13

Introduction to Foodborne Illness Outbreak Investigations

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INTRODUCTION

A foodborne illness outbreak is a serious public health concern that warrants prompt and immediate attention by the local health department (LHD). Although most outbreaks may be small and can be handled locally, some foodborne outbreaks can extend across state boundaries and require federal agency involvement. Oftentimes, foodborne illness outbreaks gain heightened public concern and media attention that demand a response from a public health authority. The responsibility of prevention and control of an outbreak often lies in the hands of the environmental health (EH) unit of the LHD. In many instances, the EH practitioner is called upon to address and inform others of the situation at hand. Therefore, it is important that the EH practitioner be capable and knowledgeable about the basic components of conducting a foodborne illness investigation to prevent the spread of further illness and disease.

To cover all of the details of carrying out a foodborne illness outbreak investigation would take an entire book. However, the purpose of this chapter is to provide an overview of the basic components of a foodborne illness outbreak investigation while offering important suggestions and considerations for the EH practitioner. There are many excellent resources, books, Web sites, guidance documents, and trainings available on conducting outbreak investigations, several which are listed at the end of this chapter.

WHAT IS A FOODBORNE ILLNESS OUTBREAK?

Foodborne outbreaks occur when two or more (usually unrelated) people experience similar illness after eating the same food. Foodborne illness outbreaks in the United States are a serious public health concern. Each year, an estimated one in six people (or 48 million people) gets sick, 128,000 persons are hospitalized, and 3,000 deaths occur as a result of foodborne diseases.[1] In addition to the pain and suffering, foodborne-related illnesses are estimated to cost $35 billion annually in medical expenses, lost productivity, and related mortality.[2]

In general terms, an *outbreak*, or *epidemic*, refers to an often-sudden increase in the number of cases of an illness or disease above what is normally expected in a population in a given area (or place). A *cluster* carries a similar meaning as an outbreak, but is generally used when a health event—real, perceived, or suspected (e.g., a cancer cluster)—is aggregated by location and time and the number of ill or diseased is greater than the number expected[3] (even though the expected number may not be known). A *pandemic* is the worldwide spread of a new disease, while *endemic* describes a disease that is always present in a region, area, or in a certain population.

WHY DO FOODBORNE ILLNESS OUTBREAKS OCCUR?

Although many food-related illnesses often go unreported and/or undiagnosed, foodborne illnesses are a common occurrence throughout the world. The World Health Organization estimates that as many as 600 million (or almost 1 in 10 people) fall ill and 420,000 deaths occur each year from eating contaminated food.[4] In the United States, hundreds of foodborne outbreaks are reported each year. In 2015 alone, the Centers for Disease Control and Prevention (CDC) identified that more than 900 foodborne illness outbreaks occurred and were associated with bacterial, chemical, toxin, parasitic, or viral etiology.[5]

With such high-quality food safety standards in the United States, why do so many food-related illnesses occur, and what are some of the leading factors that lead up to a foodborne illness? For starters, there is a variety of situations and reasons why food-related illnesses occur. However, in general, food safety experts and researchers agree that there are three primary contributing factors for why foodborne outbreaks occur:

- The introduction of contamination: This includes poor food preparation practices that allow pathogens (e.g., natural toxins, poisonous substances, bare-hand contact) and other hazards to get into food—for example, a sick food worker who does not wash his hands.
- The proliferation of a pathogen(s): This includes pathogens in food growing quickly by allowing food to remain at room temperature, the slow cooling of foods, or allowing foods to remain at warm, outdoor temperatures for several hours.
- The survival of pathogens in food: This includes food not being cooked long enough or to proper temperature to reduce pathogens in food.[2]

In the same report, it was estimated that more than half of the reported foodborne illness outbreaks were linked to sit-down dining restaurants.[5] So, what are some of the common factors contributing to foodborne illness outbreaks in restaurants? In general, these factors include inadequate worker knowledge or education of food safety, poor behavioral practices, poor management decision, economic constraints, and environmental conditions.[2,6] The CDC notes that the most common reason for outbreaks in restaurants is a sick food worker (see Box 13-1).

