing the implicated food,
  - Observing procedures to make food,
  - Talking with food workers and managers,
  - Taking measurements,
  - Collecting food and other environmental samples,
  - Collecting and reviewing documents on the source of food (e.g., invoices), and
  - Drawing a food flow diagram showing each step in the production of the food item.
- Conduct informational tracebacks/traceforwards of food items under investigation. Tracing implicated food items or ingredients through the distribution chain to the source of production can help identify epidemiologic links among cases. The convergence of food items eaten by multiple cases along a distribution pathway can help identify the source of contamination. Conversely, the 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 (5.2.4.1.6).

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 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 allows 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 issues 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.

Interpreting Results (5.2.7)

The outbreak investigator must use *all* available information to construct a coherent

Overview of Chapter 5. Investigation of Clusters and Outbreaks

narrative of what happened and why. Results of epidemiologic studies must be integrated with results of informational product tracebacks, food worker interviews, environmental health assessments, and food product and environmental testing.

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 ingredient, 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.

Conduct a Debriefing at End of Investigation (5.2.8)

Encourage a postoutbreak meeting among investigators to assess lessons learned and compare notes on final findings. This is particularly important for multiagency investigations but also is important for single agency investigations.

Summarize Investigation Findings, Conclusions, and Recommendations (5.2.9)

At a minimum, every outbreak investigation should be documented using a standardized form to facilitate inclusion in state and national outbreak databases (e.g., CDC's form 52.13 or its equivalent). Investigators are encouraged to submit preliminary reports while the investigation is ongoing to help link outbreaks occurring in multiple places at the same time 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, potentially, publication in a peer-reviewed journal.

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)

To prevent further illness in an outbreak, control measures should be initiated as soon as possible, even concurrently with ongoing investigations. However, the quality of information about which control measures are based as well as the potential positive and negative consequences of undertaking the control measures (or not undertaking control measures) should be kept in mind.

Control measures can be categorized as those that control the source (i.e., prevent continued exposure to the original source of the foodborne illness [Section 6.2]) and those that prevent secondary transmission (i.e., transmission from persons infected through the

Overview of Chapter 6. Control Measures

original source to others through food, water, or person-to-person transmission [Section 6.3]). Additional measures might be necessary to prevent future outbreaks (Section 6.8).

Control of the Source (Section 6.2)

Nonspecific Control Measures (6.2.1)

Nonspecific control measures (e.g., holding of leftovers, emphasizing hand-washing, excluding any ill employees) can be implemented as soon as a facility has been implicated in an outbreak, even though a specific food or causative agent has not been identified. Nonspecific control measures are good public health practice and are generally effective, regardless of the disease.

Specific Control Measures (6.2.2)

When a food has been implicated, control measures directed at the specific cause can be implemented. Specific control measures will vary depending on whether the implicated food is associated with food-service establishment or home processing (6.2.2.1) or is associated with a processor or producer as evidenced by its occurrence at multiple facilities or multiple locations (6.2.2.2).

Food associated with food-service establishments or home processing (6.2.2.1)

Specific control measures include

- Removing the implicated food from consumption (6.2.2.1.1),
- Cleaning and sanitizing the implicated facility and equipment (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 at the facility to prevent further contamination of food or survival and growth of microbes already present in food (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 (6.2.2.1.6), and
- Closure of the facility and an outline of actions necessary for the facility to reopen (6.2.2.1.7).

Food associated with a processor/producer (6.2.2.2)

If multiple facilities are involved in an outbreak or the outbreak is associated with a product distributed to multiple locations, the above control measures might still be appropriate; however, efforts also might be needed to recall the implicated food from the market (6.2.2.2.1). 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).

Product recall (6.2.2.2)

If evidence supports the recall of a food (6.2.2.2.1), the appropriate agency should contact the manufacturer or distributor immediately and get its cooperation. The manufacturer or distributor might decide to issue a voluntary food recall that will include removal of food from distribution and market shelves and notification of customers and the public through regulatory agencies and the media. While awaiting the manufacturer's decision about a recall, it might be appropriate to directly ask retailers and distributors to voluntarily remove the product from their shelves and withhold the product from distribution.

Removal of food from market (6.2.2.2)

Removal of food from the market goes 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

Overview of Chapter 6. Control Measures

(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.

Control of Secondary Spread (Section 6.3)

Education (6.3.1, 6.3.2, 6.3.4)

Education is key to preventing the spread of infection from individuals 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 (6.3.1). The public should be reminded of basic food-safety precautions as well as means to decrease risk for infection through the current outbreak (6.3.2). The operator of the implicated facility should be notified of the steps needed to control the situation and to prevent further outbreaks (6.3.4). 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 when handling ready-to-eat foods (6.3.4).

Excluding Infected Persons (6.3.3)

Infected persons should be excluded from settings where transmission might occur including food-preparation, health-care, and child-care settings. Individuals who are no longer ill with vomiting or diarrhea can usually return to work without testing if they practice good personal hygiene and are adequately supervised. For some diseases or settings, however, testing might be necessary to ensure the person is no longer likely to transmit the disease. Regardless, local ordinances or state statutes should determine requirements for returning to work.

Prophylaxis (6.3.5)

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

Communication (Section 6.4)

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

Outbreak Response Team (6.4.1)

Information should routinely be shared with all members of the outbreak response team including actions taken and updates on the outbreak (6.4.1). Agency heads should routinely receive information about the status of the investigation (6.4.2). If the outbreak is potentially multijurisdictional, other agencies and organizations should also routinely receive status reports.

Implicated Facility (6.4.1, 6.4.4)

The owner/manager of the implicated facility should be contacted as soon as possible about potential control measures and instructed or advised about the need to report any new information that could affect the investigation. Because enforcement action may result from the investigation, it is important to understand the local legal framework before interacting with facilities that may be linked to an outbreak.

Industry (6.4.4)

Interactions with the food industry and related trade associations can help dispel misconceptions about the outbreak and take

Overview of Chapter 6. Control Measures

advantage of a teachable moment. However, state, local and federal agencies need to have working relationships with industry *before* an outbreak occurs.

The Public (6.4.3)

Communication with the public might be necessary in response to an outbreak if risk for exposure to the source is ongoing or if urgent medical treatment is needed for individuals who already have been exposed. If the outbreak involves a distributed product that is being recalled, the public must be notified using all available sources, including the Internet, television, radio, and newspaper. Messages to the public should follow good risk communication practices and be prepared with assistance from a Public Information Officer. Attempts should be made to reach all members of the population at risk, including non-English speaking and low-literacy populations.

Conclusion of the Outbreak Investigation (Sections 6.5, 6.6, 6.7)

Determining End of Outbreak and Post-Outbreak Monitoring (6.5.1, 6.5.3)

Most outbreaks can be considered over when two or more incubation periods have passed without new cases (6.5.1). Post-outbreak monitoring is necessary to ensure the outbreak has ended and the source has been eliminated (6.5.3). 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 may require increased inspections and customized training.

Postoutbreak Briefing (6.6)

All members of an outbreak response team should be briefed on the results of the investigation, including the cause, long-term and structural control measures, effectiveness of outbreak control measures, problems with the response effort and needed changes, and need for further study.

Outbreak Report (6.7)

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 participants. Such a report should be disseminated to all participating organizations and investigators. Reports should not identify individuals or share other legally nonpublic information, unless absolutely necessary, nor should they include inappropriate language.

Control of Future Outbreaks (Section 6.8)

An outbreak investigation might point to the need for future studies or research (6.8.1). It might identify the need for broad education efforts of the public, the food preparation industry, or health-care providers (6.8.2). It 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 (6.8.3). The investigation of an outbreak might also identify the need for new measures to detect, control, or eliminate pathogenic microorganisms (or their toxins) from food (i.e., applied food research) (6.8.4).

CHAPTER 2

Fundamental Concepts of Public Health Surveillance and Foodborne Disease

At either end of any food chain you find a biological system—a patch of soil, a human body—and the health of one is connected—literally—to the health of the other.

Michael Pollan

The Omnivore's Dilemma, 2006

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

Preventing foodborne disease relies on our ability to translate knowledge of the principles of food safety to the practices of food production at each level of the food system. Foodborne disease outbreaks represent important sentinel events that signal a failure of this process.

2.0. Introduction

Determining whether this failure was due to the emergence of a new hazard or failure to control a known hazard is an important outcome of an outbreak investigation. This determination is critical to developing strategies to prevent future outbreaks and to evaluate the success of those strategies. A variety of surveillance programs are required to accomplish this complex task.

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

2.1. Trends in Diet and the Food Industry

2.1.1. Dietary Changes

That we no longer are a nation of meat and potato eaters is evidenced by the most recent dietary recommendations of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA), which emphasize the importance of eating a variety of fruit, vegetables, and protein.[2] From 1985 through 2005, the annual per capita consumption of fruit and vegetables rose from 89 to 101 pounds and from 123 to 174 pounds, respectively.[3] In 2006, the annual per capita consumption of seafood (fish and shellfish) was 16.5 pounds, compared with 12.5 pounds in 1980.[4]

The food industry has accommodated Americans' demand for a broader variety of food by moving from locally grown and raised products to routine importation of items once considered out-of-season or too exotic for Americans to buy. The burgeoning international agribusiness created by the demand for ready-to-eat and processed foods supports monoculture farming (i.e., the practice of growing one single crop), mega-feedlots (i.e., feedlots raising thousands of cattle), and mass importation and distribution of foods.[1, 5]

Concurrent with the changes in demand, technology has improved growing, harvesting, packaging, handling, and transportation practices, facilitating year-round importation of distantly grown, fragile foods, such as raspberries from the Southern Hemisphere. Less stringent trade agreements with major fruit-growing countries also have contributed to the growth of international imports: during 1990–2006, the annual cost of imports of fresh fruits and vegetables into the United States rose from $2.7 to $7.9 billion; simultaneously, the proportion of tropical fruits (primarily from Mexico and Costa Rica) constituting these imports increased from 7% to 15%.[3]

Increasingly more Americans eat their meals away from home. According to the National Restaurant Association's 2008 industry overview, 945,000 restaurant locations will have more than 70 billion meal and snack occasions. In 2005, 41% of all food spending was on food away from home, up from 26% in 1970.[86]

The increased number of meals eaten away from home most likely have influenced foodborne disease. A review of foodborne outbreaks in the seven states participating in CDC's Foodborne Disease Active Surveillance Network (FoodNet) revealed that 66% of outbreaks (222 of 336) occurring in 1998 and 1999 were associated with restaurants, and 9% (30 outbreaks) were associated with catered events.[6] In addition, a variety of studies of both sporadic and outbreak-associated foodborne illness, including infection with *Escherichia coli* O157:H7, *Salmonella* Enteritidis, *Salmonella* Typhimurium, and *Campylobacter jejuni*, suggest that commercial food-service establishments, such as restaurants, play an important role in foodborne disease in the United States.[7]

Culinary trends that use undercooked or raw

2.1. Trends in Diet and the Food Industry

foods—particularly dairy, fish, or shellfish—might be contributing to increased infections and outbreaks caused by the microorganisms associated with these foods.[19–25]

2.1.2. Changes in Food Production

Changes in what we eat and drink are not the only contributors to trends in foodborne disease. How our food is cultivated or raised, processed, and distributed and how and by whom our food is prepared also are factors. Food can be contaminated anywhere along the supply chain from farm to fork. The industrialization of food production, with concentrated animal feeding operations and increasingly intense agricultural practices, and the broadening distribution of food products have contributed to outbreaks of foodborne disease involving larger numbers of people, multiple states, and even multiple countries.[8–18] Changes in agricultural, processing, or packaging methods might facilitate bacterial contamination or growth,[8,9,16,23,26–34] and routine use of antibiotics to promote the growth of livestock and poultry has increased human infections caused by drug-resistant bacteria.[49, 50, 84, 85]

2.1.3. Trends in Food Product Recalls

Food recalls are one indicator of food-safety problems. Distributors or manufacturers voluntarily recall their food products for either of two reasons: (a) a problem discovered in the course of routine inspection of the food or its processing or distribution or (b) suspicion or identification of the product as the cause of human or animal disease. During February 2007 through February 2008, USDA and the federal Food and Drug Administration (FDA) reported more than 90 voluntary recalls of food associated with microbial contamination. These recalls demonstrate the breadth of products and pathogens responsible for foodborne diseases in the United States.[17,18]

During that period, many of the recalls were for contaminated meat, primarily ground beef and other beef products. However, distributors or manufacturers also recalled shellfish and smoked, dried, frozen, and uneviscerated fish; fresh fruit, herbs, and vegetables; canned vegetables; raw milk; cheese and other dairy products; chocolate; ready-to-eat foods; frozen pizza; peanut butter; sesame seeds; tahini; tofu; and bottled water. The products were distributed locally, nationally, or internationally and were sold not only by national chain retail stores and food services but also at farm stands and small health food stores carrying organic and "natural" products. In other words, no one is completely protected from the risk for contaminated food.[17,18]

Most of these recalls followed identification of bacterial contamination of a food or beverage. In at least 20 instances, the contamination was associated with reported human illnesses, including 628 residents of 47 states infected with *Salmonella* after eating contaminated peanut butter.[16] The contaminating pathogens most commonly identified in food recalls were bacteria: *Listeria monocytogenes*, Shiga toxin-producing *E. coli* (STEC), and *Salmonella* species; the latter two were associated most frequently with recalls resulting from foodborne outbreaks.

Products also were recalled that were contaminated with viruses (e.g., norovirus in shellfish), parasites (e.g., *Cryptosporidium* in bottled water), and toxins (e.g., *Clostridium botulinum* neurotoxin, *Staphylococcus aureus* enterotoxin, and tetrodotoxin produced by pufferfish).[17,18] The largest single food recall in the United States, a staggering 148 million pounds of beef, began after discovery that a California food processor used disabled (i.e., "downer") cows in beef production—a concern because of the theoretical risk for infection of the cattle with the agent associated with bovine spongiform encephalopathy (BSE) or "mad cow disease."[35–37]

2.2. Trends in Surveillance

Foodborne disease is an important cause of illness in the United States. In 1999, CDC estimated that foodborne diseases were responsible for 76 million illnesses each year, resulting in 325,000 hospitalizations and 5000 deaths.[38] During 1998–2002, 6427 foodborne disease outbreaks were reported to CDC, resulting in at least 128,370 individual illnesses and 88 deaths.[39]

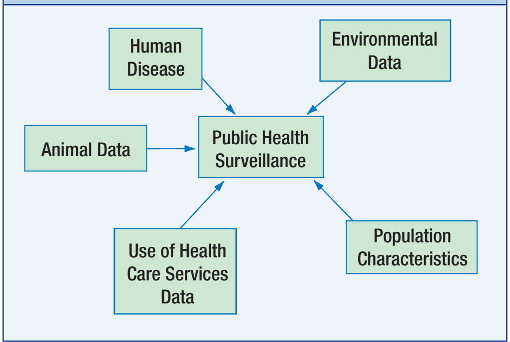
Our ability to use public health surveillance for tracking cases of foodborne disease and outbreaks, as well as behaviors and conditions that contribute to foodborne diseases, is critical to our understanding and control of these diseases.

2.2.1. Overview

Public health surveillance is the foundation of communicable disease epidemiology and an essential component of a food-safety program.[40] Surveillance data can reveal the burden of a particular disease in the community or the presence and scale of a possible outbreak. Surveillance data also can provide clues to the source of and contributing factors to disease outbreaks. Over time, surveillance data can identify disease and behavioral trends and enable investigators to learn more about the diseases being tracked and ways to prevent these diseases.

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

Figure 2.1 Sources of information for public health surveillance



2.2.2. Selected Surveillance Systems of Relevance to Foodborne Diseases

Multiple types of surveillance systems are used in the United States related to foodborne disease. Some of them, including notifiable condition surveillance, complaints from consumers about potential illness, and reports of outbreaks, focus on the detection of specific enteric diseases likely to be transmitted by food and have been used extensively by health-related agencies for decades. More recently, new surveillance methods have emerged including hazard surveillance, sentinel surveillance systems, and national laboratory networks for comparing pathogen subtypes, which are particularly applicable to foodborne disease.[41]

Each surveillance system plays a critical role in detecting and preventing foodborne disease and outbreaks in the United States and each represents one part of the public health system needed to ensure food is safe as it moves from its original source through the food chain to the tables of U.S. citizens.

2.2.2.1. Notifiable disease surveillance

One of the oldest public health surveillance systems in the country is notifiable disease surveillance. Notifiable disease surveillance begins with an ill person who seeks medical attention. The health-care provider sends a

2.2. Trends in Surveillance

specimen (for foodborne illness, this usually is a stool specimen) to the laboratory for the appropriate tests, and the laboratory identifies the agent responsible for the patient's illness so the patient can be treated. Next, the laboratory or health-care provider notifies local public health officials of the illness. Once the patient's information goes to a public health agency, the illness is no longer considered as an isolated incident but is compared with other similar reports. Combining the information in these separate reports allows investigators to identify trends and detect outbreaks.

All states and territories have legal requirements for the reporting of certain diseases and conditions, including enteric diseases likely to be foodborne, by health-care providers and laboratories to the local public health agency. In most states and territories, the law usually requires local public health agencies to report these diseases to the state or territorial public health agency. What to report and with what urgency vary by state. States and territories (or sometimes local public health agencies) then send the information to the National Notifiable Disease Surveillance System, which CDC oversees. In the past, disease reports usually arrived by mail or facsimile transmission, but many agencies now encourage telephone reporting and have developed electronic disease reporting locally. State public health laboratories also participate in national surveillance through programs such as the Public Health Laboratory Information System (PHLIS), a PC-based electronic reporting system for laboratory-confirmed isolates including *Salmonella* and *Shigella*,[42] and PulseNet (see below).[43]

Notifiable disease surveillance is "passive"—i.e., the investigator waits for a disease report from health-care providers, laboratories, and others who are requested or required to report these diseases to the public health agency—and is susceptible to diagnosis and reporting problems. As little as 5% of bacterial foodborne illness might be reported to CDC through notifiable disease surveillance.[44]

2.2.2.2. Foodborne disease complaints/notifications

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

The processing of foodborne illness complaints varies by agency on the basis of the suspected pathogen and agency resources. Some health departments are required by local or state statute to investigate all commercial food establishments named by sick persons. Most health departments record complaints in a log book or on a standardized form. Some health departments enter this information into an electronic database for easy review and analysis.

Some complaint systems are more publicized and involve community members more heavily. A Web-based system in Michigan (RUsick2) allows ill persons to share information about their illness and recent exposures and helps the health department identify clusters of persons with unsuspected foodborne disease. During a pilot test in 2002, this system resulted in an estimated fourfold increase in the reporting of foodborne illness complaints. Two foodborne outbreaks were identified that most likely would not have been identified through other means.[45]

2.2.2.3. Behavioral Risk Factor Surveillance System

The Behavioral Risk Factor Surveillance System (BRFSS) is a state-based system of health surveys that collects information about health risk behaviors, preventive health practices, and health-care access primarily related to chronic disease and injury. For many states, BRFSS is the only source of timely, accurate data on health-related behaviors.

CDC established BRFSS in 1984; currently, data are collected by random-digit–dialed telephone surveys in all 50 states, the District

2.2. Trends in Surveillance

of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam. More than 350,000 adults are interviewed each year, making BRFSS the largest telephone health survey in the world. States use BRFSS data to identify emerging health problems, establish and track health objectives, and develop and evaluate public health policies and programs. Many states also use BRFSS data to support health-related legislative efforts.

BRFSS consists of core questions asked of all respondents across the country, and state-specific questions that are added by state and local health agencies each year. Although a minimum number of respondents is needed in each state to ensure statistical significance, states can choose to over-sample (place a higher number of phone calls) in certain regions or among certain populations to increase their ability to detect trends within those regions or populations.

Because of the length of time necessary to conduct the survey and lack of clinical information, BRFSS is not an appropriate tool for detecting foodborne illness. However, BRFSS can be used to identify behaviors, such as food handling methods, or trends, such as changes in the number of meals eaten outside the home, that can provide information about efforts to prevent foodborne illness.

2.2.2.4. Hazard surveillance

Food-control authorities have a regulatory and public health mandate to prevent diseases that can be unintentionally and intentionally transmitted through food. Approximately 75 state and territorial agencies and approximately 3000 local agencies assume the primary responsibility for licensing and inspecting retail food-service establishments.[46] Many of these same agencies oversee other aspects of the domestic food supply chain. The retail food-service industry segment alone consists of more than one million establishments and employs over 12 million people.[46]

Factors that contribute to foodborne outbreaks (e.g., factors that lead to contamination of food with microorganisms or toxins or allow survival and growth of microorganisms in food) are used to develop control and intervention measures at food-service establishments. Routine inspections then focus on implementation of these measures. Often referred to as Hazard Analysis Critical Control Point (HACCP) inspections, this is the basis for hazard surveillance. No national hazard surveillance system is available to food control authorities, although work being conducted through the Conference for Food Protection may evolve into a national system.

2.2.2.5. Contributing factor surveillance

Communicable disease control officials or foodborne outbreak surveillance officials from state and local health departments gather information about contributing factors in outbreaks from environmental assessments conducted by food control officials, from their own environmental assessments, or through some combination of the two and report it to CDC. Although the contributing factors may seem to require little explanation, they are a sophisticated listing of factors based on known microbiologic characteristics of and symptoms produced by specific pathogens, toxins, or chemicals and historical associations between known causative agents and specific food vehicles.

Whether based on etiology identification, vehicle identification, or both, factors contributing to an outbreak cannot be identified through a food-safety program inspection of a food-service or food-production establishment as conducted day to day by food control authorities. The process of identifying contributing factors associated with an outbreak must be driven first by describing what and how events probably unfolded, rather than by identifying regulation violations. Failures to implement regulatory requirements will come to light over the course of this process. Unfortunately, many food control

2.2. Trends in Surveillance

authorities fail to adjust their day-to-day regulatory inspection process to adequately conduct an environmental assessment during investigation of an outbreak of foodborne; therefore, contributing factors often are not adequately assessed and reported.

CDC's Environmental Health Specialists Network (EHS-Net) was established in 2000 to better provide information about environmental causes of foodborne disease. Participants include environmental health specialists and epidemiologists from nine states and the FDA, USDA, and CDC. Improving environmental assessments in foodborne outbreak investigations and reporting contributing factor and antecedent data to CDC is one of EHS-Net's primary research activities. CDC is exploring development of a surveillance system for contributing factors and antecedents from foodborne outbreak investigations. This system would link to the existing surveillance system for foodborne outbreaks, CDC's electronic Foodborne Outbreak Reporting System (eFORS) (see below) and provide the level of detail from environmental assessments conducted during foodborne outbreak investigations that food control authorities need.

2.2.2.6. Foodborne Diseases Active Surveillance System (FoodNet)

FoodNet, a sentinel surveillance system, is an enhanced foodborne disease surveillance system led and largely funded by CDC, with 10 participating sites covering a population of about 45 million. FoodNet concentrates on a subset of enteric diseases that are documented by laboratory testing. In contrast to routine notifiable disease surveillance, it is an "active surveillance system" in that FoodNet site investigators regularly contact area laboratories to enhance reporting of foodborne disease.

FoodNet sites also conduct surveys of the frequency of enteric illness and food consumption in the population[47] and practices in clinical laboratories.[48] FoodNet reports provide valuable insight into the national incidence of, and trends in, foodborne and diarrheal diseases[25,49–56] and has identified previously unrecognized sources of foodborne infection such as chicken as a risk factor for infection with *Salmonella* Enteritidis,[55,57] hummus and melon as risk factors for infection with *Listeria monocytogenes*,[58] and riding in a shopping cart next to raw meat or poultry as a risk factor for infection with *Salmonella* and *Campylobacter* in infants.[59,60] FoodNet also provides information to evaluate new strategies for conducting epidemiologic investigations, including investigations of outbreaks.

2.2.2.7. National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet)

PulseNet is a national network of local, state or territorial, and federal laboratories coordinated by CDC that allows comparison of subtypes of pathogens isolated from humans, animals, and foods across local, state, and national jurisdictions. The name derives from pulsed-field gel electrophoresis (PFGE), a laboratory method used to determine the molecular fingerprints of bacteria. This test, developed and refined during the 1980s, revolutionized the investigation of foodborne disease outbreaks by identifying unique strains within a bacterial species. For example, each of the many strains of *Salmonella* has a unique PFGE pattern or fingerprint. Because foodborne outbreaks usually are caused by a single bacterial strain, investigators can identify illnesses in the subgroup of persons infected with the same strain of *Salmonella* as a cluster of possibly related cases, to be considered separately from persons infected with other strains of *Salmonella*, thus enabling investigators to focus on the correct group of individuals and more quickly identify the source of an outbreak. PFGE also can be used to characterize bacterial strains in food or the environment to determine whether those strains match the pattern responsible for an outbreak.[14,29,50,61–63]

2.2. Trends in Surveillance

PulseNet has standardized the PFGE methods used by participating laboratories to distinguish strains of STEC, *Salmonella*, *Shigella*, *Listeria*, and *Campylobacter.* In addition, PulseNet maintains an electronic database of PFGE patterns that enables investigators from participating sites to upload their pattern and compare it with patterns of bacterial strains circulating nationally. This capability has vastly improved investigators' ability to rapidly detect even relatively small outbreaks in multiple sites across the country.[43]

2.2.2.8. National Antimicrobial Resistance Monitoring System–Enteric Bacteria (NARMS)

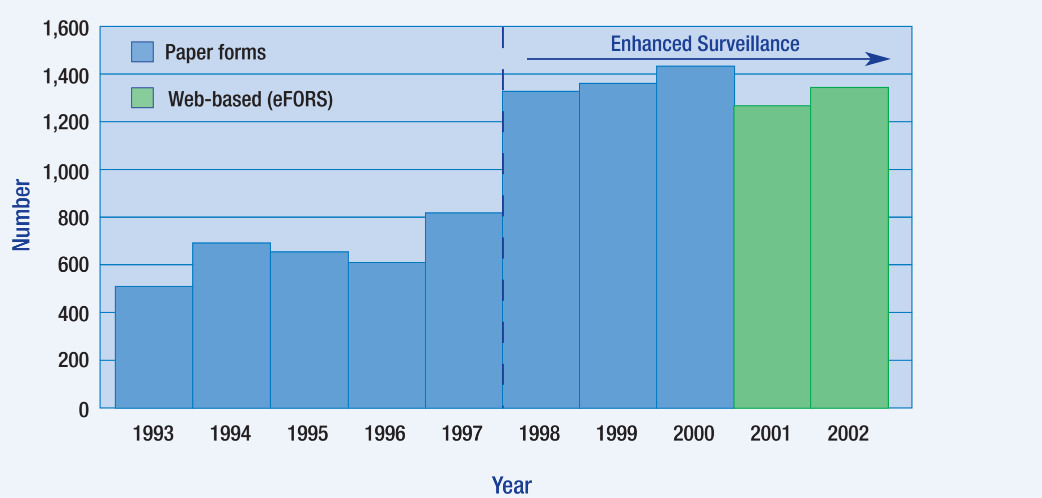
NARMS was developed to monitor antibiotic resistance patterns in selected enteric bacteria found in people, animals, and meat products. Bacterial isolates are forwarded to reference laboratories at CDC, USDA, or FDA and are tested against a panel of antimicrobial drugs important in human and animal medicine. Data collected by NARMS enables investigators to better understand the interaction between the use of antibiotics for livestock and the patterns of antibiotic resistance in animals and humans who ingest animal food products.[15,49,50,64–68]

2.2.2.9. Foodborne Outbreak Reporting System

The Foodborne Outbreak Reporting System was initiated by CDC in the 1960s to collect voluntary reports from public health agencies summarizing the results of foodborne outbreak investigations. In 1973, the database for the system was computerized. In 1998, CDC increased communication with state, local, and territorial health departments about foodborne outbreaks and formalized procedures to finalize reports from each state each year. These changes most likely led to a substantial increase in the proportion of outbreaks reported, resulting in a discontinuity in trends during 1997–1998[39] (Figure 2.2).

In 1999, the reporting form was expanded to collect information about a broader range of food items, places, and contributing factors and, in 2001, reporting became Web-based in a system called the electronic Foodborne Outbreak Reporting System (eFORS). Beginning in 2009, eFORS will include modules for reporting waterborne outbreaks and enteric disease outbreaks caused by person-to-person contact and by direct contact with animals. The expanded system will be called the National Outbreak Reporting System.

Figure 2.2 Number of reported foodborne disease outbreaks, United States, 1993-2002 *(from Lynch 2006)*



2.2. Trends in Surveillance

2.2.3. Quality and Usefulness of Surveillance Data

Shortcomings of surveillance information hinder the use and usefulness of the data. These limitations must be considered when viewing these data.

2.2.3.1. Completeness of detection and reporting of foodborne diseases

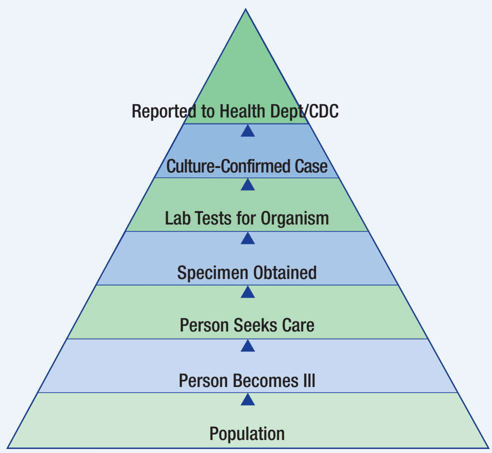
Although the national capacity for detection and surveillance of potentially foodborne disease has improved considerably in the past 20 years,[51] for a number of reasons, surveillance statistics reflect only a fraction of cases: (a) some people do not seek medical attention for vomiting or diarrhea of limited duration or do not seek care because they lack health-care coverage, (b) health-care providers do not always obtain diagnostic tests for illnesses likely to be self-limited, (c) not all types of infections can be diagnosed with routine laboratory testing, and (d) laboratories and health-care providers may fail to report the illness to their local public health agency.[6,52,69,70]

For example, according to a population-based survey undertaken in 1996–97 in selected states, only 12% of persons with a diarrheal illness (14.6% of those with bloody diarrhea and 11.6% of those with non-bloody diarrhea) sought medical care. Among those who sought medical care, 21% were asked by their physician to provide a stool specimen for culture, and 89% of these complied with this request.[71]

As a result, cases of foodborne illness are lost at each step in the diagnosis and reporting process and thus are not included in national statistics. Some investigators portray this disparity between the occurrence of foodborne illness and the reporting of cases to the health department by using a burden of illness pyramid[44] (Figure 2.3).

Key to the success of surveillance is confirmation of the agent causing a foodborne disease. However, because most diarrheal illnesses are self-limited and laboratory test results often are not used to guide the initial course of treatment for a patient, health-care providers often do not request stool cultures. Physicians are more likely to request a culture for persons with acquired immunodeficiency syndrome, history of travel to a developing country, bloody stools, diarrhea of >3 days' duration, or fever or who require intravenous rehydration.[70]

Figure 2.3 Burden of illness pyramid reflecting the proportion of foodborne illnesses that make it through each step of the diagnosis and reporting process. (*from Angulo, et al., 1998)*



Lack of laboratory confirmation can hinder appropriate management and treatment of the individual patient with acute diarrhea and inhibit surveillance and other public health actions.[70,72] For the individual patient, identification of the specific agent can

- Help in the appropriate selection of antimicrobial therapy, shortening the patient's illness and reducing morbidity.
- Support the decision not to treat, if the patient would not benefit from antimicrobial therapy or would even be harmed by the use of antibiotics (e.g., prolongation of the carrier state with salmonellosis).

2.2. Trends in Surveillance

- Guide the use of invasive diagnostic techniques (e.g., avoid colonoscopy if an infectious etiology is identified).

From a public health perspective, an pathogen-specific diagnosis and prompt notification of public health authorities can[70,72]

- Enhance actions to prevent the spread of infection to others through patient education and exclusion of ill persons from food preparation or care of individuals at increased risk for poor outcomes from foodborne diseases.
- Allow tracking of trends in foodborne diseases through surveillance.
- Enhance the detection and control of outbreaks, particularly outbreaks caused by low-level contamination of food or exposures over a wide geographic area.
- Provide antimicrobial sensitivity data for the community.
- Prevent the emergence of drug resistance through the more judicious use of antibiotics and avoidance of broad-spectrum antibiotics.

Although the costs associated with laboratory testing are an important consideration, diagnostic stool testing provides information for both individual patient care and public health purposes. Health-care providers need improved parameters for stool testing.

2.2.3.2. Quality and usefulness of information collected

Unfortunately, public health surveillance and outbreak investigation programs have evolved independently from food-safety programs, and current human health statistics address the questions of communicable disease control authorities better than the questions of food control authorities.[73]

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

Before October 1999, contributing factor data were reported and summarized into five broad categories: Improper storage or holding temperature; Inadequate cooking; contaminated equipment or working surfaces; food acquisition from unsafe source; poor personal hygiene of food handler; and other. Food control authorities used the information, but the broad categories were not detailed enough and did not fully meet their needs. Articles by Bryan et al., Guzewich et al., and Todd et al.[41,40,74,75] framed information gleaned from foodborne disease surveillance systems in terms of the key end user—those charged with foodborne disease prevention. One article was devoted to data on vehicles and contributory factors and described the value and limitations of these data, as well as how they can be summarized and presented.[75] The article included a recommended list of specific contributing factors to be reported. To meet the needs of data users, CDC incorporated the contributing factors suggested by Bryan into the new foodborne outbreak reporting form in October 1999. Another factor, glove-handed contact by handler/worker/preparer, was added.

Although CDC adjusted the foodborne outbreak reporting form to address the needs of system users with regard to contributing factor data, the change is not without controversy among those who report and use this information. Some question whether food control authorities have the expertise to accurately identify the most likely contributing factors from among the now complicated list of factors. Some believe the contributing

2.2. Trends in Surveillance

factor list is too complex for a surveillance system and should be removed entirely or returned to the pre-1999 abbreviated list. Still others believe without a context for the factors reported—even the pre-1999 abbreviated list of factors has limited, if any, value. As new information becomes available about the value of specific data elements, the contributing factor surveillance system, like all surveillance systems, will continue to evolve.

2.3. Etiologic Agents Associated with Foodborne Diseases

2.3.1. Overview

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 (Table 2.1). These agents cause human disease through a number of mechanisms and are often categorized into those caused by toxins present in food before it is ingested (preformed toxins) and those caused by multiplication of the pathogen in the host and damage resulting from toxins produced within the host (enterotoxins) or adherence to or invasion of host cells (infection).

