CHAPTER

4

Foodborne Disease Surveillance and Outbreak Detection

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

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

4.0. Introduction

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

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

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

4.1. Overview

Disease surveillance is used to identify clusters of possible foodborne illness. Investigation methods (Chapter 5) then are used to identify common exposures of ill persons in the cluster that distinguish them from healthy persons. Although, in practice, detecting individual foodborne disease outbreaks involves multiple approaches, two general methods are used in outbreak detection: pathogen-specific surveillance and complaint systems (Table 4.1). A third method, syndromic surveillance, is used in some jurisdictions, but its role in detecting foodborne disease outbreaks is limited. Although these methods are presented separately for descriptive purposes, they are most effective when used together and integrated with food, veterinary, and environmental monitoring programs, as will be described later in Chapters 4 and 5.

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

Table 4.1. Comparison of foodborne disease surveillance systems

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

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

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

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

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

¶ Exposure histories are not typically obtained.

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

4.1. Overview

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

- Complaint systems
  Health-care providers or the public identify and report suspected disease clusters (group notifications) or individual complaints. Exposure information is acquired by interviews with cases.
- Syndromic surveillance
  This surveillance method generally involves systematic (usually automated) gathering of data on nonspecific health indicators that might reflect increased disease occurrence, such as purchase of loperamide (an antidiarrheal agent), visits to emergency departments for diarrheal complaints, or calls to poison control hotlines. Exposure information is not routinely collected.

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

4.2. Pathogen-Specific Surveillance

4.2.1. Purpose

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

4.2.2. Background

Surveillance for typhoid fever began in 1912 and was extended to all *Salmonella* spp. in 1942. National serotype-based surveillance of *Salmonella* began in 1963, making it one of the oldest pathogen-specific surveillance programs and the oldest public health laboratory subtype-based surveillance system. The usefulness of pathogen-specific surveillance is related to the specificity with which agents are classified (i.e., use of subtyping and method), permitting individual cases of disease to be grouped with other cases most likely to share a common food source or other exposure (Box 4.1). The utility of bacterial surveillance increased during the 1990s with the development of PulseNet and molecular subtyping of selected foodborne pathogens, including *Salmonella*, Shiga toxin–producing *Escherichia coli* (STEC) O157:H7, *Shigella*, *Listeria*, and *Campylobacter*.

Box 4.1. Selected nationally notifiable diseases that can be foodborne

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

In addition, the following are nationally notifiable:

- Foodborne disease outbreaks
- Waterborne disease outbreaks

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

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4.2.3. Case Reporting and Laboratory Submission Process

Most diseases included under pathogen-specific surveillance are reportable (i.e., notifiable) diseases. State or local health agencies establish criteria for voluntary or mandatory reporting of infectious diseases, including those that might be foodborne (Table 4.2). These criteria describe the diseases to report, to whom, how, and in what time frame. For this type of surveillance, diseases are defined by specific laboratory findings, such as isolation of *Salmonella enterica*, or by well-defined syndromes, such as hemolytic uremic syndrome. Diseases are reported primarily by laboratories, medical staff (e.g., physicians, infection-control practitioners, medical records clerks), or both. Disease reports can be automatically generated from an electronic medical record or laboratory information system or reported through a secure website. Legacy systems, such as telephone, mail, or fax reporting, also are used but are slower and more labor intensive and error prone. Isolates or other clinical materials are forwarded from laboratories serving primary health-care facilities to public health laboratories for confirmation and further characterization, as required by state laws or regulations or as requested by the local jurisdiction.

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

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

4.2.4. Epidemiology Process

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

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

Initial cluster identification and cluster assessment might occur as two processes conducted, respectively, by the laboratory and epidemiology departments or might occur as a single process within epidemiology. Agent, time, and place are examined individually and in combination to identify possibly significant

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

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

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

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

4.2.5. Laboratory Process

Clinical diagnostic laboratories forward case isolates, specimens that were positive for a reportable enteric pathogen by a culture-independent test, or other clinical materials to public health laboratories as part of mandated or voluntary reporting rules. Such problems as mislabeling, broken-in-transit, or quantity-not-sufficient are resolved. Receipt of samples is recorded, and sample information is entered into the laboratory database. Patient information submitted with the sample may be provided to the epidemiology department for comparison with information from cases already reported and to enable reconciliation of case reports and laboratory samples and identification of previously unreported cases.