The irony, when one considers the potential public health risk of becoming ill from consuming a contaminated food product, is that foodborne illnesses are largely

Box 13-1. Contributing Factors to Foodborne Illness

1. Sick food worker contaminates ready-to-eat food through bare-hand contact.
2. Sick food worker contaminates ready-to-eat food other than through hand contact, such as with a utensil that they contaminated.
3. Sick food worker contaminated food through glove–hand contact.
4. Food handling practices; food being out of temperature, such as food not being kept cold or hot enough.

Source: Adapted from Centers for Disease Control and Prevention.[7]

preventable. By using proper control methods, observing worker health and food safety practices, and using measures to reduce the spread of microbes in food products, food-related outbreaks, unnecessary illness, disease, and even death can greatly be avoided.

WHY INVESTIGATE A FOODBORNE ILLNESS OUTBREAK?

The primary reason for investigating a foodborne illness outbreak is to identify the source(s) of the exposure so that public health action can be taken to establish control measures that will prevent continued episodes of illness and the spread of disease.[8] By objectively identifying detailed data and information gathered from the outbreak, investigators should be able to identify what went wrong to ensure that future similar events can be prevented. The trained EH practitioner plays a vital role in the investigation of such events. For example, an investigation into complaints of a local restaurant may lead an EH investigator to identify a broken refrigerator that may not have sufficient cooling capacity to maintain proper cooling temperatures for keeping dairy or meat items cold during a storage period.

Another reason why carrying out investigations can be beneficial is that it provides excellent learning opportunities for EH staff and others in the LHD to gain considerable field knowledge outside of formal outbreak investigative training. It can also strengthen the collaboration and communication among the investigative team members and help them prepare for outbreaks before they occur. Other reasons may be driven by political forces or public or legal concerns.

WHEN TO INVESTIGATE A FOODBORNE ILLNESS OUTBREAK

Deciding whether to conduct a field investigation of a suspected foodborne illness outbreak is an important decision that should be weighed by the EH practitioner before heading into the field. Several factors to consider that may influence the decision to investigate include the following:

- Evaluating current resources;
- The severity of the reported cases;
- Whether the outbreak has the potential to impact others;

- It is a rare or unusual reported case or a disease pattern; or
- Whether the outbreak is related to an intentional or deliberate action.

Although each outbreak situation will be unique, all reported food-related outbreaks require thoughtful attention. Experience gained over time will be valuable for helping with decision-making. For example, a single reported case of giardiasis may be less likely to prompt an investigation but a cluster of giardiasis cases may be more likely to trigger a full outbreak response. In addition, the EH practitioner must also consider the potential severity of the pathogen or the scenario for harm to others. For example, a single, reported case of botulism should automatically trigger an investigation because of its rarity, severe toxicity, and high potential to be fatal. The Council to Improve Foodborne Outbreak Response (CIFOR) recommends that the conventional field investigations process consider (1) waiting until enough cases are identified, making obvious the occurrence of a common source outbreak; (2) conducting hypothesis-generating interviews; and (3) developing and testing hypotheses.[6]

FOODBORNE ILLNESS DETECTION AND REPORTING

There are many ways food-related outbreaks are detected. Foodborne illness concerns or food-related complaints (e.g., concerning restaurants) are often reported directly to the health department via phone call, fax, or e-mail. These reports are generated and referred by various agencies, health care providers, laboratories, hospitals, nursing homes, or simply individuals that feel ill and suspect food or beverage is involved. Other reports may be made anonymously by someone who recognizes an unusual number of people getting sick at a particular time and place. Often the EH section of the LHD will receive this information directly, or it will be referred by another section in the LHD for follow-up and/or investigation. A word to add here is that LHDs often receive complaints from the concerned public about food safety observations made during a dining experience at a local restaurant. Some valid complaint investigations can offer a good opportunity for the EH practitioner to observe, educate, and identify any problems before an outbreak occurs.

Experts speculate that many people who are ill with foodborne infections do not seek medical treatment or their illness goes unreported or undiagnosed. In many cases, this is either because the person does not see a physician or because a specific diagnosis is not reported. For example, an individual who suspects that he/she has a food-related illness may seek treatment from a health care provider, but no laboratory testing is pursued to confirm/deny the illness. Others suggest underreporting may be attributable to consumers' lack of knowledge about where and how foodborne illness can occur and what to do in the event one becomes ill.[9,10] The majority of foodborne illnesses are considered reportable conditions. However, each state in the United States has its own laws and regulations that require practitioners, hospitals, medical facilities, laboratories, schools, nursing homes, state institutions, and others providing health services to report specific diseases or notifiable conditions of public health significance to the local (or state) health departments.