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

- American Public Health Association. *Control of Communicable Diseases Manual*. Washington, DC: APHA;2008.
- CDC. CDC A–Z Index. Available at http://www.cdc.gov/az/a.html
- U.S. Food and Drug Administration. The Bad Bug Book. Available at http://www.foodsafety.gov/~mow/intro.html
- International Association of Milk, Food and Environmental Sanitarians. *Procedures to Investigate Foodborne Illness*. 5th edition. Des Moines, Iowa: IAMFES (reprinted 2004).
- CDC. Diagnosis and management of foodborne illnesses: A primer for physicians and other health-care professionals. Morb Mortal Wkly Rep 2004:53(RR-4). Available at http://www.ama-assn.org/ama/pub/category/3629.html

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

TYPE OF AGENT	GENERAL MECHANISM OF ACTION	EXAMPLE
Bacteria	Preformed toxin	*Bacillus cereus* *Clostridium botulinum* *Staphylococcus aureus*
	Infection and production of enterotoxins	*Bacillus cereus* *Clostridium botulinum* *Clostridium perfringens* *Enterohemorrhagic Escherichia coli* Enterotoxigenic *E. coli (STEC)* *Vibrio cholerae*

2.3. Etiologic Agents Associated with Foodborne Diseases

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

TYPE OF AGENT	GENERAL MECHANISM OF ACTION	EXAMPLE
	Infection	*Bacillus anthracis* *Brucella spp. (B. melitensis, B. abortus, B. suis)* *Campylobacter jejuni* Enteroinvasive *E. coli* *Listeria monocytogenes* *Plesiomonas shigelloides* *Salmonella spp.* *Shigella spp.* *Streptococcus pyogenes* *Vibrio parahaemolyticus* *Vibrio vulnificus* *Yersinia enterocolytica and Y. pseudotuberculosis*
Virus	Infection	Hepatitis A Norovirus (and other caliciviruses) Rotavirus Astroviruses, adenoviruses, parvoviruses
Parasite	Infection	*Cryptosporidium* *Cyclospora cayetanensis* *Diphyllobothrium latum* *Entamoeba histolytica* *Giardia lamblia* *Taenia saginata* *Taenia solium* *Toxoplasma gondii* *Trichinella spiralis*
Marine algae toxins	Preformed toxin	Brevetoxin (neurotoxic shellfish poisoning) Ciguatoxin (ciguatera) Domoic acid (amnestic shellfish poisoning) Saxitoxin (paralytic shellfish poisoning)
Fungal toxins	Preformed toxin	Aflatoxin Mushroom toxins (amanitin, ibotenic acid, museinol, muscarine, and psilocybin)
Fish toxins	Preformed toxin	Gempylotoxin (escolar) Scombrotoxin (histamine fish poisoning) Tetrodotoxin (puffer fish)
Chemicals		Antimony Arsenic Cadmium Copper Fluoride Lead Mercury Nitrites Pesticides (e.g., organophosphates, carbamate) Thallium Tin Zinc

2.3. Etiologic Agents Associated with Foodborne Diseases

2.3.2. Patterns in Etiologic Agents Associated with Foodborne Disease Outbreaks

Patterns in the agents causing foodborne disease outbreaks have been identified through the voluntary reporting of outbreaks to CDC through eFORS. In the most recent CDC surveillance summary of U.S. foodborne disease outbreaks (covering 1998–2002), bacteria (including their toxins) accounted for 55% of reported outbreaks that had an identified cause (Figure 2.4). The most common bacteria were Salmonella, E. *coli, Clostridium perfringens, Staphylococcus aureus, Shigella, Campylobacter, Bacillus cereus*, and *Vibrio* species (Figure 2.5). *Listeria monocytogenes* and *Clostridium botulinum* also were reported but were less common, bacterial causes of foodborne disease.[39]

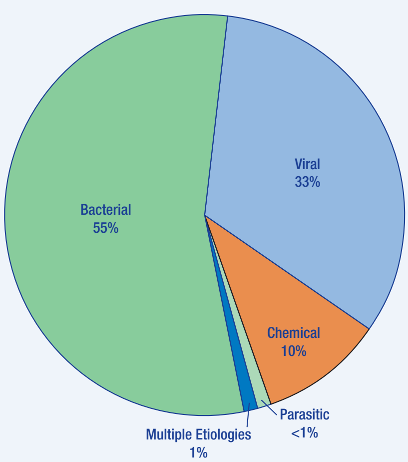
During the same surveillance period, viruses constituted 33% of identified causes of foodborne disease outbreaks, increasing from 16% in 1998 to 42% in 2002. (In 2006, 54% of outbreaks with a known etiology resulted from viruses.[76]) The increase in proportion of outbreaks from viral pathogens probably reflects the increased availability of methods to diagnose viral agents in recent years.[39,77] During 1998–2002, noroviruses were the most common viral cause of foodborne outbreaks (93%), followed by hepatitis A (7%). Astroviruses and rotaviruses played a minor role in foodborne disease outbreaks.

Parasites accounted for 0.3% of outbreaks with identified etiologies. *Cryptosporidium*, *Cyclospora*, and *Trichinella* each constituted 0.1% of reports.[39, 78]

Marine algae and fish toxins, mushroom toxins, and other chemicals accounted for 10% of outbreaks with an identified cause. The most commonly reported chemical causes were scombrotoxin (54%) and ciguatoxin (38%). Only 0.02% of outbreaks with a known etiology were caused by heavy metals and other chemicals.[39]

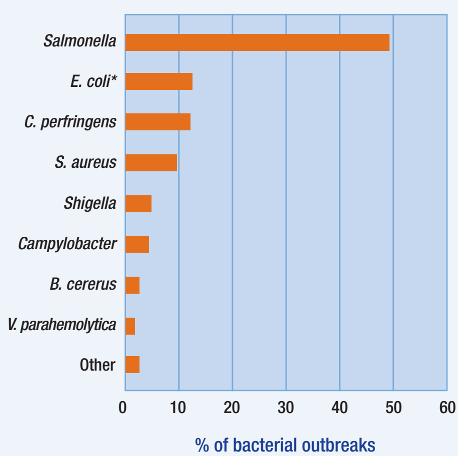
For a large proportion (67%) of outbreaks reported during 1998–2002, no etiologic agent was identified. Reasons include inadequate collection of stool specimens, delay in the

Figure 2.4 Foodborne disease outbreaks by confirmed etiology, United States, 1998–-2002* *(from Lynch, 2006)*



*Includes only outbreaks for which an etiology was determined. For 67% of outbreaks, no etiologic agent was identified.

Figure 2.5 Distribution of bacterial foodborne disease outbreaks by etiologic agent, United States, 1998–2002 *(from Lynch, 2006)*



*Most foodborne outbreaks caused by E. coli were STEC.

2.3. Etiologic Agents Associated with Foodborne Diseases

collection of specimens, and inappropriate testing of specimens.[79, 80] Because laboratory methods for confirming viral disease are less available than tests for bacteria, many outbreaks of foodborne illness from viruses probably fall into the "unknown etiologic agent" category.[79]

In addition, not all outbreaks are detected, investigated, and reported through eFORS. Outbreaks that are most likely to be brought to the attention of public health authorities include those that can cause serious illness, hospitalization, or death.[39] Furthermore, outbreaks of diseases characterized by a short incubation period, such as those caused by a chemical agent or staphylococcal enterotoxin, are more likely to be recognized than diseases with longer incubation periods, such as hepatitis A.[79] Therefore, the relative frequency of various causes of foodborne disease outbreaks based on eFORS or similar data should be interpreted with caution.

2.3.3. Determining the Etiologic Agent in an Outbreak

2.3.3.1. Laboratory confirmation of etiologic agent

Laboratory testing of clinical specimens from cases is critical in determining the etiology of a suspected foodborne disease outbreak and implementation of appropriate control measures. For most foodborne diseases, stool is the specimen of choice; however, blood, vomitus, or other tissue or body fluid occasionally are indicated. Specimens are collected as soon as possible after onset of illness from at least 10 individuals who manifest illness typical of the outbreak and who have not undergone antibiotic treatment. Methods for collection, storage, and transport vary depending on the suspected agent (e.g., bacteria, virus, parasite).[39,81,82]

Isolation of the causative agent from a suspected food item can provide some of the most convincing evidence of the source of a foodborne outbreak. Food testing, however, has inherent limitations. Specific contaminants or foods might require special collection and testing techniques, and demonstration of an agent in food is not always possible. Furthermore, results of testing are often difficult to interpret. Because contaminants in food change with time, samples collected during an investigation might not be representative of those ingested when the outbreak occurred. Subsequent handling or processing of food might result in the death of microorganisms, multiplication of microorganisms originally present at low levels, or introduction of new contaminants. If contamination of the food is not uniform, the sample collected might miss the contaminated portion. Finally, because food is usually not sterile, microorganisms can be isolated from samples but not be responsible for the illness under investigation. As a result, food testing should not be undertaken routinely but should be based on meaningful associations.

2.3.3.2. Other clues to the etiologic agent

While awaiting laboratory confirmation, the following information can help shorten the list of likely agents causing an outbreak:

- Predominant signs and symptoms among ill individuals,
- Incubation period, if known,
- Duration of illness, and
- Suspected food, if known.

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

Note: Determining the incubation period for an illness (i.e., the time from exposure to the etiologic agent to development of symptoms) is influenced by whether the calculation is based on the onset of prodromal symptoms that occur early in the course of an illness (e.g., general feeling of being unwell) or

2.3. Etiologic Agents Associated with Foodborne Diseases

specific signs of enteric disease (e.g., vomiting or diarrhea) that may occur a bit later during the illness. Because the onset of the latter typically is more clearly recalled by cases, some investigators consistently use the onset of these "harder" symptoms to calculate the incubation period.

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

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

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

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

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

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

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

The necessary growth of the microorganism, damage of tissues, and production and release of toxins takes time. Thus, the incubation periods for infections are relatively long, often days, compared with minutes or hours as with preformed toxins. The incubation periods for viruses (excluding hepatitis A) tend to be shorter than for bacteria which tend to be shorter than the incubation periods for most parasites.

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

2.3.3.2.2. Suspected food

Certain microorganisms are associated with certain food items because the food derives from an animal reservoir of the microorganism or the food provides conditions necessary for the survival and growth of the organism. As a result, the food item suspected in an outbreak, if known, occasionally can provide insight into the etiologic agent (Table 2.2). However, most foods can be associated with a variety of etiologic agents, and new vehicles for transmission emerge each year. Therefore, care must be taken in inferring the etiologic agent based on the suspected food item.

2.3. Etiologic Agents Associated with Foodborne Diseases

Table 2.2. Examples of food items and commonly associated microorganisms (from Chamberlain 2008)[83]

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

2.3.4. Mode of Transmission

Many agents responsible for foodborne illness also can be transmitted by other routes, such as water, person to person, and animal to person transmission. For example, it is estimated that only 20% of shigellosis cases, 10% of cryptosporidiosis cases, and 40% of norovirus infections result from foodborne transmission.[38] Consequently, early in the investigation of a potential foodborne disease outbreak, investigators should consider all potential sources of transmission and collect information from ill persons about sources of water, exposure to other ill persons and child care settings, contact with animals, and food and other exposures.

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 and allow investigators to focus on investigating that source.

2.3.4.1. Transmission by a food

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

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

2.3.4.2. Transmission by water

The following clues might be suggestive of transmission of an agent by public drinking water:

- Widespread illness affecting both sexes and all age groups;
- Geographic distribution of cases consistent with public water distribution but not food distribution patterns (e.g., limited to individuals residing within city limits);

2.3. Etiologic Agents Associated with Foodborne Diseases

- Absence of cases among breast-fed babies or individuals who drink only bottled water or beverages from boiled water;
- Dose-response with increasing attack rates among persons drinking more water;
- Concurrent complaints about water quality in the affected community; and
- Involvement of multiple pathogens.

A clustering of cases adjacent to cattle ranches or farms that are served by well water might suggest transmission by contaminated well water. A clustering of cases among children, particularly those who have shared a common recreational water exposure such as a water park, community pool, or lake might suggest transmission by recreational water.

2.3.4.3. Transmission from person to person

Person-to-person transmission should be suspected when:

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

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CHAPTER 3

Planning and Preparation

The primary goal of a foodborne disease outbreak investigation is to identify the processes that led to food contamination or pathogen transmission and to implement control measures as quickly as possible to halt transmission of illness. Another goal is to understand the reasons for the outbreak well enough to prevent similar outbreaks. Good planning and preparation, including the right expertise in the investigation and rapidly sharing investigation findings can accomplish these goals.

The early days of an investigation are critical. Ideally an agency should always be prepared for an investigation so it will spend as little time as possible getting organized once an outbreak is identified. This chapter describes the roles of the major organizations involved in foodborne disease outbreak response and highlights the resources, processes, and relationships that should be in place before an outbreak.

3.0. Introduction

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

3.1. Agency Roles

3.1.1. Overview

A foodborne disease outbreak may be managed solely by a single local agency or may become the shared responsibility of multiple local, state, and federal agencies. The nature of the outbreak, including the type of pathogen, the suspected or implicated vehicle, the number and location of affected persons, the geographic jurisdictions involved and the local and state food-safety rules and laws will determine the types of agencies that need to be involved. Outbreak response will also be influenced by agencies' roles and responsibilities and typically available resources. Each agency's response plan should include its likely role in a foodborne disease outbreak investigation, staff (or positions) that may be involved, contact information for relevant external agencies, and communication and escalation procedures for working with those agencies.

3.1.2. Local, State, and Federal Agencies

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

3.1.2.1. Local health agencies

- Roles and responsibilities
  Conduct surveillance; receive complaints about potential foodborne diseases; maintain and routinely review log of complaints; routinely communicate with local health-care professionals; regulate food-service operations; routinely inspect food-service operations; investigate complaints; implement control measures to stop outbreaks; educate food workers on preventing outbreaks of foodborne disease; inform the public and the media; serve as liaison with local industry representatives and with the state and federal public health and food-safety regulatory agencies. May also provide advanced laboratory testing, including subtyping, such as molecular fingerprinting in PulseNet.
- Resources
  Vary by agency but may include expertise in epidemiologic and environmental outbreak investigation and response; and health information and promotion information for dissemination to the public. Extensive knowledge of local populations and community businesses, health-care providers and organizations, and other resources.
- Contribution to outbreak investigation and response
  Detect foodborne diseases; identify local outbreaks; know about suspected facilities

3.1. Agency Roles

(e.g., facility inspection reports, previous complaints); support recall efforts; know affected communities; know local health-care professionals and diagnostic practices.

3.1.2.2. State agencies—health department

- Roles and responsibilities
  Conduct surveillance; identify local and statewide outbreaks; coordinate multijurisdictional outbreaks; provide advanced laboratory testing, including molecular fingerprinting in PulseNet; support or direct environmental, laboratory, and epidemiologic investigations with advanced expertise; provide health education and promotion materials; maintain tools for collecting and analyzing outbreak-associated information; provide public information; provide legal support for outbreak investigation and control; promote statewide policies to increase food safety; serve as liaison and coordinate communication with other state, local, and federal agencies; disseminate information to local agencies. May conduct investigations in local areas were there is no local health agency with jurisdiction.
- Resources
  Expertise in epidemiologic and environmental outbreak investigation and response (including traceback investigations); expertise in specific disease agents; advanced laboratory testing with expertise in microbial analyses and identification through their state laboratories; tools for collecting and analyzing outbreak-associated information; health information and promotion information (often in multiple languages) for dissemination to the public; additional staff to aid in outbreak investigations.
- Contribution to outbreak investigation and response
  Epidemiologic, environmental, and laboratory support for local health agencies; coordination of multijurisdictional outbreaks.

3.1.2.3. State agencies—environmental conservation or quality

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

- Roles and responsibilities
  Support or direct environmental testing; provide advanced laboratory testing of food or environmental samples; provide educational materials and public information about environmental and food safety; maintain tools for collecting and analyzing outbreak-associated information; promote statewide policies to increase food and environmental safety; serve as liaison with other state, local, and federal agencies; disseminate information to local agencies.
- Resources
  Expertise in environmental and food-safety investigation and response; advanced laboratory testing with expertise in microbial analyses and identification; additional staff to aid in outbreak investigations.
- Contribution to outbreak investigation and response
  Environmental investigation and laboratory support for local health agencies.

3.1.2.4. State agencies—food-safety regulatory authorities

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

- Roles and responsibilities
  Ensure good manufacturing practices in commercial food operations; test dairy, meat, and food products for microbial contamination; inspect plant after an outbreak; coordinate food recalls carried out by industry; and stop sales of adulterated product within their jurisdiction. Conduct regulatory sanitation inspections at retail establishments such as grocery stores, supermarkets and warehouses. Consult with health departments in outbreak

3.1. Agency Roles

investigations (e.g., with knowledge of food production and distribution and information provided by industry that may contribute to the success of the investigations) and to direct plant inspections by thoroughly understanding the epidemiologic, environmental, and laboratory data.

- Resources
  Expertise in food manufacturing and distribution; staff to conduct plant inspections and specialized testing of dairy, meat, and food products; expertise in regulatory tracebacks. Laboratory support, usually involving surveillance for food adulterants, including chemical, physical, and microbiologic adulterants and contaminants.
- Contribution to outbreak investigation and response
  Support investigations that involve commercially distributed food products through consultation with health department investigators, plant inspections, traceback investigations, and food recalls.

3.1.2.5. Federal agencies—Centers for Disease Control and Prevention

- Roles and responsibilities
  Conducts or coordinates national surveillance for illnesses caused by pathogens commonly transmitted through food and for outbreaks of foodborne diseases of any cause; leads and supports the national surveillance networks, Public Health Laboratory Information System (PHLIS), Foodnet, PulseNet, EHS-Net, and CDC's electronic Foodborne Outbreak Reporting System (eFORS); maintains clinical, epidemiologic, and laboratory expertise in pathogens of public health importance; develops and implements better tools for public health surveillance; provides consultation, assistance, and leadership in outbreak investigations; improves and standardizes laboratory testing methods for foodborne disease organisms; provides advanced laboratory testing; facilitates coordination among jurisdictions within multijurisdictional outbreaks where appropriate; coordinates communication with other federal agencies; provides training in methods; coordinates and collaborates with international surveillance, communication, and training methods; regulates ships that travel to international ports.
- Resources
  Experts (or trainees) in clinical, epidemiologic, and environmental health aspects to assist with cluster evaluation and outbreak investigations; advanced laboratory capacity (including resources to develop new testing methodologies); surge capacity to assist in large outbreaks; tools for collecting and analyzing outbreak-associated information; training programs; educational materials for the public.
- Contribution to outbreak investigation and response
  Assistance in single jurisdiction outbreaks upon request of the jurisdiction; leadership, coordination, and logistics support and coordination for multijurisdictional outbreaks; centralized data collection and analysis for large multistate outbreaks; assistance in outbreaks from new or rare disease agents or from new modes of transmission of known disease agents; advanced laboratory testing; availability of additional personnel and other resources to aid local and state health agencies; conduit to other federal agencies.

3.1.2.6. Federal agencies—Food and Drug Administration

- Roles and responsibilities
  Regulates the safety of most foods (except meat, poultry, and pasteurized egg products, which are regulated by USDA's Food Safety and Inspection Service [FSIS]); regulates food additives and food labeling for FDA-regulated foods; oversees seafood and juice

3.1. Agency Roles

regulations for Hazard Analysis and Critical Control Point; oversees imported food products under FDA jurisdiction; conducts research into foodborne contaminants; inspects food-processing plants; conducts food industry postmarket surveillance and compliance; oversees regulatory traceback investigations and recalls of the food products it regulates; publishes the Food Code; regulates ships that travel interstate such as on rivers and intercoastal waters and trains and buses that travel interstate.

- Resources
  Twenty district offices located in five regions, providing coordination, field investigators, laboratory support, technical consultation, regulatory support, and media relations; policy, technical, and scientific support to foodborne disease outbreak investigations provided by FDA's Center for Food Safety and Applied Nutrition (CFSAN); education materials for the public.
- Contribution to outbreak investigation and response
  Once an FDA-regulated product is strongly suspected as the cause of an outbreak, identification of product source and extent of its distribution; testing of product obtained from commerce or production; traceback and factory investigations; prevention of further exposure to contaminated product; and initiation of regulatory action, including requesting recalls if indicated; assistance to the Federal Bureau of Investigation (FBI) when deliberate contamination of food is suspected by providing technical, investigatory, and laboratory support for FDA-regulated products.

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

- Roles and responsibilities
  Ensures the nation's commercial supply of meat, poultry, and pasteurized egg products is safe, wholesome, and correctly labeled and packaged through a national program of inspection, investigation, and enforcement; provides data analysis, advice, and recommendations on food safety; conducts microbiologic testing of meat and poultry products; responds to foodborne illnesses, intentional food contamination, and major threats to FSIS-regulated products, including overseeing recalls for contaminated meat and poultry products; conducts audits to determine the equivalency of foreign food-safety systems and re-inspecting imported meat, poultry, and egg products; develops public information and education programs for consumers.
- Resources
  Approximately 7600 inspection program personnel in more than 6000 federally regulated establishments nationwide coordinated by 15 district offices; three field laboratories, including the Outbreaks Section of Eastern Laboratory in Athens, Georgia; field investigators with expertise in inspection, traceback, and enforcement; personnel with expertise in food-safety science; educational materials and guidance for consumers.
- Contribution to outbreak investigation and response
  Assistance, traceback coordination, and epidemiologic consultation during investigations involving FSIS-regulated meat, poultry, and egg products; testing of product from commerce or production; ability to take enforcement and regulatory control actions against food manufacturers and distributors; assistance in working with international food manufacturers and distributors; consultation to public health and state agriculture agencies.

3.1. Agency Roles

3.1.3. Other Agencies

Outbreaks can occur in facilities or communities managed by agencies that have some level of autonomy and operate their own public health programs. Such agencies include tribes, the military, and the U.S. Department of the Interior (National Park Service [NPS]). Local, state, and federal public health agencies need to understand the jurisdictional issues involved in outbreaks in these settings, these groups' resources, and establishment of relationships with them.

Outbreaks also can be associated with intentional contamination. If that is suspected, the FBI has a role in the investigation.

3.1.3.1. Tribes

- Jurisdiction
  Varies by tribal organization, but in general the tribes have complete sovereignty and are completely autonomous. Investigations may be conducted by tribal health staff, Indian Health Services (IHS) staff, or state or local health departments, but nontribal entities can become involved in an investigation only at the tribe's request. No legal requirement exists for reporting a foodborne disease outbreak to any public health officials. Control measures typically are implemented by IHS staff in cooperation with tribal government but can be implemented only when authorized by tribal government.
- Relationships
  Outbreaks may be detected by IHS staff or by tribal members and reported to IHS. IHS notifies the appropriate state and local health departments. Some tribes also may notify the local or state health department or CDC. State and local health department staff need to develop relationships with IHS public health staff, tribal health staff (if any), and tribal leadership in tribal areas within or adjacent to the public health agency's jurisdiction. During an outbreak, communication should be ongoing not only between state or local health department and IHS but also directly with tribal government. IHS has developed tribal epidemiology centers to provide regional epidemiology capacity for multiple tribes. These centers are run by tribal boards and focus on health issues selected by the boards. They may become involved in outbreak investigations and are a good place to promote routine communication. IHS is a good source of information about coordinating public health issues with tribes.
- Resources for outbreak investigation and response
  IHS has many public health staff, including sanitarians and public health nurses, at clinics on many tribal lands. These staff most likely would handle an outbreak and would request help from IHS, the state, or CDC if needed. Some tribes have public health staff, but most do not have public health laws or capacity to respond to outbreaks.

3.1.3.2. Military

- Jurisdiction
  Autonomous authority over all military bases, facilities (including food-production and food-service facilities and health-care service facilities), and vehicles. The particular branch of the military involved and the U.S. Department of Defense maintain public health responsibility.
- Relationships
  Military public health personnel communicate with local and state health agencies for outbreaks that might involve civilians. Local and state health agencies should establish communication with the public health staff of any military facilities within or adjacent to their jurisdiction before any outbreaks. Other branches of the military and other federal agencies communicate through the Foodborne Outbreak Response Coordinating Group.

3.1. Agency Roles

- Resources for outbreak investigation and response
  Military agencies conduct training in food safety and epidemiology; inspect and test food-production and food-processing facilities and delivered food products; and coordinate these programs with other military and federal agencies. Preventive Medicine and Environmental Health Officers in each branch direct and conduct epidemiologic investigations of foodborne disease outbreaks and make recommendations. Veterinary Officers conduct traceback investigations. The Department of Defense has officers trained in public health, environmental health, epidemiology, microbiology, toxicology, pathology, and food technology who can coordinate and support outbreak investigations.

3.1.3.3. National Park Service

- Jurisdiction
  Jurisdiction in National Parks is a function of the legislation designating the specific park. Three types of jurisdiction exist: (a) exclusive federal jurisdiction; (b) concurrent jurisdiction with state and local agencies; and (c) proprietary (owned by the federal government but sometimes operated by local entity and depending on support from local police, fire departments, and others for services).
- Relationships
  Notifies relevant local and state health departments of suspected outbreaks. Notifies appropriate federal agency if commercial product is suspected. Works closely with CDC. Relies on CDC or state health departments for laboratory testing. Local and state health agencies whose jurisdiction contains or is adjacent to a national park should establish communication with the NPS Office of Public Health before any outbreaks. Where appropriate, local and state health departments should include questions about visiting parks when they conduct interviews during an investigation and notify NPS if a park might be involved.
- Resources for outbreak investigation and response
  Epidemiology expertise including a medical epidemiologist in the NPS Office of Public Health; U.S. Public Health Service staff assigned to NPS to conduct investigations (including regional public health consultants based around the country); park rangers who have extensive knowledge of their jurisdiction and the population that visits that jurisdiction; scientists in the NPS system with a wide range of expertise (e.g., veterinarians, water specialists); contractors who run park operations on behalf of NPS.

3.1.3.4. Other federal lands

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

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

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

3.1. Agency Roles

- Resources
  Knowledge of and information about product identities, formulations, processing practices and distribution patterns to assist with outbreak hypothesis testing and product/ingredient tracing. Some industry members have expertise in microbiology and food-safety research.
- Contribution to outbreak investigation and response
  Source of information about the products and practices under investigation, including customers that have purchased the products; outbreak hypothesis testing; mechanisms for withdrawing/recalling products from the marketplace.

3.2. Outbreak Investigation and Control Team

3.2.1. Overview

The responsibility for investigating foodborne disease outbreaks and implementing control measures falls on a team of people who each contribute different knowledge and skills. Depending on the size and scope of the investigation, the size of the team varies from 1 or 2 to hundreds. In smaller investigations, individuals may wear many hats concurrently. A team is more likely to effectively and efficiently respond to the outbreak if team members combine their strengths and collaborate.

Team members' assigned tasks and their knowledge and skills define their roles. Job titles alone may not accurately indicate who does what. Members may come from different programs within an agency or from different agencies. Membership in the outbreak response team may vary depending on the specifics of the outbreak—for example, different disease organisms or different outbreak settings require different skills or agency associations. In many investigations, roles are defined relatively informally and may change as the investigation unfolds.

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

Most importantly, team members should work closely as a team. Their roles are not mutually exclusive—for example, epidemiologists can help laboratorians; environmental health specialists can help enpidemiologists. Furthermore, the work of 1 team member often builds on the work of others. The team cannot succeed without a strong working relationship and ongoing, effective communication among its members.

3.2.2. Roles of Core Team Member

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

3.2.2.1. Team leader

- Responsibilities
  Sets and enforces priorities; coordinates all activities associated with the investigation; serves as the point of contact about the investigation; coordinates content of messages to the public through the public information officer (PIO); communicates with other organizations involved in the investigation; communicates recommended course of action determined by team to agency decision-makers.
- Desirable skills
  Should include organization of investigation information; general knowledge of all elements of an outbreak investigation and the roles of each team member; specific expertise with outbreak investigation methods and

3.2. Outbreak Investigation and Control Team

with foodborne infections; understanding of roles of all agencies involved in investigation; ability to communicate; leadership skills.

3.2.2.2. Epidemiologic investigator

- Responsibilities
  Identifies cases; develops hypotheses and strategies to test them; interviews both cases and healthy controls; plans epidemiologic studies; collects and analyzes investigation data using statistical analyses or in collaboration with a statistician; reports results; collects clinical specimens; coordinates testing of clinical specimens and environmental samples; consults and coordinates with environmental and laboratory investigators.
- Desirable skills
  Ability to rapidly assess a situation; interpret surveillance information; design epidemiologic studies (e.g., case-control studies, cohort studies, and surveys) and develop questionnaires; conduct epidemiologic studies; conduct interviews, including hypothesis-generating interviews; with assistance from the laboratory investigator, identify appropriate clinical tests for suspected pathogens; and analyze and interpret data using standard epidemiologic methods as defined in the Applied Epidemiology Competencies, including measures of association and tests of statistical significance (www.cste.org).

3.2.2.3. Environmental investigator

- Responsibilities
  Investigates food-preparation sites, including sites involved with growing, raising, processing, manufacturing, packaging, storing, and preparing food; collects environmental and food samples; reports results; arranges for testing of samples; coordinates food sampling, management and testing procedures with laboratory investigator; interviews food workers and managers; reviews food-preparation and food-handling records; reviews food inventory and distribution records, food flow, and contributing factors; consults with epidemiologic and laboratory investigators. May also interview cases, collect stool samples, and conduct traceback investigations.
- Desirable skills
  Ability to investigate food-production and preparation processes; conduct interviews; and collect food and environmental samples. Knowledge about causative agent (e.g., likely sources, optimum growth conditions, inhibitory substances, means of inactivation), factors necessary to cause illness (e.g., infectious dose, portal of entry), and implicated vehicle (e.g., physical and chemical characteristics of the vehicle that might facilitate or inhibit growth, methods of production, processing, and preparation).

3.2.2.4. Laboratory investigator

- Responsibilities
  Analyzes clinical specimens, food and environmental samples (depending on the state, the food and environmental samples may be tested in different laboratories than the clinical specimens); interprets test results and suggests follow-up testing; reports results; coordinates testing among laboratories; advises other team members about laboratory testing, including collection, handling, storage, and transport of specimens.
- Desirable skills
  Varies with the suspected outbreak agent(s) but may include knowledge of classical or molecular microbiology and organic or inorganic chemistry or radiochemistry. Whether testing food and environmental samples, clinical specimens, or both, the laboratory investigator should be familiar with optimal specimen or sample types and with transport and storage conditions, including chain of custody, testing methodologies, and relevant laboratory-based networks (e.g., PulseNet).

3.2. Outbreak Investigation and Control Team

3.2.2.5. Public information officer

- Responsibilities
  Develops general and specific messages for the public through the media; responds to media inquiries or identifies the appropriate spokesperson; coordinates communication with multiple agencies; disseminates information about outbreak status and overall policies, goals and objectives to widespread and diverse audiences that include the executive and legislative branches of the government; local governments; the general public; and the local, state, and national news media.
- Desirable skills
  Ability to prepare health education messages and press releases using best practices in health education and risk communications; and speaking and presentation skills. Understanding of mechanisms and protocol for relating to the news media, including press, radio and television. Ability to communicate with a diverse audience with limited scientific knowledge.

3.2.2.6 Additional team members

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

3.2.3. Outbreak Investigation and Control Teams—Model Practices

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

3.2.3.1. Emergency response unit

If the population covered is large enough and the number of foodborne disease outbreaks is high enough, consider establishing a dedicated emergency response unit. This team of senior epidemiologists, environmental scientists, and laboratorians can train and work together and respond to all outbreaks, giving consistency to investigations and allowing development of advanced expertise.

3.2.3.2. Additional support for large-scale outbreaks

Some outbreaks are too large for one agency to manage independently. Advance preparations can help mitigate the impact of a large-scale outbreak and ensure effective response.

- Identify individuals within the agency or from other organizations—such as other branches of government, university students, volunteers (e.g., Medical Reserve Corp)—who would have minimal skills or knowledge and would be willing to help conduct interviews or provide other support during a large-scale outbreak.
- Develop a contact list and protocol for contacting these individuals when needed. Ensure the list includes after-hours and weekend contact information, and assign an individual or group to update it regularly.
- Develop training and job description(s) for these individuals. If possible, provide on-the-job training specific to their assigned tasks and their roles in the overall investigation. Such training could occur shortly before performance of the necessary task.

3.2.3.3. Agency-specific response protocol and other resources

At a minimum, the outbreak control team should have been trained in specific

3.2. Outbreak Investigation and Control Team

preidentified protocols. The team also needs access to additional resources that can help answer questions and provide information for decision-making during an outbreak. These protocols and resources should be assembled before an outbreak.

- Prepare a response protocol based on the CIFOR guidelines but customized to the agency's needs with specific information relevant to the agency.
- Prepare a list of people in the agency who should be contacted in the event of an outbreak, including backups, and contact people in external agencies (state, adjacent local health, and federal agencies). Ensure the list includes after-hours and weekend contact information, and update it regularly.
- Assemble a reference library (including online resources) with information about foodborne diseases, enteric illnesses, and control measures. Where possible include electronic resources that can be accessed by laptop computers during field investigations. Regularly review and update the contents of this reference library.
- Assemble a list of resource persons who have expertise in specific disease agents and investigation methodologies.

3.2.3.4. Training for the team

Ongoing training is critical for members of the outbreak control team. The training should include continuing education to maintain and improve skills within their specialty and specific training in the agency's outbreak response protocols and the member's team role. For a larger agency that investigates a large number of outbreaks, this may be on-the-job training. For a smaller agency with a limited number of outbreak investigations, special training opportunities should be arranged.

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

3.3. Resources

3.3.1. Overview

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

3.3.2. Recommended Resources

3.3.2.1. Administrative staff

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

3.3.2.2. Legal counsel

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

3.3.2.3. Equipment

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

3.3.2.4. Supplies

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

Box 3.1. Example supplies for food and water sampling kits

- Sterile sample containers (e.g., plastic bags, wide-mouth plastic and glass jars with screw caps, bottles, whirlpack bags) and mailing instructions
- Sterile and wrapped sample-collection implements (spoons, scoops, tongue-depressor blades, spatulas, swabs, knives)
- Sterilizing and sanitizing agents (e.g., 95% ethyl alcohol, sodium or calcium hypochlorite, alcohol swabs), hand sanitizers, and sanitizer test strips
- Refrigerants (e.g., ice packs), thermometer (0°–220°F), insulated containers
- Labeling and sealing equipment (e.g., fine-point felt-tip marking pen, roll of adhesive or masking tape, waterproof labels or tags, custody tape)
- Forms, including sample collection and blank laboratory submission forms, chain-of-custody and other forms for documenting activities
- Clothing (e.g., disposable plastic gloves, hair restraint, laboratory coat)
- Personal protective equipment (gloves and masks)
- Cell phones or other means to communicate in the field

3.3. Resources

3.3.2.5. Outbreak investigation documents

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

- Chain-of-custody forms
- Food illness complaint worksheets
- Blank disease-specific case report forms
- Laboratory test requisition forms
- Standardized outbreak questionnaires (available at http://www.cdc.gov/foodborneoutbreaks/standard_ques.htm)
- Environmental assessment forms such as hand hygiene assessment (examples available at http://www.cdc.gov/nceh/ehs/EHSNet/)

3.3.2.6. Reference materials

- Books, Web resources for support during outbreak (e.g., CDC's Diseases and Conditions A–Z index)
- Latest version of the American Public Health Association's *Control of Communicable Diseases Manual*
- *Procedures to Investigate Foodborne Illness*, by the International Association for Food Protection

3.4. Complaint Processing

Establish a formal process for receiving complaints from the public. Use a standard process to collect information, including a standard intake form. Collect as much information as possible at the initial call. If possible, a single person should receive or process all illness complaints so patterns can be identified quickly. Alternatively multiple staff could take the calls using standardized data collection forms, which are then reviewed by one individual. Staff receiving calls and backup staff should be trained to give appropriate instructions to callers about prevention of secondary spread and seeking health-care services. Further detail on complaint processing systems is included in Chapter 4.

3.5. Records Management

3.5.1. Overview

Records management is an important element of successful outbreak investigation and response. Appropriately managed records support the outbreak investigation and response team by giving all team members quick access to needed information. Requiring team members to use standard protocols for collecting and organizing information associated with an outbreak can serve a quality assurance role and help ensure that important investigation and response steps are followed. Finally, maintaining good records for each outbreak can help staff identify what went wrong or worked well during the outbreak and can provide valuable information for improving outbreak investigation and response protocols. All information collected about an outbreak should be organized in an electronic database to allow easy searching and analysis.

3.5.2. Recommended Records Management Practices

3.5.2.1. Information collection and sharing

- Identify standardized forms, including illness complaint forms, disease-specific report

3.5. Records Management

forms, and trawling interview questionnaires, for recording information about potential cases (examples of such forms are available through the CIFOR Clearinghouse). These forms may need to be modified in response to the specifics of the current outbreak.