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

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laboratory or epidemiology information systems; extracted from the PulseNet database; or facilitated by software, such as the CIFOR laboratory/epidemiology reporting program (http://www.cifor.us/projelr.cfm). Case cluster data are enhanced by inclusion of information about matching isolates or outbreaks through PulseNet from other jurisdictions and by matching isolates from food, animal, or environmental monitoring tests that provide information for hypothesis generation. Specimen data (including detailed subtyping results) are additionally uploaded to national surveillance systems, such as the U.S. Laboratory-based Enteric-Diseases Surveillance (LEDS [in the United States] or TESSy [in Europe]).

4.2.5.1 Cluster definition and triage

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

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

Clusters are common, and pursuing them all with equal vigor is not practical or productive. The cluster triage process is primarily manual. Incoming surveillance data are evaluated for unusual case counts based on historical frequencies (accounting for seasonality), the severity of disease, matches between human cases and food or animal monitoring samples, and competing demands for investigators' time. The time window used to delimit clusters varies by agent. For example, a wider window is used to evaluate clustering of listeriosis cases than to evaluate salmonellosis cases because of differences in the natural history of the diseases. Although cluster recognition software, such as SaTScan™, cusum outbreak detection algorithms, and query algorithms in the PulseNet Web Portal have been developed, none have yet been validated for broad-based enteric disease data. The decision to report or pursue a cluster is an important part of the outbreak detection process but not one that is easily distilled into simple best practices. An increase in frequency of a strain is only one indication of a potentially significant cluster. Furthermore, absence of an increase in case numbers from expected values does not rule out significance.

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

4.2.5.2. Microbiological Screening

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

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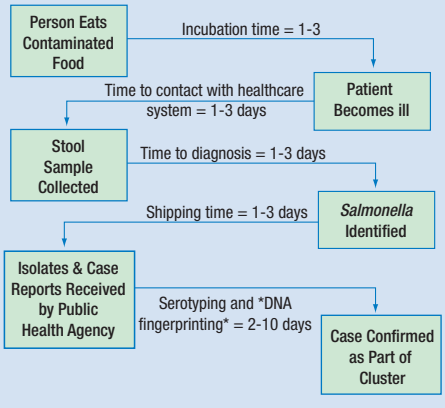
Routine food screening is conducted as part of larger food safety verification programs operated by the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state agriculture agencies. Screening information also might be available from the food industry. Incorporating this routine food or animal monitoring or regulatory surveillance test data into the disease surveillance information stream enhances hypothesis generation and improves the sensitivity and timeliness of outbreak detection. In the United States, data streams from human disease surveillance, food-testing programs, and selected live-animal testing are co-mingled in the PulseNet database, although important product details might not be readily available.

4.2.6. Timeline for Case Reporting and Cluster Recognition

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

Figure 4.1. Sample *Salmonella* case reporting timeline



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

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

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

4.2.7. Strengths of Pathogen-Specific Surveillance for Outbreak Detection

- Permits detection of widespread disease clusters initially linked only by a common agent. Most national and international foodborne disease outbreaks are detected in this manner.
- When combined with case information from clusters recognized though complaints (section 4.3), and when specific exposure information is obtained, is arguably the most sensitive single method for detecting unforeseen problems in food and water supply systems caused by the agents under surveillance. The specificity of agent or syndrome information combined with specific exposure information obtained by interviews enables the positive association of small numbers of cases with exposures.