State departments of health collect data and foodborne information reports submitted by LHDs, clinical laboratories, clinicians, hospitals, infection control nurses, or from individuals within their state or territorial jurisdictions. State and territorial health agencies then securely report this information electronically through the National Outbreak Reporting System (NORS) form to CDC (see the NORS form available at: https://www.cdc.gov/nors/downloads/form-52-13.pdf). Once the data have been received at the national level, federal agencies use these data and information for active foodborne surveillance. For example, FoodNet tracks the trends of different pathogens and specific foodborne infections to help monitor the progress of foodborne disease prevention in the United States.

COMMON PATHOGENS RELATED TO FOODBORNE ILLNESS AND DISEASE

Sometimes referred to as food poisoning, foodborne illnesses are caused when individuals consume foods or beverages that contain disease-causing microbes. Microbiological hazards are responsible for the majority of foodborne diseases in the United States with more than 250 different pathogenic microorganisms that have been associated with foodborne illness outbreaks. The microbiological hazards of concerns related to foodborne illness include a variety of bacteria, viruses, and parasites. These pathogenic microorganisms can cause one of three types of illness: infection, intoxication, or toxin-mediated infection (see Box 13-2).

Although foodborne illness outbreaks occur for a variety of reasons, they often happen when a group of people consume the same contaminated food product and have similar health symptoms. Some of the most commonly recognized foodborne infections are caused by bacteria—*Campylobacter, Salmonella,* and *Escherichia coli 0157:H7*—and by a group of viruses called caliciviruses, also known as Norwalk and Norwalk-like viruses. Other common diseases that are occasionally foodborne but can be transmitted by other routes include infections caused by hepatitis A, *Shigella,* and the parasites *Cryptosporidium* and *Giardia lamblia.*

In 2016, the CDC recognized that the five most common pathogens associated with domestically acquired foodborne illnesses in the United States were norovirus (58%), *Salmonella* (11%), *Clostridium perfringens* (10%), *Campylobacter* (9%), and *Staphylococcus aureus* (3%).[2] The leading pathogens associated with hospitalizations because of foodborne illnesses were non-typhoidal *Salmonella* spp. (35%), norovirus (26%), *Campylobacter* spp. (15%), and *Toxoplasma gondii* (8%).[11]

Box 13-2. Causative Agents in Foodborne Illnesses and Disease

Improperly cooked foods, cross-contamination, or food being left at room temperature allowing bacteria to multiply to high numbers are all food safety concerns that can lead to food-related outbreaks. Depending on the nature of the pathogen and the susceptibility of the individual, ingestion of such contaminated foods can result in acute illnesses, syndromes, or even death. These microorganisms can cause three types of illness or syndromes and are classified as follows:

Foodborne infections: Caused when a person eats food containing harmful microorganisms, which invade and multiply in the intestinal tract or other tissues. Examples include Salmonella, Campylobacter, Vibrio, and Yersinia enterocolitica.

Foodborne intoxications: Ingestion of foods containing either poisonous chemicals or toxins produced by microorganisms in the food. Examples include bacteria such as Clostridium botulinum, Staphylococcus aureus, and Clostridium perfringens; chemicals such as sanitizing products; metals; seafood toxins such as ciguatera and scombroid; plants; and mushrooms.

Foodborne toxin–mediated infections: Caused by bacteria that produce enterotoxins (toxins that affect water, glucose, and electrolyte transfer) during their colonization and growth in the intestinal tract. Some bacteria cause toxin-mediated infection; viruses and parasites do not cause a toxin-mediated infection. Examples include Shigella and Shiga toxin–producing Escherichia coli.

FOODBORNE ILLNESS AND DISEASE SYMPTOMS

A foodborne disease occurs when a person eats a contaminated food product containing harmful pathogens, which then grow in the intestinal tract and cause illness. Depending on the pathogen, organism, or chemical, foodborne illness symptoms can range from mild to severe and can last from a few hours to several days. Some foodborne illnesses can result in health impairment, such as kidney injury following an infection from *E. coli* bacteria. Although rare, some illnesses, such as that from ingestion of potent neurotoxins (e.g., botulism), may lead to paralysis or even death. A list of common pathogens, symptoms, incubation times, and sources of foodborne illness organisms are shown in Table 13-1.