- Train staff in the use of standardized forms to ensure proper completion by all members of the investigation team.
- Determine how and what information from forms and questionnaires can be properly and efficiently shared within the investigation team.
- Determine when and how to share outbreak information with the person or organization in charge of the facility implicated in an outbreak.

3.5.2.2. Data tracking and analysis

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

3.6. Communication

3.6.1. Overview

Good communication is one of the most important factors in successful outbreak control. At all points in the outbreak continuum—from detection through investigation and response to debriefing—communication is critical. Without good communication, investigations and responses can be delayed, uncoordinated, and ineffective. Furthermore, good communication can help allay public concerns and improve industry support for actions to control outbreaks. To promote better outcomes, the time before and between outbreaks should be used to lay the groundwork for communication. This includes developing and updating contact lists, defining communication processes, and establishing relationships with key individuals both internal and external to your agency.

3.6.2. Communication—Model Practices

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

3.6.2.1. Contact lists

Establish and frequently update a contact list (primary phone numbers and alternates, cell phone numbers, 24-hour numbers, home numbers, pagers, e-mail, fax numbers, and addresses) of

- Core members of the outbreak control team;
- Other officials inside the agency, such as the chief of the epidemiology unit, director of the public health laboratory, and the agency director;
- Critical contacts in other government agencies;
- Important food industry contacts, including trade associations;
- Key health-care provider contacts; and
- Primary media contacts.

3.6. Communication

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

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

- Ensure everyone who may be involved in outbreak response knows the other team members.
- Decide on the basis of roles who will be notified when an outbreak is suspected, including any changes in notification according to the nature of the outbreak (e.g., pathogen type, involvement of commercial product) and timing (weekends and holidays versus week days).
- Identify the persons who will be responsible for communication on behalf of their organizational unit (epidemiology, environmental health, laboratory) and for the outbreak control team.
- Determine how confidential information will be stored and whether and how it can be shared.
- Determine who will receive copies of written reports.
- Establish routine communication among the outbreak control team members before an outbreak.
- Define a formal communication process for agencies of the outbreak control team for use during outbreaks. Options include daily phone calls and routine e-mail alerts. Developing a consistent approach to internal communications during an outbreak helps everyone on the team know what to expect.

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

- Distribute a list of your agency's contacts to other agencies, and obtain their contacts.
- Develop standardized templates and processes (including notification triggers and timelines) for sharing information with other agencies, including who will be responsible for notifying the next level of public health agency.
- Foster working relationships with other agencies, holding joint meetings and planning sessions before any outbreaks.
- Establish processes for participating in multiagency, multijurisdiction conference calls, and train staff in appropriate conference call etiquette.
- Determine how confidential information will be stored and whether and how it can be shared.

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

- Create templates for communications with each group (e.g., press releases, fact sheets), focusing on the most common foodborne diseases and customizing by group (e.g., health-care providers, school officials, restaurant managers). Sample materials are available at the CIFOR Clearinghouse.
- Create and test tools for rapid communication with each group (e.g., blast e-mails, blast faxes, Web-based survey instruments).
- Establish routine communications with each group (e.g., newsletters, e-mails), ensuring they will know with whom to communicate, triggers for reporting, and source of information during a foodborne disease outbreak. Be aware that recipients may ignore such communications, so try to make the communications interesting, relevant, succinct, and infrequent.

3.6. Communication

- Determine who will communicate with which groups during an outbreak.

3.6.2.5. Communication with the public

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

3.6.2.6. Communication with cases and family members

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

3.6.2.7. Communication with the media

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

3.7. Planning for Recovery and Follow-Up

3.7.1. Overview

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

3.7. Planning for Recovery and Follow-Up

3.7.2. Recommended Preparations for Recovery and Follow-Up

- Establish standard protocols for actions that must be taken or results that must be achieved before an implicated facility or food source can resume normal operations.
- Establish standard protocols for monitoring an implicated facility or food source if monitoring postoutbreak should be deemed necessary.
- Establish a process for creating after-action reports following investigations, with lessons learned and action items for follow-up and quality improvement.

Detailed information about model practices for recovery and follow-up is included in Chapter 6.

3.8. Legal Preparedness

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

3.9. Escalation

3.9.1. Overview

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

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

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

3.9. Escalation

3.9.2. When to Ask for Help

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

3.9.3. How to Obtain Help

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

3.10. Incident Command System

3.10.1. Overview

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

The role of an ICS response in outbreak investigations varies and is not without controversy. Even within a single investigation, some agencies may use an ICS structure while others do not. In some states and local jurisdictions ICS are formal structures controlled by public safety officials with no other jurisdiction for food safety or outbreak control, which can distract from the conduct of a public health investigation. However, some public health and food-safety agencies are starting to embrace ICS and adapting the ICS structure to meet their needs.

3.10.2. Definition and History of ICS

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

3.10. Incident Command System

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

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

3.10.3. Context for Use

Agencies involved in foodborne disease outbreak investigation and response should decide in advance whether and how to apply an ICS, and, if applicable, incorporate the ICS structure into their response planning. Such planning should be coordinated with all other agencies that may be drawn into the investigation and response over time. Most foodborne disease outbreak investigations do not require formal activation of ICS, but may benefit from application of ICS principles and methods.

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

Early inclusion of ICS principles and methods can prevent problems over the long term. Trying to pick up and implement ICS after an incident has expanded creates many organizational issues for all responders involved. In recent years, federal departments and agencies have begun moving toward making adoption of NIMS by state, tribal, and local organizations a condition for federal preparedness assistance, including grants and contracts.

3.10.4. Training

If an agency elects to apply the ICS structure to its foodborne disease outbreak response, then ICS training should be provided to the outbreak response team before any outbreaks. Ideally that ICS training would use foodborne disease outbreak examples so all team members clearly understand how to use the ICS structure in an outbreak situation.

3.11. Reference

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

CHAPTER

4

Foodborne Disease Surveillance and Outbreak Detection

The term "foodborne disease surveillance" generally refers to the routine monitoring in a population for enteric disease for which a food vehicle may be involved. The actual vehicle usually is not known during the surveillance process, and transmission ultimately could be due to food, water, person-to-person spread, or other vehicles.

One of the primary functions of foodborne disease surveillance and outbreak investigation is to detect problems in food and water production and delivery systems that might otherwise have gone unnoticed. Rapid detection and investigation of outbreaks is a critical first step to abating these active hazards and preventing their further reoccurrence (discussed further in Chapter 5). Broader goals of surveillance include defining the magnitude and burden of disease in the community, providing a platform for applied research, and facilitating understanding of the epidemiology of foodborne diseases.

4.0. Introduction

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

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

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

4.1. Overview

Disease surveillance is used to identify clusters of potential foodborne illness. Investigation methods (Chapter 5) then are used to identify common exposures of ill persons in the cluster that distinguish them from healthy persons. Although, in practice, detecting individual foodborne disease outbreaks involves multiple approaches, three general methods are used in outbreak detection (Table 4.1):

- Pathogen-specific surveillance:
  Health-care providers and laboratorians report individual cases of disease when selected pathogens, such as *Salmonella enterica* or *Escherichia coli* O157:H7, are identified in specimens from patients. This surveillance method also includes specific clinical syndromes with or without laboratory confirmation, such as hemolytic uremic syndrome (HUS) and botulism. Exposure information is gathered by interviews with cases. Data and pathogens collected as part of food, animal, or environmental monitoring programs enhance this surveillance method. The national PulseNet system is an example of pathogen-specific surveillance.
- Notification/complaint systems:
  Health-care providers or the public identify and report suspected disease clusters or independent complaints. Exposure information is acquired by interviews of cases.
- Syndromic surveillance:
  This surveillance method generally involves systematic (usually automated) gathering of data on nonspecific health indicators that may reflect increased disease occurrence, such as use of Immodium®, visits to emergency departments for diarrheal complaints, or calls to poison control hotlines. Exposure information is not routinely collected.

4.1. Overview

Table 4.1. Comparison of foodborne disease surveillance systems

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

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

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

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

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

¶ Exposure histories are not typically obtained.

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

4.1. Overview

This chapter reviews major features, strengths, and limitations of each surveillance method and provides recommendations for increasing the effectiveness of each. Because many agents transmitted by food also can be transmitted by water and from person to person, animal to person, or other mechanisms, outbreaks are not considered "foodborne" until determined by investigation to be so.

4.2. Pathogen-Specific Surveillance

4.2.1. Purpose

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

4.2.2. Background

Surveillance for typhoid fever began in 1912 and was extended to all *Salmonella* in 1942. National serotype-based surveillance of *Salmonella* began in 1963, making it one of the oldest pathogen-specific surveillance programs and the oldest public health laboratory subtype-based surveillance system. The usefulness of pathogen-specific surveillance is related to the specificity with which agents are classified (i.e., use of subtyping and method), permitting individual cases of disease to be grouped with other cases most likely to share a common food source or other exposure. This type of surveillance greatly expanded during the 1990s with the development of PulseNet and molecular subtyping of selected foodborne diseases, including *Salmonella*, *Escherichia coli* O157:H7, *Shigella*, *Listeria*, and *Campylobacter*.

4.2.3. Case Reporting and Laboratory Submission Process

Most diseases included under pathogen-specific surveillance are reportable (i.e., notifiable) diseases. State or local health agencies establish criteria for voluntary or mandatory reporting of infectious diseases, including those that might be foodborne (Box 4.1). These criteria describe the diseases to report, to whom, how, and in what time frame. For this type of surveillance, diseases are defined by specific laboratory findings, such as isolation of *Salmonella enterica*, or by well-defined syndromes, such as HUS. Diseases are reported primarily by laboratories, medical staff (e.g., physicians, infection-control practitioners, medical records clerks), or both. Diseases can be reported by telephone, mail, or fax; through a secure website; or automatically through reports generated from an electronic medical record or laboratory information

Box 4.1. Selected nationally notifiable diseases that can be foodborne

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

From CDC. Nationally Notifiable Infectious Diseases. United States 2008. Revised. Available at: http://www.cdc.gov/ncphi/disss/nndss/phs/infdis.htm.

4.2. Pathogen-Specific Surveillance

system. In addition, isolates or other clinical materials are forwarded from laboratories serving primary health-care facilities to public health laboratories for confirmation and further characterization, as required by state laws or regulations or as requested by the local jurisdiction. CDC works with states to compile national surveillance data. Requirements for individual states are available at http://www.cste.org/nndss/reportingrequirements.htm.

4.2.4. Epidemiology Process

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

Cases may be interviewed one or more times about potential exposures and additional clinical and demographic information. The scope of these interviews may vary by jurisdiction. Interviews typically cover basic descriptive information and exposures of local importance, such as attendance at a child-care facility, occupation as a food worker, and medical follow-up information. Whereas many local agencies collect information about a limited set of high-risk exposures, detailed exposure interviews usually are reserved for investigating clusters or recognized outbreaks (Chapter 5). However, routine collection of detailed exposure information can provide a basis for the evaluation of clusters as they are detected ("real time") and may be justified for enteric pathogens of sufficient public health importance, such as *E. coli* O157:H7 and *Listeria monocytogenes*. (See Chapter 5 for further discussion.)

Agent, time, and place are examined individually and in combination to identify potentially significant clusters or trends. This is the critical first step in hypothesis generation. Clusters of unusual exposures, abnormal exposure frequencies, or unusual demographic distributions (e.g., predominance of cases in a particular age group) may be identified. Clusters of cases are examined as a group and, if a common exposure seems likely, investigated further (Chapter 5).

Hypotheses to explain the cluster can be developed in several ways. If trawling questionnaires are routinely administered after a case is reported, hypotheses can be generated through examination of previously obtained exposure data for commonality or trends and may be followed by an iterative follow-up interview (see below). In jurisdictions where trawling questionnaires are not used routinely, extensive hypothesis-generating interviews may be used only for cases suspected to be part of a common-source cluster. Unless these interviews identify an obvious exposure leading to direct public health intervention, hypotheses are tested during the ensuing investigation (see Chapter 5).

Questionnaire data are not the sole source of information available to investigators. They also should take advantage of product distribution data obtained from the food distributors or noteworthy "coincidences," such as the occurrence of a majority of cases among children, which might point to a product targeted at children. The most successful investigators develop and consider information from as wide a variety of sources as possible.

4.2.5. Laboratory Process

For some foodborne pathogens, clinical

4.2. Pathogen-Specific Surveillance

diagnostic laboratories forward case isolates or other clinical materials to public health laboratories as part of mandated or voluntary reporting rules. Problems such as mislabeling, broken-in-transit, or quantity-not-sufficient are resolved. Receipt of specimens is recorded, and specimen information is entered into the Laboratory Information Management System before or concurrently with testing. Patient information submitted with the sample may be provided to the epidemiology department for comparison with cases already reported and to allow reconciliation of case reports and laboratory samples and identification of previously unreported cases.

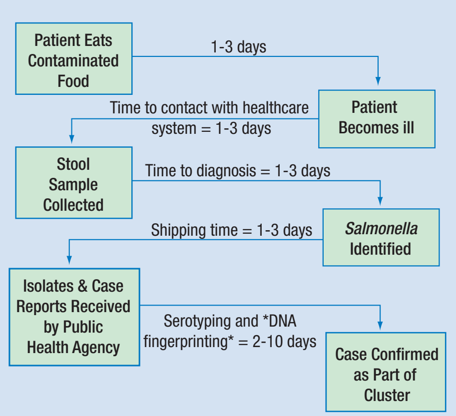
The agent identification is confirmed, and tests (such as serotyping, molecular subtyping, or antimicrobial susceptibility assays) are conducted to further characterize the agent. Reports are issued either singly or in consolidation to the epidemiology department. Reports also may be issued to submitters as permitted by local policies, and specimen data (including detailed subtyping results) are uploaded to national systems such as the Public Health Laboratory Information System (PHLIS) and PulseNet. Clusters of cases identified by the public health laboratory are reported to the epidemiology department. For suspected multijurisdictional outbreaks, national notification or inquiries can be conducted through PulseNet.

For an individual case of botulism, and occasionally for an individual case of other infections, testing food or other environmental specimens is useful (e.g., pet reptiles for *Salmonella* or frozen ground beef for an *E. coli* O157:H7 infection) but is otherwise not advised. This testing may be conducted at a state or local public health laboratory or at a state food testing regulatory laboratory. Without strong epidemiologic data or environmental information, microbiologic screening of food to investigate clusters generally is unproductive and always is resource-intensive. However, this approach occasionally is warranted when only a few foods are suspected, reasonable samples are available, and other investigation approaches do not appear to be working.

4.2.6. Timeline for Case Reporting and Cluster Recognition

Pathogen-specific surveillance requires a series of events to occur between the time a patient is infected and the time public health officials determine the patient is part of a disease cluster. This delay is one of the limiting factors of this type of surveillance. Minimizing delay by streamlining the individual processes improves the likelihood of overall success. A sample timeline for *Salmonella* case reporting is presented in Figure 4.1.

Figure 4.1. Sample *Salmonella* case reporting timeline



1. Incubation time:
   The time from ingestion of a contaminated food to beginning of symptoms. For *Salmonella*, this typically is 1–3 days, sometimes longer.
2. Time to contact with health-care provider or doctor:
   The time from the first symptom to medical care (when a diarrhea sample is collected for laboratory testing). This time may be an additional 1–5 days, sometimes longer.

4.2. Pathogen-Specific Surveillance

3. Time to diagnosis:
   The time from provision of a sample to lab identification of the agent in the sample as *Salmonella*. This may be 1–3 days from the time the lab receives the sample.
4. Sample shipping time:
   The time required to ship the *Salmonella* bacteria from the lab to the state public health authorities who will perform serotyping and DNA fingerprinting. This usually takes 0–7 days, depending on transportation arrangements within a state and distance between the clinical lab and the public health department. Diagnostic labs are not required by law in many jurisdictions to forward *Salmonella* isolates to public health labs, and not all diagnostic labs forward any isolates unless specifically requested to do so.
5. Time to serotyping and DNA fingerprinting:
   The time required for the state public health authorities to serotype and to perform DNA fingerprinting on the *Salmonella* and compare it with the outbreak pattern. Serotyping typically takes 3 working days but can take longer. DNA fingerprinting can be accomplished in 2 working days (24 hours). However, many public health labs have limited staff and space and experience multiple emergencies simultaneously. In practice, serotyping and PFGE subtyping may take several days to several weeks; faster turnarounds are obviously highly desirable.

The time from onset of illness to confirmation of the case as part of an outbreak is typically 2–3 weeks. Case counts in the midst of an outbreak investigation are therefore always preliminary and must be interpreted within this context.

4.2.7. Strengths of Pathogen-Specific Surveillance for Outbreak Detection

- Permits detection of widespread disease clusters initially linked only by a common agent. Most national and international foodborne disease outbreaks are detected in this manner.
- When combined with specific exposure information, is arguably the most sensitive single method for detecting unforeseen problems in food and water supply systems caused by the agents under surveillance. The specificity of agent or syndrome information combined with specific exposure information obtained by interviews allows the positive association of small numbers of cases with exposures.

4.2.8. Limitations of Pathogen-Specific Surveillance

- Works only for diseases detected by routine testing and reported to a public health agency.
- Is relatively slow because it requires that (a) patients seek medical attention; (b) tests are ordered; (c) samples are collected, transported, and tested; and (d) isolates are forwarded to public health laboratories for further characterization.

4.2.9. Key Determinants of Successful Pathogen-Specific Surveillance

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

4.2.9.1. Sensitivity of case detection

Surveillance represents a sampling of the true population of affected persons because most cases of foodborne disease are not diagnosed and reported. **The completeness of the reporting and isolate submission processes affects the representativeness of the reported cases and the potential number and size of outbreaks detected.** If the percentage of cases reported or isolates submitted is low (i.e., sensitivity is low), small outbreaks, or outbreaks spread over space and

4.2. Pathogen-Specific Surveillance

time are likely to be missed. Furthermore, if sensitivity is low, reported cases might differ significantly from cases not reported. Therefore, care must be taken in using characteristics of reported cases to develop hypotheses about the outbreak (see Chapter 5).

4.2.9.2. Prevalence of the agent and specificity of agent classification

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

Examination of subsets of cases using case definitions based on specific agent classifications (e.g., inclusion of subtyping results) or restricting cases using certain time, place, or person characteristics can minimize this impact. For example, *Salmonella enterica* serotype Typhimurium, a common serotype, provides the opportunity for misclassification (i.e., grouping together cases resulting from different exposures). However, *Salmonella* Typhimurium cases that are part of a common-source outbreak are more likely than cases not associated with the outbreak to share a PFGE subtype. Therefore, using the PFGE subtype in the case definition will decrease misclassification (i.e., exclude cases not related to the outbreak) and increase the chance of finding a statistically significant association between illness and exposure. This is the basic principle behind PulseNet.

Increasing the specificity of strain classification is useful only to a point. Because truly associated cases with different subtypes (or no subtyping at all) also can be eliminated from the study, increasing strain classification specificity may become problematic when the number of cases is small. For this reason, use of several different levels of agent specificity during the investigation might be helpful.

4.2.9.3. Sensitivity and specificity of interviews of cases

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

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

4.2.9.3.1. Timing

To decrease the time between exposure to the disease-causing agent and interview of the case, reporting of cases by health-care providers and laboratories should be as easy as possible. Patients should be interviewed as soon as possible because recall will be better closer to the time of the exposure and cases will be more motivated to share information with investigators closer to the time of their illness.

4.2. Pathogen-Specific Surveillance

4.2.9.3.2. Content

In pathogen-specific surveillance, the interview form itself must include a broader range of potential exposures than interview forms for event-driven investigations. Interview forms that use of a combination of question types will increase the likelihood of detecting the desired exposure information and should be used, as appropriate to the outbreak and surrounding circumstances. Interview forms can include questions that:

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

Questionnaire design involves balancing a number of competing demands; the end result is always a compromise. Questionnaires with lots of open-ended questions require more highly trained and skilled personnel than interviews using more pre-defined lists of exposures. Longer questionnaires can cover more potential exposures, but may task the patience of both subject and interviewer; cases may quit the interview before it is completed. Open-ended questions generally are more difficult and time-consuming to abstract and keypunch.

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

Regardless of interview content, use of a standardized interview form, with which the interviewer is familiar, will decrease time spent on staff training and decrease errors in data collection. In addition, use of standardized "core" questions (i.e., questions that use the same wording for collecting information about certain exposures) and data elements will enhance data sharing and allow comparisons among jurisdictions in multijurisdictional outbreaks.

4.2.9.4. Overall speed of the surveillance and investigation processes

As described in section 4.2.6 above, time delays are inherent in pathogen-specific surveillance. **The usefulness of pathogen-specific surveillance in preventing ongoing transmission of disease from contaminated food, especially perishable commodities, is directly related to the speed of the process.**

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

4.2.10. Routine Surveillance—Model Practices

This section lists model practices for routine surveillance programs. Practices used in any particular situation depend on a host of factors, including circumstances specific to the outbreak (e.g., the pathogen and number and distribution of cases), staff expertise, structure of the investigating agency, and agency resources. For example, aggressive case identification and investigation of *E. coli* O157:H7 cases can identify outbreaks and lead to abatement steps that may minimize serious illness and death, whereas investigation of more numerous *Campylobacter* cases is unlikely to lead to public health interventions. Although a systematic evaluation under different circumstances had not been performed on these practices, experiences from successful

4.2. Pathogen-Specific Surveillance

investigations support their value. Investigators are encouraged to use a combination of practices as appropriate to the specific outbreak.

4.2.10.1. Reporting and isolate submission

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

The medical rationale and specific recommendations for testing can be found in *Practical Guidelines for the Management of Infectious Diarrhea*[1] and "Diagnosis and management of foodborne illnesses: a primer for physicians and other health-care professionals."[2] The latter document provides a series of tables giving useful information about major food pathogens, including signs and symptoms, incubation periods, and appropriate laboratory tests and describes sample patient scenarios to help with the diagnostic process.

4.2.10.2. Isolate characterization

Confer with the laboratory to determine subtyping methods available for the pathogen under study. Undertake subtyping as the specimens are submitted—don't wait for a specific number of specimens to accumulate before testing them. Tests such as PFGE and serotyping ideally are performed concurrently to reduce turnaround time. Recommended turnaround times are described in the Association of Public Health Laboratories/CIFOR "yardstick" project. Post results to national databases as quickly as possible.

4.2.10.3. Case interviews

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

Obtain an exposure history consistent with the incubation period of the pathogen identified (see http://www.cdc.gov/foodborneoutbreaks/guide_fd.htm for a table of incubation for the most common foodborne agents).

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

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

Where possible, use standardized "core" questions and data elements used by other investigators to enhance data sharing and comparisons across jurisdictions. Experience can make one a better and more efficient

4.2. Pathogen-Specific Surveillance

interviewer. If investigations are infrequent, achieving and maintaining proficiency can be difficult; centralizing the interview process reduces these problems and makes questionnaires easier to modify on the fly.

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

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

4.2.10.4. Data analysis

Use daily, automated laboratory reporting and analysis systems, where possible, to compare disease agent frequencies at multiple levels of specificity (e.g., species, serotype or other subtype, more stringent subtype) and in subgroups of the population (defined by selected demographic characteristics) to historical frequencies and national trends.

Determine a "cluster" on the basis of the novelty of a subtype pattern; determine increased occurrence of a relatively common subtype on the basis of geographic spread, temporal distribution, or demographic pattern of cases. The number of cases needed to form a cluster cannot be absolutely defined; this is a area of active public health research.

4.2.10.5. Communication

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

4.2.11. Multijurisdictional Considerations for Pathogen-Specific Surveillance

Because pathogen-specific surveillance does

4.2. Pathogen-Specific Surveillance

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

4.2.12. Indicators/Measures for Pathogen-Specific Surveillance

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

4.3. Notification/Complaint Systems

4.3.1. Purpose

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

4.3.2. Background

Receiving and responding to reports of disease in the community has been a basic function of public health agencies since their inception. Whereas reports of diseases caused by specific pathogens generally follow specific disease reporting rules, complaints of illnesses by consumers associated with specific events or establishments generally have been referred to the agency responsible for licensing the establishment. These consumer complaints lead to the identification of most localized foodborne disease outbreaks and are the only method for detecting outbreaks caused by agents, such as norovirus, for which there is no pathogen-specific surveillance.

4.3.3. Group Illness/Complaint Reporting

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

- Reports from any individual or group who observes a pattern of illness affecting a group of people, usually following a common exposure. Examples include reports of illness among multiple persons eating at the same restaurant or attending the same wedding and reports from health-care providers of unusual patterns of illness, such as multiple patients with bloody diarrhea in a short time span.
- Multiple independent complaints about illness in single individuals.

Group illness and independent complaints may be used together and linked with data obtained through pathogen-specific surveillance. In contrast to pathogen-specific surveillance, reporting does not require identification of a specific agent or syndrome or contact with the health-care system.

4.3.4. Epidemiology Process

Notification of group illnesses or independent complaints can occur at the local, regional, state, or national level. Some jurisdictions mandate reporting of "unusual clusters of disease." Reports from health-care providers of unusual clusters are triaged; occurrence of the same disease is confirmed; data are analyzed; investigations are initiated; and control measures are implemented as appropriate. For reports of group illness associated with an

4.3. Notification/Complaint Systems

event or venue, investigation generally involves obtaining lists of attendees, confirming ill persons have the same disease, obtaining menus, interviewing cases, performing a cohort or case-control study, and collecting food and patient specimens (see Chapter 5). Outbreaks detected in this manner may be linked to other outbreaks or to other cases in the community by a variety of processes, such as PulseNet or eFORS, and communication conducted through Epi-X or OutbreakNet.

Two or more individuals with a common exposure identified through interview of independent complaints are used to identify clusters of illness in much the same manner as common agents are used in pathogen-specific surveillance. Exposure information captured in the initial complaint generally is limited and biased toward exposures shortly before onset of symptoms. Therefore, routine interviews are needed for this process to be robust. In the absence of common, suspicious exposures shared by two or more cases, complaints of individual illness with nonspecific symptoms, such as diarrhea or vomiting generally are not worth pursuing.

4.3.5. Public Health Laboratory Process

Laboratory activities are not essential for primary detection of outbreaks by this process but are essential for determining etiology, linking separate events during the investigation, and monitoring the efficacy of control measures (see chapters 5 and 6). Due to public health laboratory testing, links may be seen across jurisdictional boundaries, and broader, even national outbreaks may then be detected. For instance, an outbreak associated with a particular restaurant may come to the attention of authorities solely on the basis of a report by a customer who observed illnesses among multiple fellow patrons. Laboratory testing and identification of *Salmonella* Typhimurium as the causative agent can result in refinement of the case definition used in this investigation, in additional testing and restrictions for workers found to be carriers, or in connection of this outbreak with other outbreaks from a contaminated commodity.

4.3.6. Strengths of Notification/Complaint Systems for Outbreak Detection

- Because detection does not depend on identification of an agent, this system is able to detect outbreaks from any cause, known or unknown. Thus, the notification/complaint system is one of the best methods for detecting non-reportable pathogens and new or emerging agents.
- For event-related notifications only: recall of food items eaten and other exposures by cases is usually good for reported events because specific exposures associated with the event (such as menus) can normally be determined and specifically included in the interview.
- Notification and complaint surveillance systems are inherently faster than pathogen-specific surveillance because the chain of events related to laboratory testing and reporting is not required.

4.3.7. Limitations of Notification/Complaint Systems

- Notification of illness in groups generally is less sensitive to widespread low-level contamination events than is pathogen-specific surveillance because recognition by an individual of a person-place-time connection among cases is required.
- The value of complaints about single possible cases of foodborne disease in detecting outbreaks is limited by the exposure information used to link cases, and by the lack of specific agent or disease information to exclude unrelated cases. The illness reported by individuals might or might not be foodborne, and illness presentation might or might not be typical.

4.3. Notification/Complaint Systems

For any true outbreak, the inability to identify an agent makes misclassification of cases more likely. Misclassification of cases makes identification of an association between an outbreak and an exposure more difficult.

- Without a detailed food history (either in the initial report or follow up interview), surveillance of independent complaints is sensitive only for short incubation (generally chemical or toxin-mediated) illness or illness with unique symptoms because most persons associate illness with the last meal before onset of symptoms, and are thus unlikely to identify the correct exposure. This is not a limitation if routine interviews are conducted.

4.3.8. Key Determinants of Successful Notification/Complaint Systems

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

4.3.8.1. Sensitivity of case or event detection

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

4.3.8.2. Background prevalence of disease—group complaints

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

4.3.8.3. Sensitivity and specificity of case interviews—group complaints

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

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

4.3. Notification/Complaint Systems

Because exposures associated with group events are relatively few and can be described specifically, recall tends to be good and timing is less an issue than with pathogen-specific surveillance or independent complaints. In studies of food recall accuracy, the positive predictive value of individual food items ranged from 73% to 97%.[3,4] The negative predictive value ranged from 79% to 98%. Highly distinctive foods tended to be more accurately reported. Nonetheless, the more specific exposure-related questions are, the better recall will be. For example, cases asked whether they "ate German potato salad" at a particular event are more likely to remember than if they were asked whether they ate "salad" or asked to list the foods they ate. Interviews of food-preparation staff additionally provide valuable information because they can list ingredients that cases are not likely to recall or even know about and that a standardized questionnaire would not include. A good example is the 1998 international outbreak of shigellosis associated with parsley added as a garnish to restaurant-served meals.

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

4.3.9. Notification/Complaint Systems—Model Practices

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

4.3.9.1. Interviews related to individual complaints

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

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

When beginning an investigation based on multiple individual complaints, the best approach is to collect a 5-day exposure history. Given the ubiquity of norovirus infections, the investigator should pay particular attention to exposures in the 24–48 hours before onset whenever norovirus is suspected. As more information about the likely etiologic agent

4.3. Notification/Complaint Systems

is collected, this approach can be modified. The complaint and subsequent interviews can lead to a hypothesis about the pathogen that leads to a different time frame for the exposure history (e.g., vomiting leads to a different hypothesis and exposure history time frame than does bloody diarrhea).

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

4.3.9.2 Follow-up of commercial establishments named in individual complaints of potential foodborne illness

Health department staff might be required by local or state statute to investigate any commercial food establishment named by a person reporting a potential foodborne illness. However, because complainants often focus on foods prepared or eaten at commercial food establishments or the last meal eaten rather than other meals, investigation of the named establishment might not contribute to identifying the source of the reported illness or be the best use of limited health department resources.

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

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

As noted below in Section 4.3.9.6, regular review of individual complaints is critical in recognizing that multiple persons have a similar illness or diagnosis and share a common exposure.

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

- Confirmed diagnosis and/or clinical symptoms that are not consistent with the foods eaten at the establishment and/or the onset of illness (e.g., bloody diarrhea associated with a well-cooked hamburger eaten the night before illness onset).
- Signs and symptoms (or confirmed diagnoses) among affected individuals that suggest they might not have the same illness.
- Ill persons who are not able to provide adequate information for investigation including date and time of onset of illness, symptoms, or complete food histories.
- Repeated complaints by the same individual(s) for which prior investigations revealed no significant findings.

4.3.9.3. Interviews related to reported illnesses in groups

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

Focus interviews on the event shared by members of the group. However, be aware they may have more than one event in

4.3. Notification/Complaint Systems

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

4.3.9.4. Clinical specimens and food samples related to group illness

Obtain clinical specimens from members of the ill group. If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. Store the food appropriately, but generally test the food only after epidemiologic implication. Food samples that are frozen when collected should remain frozen until examined. Samples should be analyzed within 48 hours after receipt. If sample analysis is not possible within 48 hours, then perishable foods should be frozen (–40 to –80°C). Storage under refrigeration can be longer than 48 hours, if necessary, but the length of the storage period is food dependent. Because certain bacteria (e.g., *Campylobacter jejuni*) die when frozen, affecting laboratory results, immediate examination of samples without freezing is encouraged. Food samples can be collected as part of the process of removing suspected food from service.

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

Specific contaminants or foods might require special collection and testing techniques and demonstration of an agent in food is not always possible. Furthermore, results of testing are often difficult to interpret. Because contaminants in food change with time, samples collected during an investigation might not be representative of those ingested when the outbreak occurred. Subsequent handling or processing of food might result in the death of microorganisms, multiplication of microorganisms originally present in low levels, or introduction of new contaminants. If contamination of the food is not uniform, the sample collected might miss the contaminated portion. Finally, because food usually is not sterile, microorganisms can be isolated from samples but not be responsible for the illness under investigation. As a result, food testing should not be undertaken as a matter of routine, but based on meaningful associations.

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

4.3.9.5. Establishment of etiology through laboratory testing

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

4.3.9.6. Regular review of interview data

Review interview data regularly to look for

4.3. Notification/Complaint Systems

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

4.3.9.7. Improvement of interagency cooperation and communication

Improve cooperation among agencies that receive illness complaints (e.g., agriculture agencies, facility licensing agencies, poison control centers). Regularly communicate with these agencies, and ensure they have current contact information for your staff. Because complaints might be made to multiple agencies, having a robust method of sharing information is important.

4.3.9.8. Other potentially useful tools

Check complaint information against national databases, such as the USDA/FSIS Consumer Complaint Monitoring System (CCMS).

4.3.9.9. Simplification of reporting process

To increase surveillance sensitivity, make the reporting process as simple as possible for the public. For example, provide one 24/7 toll-free telephone number or one website. Such systems allow callers to leave information that public health staff can follow up.

4.3.9.10. Increased public awareness of reporting process

Promote reporting by routine press releases that educate the public about food safety, and advertise the contact phone number or website for reports of illness. Use a telephone number that easily can be remembered or found in the telephone directory. Train food managers and workers about the importance of reporting unusual patterns of illness among workers or customers and food code requirements for disease reporting.

4.3.9.11. Centralized reporting or report review process

Set up the reporting process so all reports go through one person or one individual routinely reviews reports. Centralization of the reporting or review process increases the likelihood that patterns among individual complaints and seemingly unrelated outbreaks will be detected.

4.3.9.12. Maintenance of contact with other organizations that might receive complaints

Consumers may submit complaints to multiple organizations, such as poison control centers or grocery stores. **Identify the organizations in your community that are likely to receive complaints, and maintain routine contact with them.** Ideally, set up a database that public health agencies can access and review.

4.3.10. Multijurisdictional Considerations for Notification/Complaint Systems

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

4.3.11. Indicators/Measures

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

4.4. Syndromic Surveillance

4.4.1. Overview

The utility of syndromic surveillance has not been established. In theory, the electronic collection of nonspecific health indicators could permit rapid detection of significant trends, including outbreaks. In practice, the right mix of sensitivity and specificity has proven difficult to find, and the utility of such systems may be marginal.

4.4.2. Background

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

4.4.3. Reporting

Syndromic surveillance typically relies on automated extraction of health information:

- Preclinical (i.e., not dependent on access to health care, consequently less specific and potentially less useful)—school and work absenteeism, nurse help-lines, sales of over-the-counter drugs, complaints to water companies, calls to poison control centers.
- Clinical prediagnostic (i.e., requires contact with the health-care system but does not rely on a full workup or laboratory confirmation and, therefore, takes less time)—emergency department chief complaint, ambulance dispatch, lab test orders.
- Postdiagnostic data—hospital discharge codes (ICD-9, ICD-10).

4.4.4. Epidemiology Process

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

4.4.5. Laboratory Process

Laboratories do not play a direct role in syndromic surveillance. Laboratories would be involved during epidemiologic investigations triggered by a syndromic surveillance signal.

