

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.

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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.

- o *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.

- o *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.

- o *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

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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,

- o “Will the release of this information allow consumers to take steps to protect themselves?”
- o “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

- o “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

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- 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

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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).

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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).

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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.

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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.

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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 clinical laboratories to identify additional stool specimens being cultured.

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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.

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Table 5.1. Investigation activities for outbreaks associated with events or establishments <i>Continued</i>			
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: - Verify that all food workers who pose a risk for transmission have been excluded; - Verify that potentially contaminated foods have been properly disposed; - Verify that food contact surfaces and potential environmental reservoirs have been adequately cleaned and sanitized; - Train staff in safe food-handling practices; - Modify food-production and food-preparation processes; and - 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.

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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.

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Table 5.2. Investigation activities for outbreaks identified by pathogen-specific surveillance <i>Continued</i>			
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 - Reconstruct food flow for implicated food item. - Interview food workers to determine food-preparation responsibilities and practices before exposure. - Obtain samples of implicated food or ingredients. - Obtain environmental samples from food contact surfaces or potential environmental reservoirs.	- 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.

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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.

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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

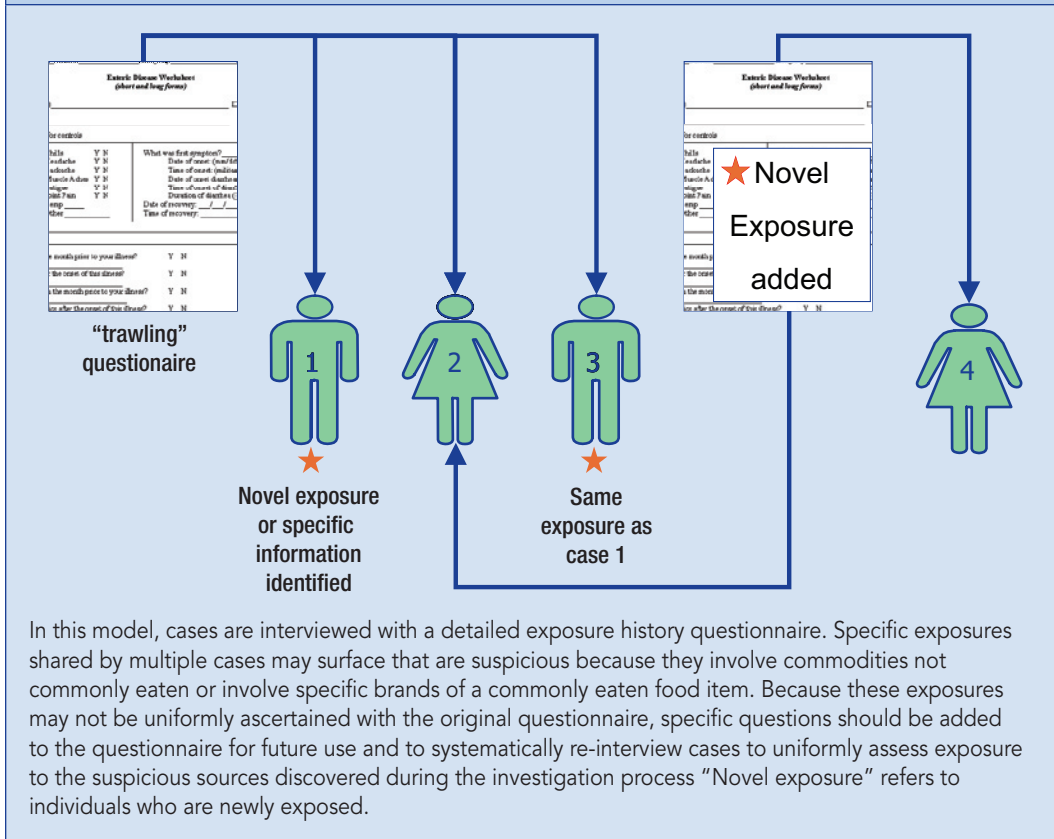
In the dynamic cluster investigation model, initial cases within a recognized cluster are interviewed with a detailed exposure history questionnaire. As new exposures are suggested during case interviews, the initial cases are systematically re-interviewed to uniformly assess exposure to the exposures 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 become infeasible. In any event, clear and timely communication with other investigators are critical to adequately

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Figure 5.1. Dynamic cluster investigation.



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,

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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

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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.

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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 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).

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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

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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.

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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

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

Strength of association

- How strong was the association between illness and implicated item? (*The strength of the association increases with the size of the odds ratio or relative risk: 1 = no association; <5 = relatively weak association; 5–10 = relatively strong association; >10 = very strong association.*)
- Was the finding statistically significant? (*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

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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.

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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.