It is important to consider the following:

- Factors affecting foods are important to know. Raw foods of animal origin are considered the most likely to be contaminated (i.e., raw meat, poultry, raw eggs, unpasteurized milk, and raw shellfish).
- The EH practitioner should have common knowledge of food microbiology.
- Factors that affect bacterial growth are important to know, such as nutrients, time/temperature, pH, water activity level, inhibitors, and atmosphere, which contribute to the growth of organisms in food.
- Review of a communicable disease manual (e.g., Heymann DL. *Control of Communicable Diseases*[12]) can assist with identifying common pathogens.

Table 13-1. Common Pathogens, Symptoms, Onset, and Sources of Foodborne Illness

Organism	Common Name of Illness	Onset Time after Ingesting	Signs and Symptoms	Duration	Common Food Sources
Bacillus cereus	*B. cereus* food poisoning	10–16 hours	Abdominal cramping, watery diarrhea, nausea	24–48 hours	Meats, stews, gravies
Campylobacter jejuni	Campylobacteriosis	2–5 days	Diarrhea, cramps, fever, vomiting; bloody diarrhea	2–10 days	Raw and undercooked poultry, unpasteurized milk
Clostridium botulinum	Botulism	12–72 hours	Vomiting, diarrhea, blurred vision, double vision, difficulty in swallowing, muscle weakness	Variable	Home-canned vegetables, fermented fish
Clostridium perfringens	Perfringens food poisoning	8–16 hours	Intense abdominal cramps, watery diarrhea	Usually 24 hours	Meats, poultry, gravy, dried foods
Cryptosporidium	Intestinal cryptosporidiosis	2–10 days	Diarrhea (usually watery), stomach cramps, upset stomach, slight fever	Remitting and relapsing over weeks to months	Uncooked foods, contaminated drinking water
Cyclospora cayetanensis	Cyclosporiasis	1–14 days, usually at least 1 week	Diarrhea (usually watery), loss of appetite, weight loss, stomach cramps, nausea, vomiting, fatigue	3–7 or more days	Fresh produce, imported lettuce, basil, berries
Escherichia coli 0157:H7	Hemorrhagic colitis	1–8 days	Diarrhea (often bloody), abdominal pain, vomiting	5–10 days	Undercooked beef/ hamburger
Hepatitis A	Hepatitis	28 days average (15–50 days)	Diarrhea, dark urine, jaundice, flu-like symptoms, fever, headache, nausea, abdominal pain	Variable, 2 weeks to 3 months	Raw produce, shellfish, uncooked foods
Listeria monocytogenes	Listeriosis	9–48 hours for gastrointestinal symptoms; 2–6 weeks for invasive disease	Fever, muscle aches, nausea, diarrhea	Variable	Unpasteurized milk, soft cheeses, deli meats

(*Continued*)

Table 13-1. (Continued)

Organism	Common Name of Illness	Onset Time after Ingesting	Signs and Symptoms	Duration	Common Food Sources
Noroviruses	Viral gastrointestinal food poisoning, food infection	12–48 hours	Nausea, vomiting, abdominal cramping, fever, headache	12–60 hours	Raw produce, uncooked foods
Salmonella	Salmonellosis	6–48 hours	Diarrhea, fever, abdominal cramps	4–7 days	Eggs, poultry, meat
Shigella	Shigellosis or bacillary dysentery	4–7 days	Abdominal cramps, fever, diarrhea (may contain mucus and blood)	24–48 hours	Raw produce, uncooked foods
Staphylococcus aureus	Staphylococcal food poisoning	1–6 hours	Sudden onset of severe nausea and vomiting; diarrhea, fever	24–48 hours	Unrefrigerated meats, egg salads, creams
Vibrio parahaemolyticus	*V. parahaemolyticus* infection	4–96 hours	Diarrhea (watery, occasionally bloody), abdominal cramps, nausea, vomiting, fever	2–5 days	Undercooked or raw seafood, shellfish
Vibrio vulnificus	*V. vulnificus* infection	1–7 days	Vomiting, diarrhea, abdominal pain, bloodborne infection, fever	2–8 days	Undercooked or raw seafood, shellfish (e.g., oysters)

ROLE OF THE ENVIRONMENTAL HEALTH PRACTITIONER

The three primary components of a foodborne illness outbreak investigation are (1) the epidemiologic assessment, (2) laboratory analysis, and (3) the environmental assessment (Figure 13-1). Without these three components, which are often performed simultaneously, an outbreak investigation cannot be conducted. Therefore, it is important that each of these components works together and communicates to complete the goals and objectives for a successful investigation.