4.4.6. Strengths of Syndromic Surveillance

- In theory, syndromic surveillance has the potential to identify clusters of disease before definitive diagnosis and reporting, thus generating a faster signal than can be expected with pathogen-specific surveillance.
- As with notification/complaint systems, outbreaks from any cause, known or unknown, potentially can be detected. Included are clusters of cases identified with discharge diagnoses that include specific agents not part of standard surveillance.
- Syndromic surveillance may be able to detect large, undiagnosed events, such as an increase in gastrointestinal illness among persons of all ages consistent with norovirus, an increase in diarrheal illness among young children consistent with rotavirus, and the arrival of epidemic influenza.
- Most syndromic surveillance systems have been built with automated electronic data transfer. This infrastructure should be useful for other types of surveillance and public health activities.

4.4.7. Limitations of Syndromic Surveillance

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

4.4. Syndromic Surveillance

Responding to false-positive signals drains an agency's resources substantially.

- Evaluating a signal usually means cross-checking it with routine surveillance reports, meaning it cannot replace routine surveillance.
- More specific signals, such as discharge diagnoses, are less timely and do not appear to offer advantage over standard surveillance methods.
- The usefulness of syndromic surveillance has not been demonstrated for foodborne disease. After examination of 2.5 million patient records in its first year of operation, the New York City surveillance system identified 18 diarrhea or vomiting alerts during 3 outbreak periods. Five institutional outbreaks were identified during one of these periods, but whether the data were sufficiently specific to allow for public health intervention is not clear.[5,6,7]
- The cost of developing syndromic surveillance systems is substantial, and if development occurs at the expense of maintaining or upgrading routine surveillance, degraded, rather than enhanced, surveillance results.

4.4.8. Key Determinants of Successful Syndromic Surveillance Systems

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

4.4.8.1. Specificity and speed

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

Lack of specificity at any level results in both type 1 probability error (the suggestion of an association between a signal and a significant health event when, in fact, none exists) and type 2 probability error (the lack of signal suggests a disease event is not occurring, when, in fact, it is). **Less specificity means that more cases are needed to overcome background noise and that false-positive alerts are likely.**

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

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

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

4.4. Syndromic Surveillance

4.4.8.2. Personal information privacy issues

In a survey on implementation of syndromic surveillance systems, more than half (54.2%) of respondents reported some or substantial problems caused by real or perceived patient confidentiality concerns and the Health Insurance Portability and Accountability Act (HIPAA). Respondents noted that many health-care providers and medical staff did not understand HIPAA and so tended to give minimal patient information. Questions also were raised about whether syndromic surveillance falls under the same regulations as reports of diagnosis-related disease. For example, whether health departments have the legal authority to collect these data is not always clear. Most respondents were using current disease reporting regulations to cover syndromic surveillance. Many respondents believed more specific syndromic indicators are needed to incorporate them into regulations. **Most agencies that had implemented a syndromic surveillance system used deidentified data, which slows investigations of positive signals from the surveillance system.**[9]

4.4.9. Practices for Improving Syndromic Surveillance

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

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

4.5. References

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CHAPTER

5

Investigation of Clusters and Outbreaks

Before development of pathogen-specific surveillance, foodborne disease outbreaks were typically recognized because of the occurrence of large numbers of illnesses among persons with a known common exposure. The development of pathogen-specific surveillance through public health laboratories has allowed the detection of widely dispersed outbreaks caused by commercially distributed food products. Outbreaks identified through pathogen-specific surveillance are initially recognized as clusters of cases defined by subtype characteristics. Distribution of these cases by time, space, and personal characteristics provides important clues about whether the cases are likely to represent an outbreak from a common source of exposure. However, only a systematic investigation of the cluster can confirm whether it actually is an outbreak and, if so, whether it is a foodborne disease outbreak. Many agents responsible for outbreaks of foodborne disease also can be transmitted by other routes, such as water and animals, and from person to person.

5.0. Introduction

Identifying the route of transmission is important to many outbreak investigations and critical for implementing effective control measures (see Chapter 6) but is not always possible through agent identification or clinical presentation.

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

5.1. Characteristics of Outbreak Investigations

5.1.1. Importance of Speed and Accuracy

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

- "Removing the pump handle."
  Stopping an outbreak in its tracks and preventing illnesses are the most obvious goals of outbreak investigations. From this perspective, there are 3 types of outbreaks.
  - *A localized one-time event, such as a specific food-preparation error or ill food worker at a food-service establishment*. By the time these outbreaks are recognized, the event may be over. However, ensuring an ill worker does not continue to spread disease or preventing secondary spread of cases might be possible.
  - *Widespread distribution of a perishable commodity, such as spinach or tomatoes.* Because product may still be in the marketplace when the outbreak is detected, the faster the source can be identified, the more likely illness from exposure to that source will be prevented. Given the large quantities of contaminated product often involved in these events, even a limited recall could significantly benefit public health.
  - *Contamination of shelf-stable commodities, such as canned or frozen foods or peanut butter, or persistent environmental contamination at a farm, food-processing facility, or restaurant.* The speed with which the source is identified and the effectiveness of a recall are directly related to the number of people exposed to the contaminated commodity and the ultimate size of the outbreak.
- Preventing future outbreaks by identifying the circumstances that led to contamination.
  Without a prompt, complete, and accurate investigation, the circumstances that led to contamination may not be identified, and the opportunity to prevent future outbreaks will be lost.
- Identifying new hazards.
  Outbreak investigations identify new agents, new food vehicles, new agent–food interactions, and other unsuspected gaps in the food-safety system. Prompt and thorough investigations while memories are fresh and specimens are available are much more likely to successfully rule out known hazards and identify new hazards. Presenting the information to the sector of the food industry involved can be critical for encouraging changes in procedures.
- Maintaining the public's confidence.
  Foodborne disease outbreaks undermine the public's confidence in the food supply and in

5.1. Characteristics of Outbreak Investigations

the public health system established to ensure food safety. Rapidly identifying outbreaks, determining their source, and limiting their scope are critical to restoring confidence in the food supply and food-safety system. On the other hand, inaccurate conclusions about the source undermine public confidence and harm food producers not involved in the cause of the outbreak. For example, strawberries from California were implicated as the source of a multistate outbreak of cyclosporiasis that actually was caused by raspberries from Guatemala. Media reports based on the erroneous conclusions led to millions of dollars in lost strawberry sales, even though the error was rapidly corrected. This situation probably could have been avoided if investigators had considered results from simultaneous investigations in other localities. Maintaining close communication and coordination among members of the investigation team and with other public health officials is the best way to avoid this type of error without delaying the investigation. See section 6.6.1 for additional discussion about the importance of collecting sufficient information before taking action.

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

  and ultimately
  - "Would I want my mother or grandmother to know about this hazard?"

5.1.2. Principles of Investigation

5.1.2.1. Outbreak detection

Outbreaks typically are detected through three general methods: pathogen-specific surveillance, notification/complaint systems, and syndromic surveillance (see Chapter 4). After receipt of a suspicious foodborne illness complaint associated with a particular event or establishment or the detection of an unusual cluster of isolates through pathogen-specific surveillance, conduct a preliminary investigation to determine whether the reported illnesses may be part of an outbreak. Preliminary investigations need to assess the epidemiologic context of the reported illnesses to determine whether they might be part of an outbreak.

5.1.2.2. Investigation leadership

Leadership of the investigation should reflect the focus of investigation activities and may change over time.

During an investigation, the focus of activities may shift among the following:

- Laboratory studies to identify an agent, including microbiologic studies and applied food-safety research;
- Epidemiologic studies to identify transmission routes, exposure sources, or food vehicles and risk factors for disease;
- Regulatory investigations of food-production sources and distribution chains to identify where, during production of the food, contamination occurred and facilitate recall of food items;
- Environmental evaluations of food production, processing, and service facilities to identify routes of contamination and contributing factors; and

5.1. Characteristics of Outbreak Investigations

- Communication of investigation findings to the public and the food industry to support control and prevention measures.

5.1.2.3. Communication and coordination

Coordinate activities and set up good lines of communication between individuals and agencies involved in the investigation. Guidelines for coordinating multijurisdictional investigations are summarized in Chapter 7. Investigations are rarely linear. Although most procedures for investigating outbreaks follow a logical process—from determining whether an outbreak is occurring to identifying and controlling the source—most actual investigations feature multiple concurrent steps. Maintaining close communication and coordination among members of the outbreak investigation team is the best way to ensure concurrent activities do not interfere with each other and important investigation steps are not forgotten.

5.1.2.4. Hypothesis generation

To narrow the focus of an investigation and most effectively use time and resources, investigators should begin to generate hypotheses about potential sources of the outbreak during the earliest stages of the investigation and refine them as they receive information. Key steps in this process include the following:

- Review previously identified risk factors and exposures for the disease;
- Examine the descriptive epidemiology of cases to identify person, place, or time characteristics that might suggest a particular exposure;
- Interview in detail the affected persons or a sample of affected persons to identify unusual exposures or commonalities among cases. These interviews can be conducted by a single interviewer or by multiple interviewers using standardized forms and interview techniques. Although a single interviewer might recognize uncommon exposures mentioned by multiple cases, completing these hypothesis-generating interviews might take several days. Multiple interviewers can interview cases simultaneously, but they then need to compare notes to recognize uncommon exposures mentioned by multiple cases. This latter process forms the basis of the dynamic cluster investigation described below.

On the basis of this information, investigators can identify possible exposures for further evaluation by epidemiologic, laboratory, or environmental studies. In practice, the generation and testing of hypotheses is an iterative process, with the hypothesis modified as more information is obtained. For example, an outbreak involving a high proportion of cases among preschool-aged children might suggest exposure to a food product marketed to young children, such as a cereal product or snack food. Identification of a specific product, such as a certain vegetable powder-coated snack, by several cases should prompt re-interview of other cases to identify unrecognized exposures to the product. Concordance of exposures among a substantial proportion of the cases could lead directly to product testing and recall or to a focused epidemiologic study to establish the association.

5.1.2.5. Standardized data collection forms

The use of standardized forms for collecting exposure histories ensures that pertinent information is collected from all cases. In addition, use of standardized "core" questions (i.e., questions that use the same wording for collecting information about certain exposures) and data elements (e.g., same variable names and attributes) will enhance data sharing and comparisons of exposures across jurisdictions. Both will aid in the investigation of multistate outbreaks. Similarly, use of standardized forms for environmental investigations provides comparable data for investigations that may involve multiple establishments. Standardized forms enable investigators to become proficient

5.1. Characteristics of Outbreak Investigations

with the forms and reduce time and effort to develop and train staff on new forms during the investigation.

Because good forms take time to develop and format, developing templates *before* a crisis is critical to their rapid deployment (see also model practices for case interviews, Chapter 4, section 4.3.9.3). The CIFOR Clearinghouse (http://www.cifor.us/clearinghouse/index.cfm) provides examples of questionnaires used by various health departments to collect exposure information for different pathogens and may be useful in the development of templates. The Environmental Health Specialists Network (EHS-Net) website (http://www.cdc.gov/nceh/ehs/EHSNet/) can be referenced for models of environmental assessment forms as well as consumer complaint forms.

5.1.2.6. Privacy of individuals, patients and their families.

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

5.2. Cluster and Outbreak Investigation Procedures

5.2.1. Conduct a Preliminary Investigation

5.2.1.1. For complaints of illness attributed to a particular event or establishment, the following questions should be answered:

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

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

5.2.1.2. For case clusters identified through pathogen-specific surveillance, the following questions should be answered:

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

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

5.2. Cluster and Outbreak Investigation Procedures

5.2.2. Assemble the Outbreak Investigation and Control Team

(See also Chapter 3, Planning and Preparation)

5.2.2.1. Alert outbreak investigation and control team

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

5.2.2.2. Assess the priority of the outbreak investigation

On the basis of the outbreak setting and descriptive epidemiology, **outbreak investigation and control team leaders should assess the priority of the outbreak.** Give highest priority for investigation to outbreaks that

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

5.2.2.3. Assemble and brief the outbreak investigation and control team

On the basis of the priority given the outbreak and on the nature of the outbreak, investigation and control team leaders should assess the availability of staff to conduct the investigation. **In particular, the team leader should ensure the presence of adequate staffing to interview cases within 24–48 hours, and solicit controls as needed.** If sufficient staff are not available, request external assistance to conduct interviews.

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

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

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

5.2.3. Establish Goals and Objectives for the Investigation

5.2.3.1. Goals

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

5.2. Cluster and Outbreak Investigation Procedures

5.2.3.2. Objectives

For outbreaks associated with events or establishments (Table 5.1)

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

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

- Identify mode of transmission and vehicle.
- Identify persons at risk.
- Identify the source of contamination.
- Identify contributing factors.
- Determine potential for ongoing transmission and the need for abatement procedures.

5.2.4. Select and Assign investigation Activities

Tables 5.1 and 5.2 outline objectives and investigation activities that can be conducted during epidemiologic, environmental health, and public health laboratory investigations of foodborne disease outbreaks. The table format highlights the major objectives of the investigation to help ensure coordination among epidemiologists, environmental health specialists, and laboratorians in meeting each objective. The assignment of investigation responsibilities to a particular discipline within each table is not intended to be prescriptive. The actual responsibilities for an individual will vary depending on the practices of the jurisdiction responsible for the investigation, roles defined in the outbreak investigation and control team, and resources.

5.2. Cluster and Outbreak Investigation Procedures

Table 5.1. Investigation activities for outbreaks associated with events or establishments

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify etiologic agent.	• Contact health-care providers of cases who have sought medical attention. • Interview cases to characterize symptoms, incubation period, and duration of illness. • Obtain stool from cases. • Establish case definition based on confirmed diagnosis or clinical profile of cases.	• Interview management to determine whether it has noticed any ill employees or any circumstances that could be the cause of a foodborne illness. • Interview food workers to determine illness. This activity could also be conducted by nursing/health-care staff. • Obtain stool from ill or all food workers. This activity could also be conducted by nursing/health-care staff. • Obtain and store samples of implicated and suspected food items and ingredients. • Determine whether setting or food item suggests a likely pathogen.	• Contact clinical laboratories that may have performed primary cultures on cases and obtain specimens. • Test stool samples to identify agent. • Test samples of implicated food items to identify agent. • Subtype all isolates as soon as possible after receipt.
Identify persons at risk.	• Obtain from event organizer a list of persons attending event, or, if possible, list of persons patronizing the establishment during the outbreak period. • Interview persons who attended event or patronized establishment to determine attack rates, by time. • Contact health-care providers to identify additional persons seeking medical care who meet the case definition.	• Obtain list of reservations for establishment, credit card receipts, receipts for take-out orders, inventory of foods ordered at establishment, or guest lists for events. Where possible, obtain information electronically.	• Contact clinicallaboratories to identify additional stool specimens being cultured.

5.2. Cluster and Outbreak Investigation Procedures

Identify mode of transmission and vehicle.	• Interview identified cases and controls or well meal companions about all common exposure sources. Calculate odds ratios for specific exposures. • Interview persons with identified exposures to determine attack rates and relative risks for specific exposures.	• Obtain menu from establishment or event. • Interview food workers to determine food-preparation responsibilities. • Reconstruct food flow for implicated meal or food item. • Identify contributing factors. • Obtain samples of implicated food. • Obtain environmental samples from food contact surfaces or potential environmental reservoirs.	• Test implicated food and environmental samples to confirm presence of agent. • Subtype all isolates as soon as possible after receipt. • Conduct applied food-safety research to determine ability of agent to survive or multiply in implicated vehicle and how vehicle might have become contaminated.
Identify source of contamination.	• Combine descriptive and analytical epidemiology results to develop a model for the outbreak.	• Interview food workers to determine food-preparation responsibilities. • Reconstruct food flow for implicated meal or food item. • Evaluate food flow for implicated meal or food item to identify contamination event at point of preparation or service. • If no contamination event identified, trace source of ingredients of implicated food item back through distribution to point where a contamination event can be identified or, if no contamination events can be identified during distribution, to source of production.	• Evaluate results of all outbreak-associated cultures to highlight possible relations among isolates from clinical, food, and environmental samples. • Conduct applied food-safety research to determine how vehicle might have become contaminated.
Identify contributing factors (specific ways that food became contaminated or capable of causing illness).	• Summarize information to identify confirmed or suspected agent. • Summarize information to identify confirmed or suspected food vehicle.	• Evaluate results of environmental investigation, given identification of agent and results of epidemiologic investigation, to identify factors most likely to have contributed to outbreak.	• Summarize information about culture results from clinical, food, and environmental samples.

5.2. Cluster and Outbreak Investigation Procedures

Table 5.1. Investigation activities for outbreaks associated with events or establishments
Continued

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Determine potential for ongoing transmission and need for abatement procedures.	• On the basis of agent, incubation period, and likelihood of secondary spread, create epidemic curve, and evaluate the course of the epidemic to determine whether additional cases may still be occurring. • If outbreak appears to be ongoing, review potential abatement procedures.	• Implement control measures to prevent further exposures: o Verify that all food workers who pose a risk for transmission have been excluded; o Verify that potentially contaminated foods have been properly disposed; o Verify that food contact surfaces and potential environmental reservoirs have been adequately cleaned and sanitized; o Train staff in safe food-handling practices; o Modify food-production and food-preparation processes; and o Modify menu. • If any of these measures cannot be verified, review additional abatement procedures, or if further exposure appears likely, alert public or close premises.	• Assess status of completed and pending cultures to identify gaps that suggest a potential for ongoing transmission.

5.2. Cluster and Outbreak Investigation Procedures

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

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify mode of transmission and vehicle.	• Interview cases as soon as possible with standardized trawling questionnaire to identify potential common exposures (described in detail below). In some situations, cases are interviewed as soon as they are reported and before an outbreak has been recognized. • Establish case definition on the basis of characteristics of agent that led to detection of outbreak. • Characterize cases by person, place, and time, and evaluate this descriptive epidemiology to identify pattern potentially associated with particular food items or diets. • Compare trawling questionnaire exposure frequencies against known or estimated background exposure rates, such as those found in FoodNet Atlas of Exposures, to identify suspected food item. • Interview non-ill community controls or nonoutbreak-associated ill persons to obtain detailed exposure information to be used in a case-comparison analysis of exposures. • Obtain shopper card information to identify and verify grocery purchases. • Document brand names and product code information for prepackaged food items. • Analyze exposure information comparing cases to relevant comparison group (e.g., non-ill controls or cases not associated with outbreak) to implicate food item or nonfood-exposure source.	• Contact restaurants, grocery stores, or other locations identified by multiple cases to verify menu choices, identify ingredients, and identify distributors and/or source(s) for ingredients and/or food items of interest. • Obtain samples of suspected food items. • Conduct informational traceback to determine whether a suspected food vehicle from multiple cases has a distribution or other point in common. • Conduct formal regulatory traceback of implicated food item or ingredient.	• Store collected food samples, pending results of epidemiologic analyses. • Culture implicated food samples to confirm presence of agent. • Conduct serotype/ genotype tests, and further characterize pathogen as necessary for investigation. • Conduct applied food-safety research to determine ability of agent to survive or multiply in implicated vehicle and how vehicle might have become contaminated.

5.2. Cluster and Outbreak Investigation Procedures

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

OBJECTIVE	EPIDEMIOLOGY	ENVIRONMENTAL HEALTH	PUBLIC HEALTH AND/OR FOOD TESTING REGULATORY LABORATORY
Identify persons at risk.	• Alert health-care providers of possible outbreak to identify additional persons seeking medical care, and review laboratory reports and medical charts at hospitals or physicians' offices to identify potential cases. • Ask cases if they know of others who are similarly ill. • Depending on nature of outbreak, take additional steps as warranted. Examples include reviewing employee or school absences, reviewing death certificates, surveying population affected, or directly asking members of the public to contact the health department if they have the illness under investigation.	• Review foodborne illness complaints to identify undiagnosed cases that could be linked to outbreak. • Contact restaurants, grocery stores, or other points of final service visited by multiple cases to identify employee illnesses or foodborne illness complaints from patrons.	• Contact clinical laboratories to identify additional stool specimens being cultured. • Speed up referral and subtyping of outbreak pathogen.
Identify source of contamination.	• Combine descriptive and analytical epidemiology results to develop a model for outbreak.	• Trace source of implicated food item or ingredients through distribution to point where a contamination event can be identified or to source of production if no contamination events can be identified during distribution. • Conduct environmental assessment of likely source of contamination, including o Reconstruct food flow for implicated food item. o Interview food workers to determine food-preparation responsibilities and practices before exposure. o Obtain samples of implicated food or ingredients. o Obtain environmental samples from food contact surfaces or potential environmental reservoirs.	• Evaluate results of all outbreak-associated cultures to highlight possible relations among isolates from clinical, food, and environmental samples. • Conduct applied food-safety research to examine likely sources of contamination.

5.2. Cluster and Outbreak Investigation Procedures

Identify contributing factors	• Summarize information to identify confirmed or suspected food vehicle.	• Evaluate results of environmental investigation, given identification of agent and results of epidemiologic investigation to identify factors likely to have contributed to outbreak.	• Summarize information about culture results from clinical, food, and environmental samples. • Provide background statistics on pathogen prevalence.
Determine potential for ongoing transmission and need for abatement procedures.	• Create and evaluate epidemic curve to determine whether additional cases might still be occurring. • If outbreak appears to be ongoing, continue surveillance, and review potential abatement procedures.	• Verify that food workers who may have been infected during outbreak and who pose a risk for transmission have been excluded. • Verify that potentially contaminated foods have been removed from distribution. • Train staff on safe food-handling practices. • Modify food-production and food-preparation processes. • Modify menu.	• Assess status of completed and pending cultures to identify gaps that may suggest a potential for ongoing transmission.

5.2. Cluster and Outbreak Investigation Procedures

5.2.4.1. Cluster investigations—model practices

This section lists model practices for cluster investigations. The practices used in any particular situation depend on a host of factors including the circumstances specific to the outbreak (e.g., the pathogen and number and distribution of cases), staff expertise, structure of the investigating agency, and the agency's resources. Although a systematic evaluation under different circumstances had not been performed on these practices, experiences from successful investigations support their value. Investigators are encouraged to use a combination of these practices as is appropriate to the specific outbreak.

5.2.4.1.1. Use interview techniques to improve food recall

In general, to help improve food recall when collecting exposure information for a cluster investigation:

- Question subjects as soon as possible after reporting.
- Do not share information about suspected food items or working hypotheses with interviewees. However, do ask specifically about suspected item(s), as described in the dynamic cluster investigation model.
- Encourage interviewees' to remember information by asking them to elaborate on where they ate, with whom they ate, and events associated with the meals. Ask interviewees to look at a calendar from the appropriate time periods to jog their memory.
- Enlist the help of those preparing meals during the period of interest
- Ask if the subject keeps cash register or credit card receipts that might indicate where or what they ate.
- If the subject uses a grocery store shopper card, ask permission to get purchase records for a specified time period. Some grocery chains readily cooperate with these requests; others do not.
- Use a structured list of the places where people might get food to get them thinking about exposures other than just restaurants and grocery stores. The list could include food pantries, farmers markets, conferences and meetings, and caterers.

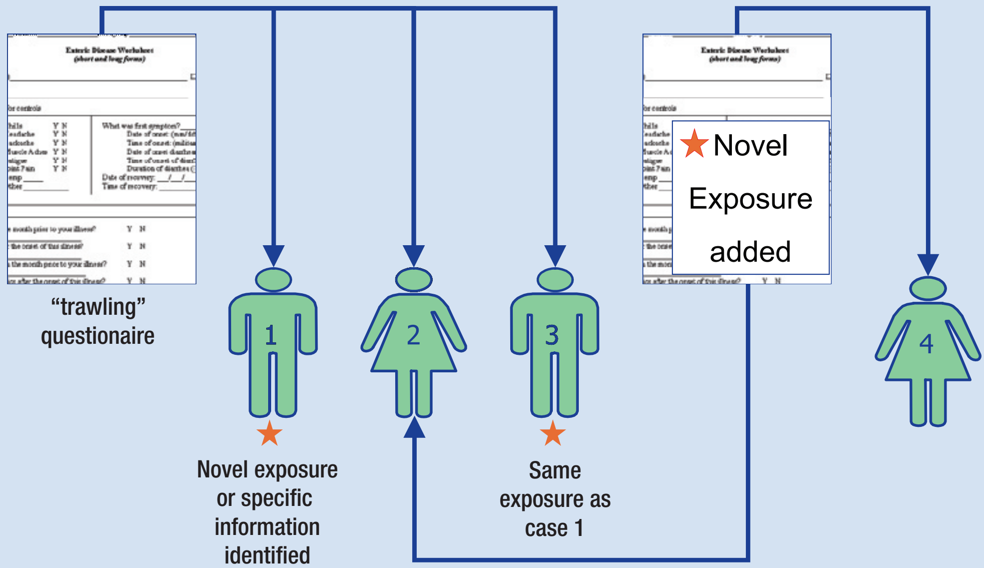
5.2.4.1.2. Use a dynamic cluster investigation process to generate hypotheses

In the dynamic cluster investigation model, initial cases within a recognized cluster are interviewed with a detailed exposure history questionnaire. As new exposures are suggested during case interviews, the initial cases are systematically re-interviewed to uniformly assess exposure to the exposures suggested by subsequent patient interviews. Newly reported cases also will be asked specifically about these exposures. See **Figure 5.1** for a visual representation of this process. Ideally, interviews of the first few (five to ten) cases will produce a relatively short list of suspicious exposures—suspicious because they involve commodities that are not commonly eaten or involve specific brands of a commonly eaten food item. Because these exposures may not have been uniformly assessed on the original questionnaire, specific questions regarding the newly suspected exposures should be added to the questionnaire for future use. Re-interviews of cases, combined with interviews of new cases in the cluster, can result in rapid identification of a unique exposure shared among multiple cases. Occasionally, this evidence is so specific and so obviously unlikely to have occurred by chance alone that it can lead to direct public health intervention. More frequently, the various hypotheses will need to be tested with a case-control study in the ensuing investigation.

As the number of cases and jurisdictions increases, strict application of this approach may be come infeasible. In any event, clear and timely communication with other investigators are critical to adequately

5.2. Cluster and Outbreak Investigation Procedures

Figure 5.1. Dynamic cluster investigation.



In this model, cases are interviewed with a detailed exposure history questionnaire. Specific exposures shared by multiple cases may surface that are suspicious because they involve commodities not commonly eaten or involve specific brands of a commonly eaten food item. Because these exposures may not be uniformly ascertained with the original questionnaire, specific questions should be added to the questionnaire for future use and to systematically re-interview cases to uniformly assess exposure to the suspicious sources discovered during the investigation process “Novel exposure” refers to individuals who are newly exposed.

consider suspicious new exposures that may be reported elsewhere.

5.2.4.1.2.1. Dynamic cluster investigation with routine interview of cases

For agencies with resources sufficient to routinely interview cases with a detailed exposure questionnaire as the cases are reported, dynamic cluster investigation can be initiated with recognition of the cluster. This increases the sensitivity and speed of outbreak identification and resolution in several ways.

- Increased recall:
  Recall is amplified by what is essentially a group dynamic. Individuals are less likely to recall exposures when asked in general about their exposure history and more likely to remember when questioned about specific exposures that other cases have identified. For example, in the 2007 multistate outbreak of *Salmonella* Wandsworth associated with a vegetable powder-coated snack, cases were less likely to report its consumption when asked to list all foods eaten during the period of interest but were highly likely to remember when asked specifically whether they had eaten the particular snack. (This same principal underlies an advantage of questionnaires with longer lists of specific exposure questions.)
- Compressed time frame:
  This process also increases recall and the likelihood of meaningful intervention because of its shortened time frame. Standard investigation methods often involve sequential attempts at hypothesis generation,

5.2. Cluster and Outbreak Investigation Procedures

followed by hypothesis testing. In this model, these processes are essentially compressed in a nested manner.

- Potential to conduct case-case analytical studies:
  In jurisdictions that routinely conduct interviews using trawling questionnaires, case-to-case comparison studies offer an efficient tool to evaluate exposures as part of cluster investigations. **Cases with microbial agents other than the agent under investigation, ideally from the same time period, are used as "controls" to identify risk factor differences.** This requires that the cases in the cluster and cases used for comparison have been interviewed using the same form. However, because some microbial agents have common food vehicles, case-to-case comparisons might lead investigators to overlook the source of an outbreak.

5.2.4.1.2.2. Dynamic cluster investigation without routine interview of cases

Because most public health agencies do not have sufficient resources to conduct detailed exposure history interviews for every case, a two-step interviewing process may represent the best alternative approach. All cases should be interviewed with a standardized questionnaire to collect exposure information about limited high-risk exposures specific to the pathogen. When it becomes apparent based on the novelty of the subtype pattern, geographic distribution of cases, or ongoing accumulation of new cases that the cluster represents a potential outbreak associated with a commercially distributed food product, all cases in the cluster should be interviewed using a detailed exposure questionnaire as part of a dynamic cluster investigation as described above.

If investigators use the trawling questionnaire on cases only after a cluster is identified, they can either a) use the results for hypothesis generation with subsequent testing of those hypotheses in a controlled study or b) they can use the trawling questionnaire on an appropriate set of controls, thereby combining hypothesis generation and hypothesis testing.

5.2.4.1.3. Use standard cluster investigation

The conventional cluster investigation process includes (a) waiting until a sufficient number of cases are identified, making obvious the occurrence of a common source outbreak, (b) conducting hypothesis-generating interviews using a trawling interview form with a subset of these cases, and (c) developing and testing hypotheses in a static manner. Limitations of this method include diminished investigation sensitivity and specificity, as well as significant delays.

The following guidance might be used to interpret the results of hypothesis-generating interviews and focus the list of exposures for subsequent study:

- If none of the cases involved in the interviews report a specific exposure, the hypothesis is no longer viable and most likely can be dropped from subsequent study.
- If more than 50% of cases interviewed report an exposure, that exposure should be studied further.
- If fewer than 50% of cases report an exposure, that exposure still may be of interest, particularly if it difficult to recognize or unusual.

5.2.4.1.4. Use the FoodNet Atlas of Exposures

Short of conducting a formal case-control study, exposure frequency data can be used to evaluate the significance of shared exposures. The FoodNet Atlas of Exposures is a compilation of the results of periodic population-based surveys undertaken at selected sites in the United States. The Atlas of Exposures includes information about exposures that might be associated with foodborne illnesses and can be used as a crude estimate of the background rate of different

5.2. Cluster and Outbreak Investigation Procedures

food exposures in the community to highlight increased rates of exposure among cases. These rates can even be compared statistically by using a standard binomial model (e.g., the one available at http://www.oregon.gov/DHS/ph/acd/keene.shtml.

For example, bagged spinach was first identified as the source of the 2006 *E. coli* O157:H7 outbreak on the basis of only six structured interviews (with five reporting consumption of bagged, prewashed spinach). FoodNet survey data suggested that only about 17% of the US population recalled eating any kind of fresh spinach within a given week. Combined with similar findings from other states conducting case investigations, these collective observations led to prompt action and further investigations, which rapidly identified the location, date, and even shift of contaminated spinach production.

Of course, comparisons with FoodNet survey results do not always yield such obvious associations with a single food item, but they still may suggest findings that can be tested in a controlled study. For example, use of a trawling interview form among *Salmonella* Tennessee cases in 2007 identified consumption rates for peanut butter (and several other foods) that were considerably higher than would be expected from FoodNet survey data. This in turn led to a focused case-control study with more detailed questions about those relatively few products, and a specific peanut butter brand then was readily identified as the source of the outbreak (Bill Keene, Oregon Public Health Services, personal communication, 2008).

Because the Atlas is based on surveys at selected sites at certain times, the findings must be extrapolated carefully to other populations and seasons. Results from the most recent FoodNet population survey are available at http://www.cdc.gov/foodnet/studies_pages/pop.htm.

Even in the absence of survey data, common-sense estimates of the prevalence of a given exposure can be used to identify exposures of interest more quickly. For example, although not included in the FoodNet surveys, the significance of finding five of five *Salmonella* Enteritidis cases reporting consumption of shelled almonds of a single brand was readily apparent not only to epidemiologists but to regulators and distributors as well, particularly because the *Salmonella* Enteritidis subtype had previously been implicated as the etiology of a large international outbreak traced to shelled almonds.

5.2.4.1.5. Conduct an environmental health assessment

When investigating a food-production or food-service establishment implicated in an outbreak, conduct an environmental health assessment. An environmental health assessment is a systematic, detailed, science-based evaluation of environmental factors that contributed to transmission of a particular disease in an outbreak. It differs from a general inspection of operating procedures or sanitary conditions used for the licensing or routine inspection of a restaurant or food-production facility. An environmental health assessment focuses on the problem at hand and considers how the causative agent, host factors, and environmental conditions interacted to result in the problem.

The goals of an environmental health assessment are to identify

- Possible points of contamination of the implicated food with the disease agent,
- Whether the causative agent could have survived (or, in the case of a toxin, not been inactivated),
- Whether conditions were conducive for subsequent growth or toxin production by the disease agent, and
- Antecedents that resulted in the conditions allowing the outbreak to happen.

5.2. Cluster and Outbreak Investigation Procedures

Although the primary goals of an environmental health assessment are to identify possible points of contamination, survival, or growth of the disease agent, to be most valuable, investigators need to identify "antecedents" that resulted in these conditions. Antecedents are the circumstances behind the problem and include inadequate worker education, behavioral risk factors, management decisions, and social and cultural beliefs. Only by identifying the problem behind the problem can investigators to develop effective interventions to prevent the problem.

The timing of the environmental health assessment depends largely on the specifics of the outbreak and available information. If you have a common location and a profile of symptoms among ill persons that indicates whether the disease agent is likely to be viral, bacterial, toxin, or chemical, then you can begin an environmental assessment. Early investigation and collection of specimens, if possible, will best reflect the conditions at the time of the outbreak. In addition, possible food vehicles can be discarded or grow old, and individuals involved in the production, processing, storage, transportation, or preparation of the item can change their practices and procedures.

5.2.4.1.5.1. Sources of information and activities included in an environmental health assessment

Epidemiologic information is necessary to initiate an environmental assessment and guides the assessment as it progresses. Once an investigation begins, sources of information for an environmental health assessment include product information (e.g., chemical and physical characteristics and source); written policies or procedures; direct observations and measurements; interviews with employees and managers; and lab testing of suspected foods, ingredients, or environmental surfaces.

The specific activities included 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 food,
- Talking with food workers and managers,
- Taking measurements (e.g., temperatures),
- Developing a flow chart or food 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 review documents on source of food.

These activities provide information needed to develop the most likely environmental picture of the facility before the exposures that led to the outbreak. Once a complete picture has been developed, contributing factors and antecedents can be determined.

5.2.4.1.5.2. Qualifications to conduct an environmental health assessment

To accurately relate the opportunities for contamination, survival, and growth of a disease agent in a food to a specific outbreak, the investigator needs a good understanding of

- Agent (e.g., likely sources, optimum growth conditions, inhibitory substances, means of inactivation),
- Factors necessary to cause illness (e.g., infectious dose, portal of entry), and
- Implicated vehicle (e.g., physical and chemical characteristics of the vehicle that might facilitate or inhibit growth, methods of production, processing, preparation).

5.2. Cluster and Outbreak Investigation Procedures

Critical thinking skills also are needed to analyze information that evolves from an environmental assessment and identify the likely source of the problem and how the disease agent, host factors, and environmental conditions interacted to support a specific outbreak. This level of knowledge and skill requires someone with special training in this field of investigation, such as a sanitarian or environmental health specialist.

5.2.4.1.6. Conduct informational tracebacks/ traceforwards of food items under investigation. Tracing the source of food items or ingredients through distribution to source of production can be critical to identifying epidemiologic links among cases or ruling them out. For nonbranded commodities, such as produce items, the convergence of multiple cases along a distribution pathway may identify the source of contamination. Conversely, failure to identify common suppliers may indicate that the food item in question is not a likely vehicle. Informational tracebacks of this type need to be conducted quickly to be incorporated into the epidemiologic studies. Formal regulatory tracebacks may be subsequently needed to confirm the distribution of implicated products.