4.2.8. Limitations of Pathogen-Specific Surveillance

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

4.2.9. Key Determinants of Successful Pathogen-Specific Surveillance

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

4.2.9.1. Sensitivity of case detection

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

4.2.9.2. Prevalence of the agent and specificity of agent classification

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

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

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

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

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

4.2.9.3. Sensitivity and specificity of interviews of cases

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

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

4.2.9.3.1. Timing

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

4.2.9.3.2. Content

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

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

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

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

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

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

4.2.9.4. Overall speed of the surveillance and investigation processes

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

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

4.2.10. Routine Pathogen-Specific Surveillance—Model Practices

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

4.2. Pathogen-Specific Surveillance

4.2.10.1. Reporting and isolate submission

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

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

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

4.2.10.2. Isolate/specimen submission and characterization

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

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

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

4.2.10.3. Case interviews

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

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

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

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

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

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

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

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

4.2. Pathogen-Specific Surveillance

4.2.10.4. Data analysis

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

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

4.2.10.5. Communication

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

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

Reporting/submission of isolates

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

Testing of specimens

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

Collection of exposure information

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

Detection of clusters/outbreaks

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

Communication

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

Making changes

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

4.2. Pathogen-Specific Surveillance

4.2.11. Multijurisdictional Considerations for Pathogen-Specific Surveillance

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

4.2.12. Indicators/Measures for Pathogen-Specific Surveillance

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

4.3. Complaint Systems

4.3.1. Purpose

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

4.3.2. Background

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

4.3.3. Group Illness and Independent Complaints

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

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

Group illness and independent complaints may be used together and linked with data obtained through pathogen-specific surveillance. In contrast to pathogen-specific surveillance,

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

4.3.4. Epidemiology Process

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

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

4.3.5. Public Health Laboratory Process

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

4.3.6. Strengths of Complaint Systems for Outbreak Detection

- Because detection does not depend on identification of an agent, this system can detect outbreaks from any cause, known or unknown. Thus, the complaint system is one of the best methods for detecting nonreportable pathogens and new or reemerging agents. Recent examples include recognition of sapovirus as a significant agent in norovirus-like outbreaks[4] and identification of *Arcobacter butzleri* as the likely agent in an outbreak of gastroenteritis at an event.[5] In one study, consumer complaint surveillance alone led to detection of 79% of confirmed foodborne outbreaks, including most norovirus outbreaks.[4]

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- For event-related complaints only: recall of food items eaten and other exposures by cases usually is good for reported events because items consumed at the event can be identified by menus or other means and specifically included in the interview.
- Complaint surveillance systems are inherently faster than pathogen-specific surveillance because the chain of events related to laboratory testing and reporting is not required (section 4.1.6). Exposure information gained through patient interviews has the potential for being high quality because patient recall is highest close to the exposure event.
- Because of the relatively limited number of exposures to consider (see 4.3.8.2 below), investigations of event-related notifications can be pivotal to solving widespread outbreaks detected through pathogen-specific surveillance. Recent examples include an international outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga infections associated with a raw scraped ground tuna product[6] and a large outbreak of *Salmonella* Typhimurium infections associated with peanut products.[7]

4.3.7. Limitations of Complaint Systems

- Notification of illness in groups generally is less sensitive to widespread low-level contamination events than is pathogen-specific surveillance because recognition of a person–place–time connection among cases by a health-care provider or member of the community is required.
- The value of complaints about single possible cases of foodborne disease in detecting outbreaks is limited by the exposure information used to link cases and by the lack of specific agent or disease information to exclude unrelated cases. The illness reported by individuals might or might not be foodborne, and illness presentation might or might not be typical. For any true outbreak, the absence of an agent makes misclassification of cases more likely. Misclassification of cases makes identification of an association between an outbreak and an exposure more difficult.
- Without a detailed food history (either from the initial report or follow-up interview), surveillance of independent complaints is sensitive only for short incubation (generally chemical- or toxin-mediated) illness or illness with unique symptoms because most persons associate illness with the last meal eaten before onset of symptoms – and are thus likely to be correct only for exposures with short incubation times. This is not a limitation if full interviews are conducted.