The overarching responsibilities of the EH investigation rest firmly on the EH practitioner and that person's knowledge of food safety and control measures to facilitate the prevention and spread of further illness. To describe all of the procedures for investigating a foodborne outbreak investigation in detail would take an entire book. See the suggested resources at the end of this chapter for more in-depth guidance.

The essential components of an outbreak investigation are outlined in conceptual order in Figure 13-2 and further described in more detail in the following section. However, it is important to note that the listed components in Figure 13-2 are a guide for carrying out a foodborne illness outbreak investigation. In an actual outbreak investigation, the listed components rarely progress in a linear fashion and some components may actually occur simultaneously. Other factors, such as a LHD's availability of staff and

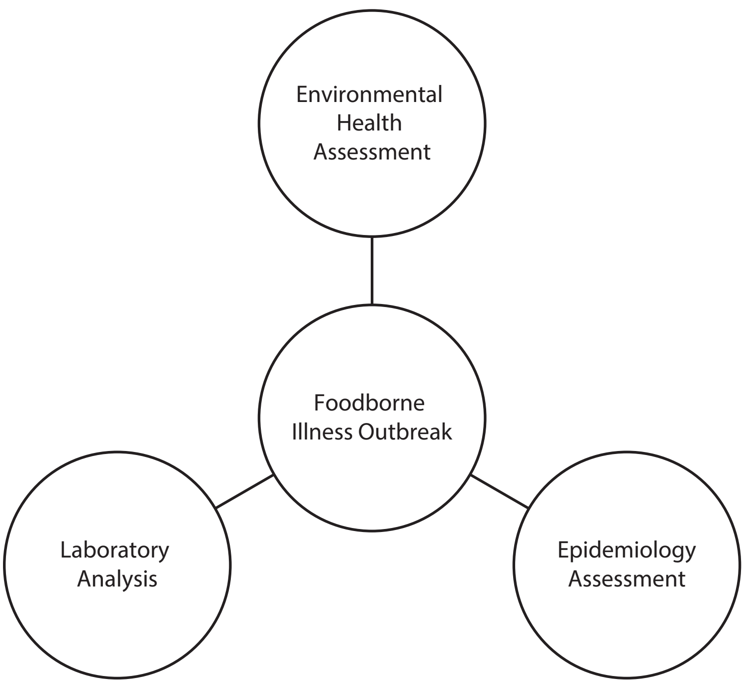
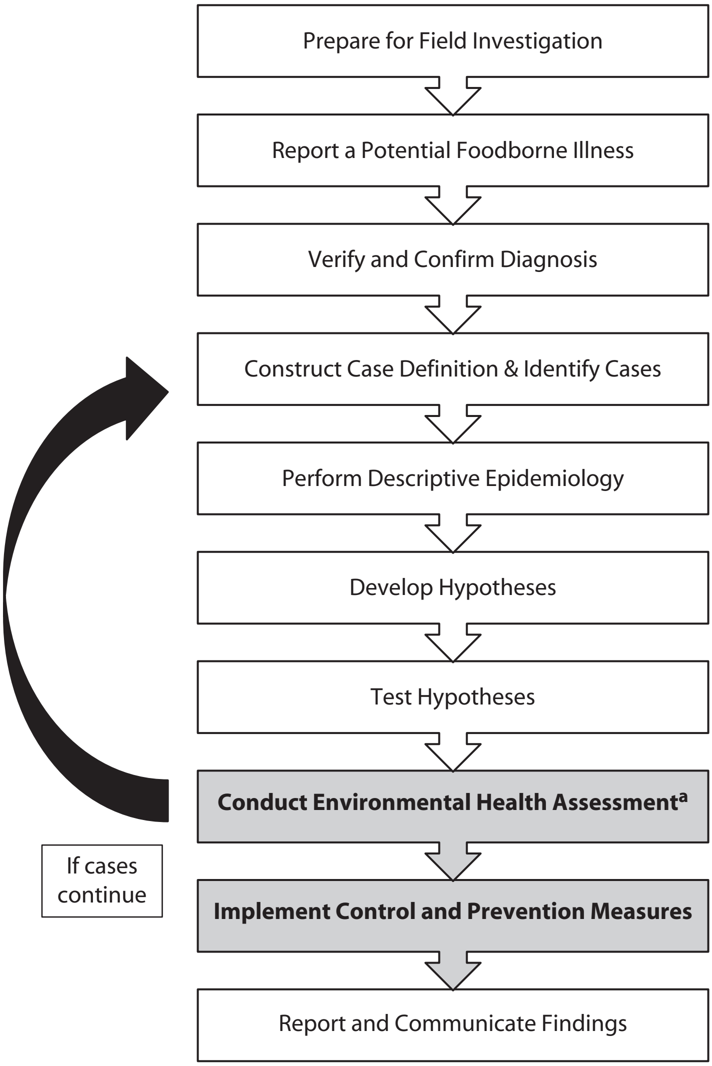