5.2.5. Coordinate Investigation Activities

Whether the outbreak is restricted to one jurisdiction or involves multiple jurisdictions, notification and updates should be provided to other interested agencies following the Guidelines for Multijurisdictional Investigations.

Arrange for outbreak control team to meet daily and to regularly update the entire outbreak control team. In particular, if the outbreak has gained public attention, the public information officer needs to prepare a daily update for the media.

During investigation of outbreaks involving events or establishments, maintaining close collaboration between epidemiology and environmental health is particularly important. Interview results from persons who attended the event or patronized the establishment will help environmental health specialists focus their environmental assessments by identifying likely agents and food vehicles. Similarly, results of interviews of food workers and reviews of food preparation can identify important differences in exposure potential that should be distinguished in interviews of persons attending the event or patronizing the establishment. For example, environmental health investigators might determine that food items prepared only on certain days or by certain food workers are likely to be risky. These refinements also can help establish the need for or advisability of collecting stool samples from food workers or food and environmental samples from the establishment.

During the earliest stages of the investigation, patrons need to be interviewed rapidly. However, the focus of outbreak activities is likely to shift to interviews of food workers, environmental evaluations of the establishment, and review of food-preparation procedures as the investigation progresses.

During investigation of outbreaks detected by pathogen-specific surveillance, the public health laboratory needs to immediately forward case information to epidemiologists for every new potentially outbreak-associated case they receive. This will ensure rapid enrollment of new cases in the outbreak investigation studies. Similarly, as investigators acquire information from cases about exposures in restaurants and other licensed facilities, they should rapidly forward that information to environmental health specialists to ensure rapid identification of commodity ingredients and their distribution sources.

During the early stages of an investigation, efforts to identify mode of transmission and food vehicle require close coordination of the outbreak team under the leadership

5.2. Cluster and Outbreak Investigation Procedures

of epidemiology. After identification of a likely food vehicle, efforts to identify the source of contamination and contributing factors require engagement of local, state, or federal food-regulatory programs. As the investigation proceeds, the outbreak control team should always consider whether any information indicates the outbreak might be multijurisdictional. See Chapter 7 for information about identifying and responding to multijurisdictional outbreaks.

5.2.6. Compile Results and Reevaluate Goals for Investigation (see also Chapter 6, Control Measures)

Compile results of outbreak investigations in a manner that allows comparisons with the original goals for the investigation. State the original goals of the investigation and demonstrate how each goal was achieved; if the goal was not achieved, explain why**.** For example, in an investigation of an outbreak of vomiting and diarrhea associated with a restaurant, document the steps taken to identify the agent. These could include identifying the number of stool specimens collected, determining the intervals between onset of symptoms and collection of stool and between collection of stool and processing by the public health laboratory, identifying the methods used to culture or test the specimens, and determining the results of the tests.

Prepare epidemic curves, and update them daily to depict the beginning and end of the outbreak. Continued motion of successive epidemic curves, day by day over time, clearly indicates continuation of the outbreak (Box 5.1). Select time scales for the epidemic curve to highlight the agent, mode of transmission, and duration of the outbreak. Notable events, such as changes in food-processing methods or personnel or implementation of control measures, can be noted on the curve. Generating an accompanying timeline of the investigation's events as they happen often can be helpful.

Novel questions or opportunities to address

Box 5.1. Interpretation of epidemic curves during an active outbreak

The epidemic curve (epi curve) shows progression of an outbreak over time. The horizontal axis is the date a person became ill (date of onset). The vertical axis is the number of persons who became ill on each date. These numbers are updated as new data come in and thus are subject to change. The epi curve is complex and incomplete. Several issues are important in understanding it.

- There is an inherent delay between the date of illness onset and the date the case is reported to public health authorities. This delay typically is 2–3 weeks for *Salmonella* infections. Therefore, someone who got sick last week is unlikely to have been reported yet, and someone who got sick 3 weeks ago may just be reported now. See the *Salmonella* Outbreak Investigations: Timeline for Reporting Cases, http://www.cdc.gov/salmonella/reportingtimeline.html.
- Some background cases of illness are likely that would have occurred even without an outbreak; therefore, determining exactly which case is the first in an outbreak is difficult. Epidemiologists typically focus on the first recognized cluster or group of cases rather than on the first case. Because of the inherent reporting delay, a cluster sometimes is not detected until several weeks after people became ill.
- For some cases, date of illness onset is not known because of the delay between reporting and case interview. Sometimes an interview never occurs. If the date is known that an ill person brought his or her specimen to the laboratory for testing, date of illness onset is estimated as 3 days before that.
- Determining when cases start to decline can be difficult because of the reporting delay but becomes clearer as time passes.
- Determining the end of an outbreak can be difficult because of the reporting delay. The curve for the most recent 3 weeks always makes the outbreak appear to be ending, even when it's ongoing. The full shape of the curve is clear only after the outbreak is over.

5.2. Cluster and Outbreak Investigation Procedures

fundamental questions about foodborne disease transmission can develop during the outbreak investigation. The opportunity to address these issues might require reevaluation of the investigation's goals.

5.2.7. Interpreting Results

The outbreak investigator's job is to use *all* available information to construct a coherent narrative of what happened and why. This begins with the initial detection of the outbreak and formation of hypotheses based on the agent's ecology, microbiology, and mechanisms of transmission in addition to the descriptive epidemiology of reported cases. Results of subsequent analytic studies (e.g., cohort or case-control study results) must be integrated with results of informational product tracebacks, food worker interviews, environmental assessments, and food product and environmental testing. When all of these data elements support and explain the primary hypothesis very strong conclusions can be drawn.

Identifying and exploiting less-obvious data sources may require some imagination. Interview questionnaires are a critical starting point, but often do not provide all the answers. For example, when cases are associated with institutional settings or restaurants, it may be necessary to use the institution rather than the case as the unit of observation. Cross-referenced lists of suppliers and food items at different institutions may be more difficult to assess statistically because of their small numbers, but they can help focus commercial product-type investigations. Similarly, relevant restaurant records include much more than menu lists.

Investigators should consider their data critically and question the strength of the association, timing, dose-response, plausibility, and consistency of findings when implicating a food item (Box 5.2). Questionnaire data are often faulty: collected long after the fact, perhaps by proxy, and sometimes tainted by biases known and unknown. Investigators can create or compound errors during transcription, keypunching, or analysis. Records are often incomplete or unavailable. Without a systematic bias, larger data sets tend to be more robust; and minor errors may be cancelled out (or ignored), but the size of the data set is often beyond one's control. Statistical association between exposure and illness may reflect a causal link but also may reflect confounding, bias, chance, and other factors. If three food items on a questionnaire have a P value <0.05, for example, it does not mean that all three (or indeed, any of them) are "implicated" as a vehicle. Conversely, the failure to achieve a P value <0.05 cannot rule out a causal role for a particular food item. As noted above, observed associations have to be placed in the context of the other investigation results.

Although epidemiologists should be open to new developments and new twists to old problems, they should be wary of explanations that depend on implausible scenarios. For example, truly localized outbreaks are unlikely to result from manufacturing defects in nationally distributed products. Outbreaks that differentially affect young children are unlikely to be caused by salad items. Salmonellosis cases are unlikely to become symptomatic within 12 hours of exposure. Minor inconsistencies are common and may be ignored, but large numbers of inconsistencies might indicate that alternate hypotheses need to be considered.

General principles underlie successful investigations; however, no one specific method works best in all situations. Investigators need to be flexible and innovate as circumstances demand. On one point we can agree: investigations that are never begun or that are haphazardly carried out are unlikely to yield satisfactory results. "Eighty percent of success is showing up," said Woody Allen—and

5.2. Cluster and Outbreak Investigation Procedures

Box 5.2. Questions to consider when associating an exposure with an outbreak

Strength of association

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

Timing

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

Dose-response effects

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

Plausibility

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

Consistency with other studies

Studies associated with current investigation

- Do the results of traceback and traceforward investigations suggest a common source?
- Have environmental health assessments identified problems in the production, transport, storage, or preparation of the implicated item that would allow for contamination, survival, and proliferation of the pathogen in that item?
- If the pathogen was isolated both from ill persons and the implicated item, do subtyping results (e.g., PFGE analysis) confirm the association?

Studies not associated with current investigation

Is the association between the pathogen and the implicated item consistent with other investigations of this pathogen?

that applies to outbreak investigations too. Jurisdictions that cannot commit resources to outbreak investigations themselves should do whatever they can to facilitate follow-up of their cases by other agencies (e.g., counties to states; states to other states or CDC).

Experience reminds us—again and again, unfortunately—that even seemingly well-executed investigations can be inconclusive. Small sample sizes, multivehicle situations, "cryptic" food items, foods with high background rates of consumption are only

5.2. Cluster and Outbreak Investigation Procedures

some of the factors that can reduce the effectiveness of standard epidemiologic methods and make investigations extremely difficult. The decision to stop an investigation depends on the gravity and scope of the outbreak and on the likelihood that it reflects an ongoing public health threat. Before giving up, extraordinary measures, such as home visits and mass testing of leftover products, may be worth considering.

5.2.8. Conduct a Debriefing at End of Investigation

Encourage a postoutbreak meeting among investigators to assess lessons learned and compare notes on ultimate findings. This is particularly important for multiagency investigations but also is important for single-agency investigations.

5.2.9. Summarize Investigation Findings, Conclusions, and Recommendations

At a minimum, document every outbreak investigation using a standardized form to facilitate inclusion in state and national outbreak databases (e.g., CDC's form 52.13 or its equivalent).

Summary data should be reported nationally to CDC's National Outbreak Reporting System (NORS) database. The usefulness of the reports depends on the quality and quantity of information submitted. Make every effort to complete both **Part 1: Basic Information, and Part 2: Additional Information,** and submit the information as soon as possible.

In addition, investigators are encouraged to submit preliminary reports of outbreaks while the investigation is ongoing. If submission is timely, these reports can help identify potentially related outbreaks occurring simultaneously in multiple places and facilitate further investigation of the outbreaks.

Routinely review and summarize data from these reports (e.g., in annual outbreak summaries) at the state and national level.

Larger or more complex investigations or investigations with significance for public health and food-safety practice demand a more complete narrative report and, potentially, publication in a peer-reviewed journal. Written reports should include the following:

- Background, including information about the outbreak setting, timing, and manner of detection, and an explicit statement of the goals of the investigation.
- Methods, including other agencies involved in the investigation, investigation methods, case definition, number of people exposed, number interviewed, number ill, number of stool samples collected, pathogens tested for in stools, and a high-level summary of the laboratory methods used.
- Results, including percentages of cases with fever, diarrhea, vomiting, and bloody diarrhea; median and range of incubation period and duration of illness; results of stool testing; food items or events associated with illness and odds ratio(s) or relative risks and confidence intervals for implicated food(s); all relevant findings from environmental investigations of establishments and food-preparation reviews; results of food worker interviews; and food worker stool culture results.
- Conclusions, including etiologic agent, discussion of transmission route, contributing factors, justifications for conclusions, and limitations of the study.
- Recommendations, including all specific recommendations for abatement of this outbreak and prevention of similar outbreaks.

5.2. Cluster and Outbreak Investigation Procedures

5.2.10. Distribute Report

Make copies of the report available to all persons involved with the investigation, including

- Investigation team members and their supervisors;
- Health department officials and press officers;
- Food-safety and regulatory agency officials and press officers;
- Health-care providers who reported cases; and
- Laboratorians who performed tests.

Also distribute copies of the report to persons responsible for implementing control measures, including

- Owners and managers of establishments identified as the source of the outbreak;
- Program staff who might oversee implementation of control measures or provide technical assistance; and
- Organizations or regulatory agencies that might develop or implement policies and regulations for which the investigation might have implications.

The report is a public record and should also be made available to members of the public who request it.

5.3. Multijurisdictional Considerations for Outbreak Investigations

Increased reliance of the United States on large-scale food distribution systems and international food sources has increased the likelihood of outbreaks in multiple jurisdictions. Local and state health agencies always need to be sensitive to the potential for rapid escalation of any outbreak to a regional or national event. (See Chapter 7).

5.4. Indicators/Measures

Key indicators and measures to assist in assessing investigation processes and the overall success of outbreak investigations can be found in Chapter 8.

CHAPTER 6

Control Measures

The purpose of outbreak investigations is to stop the current outbreak, determine how the contamination occurred, and implement prevention-based approaches to minimize the risk for future outbreaks. **Whereas the investigation is critical for understanding the cause, effective control measures are critical for actually stopping the outbreak.**

Specifically, the objectives of control measures are to

- Prevent additional exposures, and
- Alert the public, and tell people how to protect themselves.

In addition, investigation into the circumstances likely to have contaminated the food will lead to long-term prevention efforts.

The objectives of this phase of the investigation are to

- Prevent future outbreaks from the same uncorrected practices, and
- Identify changes in policy or practice changes that will prevent future outbreaks from similar causes.

6.0. Introduction

Rapid response is key. Rapidly assess information to identify suspected food or facilities, and send investigators into the field as soon as possible. Contaminated food may be served at the next meal, or an ill employee may repeatedly contaminate food products. Practices that led to the outbreak are likely to continue unless an intervention stops them. The source of the outbreak could be a nationally distributed food product, and a recall might be necessary to prevent additional illnesses across the country.

Jurisdictional differences determine when staff are sent to an implicated site. Some jurisdictions have policies of sending staff out immediately after a complaint about a food establishment. Others require multiple complaints about a site or wait until a specific food is implicated. Any time an outbreak is identified and potentially linked to a site, immediate response is critical.

The two major types of foodborne disease outbreaks—those originating from food-service establishments or home processing and those originating from commercial processors/producers—require two different types of control measures. However, early in an outbreak, investigators are unlikely to know the actual cause of the problem. Some type of poor food handling practices can be found at any time in most restaurants. Going to a restaurant and identifying these poor food handling practices may distract from the outbreak investigation, if the outbreak is not local. Control measures will vary according to setting and time and might change as more information becomes available.

Communication is critical in determining what control measures to implement and when to change an intervention's focus. Field staff implementing control measures must constantly communicate with epidemiologists and laboratorians, who might uncover a different potential cause for the outbreak. Information gathered by field staff also can lead epidemiologists in a new direction.

6.1. Information-Based Decision-Making

6.1.1. Concurrent Interventions and Investigations

Control measures can be implemented concurrently with investigations. Waiting for laboratory results, confirmed medical diagnosis, or results of all investigations is not necessary before implementing initial control measures. Sometimes nonspecific control measures can be implemented immediately to prevent further transmission of disease, regardless of the type of disease or source (see section 6.2.1 below).

Sending at least two investigators to a food establishment implicated in an outbreak is best. One investigator can make certain food about to be served is safe (e.g., no implicated leftovers are served, foods are at proper temperature, food was prepared without contact by bare hands, no ill food workers are preparing food). The second investigator conducts the investigation (e.g., obtains the menu to review everything served to cases, identifies persons who prepared suspected items, determines how the foods were prepared, determines what other groups were served the same foods). (See Chapter 5 for additional information about investigation steps.)

6.1.2. Considerations When Implementing Control Measures

Interventions such as recalling food or closing food premises can have major legal or economic consequences, just as inaction

6.1. Information-Based Decision-Making

or delayed actions can have important public health consequences. **The outbreak control team must balance potential consequences against the likelihood that any actions taken will prevent further cases of disease.** Issues to be considered when deciding whether to implement an intervention include

- The quality of information. Does evidence implicating a particular source include results of a controlled study (e.g., case-control study or cohort study)? If so, was the study well-designed and executed and of sufficient size to detect differences? What is the likelihood of information or selection bias or confounding? Are the findings of different studies consistent, e.g., several case-control studies undertaken at different sites or among epidemiologic, environmental, and microbiologic studies? Is the implicated source biologically plausible? Is the implicated source new or novel?
- The outcome of the environmental assessment. Do the findings from the environmental assessment support the conclusions drawn by the epidemiologic or laboratory team members? Does the environmental assessment establish a picture of events that could logically support the overall epidemiologic picture of the outbreak?
- The balance between consequences of taking and not taking action For example, one is more likely to take action if the illness is serious or life-threatening (e.g., botulism or *E. coli* O157:H7), the population affected is at high risk for serious complications, or exposure is thought to be ongoing. Consider the potential impact on business or industry. Does taking action present a minor inconvenience or will it have resounding and lasting effects on the business or industry? Will the actions affect only one business or an entire industry? What is the burden on the involved public of taking action?

These considerations can add confidence to decision-making, but no one person should make decisions alone unless an imminent danger is obvious (e.g., an ill food worker is found preparing food and is excluded). **Decisions about implementing, or waiting to implement, an intervention require input from the entire investigation team, including epidemiology, laboratory, and environmental health specialists, and may need input from companies or trade associations.**

6.2. Control of Source

6.2.1. Nonspecific Control Measures

6.2.1.1. Neither food nor facility has been implicated

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

Communications with health-care providers might include advice about specific treatment and follow-up of cases, instructions to cases on personal hygiene and ways to avoid spreading the infection to others, and infection control precautions for hospitalized and institutionalized patients. Communications with the public include practical measures to decrease risk for illness (e.g., avoidance of known high-risk foods or special instructions for their preparation) as well as basic food-safety messages and information about how to contact public health authorities to report suspected related illnesses.

6.2. Control of Source

Alerting the public about an outbreak early in an investigation, when little is known (or can be done) about it, is not without controversy. Announcements about an outbreak (and even implication of a food without information about its origin) can alarm (and even panic) the consumers who can do little to protect themselves and cause them to undertake unnecessary or irrational actions. Such announcements can also negatively effect industry as the public strives to avoid all foods (or other products) possibly related to the outbreak.

The balance between possible harm to consumers and industry and likely benefit of such announcements must be carefully weighed. However, if such communications could prevent additional cases of the disease, they should be considered when the disease is serious, life-threatening, or widespread and/or may particularly affect individuals at high risk for poor health outcomes from the disease.

6.2.1.2. Facility has been implicated

Nonspecific control measures can be implemented when a facility has been implicated, even though a specific food has not yet been identified. **These steps are good public health practice and generally are effective, regardless of disease.** These critical first actions include

- Properly holding the leftovers for further laboratory analysis, if warranted;
- Stopping bare-hand contact;
- Emphasizing hand washing;
- Monitoring time and temperature control of food;
- Excluding employees ill with gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea, stomach cramps); and
- Prohibiting serving of uncooked foods if any possibility of norovirus exists.

In deciding what control measures to implement, check with epidemiologists and laboratory team members to determine the type of pathogen thought to be the cause of the outbreak if the specific cause is not known. For example, on the basis of the symptoms of ill persons, these team members can characterize the type of agent involved—e.g., viral, bacterial, chemical. This information can assist in identifying and prioritizing control measures.

Check the history of the establishment for previous outbreaks or food-safety problems. What is the establishment's history of correcting violations? A history of serious hazards or of not correcting violations might warrant closure.

While taking these first actions, be sure to collect samples for laboratory analyses. Discarding suspected food can help stop the outbreak, but isolating the etiologic agent from the food provides additional evidence of a particular food as the outbreak's source. It is important to collect food samples as early in the outbreak investigation as possible. Whether to analyze these samples can be decided later when more information is available. Storage capacity for samples collected for later analysis should be considered before an outbreak. Contact your public health laboratory to find out how much food to collect, how to collect it, and how to store it.

6.2.2. Specific Control Measures

When a specific food(s) has been implicated, specific control measures can be implemented. Although all of the following control measures are recommended, full implementation of all these practices might not be possible in many jurisdictions because of limited resources and competing priorities. Implementing as many as possible and as completely as possible will improve the effectiveness of the control measures.

6.2. Control of Source

Control measures to be implemented vary depending on whether the implicated food is associated with food-service establishments (whether single or multiple facilities) or home processing or is processor/producer-based. The outbreak response team must initially determine whether a single facility or multiple facilities are involved.

6.2.2.1. Foods associated with food-service establishments or home processing

6.2.2.1.1. Removing food from consumption

- Samples should be collected of any foods discarded by the owner of an establishment or foods embargoed by public health officials.
- Ask that the owner discard or hold and discontinue serving all implicated food. If a facility, but no specific food, has been implicated, ask that the owner discard or hold and discontinue serving all food for which a link to the outbreak is biologically plausible. Before making this request, consider the severity of the illness and the nature of the implicated pathogen. For example, this action may be appropriate for *E. coli O157:H7*, but not for suspected norovirus. Reserve samples for testing.
- If the owner will not discard or hold and discontinue serving the food voluntarily, the agency might need to issue a public health order to require action. (This varies by jurisdiction; some agencies might be able to embargo food without a public health order.) In investigation and enforcement matters, issuing a written hold or embargo order establishes a clear expectation for holding the food. This will prevent the owner from destroying the food before the investigation is complete.
- Fully document the information that led to the decision (whether to remove or not remove food) and the process used to make the decision.

6.2.2.1.2. Cleaning and sanitizing

- Ensure the facility is thoroughly cleaned and sanitized, followed by microbial verification of the effectiveness of the cleaning and sanitizing processes. This includes disassembling all equipment and retraining staff on proper cleaning and maintenance procedures for the equipment. The cleaning and sanitizing process is particularly important if norovirus is suspected.

6.2.2.1.3. Training

- Require training of staff on general practices of safe food preparation and, if the specific pathogen is known, practices specific to control of that pathogen
- Require the facility manager to document training of both current and newly hired staff.

6.2.2.1.4. Modifying a food-production or food-preparation process

- Ensure that food-production or food-preparation processes are appropriate and adequate to prevent further contamination of food or survival and growth of microbes already present in food.
- Modify processes if needed to reduce risk, such as changing a recipe, changing a process, reorganizing preparation processes, changing storage temperatures, or modifying instructions to consumers. Evaluate the proposed times, temperatures, pH, and water activity level for controlling the pathogen of interest, on the basis of sufficient scientific evidence.
- Conduct follow-up monitoring to ensure that modified processes have been implemented and are effective in addressing the food-safety problem.
- Put in place a Hazard Analysis and Critical Control Point (HACCP) system or other preventive controls.

6.2. Control of Source

6.2.2.1.5. Modifying the menu

- Eliminate implicated foods from the menu until control measures are in place. For example, if shell eggs are implicated, remove all foods that contain shell eggs, and substitute pasteurized egg product until the investigation is complete and proper controls are in place.

6.2.2.1.6. Removing infected food workers

- Ensure that infected food workers are removed from the workplace (see section 6.3.3).

6.2.2.1.7. Closing food premises

- If the facility has multiple problems, and if the owner is unable or unwilling to take immediate corrective action, closing the premises might be necessary. The facility must meet closure requirements as defined in local regulations, such as lack of hot water, vermin infestation, or raw surfacing sewage, or be determined from observation or evidence that disease could be spread due to increased risk factors.
- Ask "If this place is not closed, are more people highly likely to become ill? Would I let a family member eat here?"
- If the food premises are in an institution in which residents have no alternatives, work with institution staff either to identify options for bringing in food or to leave food premises open but eliminate high-risk items from the menu.
- If the facility owner will not act voluntarily, employ other control measures, such as cease-and-desist orders, permit action, and hearing in front of a judge.
- Follow local regulations when requiring closure of food premises. Reopen only when risk factors have been eliminated and testing indicates the problem has been eliminated.

6.2.2.1.8. Communication with the public

- If the outbreak involves only one facility, determine whether public notification is necessary. All members of the outbreak response team (epidemiology, environmental health, and laboratory) should be involved in making this decision. Ask the following questions:
  - Is medical treatment necessary for persons who may have been exposed to the etiologic agent? If so, public notification is critical.
  - Is public reporting of suspected illness necessary to determine the scope of the outbreak? If so, public notification might be appropriate.
  - Is the outbreak short-term so no further risk exists to the public? If so, public notification generally is not necessary.
  - Does risk for exposure still exist? People take food home from restaurants, so public notification still might be appropriate.
- Prepare communication following the agency's risk communication protocols. Seek assistance from the agency Public Information Officer or the Public Information Officer at another agency if the agency with jurisdictional responsibility does not have this resource.

6.2.2.2. Foods associated with a processor/producer

Implication of multiple food establishments in an outbreak or receipt of multiple, seemingly unrelated reports of illness from consumers eating the same type of food suggest an outbreak caused by food contaminated at the processor/producer-level. Traceback investigations can help identify the point in the production and distribution process at which the implicated food most likely became contaminated and allow for targeted environmental health assessments to determine how the food became contaminated and to recommend specific interventions.

6.2. Control of Source

Depending on the outbreak and probable point of contamination, most of the specific control measures listed above (6.2.2.1. Food associated with food-service establishments, or home processing) will also be appropriate once the point of contamination is identified. However, food implicated in these outbreaks might be more likely to be in distribution, at retail establishments or in the homes of consumers. Therefore, public health and food-regulatory agencies also will need to decide whether to remove the suspected food from the market using the procedures defined in 6.2.2.2.1 below.

Questions to ask in considering whether to remove food from the market

- Is risk to consumers ongoing?
- Is the product still on the market?
- Is the product likely to be in the homes of consumers?
- Does the information justify removing food from the market? Remove the food if
    - o Definitive lab results show the outbreak pathogen is present in the product. The results must be based on a food sample that is representative of the food eaten by the cases and has been handled properly to avoid cross-contamination.
    - o The illness and consumption of that food show a strong epidemiologic association (e.g., through a case-control or cohort study), even if the pathogen has not been isolated from the food. Strong epidemiologic association requires a good quality analytic study that definitively links the implicated food to the cases.
    - o Epidemiologic association is not strong, but pathogen is so hazardous that the risk to the public is very high. Under these circumstances, there may be no analytic, controlled studies, but the descriptive epidemiology suggests an association between the disease and the suspected food.

Fully document the information that led to the decision (whether to remove or not remove food) and the process used to make the decision.

6.2.2.2.1. Procedures for removing food from the market

Once a decision is made to remove food from the market, the goal is to remove it as quickly and efficiently as possible. Foods with short shelf lives (e.g., fresh produce, meat, dairy products) generally are consumed or discarded within 7–10 days and already may have been disposed of. Foods with longer shelf lives most likely will still be around. Try to prevent additional exposure by ensuring suspected food is not eaten.

Contact the federal or state regulatory agency that has jurisdiction over the product. The Food and Drug Administration regulates the safety of most foods, except meat, poultry, and pasteurized egg products which are regulated by the U.S. Department of Agriculture. FDA (or USDA) will contact the manufacturer about the decision to remove the product from the market and will obtain the manufacturer's cooperation. The manufacturer may decide to issue a food recall. In addition, ask retailers within your jurisdiction to voluntarily remove the product from their shelves and distributors to voluntarily withhold the product from distribution.

Recall of food at the processor level generally requires federal and/or state action. In some jurisdictions, the local health jurisdiction will embargo (impound) the food (tagging the food to make sure it is not moved or sold or ordering it destroyed). USDA or FDA do not have authority to mandate such action without court order, so they may ask a state or local health jurisdiction to embargo the food temporarily. However, state and local jurisdictions must evaluate the merits of an embargo independently, according to their statutes or ordinances.

6.2. Control of Source

The following recommendations for manufacturers and retail establishments can help ensure the recall is effective:

Manufacturers

Recall preparedness (before an outbreak occurs):

- Maintain product source and shipping information for quick access in conducting tracebacks and traceforwards during an investigation and/or recall.
- Develop the ability to rapidly notify all customers of a recall through blast e-mail and fax, calls, and mail to retail establishments who purchased recalled foods.
- Identify and develop procedures to prevent common errors that lead to recalled food being put back into commerce (e.g., recalled food is returned and accidentally put back into distribution by workers).

After a recall is announced:

- Quickly remove recalled contaminated product from the distribution system.
- Notify customers through the regulatory agencies and news media as needed.
- Ensure retail customers have clearly defined storage areas and handling processes for recalled products, including denaturing or other process to ensure foods are not resold.
- Put in place systems for safe handling or disposal of recalled products to avoid cross-contamination to other products, accidental redistribution, diversion, and creation of other hazards.

Retail Establishments

Recall preparedness (before an outbreak occurs):

- Maintain product source and shipping information for quick access in conducting tracebacks and traceforwards during an investigation and/or recall.
- When store cards are issued, obtain customers' e-mail addresses, and inform them they will receive notifications of any recalls concerning items they purchase. Develop a standardized template for consumers giving permission to retail stores to provide their store card information to outbreak investigators.
- Develop the ability to rapidly notify all customers of a recall through blast e-mail and fax, calls, and mail to people who purchased recalled foods.
- Identify and develop procedures to prevent common errors that lead to recalled food being put back into commerce (e.g., recalled food is returned and accidentally put back onto shelves or into distribution by workers; product is pulled from sale, but another shipment arrives and is put onto the shelves or into distribution).

After a recall is announced:

- Quickly remove recalled contaminated product from commerce at the site.
- Notify customers through the regulatory agencies and news media as needed.
- Post signs at the point of sale to advise consumers about the recall.
- Put in place fail-safe systems that do not allow sale of recalled products (e.g., cash register flags recalled products and prohibits sale). Ensure stores have clearly defined storage areas and handling processes for recalled products, including denaturing or other process to ensure foods are not resold.
- Put in place systems for safe handling or disposal of recalled products to avoid cross-contamination to other products, accidental restocking, diversion to unsuspecting consumers, and creation of other hazards.

6.2. Control of Source

Consider the possibility of homeless persons removing discarded product from the trash.

- For a highly dangerous condition such as botulism, food seizure by the health department or regulating agency is appropriate to ensure immediate and complete removal of the suspected food from the market

To improve the effectiveness of recall measures and industry response, health departments can

- Develop a list of control measures to implement immediately when an outbreak-related or illness-related recall has been identified.
- Identify industry needs, and develop guidance for interacting with health or agriculture officials investigating an outbreak. Provide retailers and manufacturers with 24/7 contact numbers and e-mails for regulators at the local, state, and federal levels, including FDA and USDA/FSIS.
- Develop guidance for communicating with the news media.
- Develop guidelines for mitigating impact of the recall, such as providing refunds for returned product.
- Develop templates, message maps, or community information sheets for common foodborne agents for use during an outbreak.

Regulators responsible for retail food facilities need a means to notify all food facilities in their jurisdiction immediately through e-mail, blast fax, or phone calls. Identifying subcategories of facilities is highly recommended so notices can be targeted to specific facilities (e.g., notices of a seafood recall sent specifically to seafood restaurants). Lack of such a system is not acceptable. This process should include food bank donation centers and other sites that might have received food donations.

If any distributors or retailers refuse to remove the food, issuance of a public health warning and order to require action might be necessary. The appropriate agency for taking this action depends on the type of food and etiologic agent.

Monitor to ensure the food is completely removed. This often requires close cooperation among local, state, and federal agencies on recall effectiveness checks. If the product is not immediately removed, determine why. (Did the manufacturer notify the distributor? Did the distributor notify retailers of the recall? Did notifications occur but no action was taken? Was returned recalled product diverted and sold elsewhere?)

6.2.2.2.2. Communication with the public

Messages to the public about foodborne disease outbreaks should follow good risk communication practices. Ideally, templates for public messages should be prepared before the outbreak and used consistently. See general communication section below.

Notify the public if the outbreak involves distributed product. Provide information about how to handle the suspected product (discard, special preparation instructions, or return to retailer). Provide information about the disease, including symptoms, mode of transmission, prevention, and actions to take if illness occurs.

If the manufacturer refuses to recall the food, it should be advised promptly that public health agencies or regulators might issue their own notice to the public, and the notice could include the message that the firm declined to voluntarily recall the product. **The message to the public should describe the problem and provide clear actions.**

Means of notification depend on the public health risk and might include press releases, radio, television, fax, telephone,

6.2. Control of Source

e-mail, or letters. The manufacturer, public health agencies, regulatory agencies, retail food establishment, or all four can initiate notification. These releases should be coordinated and include consistent messages to avoid confusing the public.

Attempt to reach all members of the population at risk, including non-English–speaking and low-literacy populations. Provide only objective, fact-based information about the outbreak. Do not give preliminary, unconfirmed information. If a specific food—such as a particular brand of bagged baby spinach—is implicated, the press releases need to inform consumers whether the local jurisdiction is interested in obtaining the product from households that still have it, and if not, the proper method of disposal.

If the outbreak is large or the etiologic agent is highly virulent, consider setting up an emergency hotline so the public can call with questions. Persons answering the phones should be trained to give consistent responses. This may require authorizing emergency overtime to answer phones after the early evening news.

If press releases are to be issued by retailers or manufacturers, relevant local, state, or federal officials should review and approve them before release. Manufacturers often seek guidance on the contents of their press releases, and public health agencies can provide needed information.

The state or local agencies responsible for the investigation should issue their own press releases, even if the affected industry or business also is issuing a release. Local press releases often result in better coverage from the local media. If more than one state or local agency is involved, coordination of press releases is important. If time allows, give affected industry members or businesses an opportunity to comment on your releases. However, avoid prolonged negotiations about wording.

6.2.2.2.3. Postrecall reporting by the business

If a business or manufacturer recalls a product, it should prepare interim and final reports about the recall. The contents of these reports are used to determine the need for further recall actions.

The reports should include copies of all notices distributed to the public and through the distribution chain, as well as the following information:

- Circumstances leading to the recall and actions taken,
- Extent of distribution of the suspected food,
- Result of recall (percentage of suspected food recovered),
- Method of disposal or reprocessing of suspected food,
- Difficulties experienced in recall, and
- Actions taken to prevent recurrence of food-safety problems and any recall difficulties.

6.3. Control of Secondary Transmission

6.3.1. Information for Health-Care Providers

Communicate with health-care providers in the community to encourage them to report cases of the illness under investigation and to provide specific treatment and infection control guidance. Encourage health-care providers to collect appropriate patient specimens.

6.3. Control of Secondary Transmission

6.3.2. Information for the Public

Any outbreak is an opportunity—or "teachable moment"—to reinforce basic food-safety messages to the public and to inform the public about how to contact appropriate authorities to report suspected foodborne illnesses.

6.3.2.1. Personal protection from disease outbreak

- Thoroughly wash hands with soap and warm water after defecation and urination, and before preparing or consuming food. Also wash hands after changing diapers, assisting a child at the toilet, and handling animals or animal waste. Hand washing is the single most important measure to protect the health both of an individual and other people.
- At home or at a social gathering (e.g., potluck dinner), avoid eating food that has not been handled properly (e.g., hot food that has not been kept hot, cold food that has not been kept cold).

6.3.2.2. Proper food preparation

- Use best practices when handling food at home (thoroughly cook food; keep hot food hot and cold food cold; thoroughly clean all food-preparation surfaces and utensils with soap and water; avoid contaminating food that will not be cooked, such as salads, with food that must be cooked, e.g., chicken; and wash hands frequently with soap and water).

6.3.2.3. Advice on personal hygiene

- If you are ill, avoid preparing food for others until free of diarrhea or vomiting.
- Wash hands as described above (Section 6.3.2.1).
- If someone in the household has diarrhea or vomiting, clean toilet seats and flush handles, and wash basin taps and washroom door handles with disinfectant after use. If young children are infected, undertake these cleaning procedures on their behalf. If norovirus (which is highly resistant to adverse environmental conditions) is involved, promptly clean contaminated surfaces with at least a 1:50 dilution of chlorine bleach and then rinse. Wash clothes, towels, and linens soiled with vomitus or stool at the highest temperature the item will allow.

6.3.3. Exclusion of Infected Persons from Settings Where Transmission Can Occur

(including food-preparation, health-care, and child-care settings)

Persons with an enteric illness can shed viruses, bacteria, or parasites for weeks after symptoms end. Infected skin lesions can be a reservoir for pathogens, which can be transmitted to food through bare-hand contact.