4.3.8. Key Determinants of Successful Complaint Systems

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

4.3.8.1. Sensitivity of case or event detection

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

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

4.3.8.2. Background prevalence of disease—group complaints

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

4.3.8.3. Sensitivity and specificity of case interviews—group complaints

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

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

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

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

4.3.9. Complaint Systems—Model Practices

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

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

4.3.9.1. Interviews related to individual complaints

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

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

Collection of a 5-day exposure history is also recommended when an investigation begins that is based on multiple individual complaints. Given the ubiquity of norovirus infections, the investigator should pay particular attention to exposures in the 24–48 hours before onset whenever norovirus is suspected. As more information about the likely etiologic agent is collected, this approach can be modified.

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

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

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

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

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

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

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

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

4.3.9.3. Interviews related to reported illnesses in groups

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

Focus interviews on the event shared by members of the group. However, be aware they might have more than one event in common, and explore that possibility. For example, an outbreak associated with a wedding reception might actually result from the rehearsal dinner, which involves many of the same people. Interviews should ask about other possible exposures either for the interviewee or for others he or she might have contacted, such as child-care attendance, employment as a food worker, or ill family members.

4.3.9.4. Clinical specimens and food samples related to group illness

Obtain clinical specimens from members of the ill group. If the presumed exposure involves food, collect and store—but do not test—food from the implicated event. All sampling must be conducted using legally defensible procedures (e.g., chain-of-custody) and using protocols as guided by the laboratory that will do the analysis. Store the food appropriately, but generally test the food only after epidemiologic implication or identification of specific food-safety problems through an environmental health assessment. Food samples that are frozen when collected should remain frozen until examined. Samples should be analyzed within 48 hours after receipt. If sample analysis is not possible within 48 hours, then perishable foods should be frozen (−40°C to −80°C). Storage under refrigeration can be longer than 48 hours, if necessary, but the length of the storage period is food dependent. Because certain bacteria (e.g., *Campylobacter jejuni*) die when frozen, affecting laboratory results, immediate examination of samples without freezing is encouraged. Food samples can be collected as part of the process of removing suspected food from service.

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

Furthermore, results of testing are often difficult to interpret. Because contaminants in food change with time, samples collected during an investigation might not represent food ingested when the outbreak occurred. Subsequent handling or processing of food might result in the death of microorganisms, multiplication of microorganisms originally present in low levels, or introduction of new contaminants. If the food is not uniformly contaminated, the sample collected might miss

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the contaminated portion. Finally, because food usually is not sterile, microorganisms can be isolated from samples but not be responsible for the illness under investigation. As a result, food testing should not be routinely undertaken but should instead be based on meaningful associations identified through data analysis of interviews with suspected cases or during environmental health assessments at the implicated food-service establishment.

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

4.3.9.5. Establishment of etiology through laboratory testing

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

4.3.9.6. Regular review of interview data

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

4.3.9.7. Improvement of interagency cooperation and communication

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

Improve communication and cooperation among agencies that receive illness complaints. Regular communication should be established between agencies that receive illness complaints, epidemiology staff, and laboratory staff. Contact information should be kept current at all times. Because complaints might be made to multiple agencies, having a robust method of sharing information is important. If possible, set up a database that public health agencies can access and review.

4.3.9.8. Other potentially useful tools

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

4.3.9.9. Simplification of reporting process

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

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

4.3.9.10. Increased public awareness of reporting process

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

4.3.9.11. Centralized reporting or report review process

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

4.3.10. Multijurisdictional Considerations for Complaint Systems

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

CIFOR Keys to Success: Focus Area 4—Complaint systems

Soliciting and receiving reports

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

Detection of clusters/outbreaks

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

Responding to complaints

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

Making changes

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

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4.3.11. Indicators/Measures

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

4.4. Syndromic Surveillance

4.4.1. Overview

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

4.4.2. Background

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

4.4.3. Reporting

Syndromic surveillance typically relies on automated extraction of health information:

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

4.4.4. Epidemiology Process

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

4.4.5. Laboratory Process

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

4.4.6. Strengths of Syndromic Surveillance

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

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

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

4.4.7. Limitations of Syndromic Surveillance

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

4.4.8. Key Determinants of Successful Syndromic Surveillance Systems

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

4.4.8.1. Specificity and speed

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

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

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

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

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

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

4.4.8.2. Personal information privacy issues

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

4.4.9. Practices for Improving Syndromic Surveillance

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

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

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