In general, if a person has been ill and is considered a possible source of pathogens, he or she should be restricted to specific areas and tasks that provide minimal risk for transmitting the disease. Even if given duties not involving food preparation, workers infected with norovirus can transmit infection, must wash their hands carefully, and avoid bare-hand contact with food.

If restricting the individual is not possible, excluding him or her from the facility might be necessary until all likelihood of shedding pathogens has passed. Testing the person may be necessary to ensure no further risk. Persons who are no longer ill with vomiting or diarrhea usually can return to work without testing if they practice good personal hygiene and are adequately supervised. The potential for risk is agent-dependent. For example a person shedding *E. coli* O157:H7 or *Shigella* is more likely to be a public health threat than someone shedding *Salmonella*.

For pathogen-specific guidance and other information about restriction and exclusion of food workers, consult the latest version of the FDA Food Code at http://www.cfsan.fda.gov/~dms/fc05-toc.html. State and local

6.3. Control of Secondary Transmission

health departments may not have the legal authority to exclude food workers unless that individual has acute symptoms. In addition, scientific evidence supporting exclusion of food workers may not be reflected in state or local food codes or may not be available at all. However, if the outbreak control team believes a public health threat exists, the team should strongly recommend exclusion of food workers. Consult your local ordinances and state statutes to understand the legal authorities under which you must operate.

One issue to consider in deciding whether to exclude infected persons is the occasional retaliation by employers against workers, either by having their pay docked during or after the exclusion period or being fired. This can hamper investigations because employees may be reluctant to provide truthful health information to avoid exclusion. Strategies that can mitigate this concern include developing regulations that prohibit retaliation and helping employers identify alternate jobs that ill food workers can perform.

Identify and dispose of or embargo all food potentially contaminated by the ill or infected worker. When determining which food is at risk, consider food-preparation procedures, dates the food worker worked, and dates the food worker probably was able to transmit disease.

6.3.4. Infection Control Precautions

Work with the facility operator to create a risk-control plan or consent agreement so the operator knows exactly what steps need to be taken and has committed to control the situation and prevent additional outbreaks. The risk-control plan or agreement can include actions above and beyond those required by regulation (e.g., extra temperature checks and logging of temperature, mandatory glove use by all food workers, routine inquiries of staff before their shifts about whether they have had diarrhea or vomiting in the last 24 hours). Ideally both epidemiologists and environmental health specialists are involved in creating this plan or agreement. Important aspects of the plan are (a) employee training and (b) adequate oversight to ensure employees follow proper procedures.

Educate food workers about the implicated disease (symptoms, mode of transmission, and prevention) and about general infection control precautions.

Emphasize the importance of thorough hand washing and not working when ill.

Reinforce the following:

- Policy of no bare-hand contact with ready-to-eat foods,
- Proper use of gloves and utensils when handling ready-to-eat foods,
- Proper holding temperatures, and
- Proper procedures for rapid cooling and thorough cooking and reheating of foods.

Infection control precautions for hospitalized and institutionalized persons with infectious diarrhea (particularly easily transmissible infections such as *Salmonella* serotype Typhi, *Shigella*, and norovirus) include

- Isolation of patients (e.g., in a private room with separate toilet if possible);
- Barrier nursing precautions;
- Strict control of the disposal or decontamination of contaminated clothing, surfaces, and bedding; and
- Strict observation of personal hygiene measures (see above).

Use chlorine solutions or other approved effective sanitizers or methods (e.g., steam cleaning carpets) rather than standard cleaning chemicals to clean and disinfect all surfaces after a norovirus outbreak.

6.3. Control of Secondary Transmission

Recommended practices for infection control frequently are changed and updated. Routinely check key sources, such as CDC, to ensure your organization's recommended practices are current.

6.3.5. Prophylaxis

Set up processes with area hospitals, physicians, local health departments, specialty clinics, or other health-care providers to provide prophylaxis if needed. Have tested plans in place for large-scale prophylaxis.

Develop processes to identify and communicate with persons who may need prophylaxis. Depending on the organism, this might include giving special consideration to protecting special risk groups. For example,

- Certain groups are at higher risk than others for severe illness and poor outcomes from foodborne disease, including infants, pregnant women, and immunocompromised persons. Safe food-preparation practices and hand washing particularly need to be emphasized to these groups.
- Specific advice might need to be issued to certain groups, such as advising pregnant women and immunocompromised persons against consuming unpasteurized dairy products or other products potentially containing *Listeria*.
- Persons with underlying chronic hepatitis B or C may need to be advised to be vaccinated against hepatitis A.

6.4. Communication

6.4.1. With Other Members of the Investigation and Control Team

Communicate actions taken and outbreak status information to all persons involved in an outbreak investigation, including those in different agencies or different departments within the agency.

Keep the owners or managers of the implicated establishment informed, and notify them that they must share any new reports of illness or other new information that could affect the investigation. Illness complaints reported to retail food chains or the manufacturer about a commercial product may lead to expansion of a recall if additional product codes are associated with illness.

6.4.2. With Agency Executives and Other Agencies

Ensure that agency heads routinely receive information about the status of the outbreak investigation and cleanup.

If the outbreak is potentially multijurisdictional, ensure that other relevant agencies and organizations routinely receive status reports. These might include local, state, and federal health, agriculture, and regulatory agencies. If an outbreak potentially involves a food from a source outside the jurisdiction identifying the problem, notify all appropriate surrounding health jurisdictions, and call the manufacturer and the retail food store chain (if one is involved) to determine whether they also have received illness complaints. This early communication may help to identify the source quickly.

6.4.3. With the Public

If the public has been informed about an outbreak, periodically issue updates about the outbreak's status.

Recognize that the public obtains news from multiple sources—the Internet, television, radio, and newspapers. Use all available sources to disseminate information. Know the typical deadlines for local news outlets, and try to release information within those timelines.

6.4. Communication

If the public is not receiving needed information from the public health agency, people will get it from other sources (which might not be accurate). The public health agency should be seen as and act as the most reliable source of information.

An agency cannot wait until all the facts are available before communicating with the public. People need enough information to help them make good decisions to protect their health.

Important terms (e.g., risk, bacteria) might seem common but in fact often are misunderstood. Adopt a standardized format for reporting risk information. Communications about foodborne disease risks should be routine (meaning the same process should be used each time); this helps make the process more familiar and reduces concerns about the message.

In communication planning, adopt standardized scripts for reporting complex procedural or technical information about the investigation and actions the public should take. Messages to the public should be tested first with representatives of the target population.

6.4.4. With the Industry

Contact the firm(s) directly linked to an outbreak as soon as possible, and tell them as much as possible. Tell them about the findings that have implicated their product and clearly explain the significance of the findings. Advise them about potential outbreak control measures, such as voluntary recall of an implicated product. This communication can be complicated by an enforcement action that may result from the investigation, but honesty and forthrightness with the regulated firms remain important. Large firms often have their own staff who understand risk communication and know what decisions to make. Some medium-sized and many small firms do not have such expertise and need more guidance. Laws and policies of state and local governments differ for these situations. **Understand your own legal framework so you know how to interact with firms potentially linked to an outbreak.**

The food industry has many trade associations. Some overlap, but in general, every segment of the food industry has an association. **State, local, and federal agencies need existing working relationships with these associations before an outbreak.** At the time of an outbreak, outreach by government agencies to the appropriate associations with information about the outbreak and about actions members should take is helpful to prevent spread of the current problem or similar problems in their firms. Similarly, establishing working relationships with food manufacturing facilities in an agency's jurisdiction can help smooth the investigation and control process should an outbreak be associated with those facilities.

Outbreaks can be a teachable moment for the food industry. When the news media carries stories about an outbreak, communication within the industry is lively, often with misinformation. Food-safety and public health agencies need to dispel misconceptions before they lead to other problems. These agencies also need to explain their response to the outbreak and restore public faith in the future safety of the implicated product.

Food-safety and public health agencies also can collaborate with industry on long-term development of training materials for members and can speak at industry meetings to clarify the prevention message.

6.5. End of the Outbreak

6.5.1. Determining When an Outbreak is Over

Most outbreaks are considered over when two or more incubation periods have passed with no new cases. This arbitrary rule may not apply to clusters with low attack rates, and cases from some sources may appear intermittently for years.

6.5.2. Determining When to Remove Restrictions

Remove restrictions when no further risk to the public exists, i.e., when

- Risk factors in the facility have been eliminated,
- Ill food workers have recovered and are no longer shedding pathogens,
- Tests indicate no further contamination,
- Employees have been taught how to avoid a problem, and
- Managers agree to provide appropriate oversight.

6.5.3. Postoutbreak Monitoring

Monitor the population at risk for signs and symptoms to ensure the outbreak has ended and the source has been eliminated. Consider conducting active surveillance, working with health-care providers to increase their vigilance for cases, and collecting stool samples from the population at risk.

Monitor the implicated foods or facilities to make sure no further contamination is occurring.

Maintain communication with the implicated facility, and tell them if additional information becomes available.

Increase the number of routine inspections at the implicated facility to ensure they comply with all required procedures. Old, unsafe practices often are difficult to change, and new practices might need to be used for $\geq$1 months before they become routine. Consider customized training to support the desired behavior change. Determine whether behavioral change has occurred long-term. If the inspection program is fee-based, consider charging more for additional inspections needed when a facility is implicated in an outbreak.

6.6. Debriefing

All members of an outbreak control team should be briefed about the results of the investigation. The complexity of the debriefing depends on the size of the outbreak. For a small outbreak associated with a single facility or event, a short written summary may be sufficient. For a large outbreak involving multiple agencies, a formal debriefing meeting is appropriate.

A formal debriefing meeting should

- Identify the cause of the outbreak and measures to prevent additional outbreaks at this and other facilities;
- Identify the long-term and structural control measures, and plan their implementation;
- Assess the effectiveness of outbreak control measures and difficulties in implementing them;
- Assess whether further scientific studies should be conducted;
- Clarify resource needs, structural changes, or training needs to optimize future outbreak response;
- Identify factors that compromised the investigations, and seek solutions;

6.6. Debriefing

- Identify necessary changes to current investigation and control guidelines and development of new guidelines or protocols as required; and
- Discuss any legal issues that may have arisen.

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

6.7. Outbreak Report

Prepare reports for all outbreaks. Again, the complexity will depend on the size of the outbreak. For small outbreaks, a simple summary (following a template established by the agency) should suffice. The report can be used to educate staff and to look for trends across outbreaks that can be useful in future investigations.

Use outbreak reports as a continuous quality improvement opportunity. If all the after-action reports say the same thing, then nothing is being corrected.

The final report of a large outbreak should be comprehensive, with information provided by all team participants, and should be disseminated to all participating organizations.

Sample outbreak reports are available on the CIFOR Clearinghouse website.

Given that outbreak reports, especially reports for large outbreaks, are likely to be subject to Freedom of Information Act requests, they should be written with public disclosure in mind. **The reports should not identify individuals or other legally nonpublic information unless absolutely necessary, nor should they include inappropriate language.** Proper care in writing the report will save time redacting information when the report is released to the public. Some jurisdictions allow or mandate the inclusion of identifying information, so know your local policies and laws.

6.8. Other Follow-Up Activities

6.8.1. Future Studies and Research

The outbreak investigation findings may indicate the need for future research. For example, investigators may determine that for certain pathogens in certain foods, standard control measures do not seem effective or that routine handling practices and their role in outbreaks are not completely understood. Such observations should be considered for in-depth study, either by the food-safety or public health agency or by research centers. **Identifying issues that need follow-up research is important to improving the practice of responses to outbreaks of foodborne diseases.**

6.8.2. Publication of Outbreak Results

If something unusual characterized the outbreak (e.g., unusual exposure, presence of a pathogen in a food where it had not previously been seen) the report should be disseminated more widely (Epi-X, *MMWR*, or other national forum; peer-reviewed journals).

Important lessons learned (such as new investigation methods that proved particularly helpful, control measures that seemed particularly effective, actions taken that seemed to shorten the outbreak) should be published in an appropriate national forum.

6.8. Other Follow-Up Activities

6.8.3. Education

An outbreak may identify the need for broad education of the public, the food-service and food-processing industries, or health-care providers. Public service announcements may be necessary to remind the public about food-preparation precautions. Training for food-service workers and managers and food processors might need to be modified to address specific concerns. Managers need to oversee training of food-service workers and food processors and their use of recommended procedures. Health-care providers may need continuing education focused on diagnosing, treating, or reporting foodborne diseases. Such actions can help prevent future outbreaks or reduce the number of cases or severity of illness during an outbreak.

6.8.4. Policy Action

Information gained during an outbreak may identify the need for new public health or regulatory policy at the local, state, or federal level. Establishment of different inspection practices, source controls, or surveillance procedures, or of increased control over the recall process might be necessary. Reports of past outbreaks should be analyzed to determine whether multiple outbreaks support the need for new policy. Other public health and environmental health agencies also should be consulted to determine whether concurrence exists on the need for new policy. If so, the issue should be presented to the appropriate jurisdictional authority using the appropriate policy development processes.

6.9. Multijurisdictional Considerations for Control Measures

Although control measures typically are implemented at the local level, multijurisdictional outbreaks require extensive coordination among agencies to ensure control measures are implemented consistently and are effective. See Chapter 7 for Multijurisdictional Investigation Guidelines.

6.10 Indicators/Measures

Key indicators to help assess control measures and the overall success of efforts to halt outbreaks have been developed and can be found in Chapter 8.

CHAPTER 7

Special Considerations for Multijurisdictional Outbreaks

A multijurisdictional foodborne disease event requires the resources of more than one local, state, territorial, tribal, or federal public health or food-regulatory agency to detect, investigate, or control. A multijurisdictional investigation may involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

These guidelines are intended to help improve communication and coordination among agencies at all levels of government that are investigating multijurisdictional outbreaks. The guidelines are proposed to help agencies identify multijurisdictional outbreaks and increase the speed of investigation and control of outbreaks.

7.0. Introduction

Specifically the guidelines have the following objectives:

A. Define when an outbreak is considered multijurisdictional,

B. Establish a framework for rapidly assessing whether a given foodborne disease event affects multiple jurisdictions,

C. Promote early and effective communication and coordination among agencies involved in multijurisdictional investigations,

D. Detail specific actions that might be needed in a multijurisdictional outbreak,

E. Provide guidance on managing the transition between the phases of an outbreak investigation during which leadership of the investigation changes, and

F. Provide guidance on post-outbreak debriefing and dissemination of findings.

7.0.1. Scope

These guidelines are subject to two major limitations. First, foodborne disease outbreak investigation activities are subject to state law. Thus, these guidelines may need to be adapted to reflect the relationships between state and local agencies within a state. Second, they cannot cover all possibilities that might emerge during an outbreak investigation. However, the principles of communication and coordination established by these guidelines should help to quickly resolve problems.

For ease of reading, these guidelines focus on relationships among local, state, and federal levels. Although territories, tribal lands, and the District of Columbia represent independent administrative structures with unique legal standing, the general principles of multijurisdictional investigations articulated here should be useful for health officials in these areas as well.

7.1. Background

In the United States, local or state public health or food-regulatory agencies conduct most investigations of foodborne illness following routine policies and procedures. In many local agencies, sporadic cases of specific foodborne disease are investigated by communicable disease control or public health nursing programs. Consumer complaints about foodborne illness frequently are investigated by food-regulatory programs. However, outbreak investigations usually require coordination among these programs at the local level. Thus, effective communication and coordination generally are required for successful investigations of foodborne disease outbreaks.

In 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 NFSS multistate guidelines were developed specifically to address the challenges of coordinating large and complex investigations of foodborne disease outbreaks among multiple state and federal public health and food-regulatory agencies.

Since development of these guidelines, the terrorist attacks on September 11, 2001, raised concerns about the potential for intentional contamination of food at all levels of the food system, which would require interaction among agencies that previously had not worked together. In addition, large multistate case clusters and foodborne disease outbreaks have continued. For example, during 2002–2005, at least 6% of foodborne disease outbreaks reported to the CDC electronic Foodborne Outbreak Reporting System (eFORS) involved

7.1. Background

multistate or multicounty exposures or affected residents of multiple states or counties (Table 7.1). Furthermore, 40% of *E. coli* O157:H7 outbreaks and 25% of *Salmonella* or hepatitis A outbreaks were multijurisdictional, largely due to the use of PulseNet for surveillance of infection with *E. coli* O157:H7 and *Salmonella*. Thus, for these most important foodborne pathogens, the need for multijurisdictional coordination should be anticipated during the earliest stages of an investigation.

The Council to Improve Foodborne Outbreak Responses (CIFOR) was created in 2006 to help develop model programs and processes to facilitate the investigation and control of foodborne disease outbreaks. CIFOR determined that one priority would be to go beyond multistate outbreaks by also developing guidelines for multijurisdictional outbreaks. Multijurisdictional guidelines apply to multiple states but also include localities within a state and outbreaks involving multiple agencies (Table 7.2).

Recent experiences with multijurisdictional investigations have pointed to two overriding concerns with communication and coordination of multijurisdictional investigations. The first is to establish criteria by which a local health agency can recognize that a foodborne disease outbreak under investigation is multijurisdictional and to facilitate rapid communication of that fact to all affected agencies. The second is to establish effective means of integrating local agencies into large, multistate investigations that are detected and coordinated on a national level.

Table 7.1. Number of multistate exposure, multistate resident, multicounty exposure, and multicounty resident outbreaks, by etiology, 2002–2005

	NO. OUTBREAKS				
ETIOLOGY AND AGENT	TOTAL OUTBREAKS	MULTISTATE EXPOSURE	MULTISTATE RESIDENT	MULTICOUNTY EXPOSURE	MULTICOUNTY RESIDENT
Confirmed Etiology	1903	43	34	122	31
Escherichia coli O157:H7	75	11	1	17	1
Salmonella	448	24	10	65	14
Clostridium perfringens	90	0	1	1	2
Staphylococcus aureus	61	0	2	3	1
Hepatitis A	24	1	0	5	0
Norovirus	770	0	13	12	9
Other	391	4	6	18	3
Multiple	44	3*	1†	1‡	1§
Suspected Etiology	1402	0	3	17	18
Unknown Etiology	1438	0	10	17	12
TOTAL	4743	43	47	156	61

* Three multistate exposure outbreaks involving multiple etiologies; 1 *Salmonella* outbreak caused by serotypes Anatum, Muenchen, Javiana, Thompson, and Typhimurium; another *Salmonella* outbreak caused by serotypes Saint Paul and Typhimurium; and a third *Salmonella* outbreak caused by serotypes *Enteritidis, Kentucky, and Typhimurium.*

†One multistate resident outbreak caused by *C. parvum* and *E. coli* O111.

‡ One multicounty exposure *Salmonella* outbreak caused by serotypes Adelaide and Hadar.

§ One multicounty resident *Salmonella* outbreak caused by serotypes Newport and Typhimurium.

7.1. Background

Table 7.2. Categories of multijurisdictional outbreaks
1. Outbreaks affecting multiple local health jurisdictions (e.g., city, county, town) within the same state
2. Outbreaks involving multiple states
3. Outbreaks involving multiple countries
4. Outbreaks affecting multiple distinct agencies (e.g., public health, food-regulatory, emergency management)
5. Outbreaks, regardless of jurisdiction, caused by highly pathogenic or unusual agent (e.g., *Clostridium botulinum*) that may require specialized laboratory testing, investigation procedures, or treatment
6. Outbreaks in which the suspected or implicated vehicle is a commercially distributed, processed, or ready-to-eat food contaminated before the point of service
7. Outbreaks involving large numbers of cases that may require additional resources to investigate
8. Outbreaks in which intentional contamination is suspected

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

After recognizing a foodborne disease event requires multijurisdictional investigation, agencies that might need to participate in the investigation and agencies that might be otherwise affected by the event should be immediately notified (Table 7.2, Figure 7.1). Specific examples of these indicators and required notification steps are described below (Table 7.3). In some states, functions identified as occurring at the local level may be performed at the state level.

Table 7.3. Examples of major indicators and required notification steps

OUTBREAK DETECTION	MAJOR INDICATOR	NOTIFICATION STEPS
Local Level	Commercially distributed, processed, or ready-to-eat food contaminated before point of service suspected or implicated as outbreak vehicle.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA/FSIS (depending on product and on local and state reporting requirements).
	Fresh produce item contaminated before point of service is suspected or implicated as outbreak vehicle.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA, depending on state and local reporting requirements.
	Ground beef is implicated in an outbreak of *Escherichia coli* O157:H7 infections.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and USDA/FSIS, depending on state and local reporting requirements.

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

Table 7.3. Examples of major indicators and required notification steps
Continued

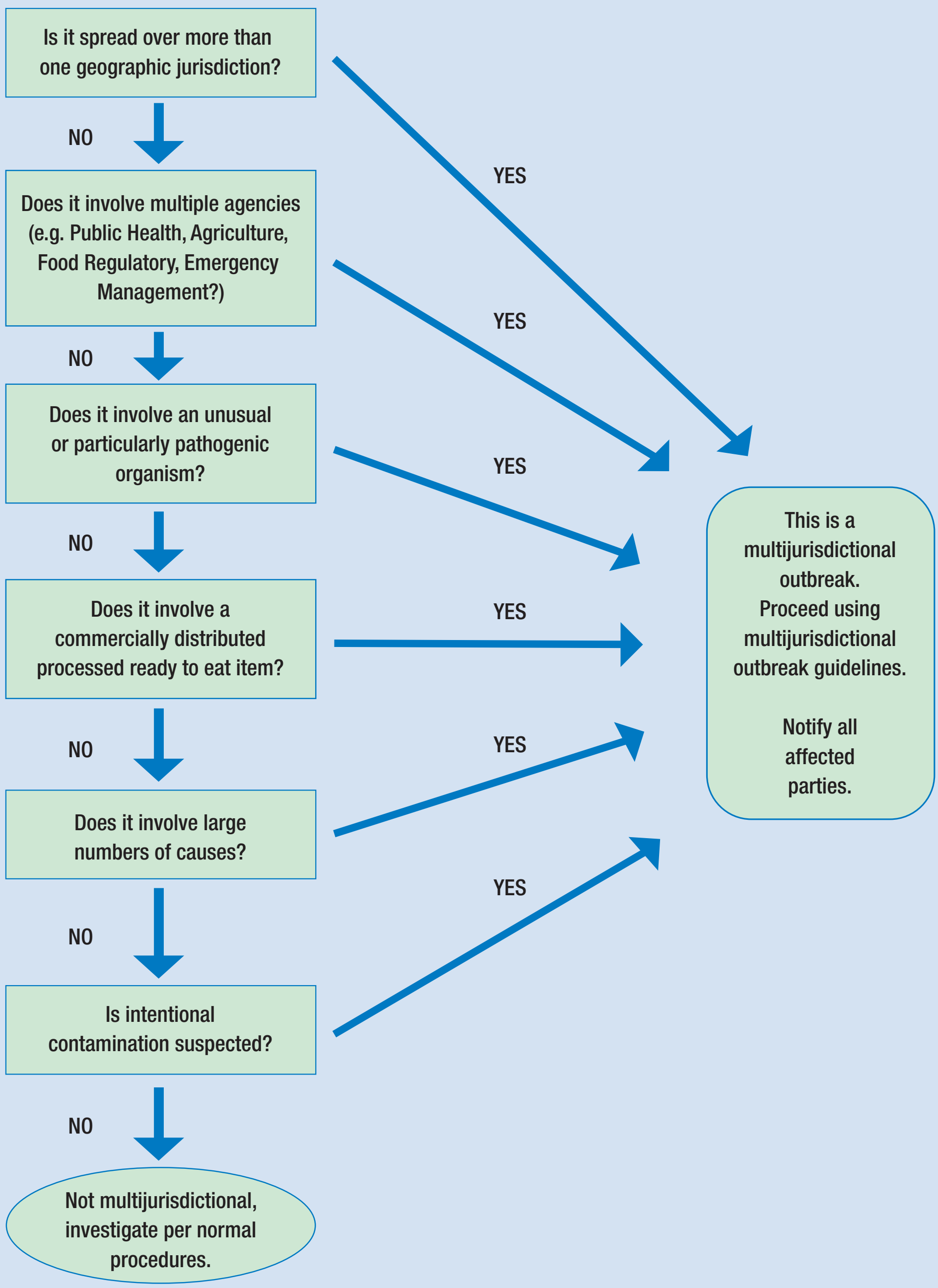
OUTBREAK DETECTION	MAJOR INDICATOR	NOTIFICATION STEPS
Local Level	Molecular subtype characteristics of etiologic agent matches the pattern of an agent independently associated with other foodborne disease outbreaks.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA/FSIS, depending on product and state and local reporting requirements.
	Intentional contamination of food item is suspected or implicated.	Immediately notify state health department, relevant state food-regulatory agency, CDC, and FDA or USDA/FSIS (depending on product), local law enforcement, and FBI.
	Illnesses are associated with multiple restaurants or food-service establishments, especially when those establishments are part of the same chain.	Immediately notify state health department, relevant state food-regulatory agency, and CDC, depending on local and state reporting requirements.
State Level	Increase of sporadic infections with common subtype characteristics identified across multiple jurisdictions.	Immediately notify affected local agencies, CDC, and state and federal food-regulatory agencies.
	Multiple common-source outbreaks linked by common agent, food, or water.	Immediately notify affected local agencies, CDC, and relevant state and federal food-regulatory agencies.
	Microbiologic food testing by state food-regulatory agency prompts recall.	Immediately notify affected state and local public health agencies, CDC, relevant federal food-regulatory agencies.
	Illnesses are associated with multiple restaurants or food-service establishments, especially when those establishments are part of the same chain.	Immediately notify relevant state food-regulatory agency and CDC, depending on product and local and state reporting requirements.
Federal Level	Increase of sporadic infections with common subtype characteristics identified across multiple states.	Immediately notify affected state and local public health agencies, federal food-regulatory agencies.
	Multiple common-source outbreaks linked by common agent, food, or water.	Immediately notify affected state and local public health agencies, CDC, relevant state and federal food-regulatory agencies.
	Microbiologic food testing by, or reported to, FDA or USDA/FSIS prompts recall.	Immediately notify affected state and local public health agencies, CDC, relevant state and federal food-regulatory agencies.

Abbreviations: CDC = Centers for Disease Control and Prevention; FDA = Food and Drug Administration; USDA/FSIS = U.S. Department of Agriculture's Food Safety and Inspection Service; FBI = Federal Bureau of Investigation.

7.2. Major Indicators of a Multijurisdictional Outbreak and Notification Steps

Figure 7.1. Multi-jurisdictional Outbreak Decision Tree for Primary Agency Investigating Foodborne Illnesses

This decision tree can assist in determining if a detected outbreak or case cluster is multijurisdictional in nature.



7.3. Coordination of Multijurisdictional Investigations

After notification of affected agencies, coordinating the multijurisdictional investigation may require establishment of a coordinating office to collect, organize, and disseminate collective 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 health or food-regulatory agency or at CDC, FDA, or USDA/FSIS.

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

- **Outbreaks are most efficiently investigated as close to the source as possible.** In general, investigations should be coordinated at the level at which the outbreak originally was detected and investigated. This is likely to be where most relevant investigation materials will reside, which can facilitate organization and analysis of the data. An outbreak involving several local health agencies might best be coordinated by a lead local agency. Similarly, investigation of a multistate outbreak with most cases in one or a few adjacent states might best be coordinated by a lead state agency. Investigations of outbreaks of more widely dispersed sporadic cases might best be coordinated by CDC.
- **The coordinating office must have sufficient resources, expertise, and legal authority to collect, organize, and disseminate data from the investigation.** Many local agencies might not have sufficient resources to effectively coordinate a multijurisdictional investigation, or state rules might assign jurisdiction over multicounty investigations to the state health department. In these situations, the coordinating office should be located at the state level. In multistate investigations, the coordinating office should be located at CDC if no individual state is prepared to do so. In multistate investigations led by an individual state, CDC should support the investigation in coordination with the lead agency.
- **Outbreak investigations progress through phases of activity, and leadership of the investigation should reflect the focus of the investigation at the time.** Typically, epidemiologic efforts to characterize the outbreak by person, place, and time dominate the early stages of an outbreak investigation. Efforts to identify the mode of transmission and food vehicle begin to incorporate environmental health specialists and food regulators. Determining contributing factors, conducting regulatory tracebacks, and implementing control measures move the investigation into the food-regulatory realm. Transition of leadership within the outbreak control team should be planned in advance by consensus and communicated to the entire team. These phases of activity can be elaborated as follows:
  - **Investigation of human illness outbreaks should be coordinated within public health agencies.** In addition to public health agencies' greater expertise and experience in conducting these investigations, rules governing the reporting and collection of information about human patients require that authorized public health agencies maintain and protect that information. Although deidentified information may be shared across agencies, the redaction process may reduce the value of the information available for analysis.
  - **Investigations of food contamination events should be coordinated within food-regulatory agencies.** In addition to food-regulatory agencies' greater expertise and experience with these investigations, rules governing the collection of

7.3. Coordination of Multijurisdictional Investigations

product manufacturing and distribution information may dictate that authorized food-regulatory agencies not share that information with outbreak investigators in other agencies. If that information is important to the investigation, outbreak investigators should consider collecting that information directly, even if doing so results in some duplication of effort.

- **Sharing of information between public health and food-regulatory agencies is critical to the effectiveness of multijurisdictional investigations.** The need to share information frequently challenges the legal authority of each party. However, rapid and open information sharing can greatly enhance the efficiency and effectiveness of multijurisdictional investigations. For example, public health agencies need access to detailed product source and distribution data to conduct epidemiologic investigations and evaluate potential public health interventions. Similarly, food-regulatory agencies need detailed case information and preliminary results of epidemiologic investigations to guide environmental assessments and tracebacks. Because these activities build on each other, establishing information-sharing protocols during the earliest stages of the investigation is critical. State, local, and federal public health officials should ensure that their agencies have the legal authorities needed to share information and that their professional staff understand those authorities. Because federal agencies, by law, are prevented from sharing certain data, state and local public health officials may need to work directly with the establishment implicated in the outbreak to obtain those data.
- **When an incident involves an agricultural commodity and the bulk of the commodity is produced in a limited number of states, those state agricultural agencies should be informed of the outbreak and its progress.** They too will be receiving inquiries about the safety of their produce/product and have a legitimate interest and role to play in determining potential sources of the vehicle, as well as preparing for potential environmental assessments to determine possible points of contamination, take appropriate samples etc. Communication with those states, even where no cases occur in those states, is essential.
- **Identifying the source of a multi-jurisdictional outbreak represents a collaborative process among local, state, and federal agencies and industry.** Individual food companies and trade associations should be engaged early on to help with the investigation. Industry collaborators may be able to provide important information about food product identities, formulations and distribution patterns that can improve hypothesis generation and assist in traceback efforts to aid hypothesis testing. Early engagement of industry also can facilitate control measures by allowing affected industries opportunity to implement product withdrawal or recall procedures in an orderly way.
- **Releasing public information about the outbreak should be coordinated with the lead investigating agency, when feasible.** Although the public and news media are not aware of most outbreak investigations, the results of investigations are public information. In addition, responding to media attention is important to address public concerns about the outbreak. Although individual agencies participating in the investigation may be obligated to respond to media inquiries, a coordinated communications plan can help provide a consistent message about the progress of the investigation or the source of the outbreak. Coordinating communications with the media is particularly important when media attention is needed for public action to avoid

7.3. Coordination of Multijurisdictional Investigations

exposure to a specific contamination source, such as a recalled food product.

- **Most health departments have incident command systems (ICS) that guide outbreak responses within the public health agencies. Historically multijurisdictional foodborne disease outbreak investigations have not required formal activation of ICS.** ICS are structures that provide for internal communications within a government system among primary event responders, public information officers, and security and safety officers and for external liaison with various organizations. In concept, the ICS structures provide for communication and coordination among agencies involved with responding to a multijurisdictional outbreak of foodborne disease. However, even though the principles of multijurisdictional investigations might be similar to ICS responses, in many states and local jurisdictions, ICS are formal structures controlled by public safety officials with no other jurisdiction for food-safety or outbreak control. In these situations, activating ICS might initiate actions that distract from the prompt conduct of the investigation. Agencies involved in foodborne disease outbreak investigation and response should decide in advance whether and how to apply an ICS, and, if applicable, incorporate the ICS structure into their response planning. Such planning should be coordinated with all other agencies that may be drawn into the investigation and response over time. Most foodborne disease outbreak investigations do not require formal activation of ICS, but may benefit from application of ICS principles and methods. **However, if someone who claims to have tampered with food contacts an agency, or in any outbreak in which intentional contamination is suspected, notification of law enforcement officials and assessment of the credibility of the threat are essential.** If the threat is credible, the outbreak will move into a law enforcement realm with activation of the ICS.
- **The agency coordinating the investigation should conduct an after-action review.** The coordinating agency should review the conduct of the investigation with collaborating agencies, summarize the effectiveness of communication and coordination among jurisdictions, and identify specific gaps or problems that arose during the investigation. Industry representatives should also be included to share lessons learned.
- **All multijurisdictional outbreak investigations should be reported as such to eFORS.**

7.4. Outbreak Detection and Investigation by Level

The following sections are organized by the level at which an outbreak is recognized and the actions that should follow that recognition.

7.4.1. Outbreak Detection and Investigation at the Local Level

7.4.1.1. Detect outbreak

Outbreaks are detected at the local level by one1 of the following means:

- Consumer complaint identifies group exposure with multiple illnesses.
- Multiple consumer complaints received about the same source.
- Health-care provider reports group exposure with multiple illnesses.
- Investigation of sporadic case identifies group exposure with multiple illnesses.
- Investigation of sporadic case cluster identifies common source.

7.4. Outbreak Detection and Investigation by Level

7.4.1.2. Ensure notification

With initiation of an outbreak investigation, a local agency should **ensure notification of the following agencies,** and provide subsequent updates as appropriate in accordance with state procedures**:**

- Affected and surrounding county and city health departments (epidemiology, environmental health, public health laboratory).
- State health department (epidemiology, environmental health, laboratory).

7.4.1.3. Provide coordination

During the investigation, a local agency needs to **coordinate** the epidemiology, environmental health, regulatory, and laboratory components of the investigation.

When findings indicate that multiple jurisdictions might be involved, additional communication and coordination are needed:

- Referrals and requests for assistance in **incidents of local significance.**

  Incident: Local agency identifies a likely foodborne disease outbreak in another jurisdiction.

  Action: Ensure notification of the affected jurisdiction immediately.

  Incident: Common-source outbreak identified in one jurisdiction has cases among persons who reside in two or more local jurisdictions.

  Action: Request assistance to contact and interview cases in other jurisdictions.

These investigations are handled in accordance with **routine polices and procedures** under **local agency leadership** unless otherwise specified by state procedures. The level of state involvement depends on local or state protocols.

- Referrals and requests for assistance in incidents representing a **transition from local to state significance.**

Incident: Common-source outbreak identified in one jurisdiction, investigation implicates processed food or fresh produce item, contaminated before the point of service, in absence of other contributing factors.

Action: Ensure notification of appropriate food-regulatory agencies of probable contaminated food vehicle; **trace back** source to the point where contamination most likely occurred; or determine whether responsibility for the investigation needs to be transferred to a state or federal agency.

Action: Ensure notification of other jurisdictions that might be investigating similar related events of results of outbreak investigations regarding agent and vehicle.

Action: Subtype agent; **upload patterns** to PulseNet.

Incident: Common-source outbreak identified in one jurisdiction, linked to outbreaks identified in other local jurisdictions, by common agent, food, or water.

Action: Ensure notification of appropriate food-regulatory agencies and other jurisdictions as described above.

Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

Action: Establish coordinating office (or individual) for the investigations to **collect, organize, and disseminate** all the data.

Incident: Cluster(s) of sporadic infections with common subtype characteristics identified in one local jurisdiction.

Action: Upload patterns to PulseNet.

Action: Interview cases and, once hypotheses are generated, controls using standardized questionnaire to obtain detailed food and environmental exposure histories, including product brand and retail source.

7.4. Outbreak Detection and Investigation by Level

Action: Ensure notification of appropriate food-regulatory agencies of investigation and potential need to initiate investigations to elaborate and test hypotheses.

Action: Ensure notification of other jurisdictions likely to have additional cases, and **distribute** summary data about cases, descriptive epidemiology, investigation protocols, and standardized questionnaires to jurisdictions.

Action: Establish coordinating office (or individual) for investigation to **collect, organize, and disseminate** collective data.

These investigations **require information sharing and coordination** among multiple local agencies under **local agency leadership** unless otherwise specified by state procedures. The state receives information and provides consultation. Emergency management systems are not activated.

7.4.2. Outbreak Detection and Investigation at the State Level

7.4.2.1. Detect outbreak

Outbreaks typically are detected at the state level by one of the following means:

- Common-source outbreaks in multiple local jurisdictions, or multiple states linked by common agent, food, or water.
- Cluster(s) of sporadic infections with common subtype characteristics identified across multiple local jurisdictions.
- Statewide increase identified of sporadic infections with common subtype characteristics.
- Information or alert from another public health agency, food-regulatory agency, or another country.

7.4.2.2. Ensure notification

With initiation of an outbreak investigation, the state public health agency should **ensure notification of the following agencies** and provide subsequent updates as appropriate:

- All local health departments likely to be affected by the outbreak or involved in the investigation.
- The state food-regulatory agency.
- Other state health departments (e.g., regional counterparts, or potentially nationally through Epi-X, PulseNet, or similar networks).
- CDC (Outbreak Response and Surveillance Team).
- Federal regulatory agency offices (e.g., USDA/FSIS, FDA, Environmental Protection Agency [EPA]), depending on the nature and status of the investigation.

Agency media personnel should also be engaged as early as possible, to assist with messaging and to ensure consistency of message among agencies.

7.4.2.3. Provide coordination

During the course of the investigation, a state agency needs to **coordinate** among the epidemiology, environmental health, and laboratory components of the investigation at the state level and **ensure that state** epidemiology, environmental health, and laboratory **programs are communicating and coordinating** activities with counterparts at both the local and federal levels.

- Referrals and requests for assistance in **incidents of state significance.**

  Incident: Case clusters in multiple local jurisdictions or statewide increase of sporadic infections with common subtype characteristics identified.

  Action: Upload patterns to PulseNet.

  Action: Ensure notification of all local jurisdictions; **distribute** summary data about cases, descriptive epidemiology, investigation protocols, and standardized questionnaires.

7.4. Outbreak Detection and Investigation by Level

Action: Request that local agencies **interview cases and controls** as soon as possible using standardized questionnaire to obtain detailed food-exposure histories, including product brand and retail source. **Assess** the availability and willingness of local agency staff to conduct timely interviews. **Provide support** needed to ensure **timely conduct of interviews.** As investigations heat up, priorities will need to be adjusted. Evening and weekend work commonly is required. Interviews should not be delegated to agencies or individuals unable to make the investigation a top priority.

Action: Ensure notification of appropriate food-regulatory agencies of the investigation and the potential need to initiate investigations to elaborate and test hypotheses.

Action: Establish coordinating office (or individual) for investigations to **collect, organize, and disseminate** collective data.

Incident: Common-source outbreaks in multiple jurisdictions or multiple states linked by common agent, food, or water. When a particular exposure is epidemiologically implicated or strongly suspected:

Action: Ensure notification of all local jurisdictions, all states, and federal agencies of results of outbreak investigations about agent and vehicle.

Action: Ensure notification of appropriate food-regulatory agencies of the probable contaminated food vehicle in commercial distribution; **trace back** source to the point where contamination most likely occurred; or determine whether responsibility for action needs to be transferred to a federal agency.

Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

Action: Establish the coordinating office (or individual) for investigations to **collect, organize, and disseminate** collective data. In cooperative investigations, make raw data readily available in a common format to interested participants from all participating agencies.

The resources of one or more local jurisdictions cannot adequately respond to these events following routine procedures. These investigations **require active participation** from multiple local agencies, typically under **state agency leadership.** The state provides response coordination, consultation, and information sharing. On the basis of established procedures, emergency management systems may be activated at the local level or possibly state level. Federal agencies are notified and involved depending on product type and distribution.

Multistate outbreaks, and outbreaks associated with regionally or nationally distributed food products involve a **transition from state to national significance**. These outbreaks 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. In a small number of events, emergency management systems may be activated at local and state levels and possibly at federal level.

7.4.3. Outbreak Detection and Investigation at the Federal Level

7.4.3.1. Detect outbreak

Outbreaks are detected at the federal level by one of the following means:

- Common-source outbreaks in multiple states linked by common agent, food, or water.
- Cluster(s) of sporadic infections with common subtype characteristics identified in multiple states.

7.4. Outbreak Detection and Investigation by Level

- Regional or national increase of sporadic infections with common subtype characteristics identified.

7.4.3.2. Ensure notification

When an outbreak investigation begins, the CDC OutbreakNet Team should **ensure notification of** and provide subsequent updates as appropriate to

- State and local health departments (e.g., Epi-X, the Foodborne Outbreak Listserve, PulseNet).
- Federal regulatory agency offices (USDA/ FSIS, FDA, EPA).

7.4.3.3. Provide coordination

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

- Referrals and requests for assistance in **incidents of national significance.**

  Incident: Common-source outbreaks in multiple states linked by common agent, food, or water

  Action: Ensure notification of all state and local jurisdictions, as appropriate, of results of outbreak investigations regarding agent and vehicle.

  Action: Ensure notification of appropriate food-regulatory agencies of likely contaminated food vehicle in commercial distribution; **trace back** source to the point where contamination most likely occurred.

  Action: Subtype agents associated with outbreaks; **upload patterns** to PulseNet.

  Action: Establish coordinating office (or individual) for investigations to **collect, organize, and disseminate** collective data.

  Incident: Case clusters in multiple states or regional or national increase of sporadic infections with common subtype characteristics identified.

  Action: Ensure notification of all states and local jurisdictions, as appropriate; **distribute** summary data about cases, descriptive epidemiology, investigation protocols, and standardized questionnaires.

  Action: Request that local or state agencies **interview cases and controls** as soon as possible using standardized questionnaire to obtain detailed food-exposure histories, including product brand and retail source. **Assess** the availability and willingness of local or state agency staff to conduct interviews in a timely manner. **Provide support** needed to ensure that **timely conduct of interviews.**

  Action: Ensure notification of appropriate food-regulatory agencies of the investigation and the potential need to initiate establishment investigations to elaborate and test hypotheses.

  Action: Establish coordinating office (or individual) for investigations to **collect, organize, and disseminate** collective data.

These outbreaks require activation of local, state, regional, and national resources to contain disease and protect human health. They **require active participation** from multiple local agencies, state **response coordination, consultation and information sharing,** and **federal agency leadership.** Emergency management systems may be activated at local, state, and federal levels.

7.5. Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS

The organizations involved should hold a conference call 1–3 months after the initial investigation ends to review lessons learned and to update participants on findings, conclusions, and actions taken. Consider including consumer groups in this conference call or hosting a conference call specifically for consumer groups, to help them understand what happened and what's being done to prevent recurrence. Also consider including industry representatives to help disseminate lessons learned from the investigation.

The lead agency(ies) coordinating the investigation should prepare an after-action report after the conference call. The report should summarize the effectiveness of communication and coordination among jurisdictions and identify specific gaps or problems that arose during the investigation. All participating agencies should have the opportunity to review and comment on the report before it is more widely distributed. The lead agency(ies) should review after-action reports periodically to determine whether common problems in investigation or response are occurring over time. This can help with an agency's quality improvement efforts.

All multijurisdictional investigations should be reported by individual states to eFORS. The multijurisdictional nature of the investigation should be indicated by completion of appropriate data fields in the eFORS report form. Individual state reports will be consolidated by the CDC as part of a multistate outbreak report.

CHAPTER

8

Performance Indicators for Foodborne Disease Programs

A long-standing goal of CDC and national public health professional organizations has been to build state and local capacity for detecting and preventing foodborne illness. In 1997, CDC convened an expert panel to draft a core competencies report for foodborne disease outbreaks and response, focusing on epidemiologic and laboratory capacity. The panel's report was entitled *Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program*. In 1999, as a follow-up to these activities, CDC funded the Council of State and Territorial Epidemiologists (CSTE) and the Association of Public Health Laboratories to assess states' foodborne investigation capacity with the goal of providing background data by which to determine priority areas for building food-safety program support. Subsequently, CSTE's Enteric Diseases Investigation Timelines Study (EDITS) was developed to objectively assess intervals from disease onset to reporting to CDC for the surveillance of foodborne diseases and investigation of foodborne disease outbreaks.

8.0. Introduction

Surveillance and outbreak response are major components of states' foodborne investigation capacity and are essential for preventing and controlling foodborne illness. Multiple entities—almost 3000 local health departments, more than 50 state and territorial health departments, and several federal agencies—interact in a complex system covering surveillance to detect and respond to enteric and other foodborne diseases.

The occurrence of large and multistate foodborne disease outbreaks and concerns about bioterrorism have increased the need to rapidly detect and distinguish between outbreaks of foodborne disease and possible intentional contamination. Evaluating the timeliness and effectiveness of foodborne disease surveillance is a major step toward assessing and improving U.S. capacity for foodborne disease surveillance and outbreak response.

CDC's Public Health Emergency Preparedness Goals established a general framework and a few specific performance measures relevant to foodborne disease surveillance. However, no comprehensive national performance standards, measures, or models exist for public health agencies to follow to ensure foodborne illness surveillance and outbreak detection and response systems work at maximum efficiency.

8.1. Purpose and Intended Use

CIFOR has developed measurable indicators of effective surveillance for enteric foodborne diseases and for response to outbreaks of such diseases by state and local public health officials. These indicators are intended for use by state and local public health agencies to evaluate the performance of their foodborne disease surveillance and control programs. Specific indicators and subindicators have been identified to support the overall objectives of the foodborne disease surveillance program. Metrics have been developed to standardize evaluation of the indicators.

The use of standardized performance criteria and metrics serves several functions:

- They promote a common understanding of the key elements of foodborne disease surveillance and control activities across local, state, and federal public health agencies;
- They facilitate training of food program staff in the use and interpretation of the performance criteria; and
- They allow for the aggregation of data at state, regional, or national levels to evaluate program effectiveness and to identify specific needs for improvement and additional resource investment.

The indicators are not intended as performance standards. Where specific performance standards have been established (e.g., PulseNet turnaround times, Draft Voluntary National Retail Food Regulatory Program Standards), meeting the performance standard has been adopted as a performance indicator. The development of performance standards depends on the availability of specific indicators such as these to provide a basis for program evaluation. However, defining the level of performance expected from foodborne disease surveillance and control programs exceeds the scope of these Guidelines. Likewise, the performance indicators are not intended to be used for comparing individual local or state programs. The aggregation of data at state, regional, or national levels is intended to provide a comprehensive overview of foodborne disease surveillance and control programs, rather than a system for ranking them.

8.2. Performance Indicators

This chapter contains tables organized to highlight major performance indicators by program function. The roles and responsibilities of foodborne disease surveillance and control programs vary by state according to state law.

Individual agencies that wish to evaluate their programs using these indicators should select indicators and metrics that best reflect their activities, regardless of where they fall in the document's table structure.

Overall Foodborne Disease Program Objectives and Indicators

Major Performance Indicators and Metrics for Program Evaluation

Overall Foodborne Disease Program Objectives and Indicators

Table 8.1. Objectives of foodborne disease surveillance program

SHORT-TERM OBJECTIVES	INTERMEDIATE OBJECTIVES	LONG-TERM OBJECTIVES
Detect foodborne disease events of public health importance. Respond to events in a timely manner. Intervene when appropriate to prevent illness.	Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks. Monitor trends to identify emerging foodborne diseases and food-safety problems. Increase knowledge of foodborne disease causes and abatement strategies.	Prevent future outbreaks. Reduce incidence of foodborne illness. Increase health of the general population.

8.2. Performance Indicators

Overall Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Detect foodborne disease events of public health importance.	8.2.1. Foodborne complaints investigated	PROCESS • Program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury, or intentional food contamination. The final disposition for each complaint is recorded in the log or database and filed in or linked to the establishment record for retrieval purposes (Draft Voluntary National Retail Food Regulatory Program Standards, standard 5, part 1.d). • Demographic information obtained • Food history obtained OUTCOME • Disposition, action, or follow-up on complaint or referral report alleging food-related illness or injury within 24 hours • Establishment investigated, where appropriate • Outbreak detected	PROCESS • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 1.d, met, yes/no • % of complaints for which complete demographic information was available • % of complaints for which food history was obtained OUTCOME • % of reports resulting in disposition, action, or follow-up within 24 hours • No. establishments investigated • No. outbreaks detected
Detect foodborne disease events of public health importance.	8.2.2. Reported cases with specified foodborne illnesses interviewed	PROCESS • Demographic information obtained • Exposure history obtained • Case onset date obtained • Date of report documented • Case report maintained in searchable database	PROCESS • % of reported cases for which complete demographic information was available • % of reported cases for which food history was obtained • % of reported cases for which onset date was available

8.2. Performance Indicators

Detect foodborne disease events of public health importance.	8.2.2. Reported cases with specified foodborne illnesses interviewed	OUTCOME • Interval from receipt of report to interview of case • Need for public health intervention identified (e.g., exclusion of workers, conduct of investigation)	• % of reported cases for which report date was available • Searchable database maintained, yes/no OUTCOME • Median no. days from receipt of report to interview of case • % of cases for which an intervention was identified or ruled out
Detect foodborne disease events of public health importance.	8.2.3. Isolates of specified foodborne pathogens submitted to PHL	PROCESS • Stool collection date obtained • Date of clinical laboratory finding obtained • Date of submission to PHL documented • Date of serotyping documented • Date of subtyping by PFGE documented • Isolate report maintained in searchable database OUTCOME • No. reported cases for which isolates submitted to PHL • No. days from clinical laboratory finding to submission of clinical specimen to PHL • No. days from receipt of clinical speciment by PHL to subtyping results • Subtype-clusters identified • For each type of agent, 90% of PFGE subtyping data results submitted to PulseNet database within 4 working days (CDC preparedness goal)	PROCESS • % of cases for which stool collection date was available • % of investigated cases for which date of clinical laboratory finding was available • % of cases for which date of sample submission to PHL was available • % of cases for which PFGE subtyping date was available • Searchable database maintained, yes/no OUTCOME • % of cases for which isolates were submitted to PHL • Median no. days from report of clinical findings to receipt of isolate at PHL • Median no. days from receipt of specimen to serotyping or subtyping results • No. subtype clusters identified • CDC preparedness goal met, yes/no

8.2. Performance Indicators

Overall Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics
Continued

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Respond to events in a timely manner.	8.2.4. Foodborne outbreaks investigated	PROCESS • Cases interviewed to determine illness and exposure histories • Stool samples obtained from cases • Controls (non-ill persons) interviewed to determine exposure histories • Environmental health assessment of establishment conducted, where appropriate • Food flow documented • Food workers interviewed • Stool samples obtained from food handlers • Food or environmental samples obtained OUTCOME • No. days from onset of symptoms to initiation of outbreak investigation • No. days from collection of stool samples to confirmed culture results • No. days from collection of environmental or food samples to confirmed culture result • Foodborne disease outbreak source identified	PROCESS • % of investigations for which cases were interviewed • % of investigations for which stool samples were collected from at least 1 case • % of investigations for which controls were interviewed to determine exposure history • % of investigations in which an establishment was investigated, if appropriate • % of environmental investigations that included a food flow, interviews of food workers, collection of stool samples from food handlers, collection of food or environmental samples OUTCOME • Median no. days from onset of symptoms of first/index case to outbreak investigation • Median no. days from submission of stool samples to receipt of results • Median no. days from submission of food or environmental samples to receipt of results • % of foodborne disease outbreaks for which a source was identified

8.2. Performance Indicators

Respond to events in a timely manner.	8.2.5. Case clusters investigated	PROCESS • Cases interviewed to determine exposure histories • Controls or persons with noncluster cases interviewed to determine exposure histories OUTCOME • No. days from cluster recognition to completion of interviews of cases and controls • Cluster source identified	PROCESS • % of case clusters for which at least half the cases were interviewed to determine exposure history • % of clusters in which controls were interviewed to determine exposure history OUTCOME • Median no. days from identification of a cluster to completion of all planned interviews • % of clusters in which a source was identified
Respond to events in a timely manner.	8.2.6 Sentinel foodborne events investigated	PROCESS • Event-specific data collected	PROCESS • % of sentinel events in which cases were interviewed • % of events in which environmental samples were collected, when appropriate • % of events in which stool samples were collected, when appropriate
Intervene when appropriate to prevent illness.	8.2.7. Ill or infected food handlers identified and excluded		OUTCOME • Median no. days from initiation of investigation to implementation of intervention
	8.2.8. Deficient food-handling practice identified and corrected		OUTCOME • Median no. days from initiation of investigation to implementation of intervention
	8.2.9. Advisory issued about outbreak and implicated source		OUTCOME • Median no. days from initiation of investigation to implementation of intervention
	8.2.10. Contaminated food recalled and removed from marketplace		OUTCOME • Median no. days from initiation of investigation to implementation of intervention

8.2. Performance Indicators

Overall Foodborne Disease Program Objectives and Indicators

Table 8.2. Short-term objectives, indicators, subindicators, and metrics
Continued

SHORT-TERM OBJECTIVES	INDICATOR	SUBINDICATOR	METRICS
Respond to events in a timely manner, and intervene when appropriate to prevent illness.	8.2.11. After-action reviews of outbreak investigations conducted within a mean of 60 days after investigation ends (CDC preparedness goal)		PROCESS • CDC preparedness goal met, yes/no
	8.2.12. Staff trained on the agency's outbreak response protocol		PROCESS • % of staff likely to be involved in an outbreak investigation that have received training
	8.2.13. Contact lists of individuals or organizations key to foodborne disease outbreak investigations created and regularly updated		PROCESS • Contact list created, yes/no • Intervals between updates

Table 8.3. Intermediate objectives, indicators, subindicators, and metrics

INTERMEDIATE OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks.	8.3.1. Etiology of outbreak identified	PROCESS • Clinical characteristics of outbreak characterized • Stool samples collected and tested for likely agents • Food and environmental samples collected and tested for likely agents OUTCOME • Etiology of outbreak identified	PROCESS • % of outbreaks for which clinical characteristics were described • % of outbreaks for which at least 1 stool sample was tested for likely agents • % of outbreaks for which food or environmental samples were tested for likely agents OUTCOME • % of outbreaks for which etiology was identified

8.2. Performance Indicators

Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks.	8.3.2. Vehicle of outbreak identified	PROCESS • Suitable epidemiologic study conducted to identify vehicle • Informational traceback conducted to subtype exposure histories • Regulatory traceback conducted to confirm production source of implicated food vehicle • Isolates from case specimens and potential vehicles subtyped OUTCOME • Vehicle of outbreak identified	PROCESS • % of outbreaks for which epidemiologic study was conducted to identify a vehicle • % of outbreaks for which informational traceback was conducted to help elucidate exposure histories • % of outbreaks for which regulatory traceback was conducted to confirm production source of implicated food vehicle • % of outbreaks for which subtyping of isolates from cases and potential vehicles was conducted OUTCOME • % of outbreaks for which vehicle was identified
Determine etiology, vehicle, and contributing factors of foodborne disease outbreaks.	8.3.3. Contributing factors identified	PROCESS • Preparation of implicated food items reviewed • Food-preparation review guided by identification of suspected agent • Possible contributing factors to the illness, injury, or intentional food contamination identified in each on-site investigation report OUTCOME • Contributing factors identified	PROCESS • % of outbreaks for which food-preparation flow was reviewed for implicated food item • % of outbreaks for which food-preparation flow was reviewed, with specific agent suspected • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 2.a, met, yes/no OUTCOME • % of outbreaks for which contributing factors were identified

8.2. Performance Indicators

Overall Foodborne Disease Program Objectives and Indicators

Table 8.3. Intermediate objectives, indicators, subindicators, and metrics
Continued

INTERMEDIATE OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Monitor trends to identify emerging foodborne diseases and food-safety problems.	PROCESS • At least annually, data in complaint log or database and illness and injury investigations reviewed to identify trends and possible contributing factors most likely to cause illness or injury. These reviews may suggest a need for further investigations and steps for illness prevention (Draft Voluntary National Retail Food Regulatory Program Standards, standard 5, part 7.a) • Routine review of cases of reported foodborne diseases for trends in emerging foodborne diseases • Routine review of outbreak investigation findings for trends		PROCESS • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a, met, yes/no • Analysis of foodborne disease case reports, yes/no • Analysis of outbreak reports, yes/no
Increase knowledge of foodborne disease causes and abatement strategies.	Incorporation of results of outbreak investigation summaries into food-safety training activities		• Training activities updated annually, yes/no • % of staff that receive training related to foodborne disease outbreak investigations

8.2. Performance Indicators

Table 8.4. Long-term objectives, indicators, subindicators, and metrics

LONG-TERM OBJECTIVE	INDICATOR	SUBINDICATOR	METRICS
Prevent future outbreaks.	8.4.1. Decrease in no. outbreaks attributable to previously identified sources and contributing factors		Change in no. and % of outbreaks with specific sources and contributing factors, from baseline
Reduce incidence of foodborne illness.	8.4.2. Trends in no. confirmed foodborne outbreaks	OUTCOME • No. outbreaks reported to individual state health departments • Outbreaks per million population • Outbreaks per 1000 reported cases of specified foodborne disease agents • Outbreaks in restaurants per 1000 restaurants • No. outbreaks reported to eFORS	OUTCOME • % of outbreaks reported to state health department by year and type of agent, compared over time
Reduce incidence of foodborne illness.	8.4.3. Trends in incidence of specified foodborne illnesses	OUTCOME • Statewide annual summaries of reported foodborne diseases with trend analysis • FoodNet trend analyses	
Increase health of population.	Beyond scope of project		

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.5. Local health department: overall foodborne disease surveillance and control programs*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.5.1. Foodborne complaints investigated.	Disposition of, action on, or follow-up of complaint or referral report alleging food-related illness or injury within 24 hours	% of reports resulting in disposition, action, or follow-up within 24 hours
8.5.2. Reported cases with specified foodborne illnesses interviewed.	Case report maintained in searchable database	Searchable database maintained, yes/no
	Time interval from receipt of report to case interview	Median no. days from receipt of report to interview of case
8.5.3. Isolates of specified foodborne pathogens submitted to PHL.	Reported cases for which isolates submitted to PHL	% of cases for which isolates were submitted to PHL
8.5.4. Foodborne disease outbreaks investigated.	Time from onset of symptoms to initiation of outbreak investigation	Median no. days from onset of symptoms of the first/index case to outbreak investigation
8.5.5. Appropriate control measure initiated.		Median no. days from initiation of investigation to implementation of intervention
8.5.6. Etiology of outbreak identified.	Etiology of outbreak identified	% of outbreaks for which etiology was identified
8.5.7. Vehicle of outbreak identified.	Vehicle of outbreak identified	% of outbreaks for which vehicle was identified
8.5.8. Contributing factors identified.	Contributing factors identified	% of outbreaks for which contributing factors were identified
8.5.9. Trends in no. confirmed foodborne disease outbreaks.	No. outbreaks reported to eFORS	% of outbreaks reported to state health department by year and type of agent, compared over time

* Includes functions variously assigned to communicable disease or environmental health programs, depending on local jurisdiction.

ABBREVIATIONS:
PHL = public health laboratory; eFORS = CDC's electronic Foodborne Outbreak Reporting System.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.6. Local health department: communicable disease program*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.6.1. Reported cases with specified foodborne illnesses interviewed.	Demographic information obtained	% of reported cases for which complete demographic information was available
	Exposure history obtained	% of reported cases for which exposure history was obtained
	Case onset date obtained	% of reported cases for which onset date was reported
	Date of report documented	% of reported cases for which a report date was available
	Need for public health intervention identified	% of cases for which intervention was identified or ruled out
8.6.2. Foodborne disease outbreaks investigated.	Cases interviewed to determine illness and exposure histories	% of investigations for which cases were interviewed
	Stool samples obtained from cases	% of investigations for which stool sample were collected from at least 1 case
8.6.3. Etiology of outbreak identified.	Clinical characteristics of outbreak characterized	% of outbreaks for which clinical characteristics were described
8.6.4. Vehicle of outbreak identified.	Suitable epidemiologic study conducted to identify vehicle	% of outbreaks for which an epidemiologic study was conducted to identify a vehicle
	Informational traceback conducted to subtype exposure histories	% of outbreaks for which an informational traceback was conducted to help elucidate exposure histories

* Includes functions typically assigned to communicable disease programs, not included in overall foodborne disease surveillance and control program indicators.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.7. Local Health Department: Environmental Health Program*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.7.1. Foodborne complaints investigated.	Logs or databases maintained for all complaint or referral reports from other sources alleging food-related illness, injury, or intentional food contamination. Final disposition for each complaint recorded in log or database and filed in or linked to establishment record for retrieval purposes	Draft Voluntary National Retail Food Regulatory Program Standards, standard 5, part 1.d, met, yes/no
	Demographic information obtained	% of complaints for which complete demographic information was available
	Food history obtained	% of complaints for which food history was obtained
	Outbreak detected	No. outbreaks detected
8.7.2. Foodborne disease outbreaks investigated.	Environmental health assessment of establishment conducted, where appropriate	% of outbreaks for which an establishment was investigated, if appropriate
	Food flow documented	% of environmental assessments that included a food flow
	Food workers interviewed	% of environmental assessments that included food worker interviews
8.7.3. Ill or infected food handlers identified and excluded.		Median no. days from initiation of investigation to implementation of intervention
8.7.4. Deficient food-handling practice identified and corrected.		Median no. days from initiation of investigation to implementation of intervention
8.7.5. Contributing factors identified.	Possible contributing factors to the illness, injury, or intentional food contamination identified in each on-site investigation report	Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a, met, yes/no

* Includes functions typically assigned to environmental health programs, not included in overall foodborne disease surveillance and control program indicators.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.8. Local health department: public health laboratory*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.8.1. Isolates of specified foodborne pathogens submitted to PHL.	Stool collection date obtained	% of cases for which stool collection date was available
	Date of submission to PHL documented	% of cases for which date of submission to PHL was available
	Date of serotyping documented	% of cases for which serotype date was available
	Date of subtyping by PFGE documented	% of cases for which PFGE subtyping date was available
	Isolate report maintained in searchable database	Searchable database maintained, yes/no
	Turnaround time from submission to serotyping result determined	Median no. days from submission of specimen to serotyping results
	Turnaround time from submission to subtyping result Determined	Median no. days from submission of specimen to subtyping results
8.8.2. Foodborne disease outbreaks investigated.	Turnaround time from collection of stool samples to confirmed culture results detemined	Median no. days from submission of stool samples to receipt of results
8.8.3. Etiology of outbreak identified.	Stool samples collected and tested for likely agents	% of outbreaks for which at least 1 stool sample tested for likely agents
	Food and environmental samples collected and tested for likely agents	% of outbreaks for which environmental samples tested for likely agents

* Includes functions typically assigned to public health laboratory programs, not included in overall foodborne disease surveillance and control program indicators. Many local health departments do not perform culture, serotyping, or subtyping and should focus only on the indicators that apply to them.

ABBREVIATIONS:
PHL = public health laboratory; PFGE = pulsed-field gel electrophoresis.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.9. State health department: overall foodborne disease surveillance and control programs*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.9.1. Reported cases with specified foodborne illnesses interviewed.	Case report maintained in searchable database	Searchable database maintained, yes/no
8.9.2. Isolates of specified foodborne pathogens submitted to PHL.	Reported cases for which isolates submitted to PHL	% of cases for which isolates submitted to PHL
	Turnaround time from submission to PFGE subtyping result	Median no. days from submission of specimen to PFGE subtyping results
8.9.3. Foodborne disease outbreaks investigated.	Time from onset of symptoms to initiation of outbreak investigation	Median no. days from onset of symptoms of the first/index case to outbreak investigation
8.9.4. Case clusters investigated.	Cluster source identified	% of clusters for which source identified
8.9.5. Sentinel foodborne events investigated.	Event-specific data collected	% of sentinel events for which data collected
8.9.6. Appropriate control measures initiated.		Median no. days from initiation of investigation to implementation of intervention
8.9.7. After-action reviews of outbreak investigations conducted within a mean of 60 days after investigation ends (CDC preparedness goal).		CDC preparedness goal met, yes/no
8.9.8. Trends in no. confirmed foodborne disease outbreaks.	No. outbreaks reported to eFORS	% of outbreaks reported to state health department by year and type of agent, compared over time
8.9.9. Trends in incidence of specified foodborne illnesses.	Statewide annual summaries of reported foodborne diseases	Annual summary prepared, yes/no

* Includes functions that may be variously assigned to communicable disease or environmental health programs, depending on local or state jurisdiction.

ABBREVIATIONS:
PHL = public health laboratory; PFGE = pulsed-field gel electrophoresis; eFORS = electronic Foodborne Outbreak Reporting System; CDC = Centers for Disease Control and Prevention.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.10. State health department: communicable disease program*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.10.1. Reported cases with specified foodborne illnesses interviewed.	Cases interviewed following receipt of report.	Median no. days from receipt of report to case interview
8.10.2. Foodborne disease outbreaks investigated.	Cases interviewed to determine illness and exposure histories	% of investigations for which cases interviewed
	Stool samples obtained from cases	% of investigations for which stool samples collected from at least 1 case
	Controls interviewed to determine exposure histories	% of investigations for which controls interviewed
8.10.3. Case clusters investigated.	Cases interviewed to determine exposure histories	% of case clusters for which at least half the cases interviewed to determine exposure history
	Time from cluster recognition to completion of case and control interviews determined	Median no. days from identification of cluster to completion of all planned interviews
8.10.4. Etiology of outbreak identified.	Clinical features of outbreak characterized	% of outbreaks for which clinical characteristics described
8.10.5. Vehicle of outbreak identified.	Suitable epidemiologic study conducted to identify vehicle	% of outbreaks for which epidemiologic study conducted to identify a vehicle
	Information traceback conducted to subtype exposure histories	% of outbreaks for which information traceback conducted to help elucidate exposure histories
8.10.6. Trends in no. confirmed foodborne disease outbreaks identified.	Outbreaks per million population determined	Agent-specific outbreak rate determined

* Includes functions typically assigned to communicable disease programs, not included in overall foodborne disease surveillance and control program indicators.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.11. State Health Department: Environmental Health Program*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.11.1. Foodborne complaints investigated.	Complaints maintained in searchable database	Searchable database maintained, yes/no
8.11.2. Foodborne disease outbreaks investigated.	Environmental health assessment conducted of food establishment	% of investigations for which establishment investigated, if appropriate
8.11.3. Ill or infected food handlers identified and excluded.		Median no. days from initiation of investigation to implementation of intervention
8.11.4. Deficient food-handling practice identified and corrected.		Median no. days from initiation of investigation to implementation of intervention
8.11.5. Source of outbreak identified.	Regulatory traceback conducted to confirm production source of implicated vehicle	% of outbreaks for which regulatory traceback conducted to confirm production source of implicated food vehicle
8.11.6. Contributing factors identified.	Preparation of implicated food items reviewed	% of outbreaks for which food-preparation flow reviewed on implicated food item
	Food-preparation review guided by identification of suspected agent	% of outbreaks for which food-preparation flow reviewed, with specific agent suspected
8.11.7. Trends in no. confirmed foodborne disease outbreaks identified.	No. outbreaks in restaurants per 1000 restaurants determined	Restaurant-specific outbreak rate determined
8.11.8. Results of outbreak investigation summaries incorporated into food-safety training activities.		Training activities updated annually, yes/no
8.11.9. Future outbreaks prevented.	Decrease in no. outbreaks attributable to previously identified sources and contributing factors	Change from baseline in no. and % of outbreaks with specific sources and contributing factors

* Includes functions typically assigned to environmental health programs, not included in overall foodborne disease surveillance and control program indicators.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.12. State health department: public health laboratory*

PERFORMANCE INDICATOR	SUBINDICATOR	METRIC
8.12.1. Isolates of specified foodborne pathogens submitted to PHL.	Date of submission to PHL documented	% of cases for which date of submission to PHL was available
	Date of serotyping documented	% of cases for which serotyping date was available
	Date of subtyping by PFGE documented	% of cases for which PFGE subtyping date was available
	Isolate report maintained in searchable database	Searchable database maintained, yes/no.
	Turnaround time from submission to serotyping result determined	Median no. days from submission of specimen to receipt of serotyping results
	Subtype clusters identified	No. subtype clusters identified
	For each type of agent, 90% of PFGE subtyping data results submitted to PulseNet database within 4 working days	CDC preparedness goal met, yes/no
8.12.2. Foodborne disease outbreaks investigated.	Turnaround time from collection of stool samples to confirmed culture results determined	Median no. days from submission of stool samples to receipt of culture results
8.12.3. Etiology of outbreak identified.	Stool samples tested for likely agents	% of outbreaks for which at least 1 stool sample tested for likely agents
	Food and environmental samples tested for likely agents	% of outbreaks for which environmental samples tested for likely agents

* Includes functions typically assigned to public health laboratory programs, not included in overall foodborne disease surveillance and control program indicators.

ABBREVIATIONS:
PHL = public health laboratory; PFGE = pulsed-field gel electrophoresis.

8.2. Performance Indicators

Major Performance Indicators and Metrics for Program Evaluation

Table 8.13. Benchmark data established by Enteric Diseases Investigation Timelines Study (EDITS)

SHORT-TERM OBJECTIVE	INDICATOR	SUBINDICATOR	METRIC
Detect foodborne disease events of public health importance.	8.13.1. Reported cases with specified foodborne illnesses interviewed	PROCESS • Exposure history obtained • Case onset date obtained • Date of report documented OUTCOME • Time from receipt of report to interview of case determined	PROCESS • 49% of reported cases had some exposure history obtained • 66% of reported cases had an onset date given • 42% of reported cases had a report date OUTCOME • 0 = Median no. days from receipt of report to interview of case
Detect foodborne disease events of public health importance.	8.13.2. Isolates of specified foodborne pathogens submitted to PHL	PROCESS • Stool collection date obtained • Date of submission to PHL documented • Date of subtyping by PFGE documented OUTCOME • Reported cases for which isolates submitted to PHL determined • Turnaround time from submission to subtyping result determined	PROCESS • 82% of cases had stool collection date available • 98% of cases had a date of submission to PHL • 100% of cases had PFGE subtyping date OUTCOME • 68% of cases had isolates submitted to PHL • 3 = Median no. days from submission of specimen to receipt of subtyping results

ABBREVIATIONS:
PHL = public health laboratory; PFGE = pulsed-field gel electrophoresis. PHL = public health laboratory; PFGE = pulsed-field gel electrophoresis.

CHAPTER 9

Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

9.0.1. Public Health Legal Preparedness

Legal preparedness is an indispensable part of comprehensive preparedness for public health threats. CDC defines public health legal preparedness as attainment by a public health agency or system of specified legal benchmarks or standards of preparedness for specified public health concerns. Public health legal preparedness has four core elements: a) laws and legal authorities, b) competency in understanding and using law, c) coordination across sectors and jurisdictions in the implementation of law, and d) information about best practices in using law for public health purposes

9.0. Introduction

9.0.2. Ensuring Legal Preparedness for Foodborne Disease Outbreaks

State and local health officials should ensure their agencies and jurisdictions are legally prepared for surveillance and control of foodborne disease outbreaks. This means

- They should have the laws and legal authorities needed to conduct all the functions key to effective surveillance and control (e.g., surveillance, reporting, enforcement, prevention, mitigation, investigation, and regulation);
- Their professional staff should be trained and demonstrate competence in applying those laws;
- They should have mutual aid agreements or memoranda of agreement in place to facilitate investigation and response across jurisdictions and jointly by public health and other agencies; and
- They should have access to information about and apply best practices in using their relevant legal authorities.

The adequacy of state and local legal preparedness for foodborne disease outbreaks should be evaluated regularly through exercises and after-action reports following responses to actual outbreaks.

As part of ensuring their jurisdictions' legal preparedness, state and local health officials should consult with their legal counsel and with counterparts in other government agencies and private organizations that have legal authorities or legal duties relevant to successful surveillance and control of foodborne disease outbreaks. These include such public entities as food-regulatory and law enforcement agencies, legal counsel to municipal and state governments, and local and state courts and court administrators. Relevant private entities include private laboratories, food wholesalers, grocery retailers, and restaurants and other food vendors. Where possible, these entities should be included in foodborne disease exercises to test their understanding of their legal authorities and duties related to outbreaks.

9.0.3. The Constitutional Setting for Foodborne Disease Surveillance and Control

As government bodies, public health agencies operate in the context of the U.S. Constitution, the fundamental law of the land. Some of the principal constitutional features relevant to public health agencies are the three-branch system of government, federalism, and protection for civil liberties and property rights. Public health agencies belong to the executive branch and are broadly charged to implement laws enacted by the legislature and as interpreted by the courts. In the federal system, the Constitution enumerates specified powers for the federal government and delegates other powers to the states. (Tribes are autonomous or sovereign bodies.) In addition, state and local governments possess inherent police powers to protect the health and safety of the public. Finally, the Fourth, Fifth, and Fourteenth amendments protect citizens from unreasonable searches and from deprivation of life, liberty, and private property without due process of law. States' constitutions, statutory law, and court rulings provide additional protections relevant to public health agencies' conduct of foodborne disease surveillance and conduct operations.

9.0.4. Legal Basis for State and Local Public Health Agencies in Surveillance and Control of Foodborne Disease

The primary role of local and state public health agencies is protection and promotion of the public's health. The legal authority supporting that role stems from statutory, regulatory, and case (judge-made) law as well as from the general police powers.

9.0. Introduction

Important legal parameters for public health practice were articulated in the 1905 U.S. Supreme Court ruling in the case *Jacobson v. Massachusetts*:

- With compelling reason, individual liberties may be subordinated to the well-being of the community.
- The police power of the state authorizes issuance and enforcement of reasonable regulations to protect the health of the community.
- Courts defer to the authority that legislative bodies give to public health agencies if exercised on the basis of persuasive public health and medical evidence
- Public health agencies may not act in an arbitrary manner nor pose unreasonable risks for harm.

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

9.0.5. Legal Basis for CDC in Surveillance

CDC operates under Congressionally enacted statutory law and, especially, in the case of foodborne disease surveillance, under provisions of the Public Health Service Act. CDC is not authorized to mandate reporting of diseases and conditions either by state and local governments or by private entities.

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

The Act also authorizes CDC to perform laboratory tests on specimens received from state and local governments (and from other sources) to identify pathogens, confirm serotypes of molecular subtypes, and perform diagnostic assays and report findings to appropriate state and local health departments. Virtually all enteric disease specimens tested in CDC laboratories are initially tested in state or local public health laboratories.

By providing botulinum antiserum, CDC learns of cases of botulism and verifies that the appropriate state or local health department is aware of them.

9.1. Legal Framework for Mandatory Disease Reporting

9.1.1. Statutes and Regulations

9.1.1.1. Authorization by legislature

The legislature generally gives broad statutory authority to the state health department to collect information and require reports of conditions of public health importance, without specifying the exact diseases or infections.

In addition to broad authority, states typically have several disease-specific statutes, such as human immunodeficiency virus/acquired immunodeficiency syndrome, tuberculosis,

9.1. Legal Framework for Mandatory Disease Reporting

and vaccine-preventable diseases, that authorize surveillance and control activities. All states have statutes addressing response to bioterrorism incidents.

9.1.1.2. Regulatory process for maintaining and updating list of reportable diseases
Every state has an oversight body or entity authorized to promulgate regulations (typically a board of health established by statute). The reportable disease list is revised or updated after study of, and public input on, the proposed changes.

The list of reportable diseases and conditions and laboratory findings is maintained and updated by epidemiologists and health officers in state and local agencies, with review and approval by the oversight body. Required reporting of specific laboratory test results (as opposed to regulatory language of "any positive test for …") generally means the list must be regularly updated.

Reportable disease regulations are established within the context of the basic public health compact. In return for allowing the government to collect without consent medical and personal information about selected conditions, the public requires the government to maintain confidentiality of the records and to prevent or minimize public health threats.

9.1.2. Reporting Processes

9.1.2.1. Time frame and content of reports
Regulations usually specify the time frame for reporting (e.g., within 7 days, within 24 hours, immediately) and the information to be reported (e.g., diagnosis; personal identifying and locating information; and date of onset or diagnosis, regardless of whether the case is suspected or confirmed).

9.1.2.2. Sources of reports
Regulations specify what entities are required to report. The usual sources of mandatory reports are

- Laboratories, including
  - Hospital-based laboratories,
  - National or regional commercial referral laboratories,
  - Local or state health department laboratories, and
  - CDC laboratories;
- Hospitals (e.g., hospitalized patients reported by infection control practitioners);
- Emergency departments;
- Office-based health-care providers;
- Long-term–care facilities or nursing homes; and
- Schools and child-care centers.

An agency may also receive reports from other public health agencies, for example, in other state health departments.

Arrangements and ongoing communication should be established with national or regional commercial laboratories to ensure results for relevant cases are received by the investigating agencies, even when those tests are conducted out-of-state. The same communication channels should be established with hospitals that are out-of-state but serve a population within the community affected by the outbreak.

The source of a report does not affect the legalstatus of the information—if it is required, it is protected by statutes and regulations. Conversely, reports to the agency of illness not listed as a reportable condition may not be subject to disease surveillance regulations and confidentiality protections (see section 9.1.5. below).

9.1.2.3. Reporting methods
A state or municipality can use any of a variety of methods for reporting. Specifics vary from one locale to another. These methods include

- Telephone;

9.1. Legal Framework for Mandatory Disease Reporting

- Hardcopy (fax or mail);
- Electronic batch reports sent by e-mail; and
- Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies.

9.1.2.4. Required submission of laboratory specimens

Some public health agencies have adopted regulations that require hospital and national diagnostic laboratories to submit isolates of specific pathogens to a state or local health department laboratory for further testing. One example would be a requirement for submission of all *Escherichia coli* O157:H7 isolates for PFGE testing. This requirement improves surveillance for foodborne disease as common subtypes are identified. In some locales, voluntary submission of specimens to the central referral laboratory achieves the same goal.

9.1.3. Accessing Medical and Laboratory Records

Typically, broad authority to conduct surveillance includes authority to investigate and control diseases of public health significance, including review of relevant and pertinent medical and laboratory records and reports, i.e., information that is not necessarily included in the basic case report.

9.1.4. Enforcement

Because non-reporting by health-care providers is common, redundant reporting systems have been established (e.g., *Salmonella* infection is reportable by both physicians and laboratories) to ensure a case will be reported. Nonetheless, failure to comply with reporting regulations is punishable. This is rarely enforced because penalizing a health-care provider may not result in future compliance and may reverberate throughout the clinical sector (i.e., may be counterproductive to the system).

Penalties or sanctions, however, may be imposed if lack of a report leads directly to an outbreak (for example, a food worker with hepatitis A is not reported, and immuneglobulin is thus not administered to restaurant customers). In most cases of non-reporting, the public health agency explains the regulatory requirement and its rationale and asks for future compliance, rather than seeking penalties or sanctions.

Reporting is difficult to enforce with a laboratory or health-care provider outside the agency's jurisdiction, such as when state X seeks reports from a referral laboratory in state Y. In this situation, lack of reporting usually results from misunderstanding of how to report.

Occasionally a laboratory will state it complies with requirements of the agency in which it is physically located—which might or might not require reporting of the particular disease, infection, or laboratory result.

9.1.5. Protection of Confidentiality

Personally identifying information in disease reports and investigation records is confidential and exempt from disclosure in response to freedom of information requests. If personally identifying information can be redacted and no other exemptions from disclosure apply, such records may have to be released. In redacting personally identifying information, descriptors such as age, sex, race/ethnicity, residence, and date of diagnosis may make the person identifiable. Preparing final outbreak investigation summary reports without any personally identifying information can speed up and simplify release of those reports to attorneys or media when they are requested.

Occasionally a public health agency must respond to a media inquiry in which the media has learned the name of a particular case from another source. The agency's response to the media inquiry must be carefully structured

9.1. Legal Framework for Mandatory Disease Reporting

to avoid to unintentional confirmation of the patient's name.

The public health agency generally is restricted from sharing personal identifying information with other government agencies without the consent of the reported person, except

- Virtually every state has an exception for sharing information with law enforcement agencies when investigating a bioterrorism incident;
- Many state statutes contain an exception for sharing information when, in the agency's judgment, sharing is necessary to protect the public health;
- State and local public health agencies often expect that when they provide epidemiologic and laboratory data to federal food-safety agencies (such as FDA or USDA), they will receive from those agencies results of the product investigations. However, this rarely is the case because results of the investigations may contain trade secrets or confidential commercial information or be part of a legal enforcement action or criminal case.

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 without individual authorization to a public health agency authorized by law to collect or receive such information, including a contractor (e.g., academic institutions) to which a government agency has granted authority. This disclosure without individual authorization does not include disclosure of protected health information for research purposes.

The legal requirement to report relieves the reporting source (e.g., physician) of concern that reporting breaches the privacy of the doctor-patient relationship. Explaining this to physicians often results in better reporting by them.

9.1.6 Cross-Jurisdiction and Cross-Sector Coordination

Effective reporting of foodborne disease cases hinges on coordination of reporting across jurisdictions (e.g., local, state, and federal government) and across sectors (e.g., health care and public health). State and local health officials should periodically assess the need for memoranda of agreement (or other legal agreements) with partners in other jurisdictions and sectors to ensure timely and effective reporting. (Note: A valuable resource for assessing and improving cross-jurisdictional and cross-sector coordination is the "Menu of Suggested Provisions for Public Health Mutual Aid Agreements," available at http://www.cdc.gov/phlp/mutualaid).

9.2. Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

9.2.1. Sources of Surveillance Information

Reports of food-related illness may come to the attention of the state or local health agency in a variety of ways:

A. Surveillance reports for enteric diseases, such as *Salmonella*, *Shigella*, and *Campylobacter*;

B. Request for antitoxin for botulism;

C. Reports of food poisoning or gastrointestinal illness in defined groups, such as diarrhea and vomiting among residents of a nursing home or school or among attendees at a work-related meeting;

9.2. Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

D. Enteric disease suspected of being caused intentionally;

E. Complaints of alleged contaminated, adulterated, or improperly cooked food purchased from stores or in restaurants and reported voluntarily by the general public; and

F. Syndromic surveillance using deidentified emergency department or pharmacy data.

9.2.2. Statutes and Regulations Governing Surveillance and Investigation

Confirmed or probable cases identified from items a–d above are subject to the reporting statute(s) and regulations of the health agency.

Items e and f generally do not have as strong a level of legal protection as do named case reports because they are either voluntary, unconfirmed disease reports (item E) or diagnoses for which names collected are not confirmed (item F).

Routine investigation of enteric diseases to determine the source of exposure, risk factors for infection, and contacts of a contagious case is usually considered part of surveillance activities authorized by state and local statutes.

CDC may participate in an investigation of an outbreak of enteric disease if invited by the state.

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

9.3.1. General

Because of (a) improvements in laboratory and communication technologies that can be used to link cases previously termed "sporadic" and (b) globalization of the food-production industries, more multistate and international foodborne disease outbreaks are being discovered, thus changing the locus of outbreak investigations and control measures.

9.3.2. Federal Role

The changes noted above have resulted in an increasingly direct, leading role in the control of foodborne diseases by several federal public health and regulatory agencies: US Department of Health and Human Services/CDC; Food and Drug Administration; US Department of Agriculture/Food Safety Inspection Service; U.S. Environmental Protection Agency; and when bioterrorism is suspected, U.S. Department of Justice and U.S. Department of Homeland Security. These agencies exercise their authority over food safety at various stages along the farm-to-table continuum primarily by inspections:

- Safety of food, feed, and animals on the farm;
- Plant and animal health on the farm, including animal vaccines;
- Pesticide use on the farm;
- Food processing;
- Slaughter and processing of meat and poultry products and egg products;
- Labeling, transportation, storage, and retail sale of food; and
- Cruise ships, trains, buses, airplanes (e.g., all interstate transportation) and the servicing areas for these transportation vehicles (21 CFR 1240 and 1250).

These agencies also coordinate and collaborate in multistate investigations.

FDA has jurisdiction over restaurants,

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

groceries, and other retail establishments, but it generally defers to state and local health agencies to enforce their own requirements through inspections.

The primary legislation by which FDA exercises authority over food is the Federal Food, Drug, and Cosmetic Act (FFDCA). A goal of FDA is to prevent contamination of food product before distribution, but the legislation allows it to pursue

- Voluntary compliance through the issuance of inspectional observations, untitled letters, and warning letters;
- Civil action, such as an injunction to prevent future violations of the FFDCA (i.e., continued distribution of adulterated food);
- Seizure action to remove specific lots of adulterated food (FDA also asks the producer or distributor, as appropriate, to voluntarily recall an adulterated food);
- Criminal action against an individual or company that violates the FFDCA, such as by causing food to become adulterated by inadequate processing and handling;
- Since the Bioterrorism Act of 2002, FDA has the authority to administratively detain certain food for up to 30 days (administrative detention does not require a court order);
- FDA's authority under the FFDCA is limited by the requirement for interstate commerce. However, under the Public Health Service Act, FDA can regulate intrastate commerce in some circumstances;
- State agencies may in some instances be swifter than FDA because they may require less evidence of problems before taking action than the requirements imposed on FDA by its legislation; and
- Amendments to the FFDCA in 2007 require FDA to establish a registry for reporting by individuals, companies, and local and state agencies of food that may cause serious adverse health consequences or death to humans or animals.

A good discussion of the differences in the jurisdictional authority between the USDA and the FDA can be found in Kux L, Sobel J, and Fain KM. Control of Foodborne Diseases; In: Goodman RA, Hoffman RE, Lopez W, Matthews GW, Rothstein MA, Foster KL. *Law in Public Health Practice.* 2nd ed. New York: Oxford University Press; 2007: 361-384.

9.3.3. Roles and Legal Authority of State and Local Public Health Agencies

Environmental health specialists and epidemiologists should understand their respective roles and legal authorities for various public health actions. In addition, they should know how and when they need to obtain expert legal counsel and upper-level management support and decision-making.

In instances in which improper food preparation and preparation at the local level results in foodborne disease, the broad authority of public health agencies to control epidemics and end nuisances, as well as specific authority they have to inspect restaurants and ensure proper food safety, is used to

- Close restaurants;
- Embargo, seize, or destroy contaminated food or require removal of contaminated lots from retail stores;
- Require changes in food preparation; and
- Temporarily remove infectious persons from the workplace.

These actions typically are taken through agency administrative orders. Such orders should contain time limits and specificy the conditions for removing them. If necessary, agencies may seek enforcement through court orders.

9.4. Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution

9.4.1. Chain of Custody

Laboratory specimens must be collected and submitted using procedures that ensure the chain of custody of the specimen, defined by one author as follows: "Everyone handling the sample [or specimen] must be able to demonstrate it is, and has been, identified as coming from the person [or item] in question to be admissible and probative in court"[1]

9.4.2. Joint Investigation and Collection of Evidence

Some investigations are initiated by public health officials but widen to other interests and agencies when a public health event results from a potential criminal act. Joint investigation by public health, food-safety and law enforcement agencies may be hindered by the different legal powers and investigatory practices each agency brings to such an event. For example, officials from food-safety and public health agencies are authorized to collect and test samples to determine their public health threat while law enforcement officials may consider samples subject to seizure as evidence. Food-safety, public health and law enforcement officials all must conform to constitutional standards (e.g., Fourth and Fifth Amendments) about collection of evidence, especially in situations requiring a joint investigation by public health, food safety, and law enforcement.

State and local 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. State and local health and law enforcement officials who have roles in investigating foodborne disease outbreaks should understand, and demonstrate competence in applying, their legal authorities in conducting joint investigations. (Note: Valuable resources for improving competency in joint investigation are the training curriculum "Forensic Epidemiology, v. 3.0", and the "Model Memorandum of Understanding for Joint Public Health-Law Enforcement Investigations", both accessible at accessible at http://www.cdc.gov/phlp/).

9.4.3. Role of Data in Regulatory Action

Epidemiologic and laboratory data may provide strong evidence linking illness to consumption of a particular food, resulting in a traceback investigation. When involving multiple states, federal regulatory agencies typically lead the traceback investigation.

Because of the need to link epidemiologic data with product information to take actions that protect the public health, the roles of state and local public health agencies and CDC must be coordinated with the roles of federal regulatory agencies.

9.5. Reference

1. Lazzarini Z, Goodman RA, Dammers KS. Criminal law and public health practice; In: Goodman RA, Hoffman RE, Lopez W, Matthews GW, Rothstein MA, Foster KL. *Law in Public Health Practice.* 2nd ed. New York: Oxford University Press; 2007:136–67.

Appendices

Appendix 1

GLOSSARY

Note: The definitions given are valid as they are used in this publication, but different definitions may be used in other contexts.

Active surveillance:
Actively contacting potential sources of disease reports to solicit and collect reports or specimens, rather than waiting until they are submitted to the mandated government agency. Potential sources of disease reports or specimens include laboratories, hospitals, and physicians.

Adulterated:
A legal term meaning a food product fails to meet federal or state standards. Adulteration usually refers to noncompliance with health or safety standards as determined in the United States by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

Analytic study:
In epidemiology, a study designed to examine associations, commonly putative or hypothesized causal relationships; usually concerned with identifying or measuring the effects of risk factors or with the health effects of specific exposures.

Bare-handed contact:
Contact between bare skin and food items during preparation or serving (covered under section 3-301.11 of the FDA Food Code).

Case:
In epidemiology, a countable instance in the population or study group of a particular disease, health disorder, or condition under investigation; in these guidelines, an individual with the particular disease.

Case-control study:
A type of observational analytic study. Enrollment into the study is based on presence ("case") or absence ("control") of disease. Characteristics such, as previous exposure, are then compared between cases and controls.

Case definition:
Standardized criteria for deciding whether a person has a particular disease or health-related condition, by specifying clinical criteria and limitations on time, place, and person.

Chain-of-custody:
Standards and procedures for which evidentiary documentation and strict record keeping are indicated or required. The chain-of-custody establishes proof that the items of evidence collected during an investigation are the same as those being presented in a court of law. The chain-of-custody requires direct interviews and collection of supporting documentation (e.g., invoices, bills of lading, import documents) during the investigation. The chain-of-custody also establishes who had contact with the evidence; the date and time the evidence was handled; the circumstances under which the evidence was handled; and what changes, if any, were made in the evidence.

Cluster:
An unusual aggregation of cases grouped in time or space. The term is commonly used in pathogen-specific surveillance, when multiple infections caused by similar microbial strains are identified by a public health laboratory. The purpose of identifying clusters is to trigger further investigations to determine whether they may represent an outbreak. The number of cases needed to form a cluster cannot be absolutely defined; cluster definition may vary by type of agent, novelty of the subtype, season, and resources available for further investigation.

Cohort:
A well-defined group of people who have had a common experience or exposure, who are then followed up for the incidence of new diseases or events, as in a cohort or prospective study. A group of people born during a particular period or year is called a birth cohort.

Cohort study:
A type of observational analytic study. Enrollment into the study is based on exposure characteristics or membership in a group. Disease, death, or other health-related outcomes are then ascertained and compared.

Contributing Factors:
The food safety practices and behaviors which most likely contributed to a foodborne illness outbreak.

Appendix 1

Control:
In a case-control study, comparison group of persons without disease.

Denaturing:
Applying substance, such as household bleach or carbolic acid, to all portions of food products to prevent their use for food purposes.

eFORS:
Electronic Foodborne Outbreak Reporting System. A secure Web-based reporting system that allows state health departments to report foodborne disease outbreaks electronically to CDC. eFORS is being subsumed into the National Outbreak Reporting System (NORS), which will include outbreaks from all transmission routes, including water, person to person, and animal contact.

Embargo:
An order issued by a permit-issuing official or his/her designated representative at a state or local agency that prevents food from being used, sold, donated, discarded, repackaged or otherwise disposed of until the order is lifted by the permit-issuing official, his/her designated representative, or court of competent jurisdiction.

Environmental health specialist:
An environmental health specialist, or sanitarian, conducts research or performs investigations to identify, diminish, and/or eliminat sources of pollutants and hazards that affect either the environment or the health of the population. They may collect, synthesize, study, report, and take action on the basis of data derived from measurements or observations of air, food, soil, water, and other sources.

Epidemiologist:
An investigator who studies the occurrence of disease or other health-related conditions or events in defined populations. The control of disease in populations also is often considered to be a task for the epidemiologist. Epidemiologists conduct surveillance and carry out investigations using hypothesis testing and analytic research to identify the causes of disease, including the physical, biologic, social, cultural, and behavioral factors that influence health.

Epi-X:
Epi-X is CDC's Web-based communications solution for public health professionals. Through Epi-X, CDC officials, state and local health departments, poison control centers, and other public health professionals can access and share preliminary health surveillance information—quickly and securely. Users can also be notified of breaking health events as they occur.

Food code:
A reference guide published by FDA. The guide instructs retail outlets, such as restaurants and grocery stores, and institutions, such as nursing homes, how to prevent foodborne illness. It consists of a model code adopted by nearly 3000 state, local and tribal jurisdictions as the legal basis for their food inspection program for safeguarding public health. It ensures that food is safe and unadulterated (free from impurities) and honestly presented to the consumer. It also provides references and public health reasons and explanations for code provisions, guidelines, and sample forms. FDA first published the Food Code in 1993 and revises it every 4 years.

Food- establishment:
An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a restaurant; satellite or catered food location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution or food bank; and (b) relinquishes possession of food directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food-safety regulatory agency:
Government agencies at the local, state, or federal level that are granted regulatory oversight of some aspect of the food industry. The goal of food-regulatory agencies is to ensure the public food supply is safe from disease caused by infection from human handling or by contamination from chemical or other hazardous substances.

Appendix 1

Foodborne disease:
Any disease caused by ingestion of contaminated food. Although some agents are more likely than others to be transmitted by food, identification of foodborne, waterborne, person-to-person, or animal-to-person transmission requires investigation. Furthermore, multiple modes of transmission may be involved in any single outbreak.

Foodborne disease surveillance:
Surveillance of diseases or conditions that *might* be foodborne. Thus, all diseases of enteric origin may be tracked by this mechanism, including norovirus infection (which involves substantial person-to-person transmission), listeriosis (which may have a diarrheal stage but generally is detected by blood culture), or botulism (which presents as neurologic disease).

Foodnet Atlas of Exposures:
The results of periodic population-based surveys undertaken at selected sites in the United States. The survey collects information about exposures that might be associated with foodborne illnesses and can be used to estimate the background rate of different food exposures in the community.

HACCP (Hazard Analysis and Critical Control Point):
A science-based and systematic approach to prevent potential food-safety problems by anticipating how biologic, chemical, or physical hazards are most likely and by installing appropriate measures to prevent them.

Imminent hazard:
An important threat or danger to health that exists when evidence is sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on (a) the number of potential injuries and (b) the nature, severity, and duration of the anticipated injury.

Impound:
To take possession of or to seize and hold in the custody of the law.

Jurisdiction:
A government entity with the legal authority to interpret and apply the law. Also refers to the limits or territory within which that authority may be exercised.

Multijurisdictional:
A multijurisdictional foodborne disease event requires the resources of more than one local, state, territorial, tribal, or federal public health or food-regulatory agency to detect, investigate, or control. A multijurisdictional investigation may involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

Outbreak:
Two or more cases of a similar illness shown by an investigation to result from a common exposure, such as ingestion of a common food. An outbreak is a cluster with a clear association between cases, with or without a recognized common source or known disease agent. Single cases of certain rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera, elicit an outbreak-like response.

Outbreak Response Protocol:
A comprehensive document outlining the roles, responsibilities and required actions of all individuals and organizations involved in the investigation of a foodborne disease outbreak. Outbreak response protocols may be developed for a specific organization or may encompass multiple organizations and jurisdictions.

OutbreakNet:
A national collaboration of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States. The purpose of OutbreakNet is to ensure rapid, coordinated detection and response to multistate outbreaks of enteric diseases and promote comprehensive outbreak surveillance.

Appendix 1

Public health agency:
A government agency established at the local, state, or federal level that is responsible for developing and managing public health programs, including surveillance for infectious disease and noninfectious conditions, interventions to prevent and limit the spread of disease, and promotion of healthy behaviors and environments.

PulseNet:
An international surveillance network comprising national, state, and local public health and food-regulatory agency laboratories that conduct standardized molecular subtyping of foodborne disease pathogens (i.e., DNA fingerprinting) and maintain centrally accessible databases of patterns. PulseNet also functions as a communication hub for laboratories involved in food and foodborne disease monitoring.

Recall:
A voluntary action of removing a product from retail or distribution. The action is conducted by a manufacturer or distributor to protect the public from products that may cause health problems or possible death.

Reportable conditions (notifiable diseases):
The list of diseases based on state laws or regulations that should be reported by health-care providers (e.g., physicians and their medical staff, laboratories, and hospitals) to local or state health agencies. The list of notifiable diseases and legal obligation for reporting differ from state to state. States can report notifiable diseases to CDC, which maintains a list of nationally notifiable diseases, but compliance is voluntary. CDC reports selected diseases to the World Health Organization in compliance with International Health Regulations.

Sporadic case:
A case not linked epidemiologically to other cases of the same illness. Single sporadic cases of extremely rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera, merit a detailed investigation as soon as possible, as though they were outbreaks, to prevent any further cases.

Surveillance:
The systematic collection, analysis, interpretation, and dissemination of data for public health action.

Traceback:
The process by which the origin or source of a cluster of contaminated food is identified.

Traceforward:
Tracking a recalled product from the origin or source through the distribution system.

Trawling, trolling, shotgun or hypothesis-generating questionnaire:
A variety of interview forms designed to capture a wide range of exposures. These forms may be designed with embedded questions focused on disease-specific hypotheses (e.g., exposures previously associated with the pathogen or plausibly associated with the pathogen) as well as other food items and exposures that have not been associated with the pathogen, which may consolidate the hypothesis-generation and testing processes into a single step. For instance, the trawling questionnaire for an outbreak of *E. coli* O157:H7 infection may contain standardized questions about known transmission mechanisms for this agent, such as hamburger consumption, child-care attendance, recreational pool use, animal exposures, and other exposures identified in previous outbreaks which function as a priori hypotheses.

USDA/FSIS Consumer Complaint Monitoring System (CCMS):
An electronic database for capturing consumer complaints. Since 2001, USDA/FSIS has used this database to record, triage, and track complaints about FSIS-regulated meat, poultry, and egg products. CCMS helps to identify and trace adulterated product in commerce and allows the agency to respond and mitigate possible food-safety hazards.

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
Upper gastrointestinal tract symptoms (nausea, vomiting) occur first or predominate		
<1 hrs	Nausea, vomiting, unusual taste, burning of mouth	Metallic salts
1–2 hrs	Nausea, vomiting, cyanosis, headache, dizziness, dyspnea, trembling, weakness, loss of consciousness	Nitrites
1–6 hrs (mean 2–4 hrs)	Nausea, vomiting, retching, diarrhea, abdominal pain, prostration	*Staphylococcus aureus* and its *enterotoxins*
8–16 hrs (2–4 hrs emesis possible)	Vomiting, abdominal cramps, diarrhea, nausea	*Bacillus cereus*
6–24 hrs	Nausea, vomiting, diarrhea, thirst, dilation of pupils, collapse, coma	Amanita species mushrooms
Sore throat and respiratory symptoms occur		
12–72 hrs	Sore throat, fever, nausea, vomiting, rhinorrhea, sometimes a rash	*Streptococcus pyogenes*
2–5 days	Inflamed throat and nose, spreading grayish exudate, fever, chills, sore throat, malaise, difficulty swallowing, edema of cervical lymph node	*Corynebacterium diphtheriae*
Lower gastrointestinal tract symptoms (abdominal cramps, diarrhea) occur first or predominate		
2–36 hrs (mean 6–12 hrs)	Abdominal cramps, diarrhea, putrefactive diarrhea associated with *Clostridium perfringens*, sometimes nausea and vomiting	*Clostridium perfringens, Bacillus cereus, Streptococcus faecalis, Staphylococcus faecium*
12–74 hrs (mean 18–36 hrs)	Abdominal cramps, diarrhea, vomiting, fever, chills, malaise, nausea, headache possible. Sometimes bloody or mucoid diarrhea, cutaneous lesions associated with Vibrio vulnificus. *Yersinia enterocolitica* infection mimics flu and acute appendicitis	*Salmonella species* (including *S. arizonae*), *Shigella*, enteropathogenic *Escherichia coli*, other *Enterobacteriacae*, *Vibrio parahaemolyticus, Yersinia enterocolitica, Aeromonas hydrophila, Plesiomonas shigelloides, Campylobacter jejuni, Vibrio cholerae* (O1 and non-O1) *Vibrio vulnificus, Vibrio fluvialis*
3–5 days	Diarrhea, fever, vomiting abdominal pain, respiratory symptoms	Enteric viruses

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
1–6 wks	Mucoid diarrhea (fatty stools) abdominal pain, weight loss	*Giardia lamblia*
1 to several weeks	Abdominal pain, diarrhea, constipation, headache, drowsiness, ulcers, variable—often asymptomatic	*Entamoeba histolytica*
3–6 mos	Nervousness, insomnia, hunger pains, anorexia, weight loss, abdominal pain, sometimes gastroenteritis	*Taenia saginata, T. solium*
Neurologic symptoms (visual disturbances, vertigo, tingling, paralysis) occur		
<1 hr	*** See Gastrointestinal and/or neurologic symptoms (shellfish toxins) below	Shellfish toxin
	Gastroenteritis, nervousness, blurred vision, chest pain, cyanosis, twitching, convulsions	Organic phosphate
	Excessive salivation, perspiration, gastroenteritis, irregular pulse, pupils constricted, asthmatic breathing	Muscaria-type mushrooms
	Tingling and numbness, dizziness, pallor, gastrohemmorrhage, and desquamation of skin, fixed eyes, loss of reflexes, twitching, paralysis	Tetradon (tetrodotoxin) toxins
1–6 hrs	Tingling and numbness, gastroenteritis, dizziness, dry mouth, muscular aches, dilated pupils, blurred vision, paralysis	Ciguatera toxin
	Nausea, vomiting, tingling, dizziness, weakness, anorexia, weight loss, confusion	Chlorinated hydrocarbons
2 hrs–6 days, usually 12–36 hrs	Vertigo; double or blurred vision; loss of reflex to light; difficulty swallowing. speaking, and breathing; dry mouth; weakness; respiratory paralysis	*Clostridium botulinum* and its neurotoxins
>72 hrs	Numbness, weakness of legs, spastic paralysis, impairment of vision, blindness, coma	Organic mercury
	Gastroenteritis, leg pain, ungainly high-stepping gait, foot and wrist drop	Triorthocresyl phosphate

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
Allergic symptoms (facial flushing, itching) occur		
<1 hr	Headache, dizziness, nausea, vomiting, peppery taste, burning of throat, facial swelling and flushing, stomach pain, itching of skin.	Histamine (scombroid)
	Numbness around mouth, tingling sensation, flushing, dizziness, headache, nausea	Monosodium glutamate
	Flushing, sensation of warmth, itching, abdominal pain, puffing of face and knees	Nicotinic acid
Generalized infection symptoms (fever, chills, malaise, prostration, aches, swollen lymph nodes) occur		
4–28 days (mean 9 days)	Gastroenteritis, fever, edema about eyes, perspiration, muscle pain, chills, prostration, labored breathing	*Trichinella spiralis*
7–28 days (mean 14 days)	Malaise, headache, fever, cough, nausea, vomiting, constipation, abdominal pain, chills, rose spots, bloody stools	*Salmonella typhi*
10–13 days	Fever, headache, myalgia, rash.	*Toxoplasma gondii*
10–50 days, mean 25–30 days	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice	Etiologic agent not yet isolated—probably viral
Varying periods, depending on specific illness	Fever, chills, headache or joint ache, prostration, malaise, swollen lymph nodes, other specific symptoms of disease in question	*Bacillus anthracis, Brucella melitensis, B. abortus, B. suis, Coxiella burnetii, Francisella tularensis, Listeria monocytogenes, Mycobacterium tuberculosis, Mycobacterium* species, *Pasteurella multocida, Streptobacillus moniliformis, Campylobacter jejuni, Leptospira* species.
Gastrointestinal and/or neurologic symptoms (shellfish toxins)		
0.5–2 hrs	Tingling, burning, numbness, drowsiness, incoherent speech, respiratory paralysis	Paralytic shellfish poisoning (saxitoxins)

Appendix 2

Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin* *(Continued)*

APPROXIMATE ONSET TIME TO SYMPTOMS	PREDOMINANT SYMPTOMS	ASSOCIATED ORGANISM OR TOXIN
2–5 mins to 3–4 hrs	Reversal of hot and cold sensation, tingling; numbness of lips, tongue and throat; muscle aches, dizziness, diarrhea, vomiting	Neurotoxic shellfish poisoning (brevetoxins)
30 mins to 2–3 hrs	Nausea, vomiting, diarrhea, abdominal pain, chills, fever	Diarrheic shellfish poisoning (dinophysis toxin, okadaic acid, pectenotoxin, yessotoxin)
24 hrs (gastrointestinal) to 48 hrs (neurologic)	Vomiting, diarrhea, abdominal pain, confusion, memory loss, disorientation, seizure, coma	Amnesic shellfish poisoning (domoic acid)

* From FDA. Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. January 1992. Available at http://www.cfsan.fda.gov/~mow/app2.html. Accessed November 28, 2008.

Appendix 3

List of Key Websites and Resources Cited

Applied Epidemiology Competencies:
www.cste.org

CDC's Diseases and Conditions A–Z index:
http://www.cdc.gov/diseasesConditions

CIFOR Clearinghouse:
www.cifor.us

Control of Communicable Diseases Manual (latest edition),
American Public Health Association Press

Environmental Assessment Forms and Consumer Complaint Forms:
http://www.cdc.gov/nceh/ehs/EHSNet/

FDA Food Code:
http://www.cfsan.fda.gov/~dms/fc05-toc.html

FoodNet Atlas of Exposures:
http://www.cdc.gov/foodnet/studies_pages/pop.htm

Forensic Epidemiology, v. 3.0: training curriculum,
http://www.cdc.gov/phlp/

Model Memorandum of Understanding for
Joint Public Health-Law Enforcement Investigations:
http://www.cdc.gov/phlp/

National Botulism Surveillance Program:
http://www.cdc.gov/nczved/dfbmd/disease_listing/files/botulism.pdf

Procedures to Investigate Foodborne Illness (latest edition),
International Association for Food Protection

Standardized Outbreak Questionnaires:
http://www.cdc.gov/foodborneoutbreaks/standard_ques.htm

State-Specific Notifiable Condition Reporting Requirements:

- http://www.cste.org/nndss/reportingrequirements.htm
- http://www.cifor.us/clearinghouse/index.cfm

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CIFOR Council to Improve Foodborne Outbreak Response

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