Figure 13-1. The Three Components of a Foodborne Illness Investigation



Note: The components of an outbreak investigation can occur in varying order.

[a]The timing of the environmental health investigation depends largely on the specifics of the outbreak and available information.

Figure 13-2. Essential Components of an Outbreak Investigation with Emphasis on Environmental Health Assessment and Implementing Control and Prevention Measures

resources, which may also dictate which components determine responsibilities and which team members should be involved, should also be considered. For example, LHDs with limited trained staff may find themselves performing only a few of the components, while the remainder of the investigation is handled by regional, state, or federal public health partners. These activities are not intended to be prescriptive, but to provide an overview of the foodborne illness outbreak investigation procedures and insightful, important considerations.

ESSENTIAL COMPONENTS AND CONSIDERATIONS FOR THE ENVIRONMENTAL HEALTH PRACTITIONER IN A FOODBORNE ILLNESS OUTBREAK INVESTIGATION

Prepare for a Field Investigation

Teamwork forms the basis of a successful foodborne illness outbreak investigation. In a traditional LHD setting, an investigative team may include an epidemiologist, an EH specialist, and a health professional or disease specialist. Ideally, each person on the team possesses the necessary skills to carry out the functions that relate to the foodborne illness investigation and reflect their expertise (Table 13-2). The person to lead the investigative team will have been properly trained in foodborne illness investigations; be familiar with epidemiologic methods, food safety, and disease reporting structure; and carry the ability to coordinate activities when a foodborne outbreak occurs.[14]

In terms of size of teams, there are no specific rules for how small or large an investigative team should be for conducting an outbreak investigation. A small LHD with limited staff may have to look to neighboring LHDs, state health departments, or other agencies for assistance. In the event of large, severe, or unusual cases, federal agency involvement should be requested.

Regardless of team size, each team member should have the proper knowledge, training, and skills to carry out his/her part of the investigation. It is important to allow staff to develop disease surveillance and outbreak skills through regional seminars, conferences, and other trainings. Many of these events are freely available through agencies and organizations (see end of chapter for suggestions). Monthly meetings among team members are encouraged to ensure effective communication and that protocol, guidelines, and other resources are up to date and properly maintained.

Maintain Communication and Information Sharing

Communication among the investigative team and others involved is an essential and critical component throughout the entire investigative process. Because foodborne illnesses often cross jurisdictional boundaries, it is important to establish in advance relationships with key stakeholders in other city, county, regional, and state agencies.[15] Being able to call on other authorities in jurisdictions may help improve the investigative process. Whereas LHDs may have authority to investigate outbreaks in a local city, town, or county, state health departments have broader jurisdictional authority, usually across several cities or counties. Local and state health departments often work and consult with

Table 13-2. Primary Roles and Activities of Outbreak Team Members

Position	Primary Activities[a]
Environmental health specialist	Interview management and workers.
	Alert lab of forthcoming samples.
	Obtain suspected food and environmental specimen samples.
	Obtain stool sample from ill or all food workers.
	Obtain list of attendees, credit card receipts, menu items.
	Reconstruct food flow diagram.
	Traceback source ingredients of implicated food back to origination point.
	Evaluate results with epidemiologist and lab to identify contributory factors to outbreak.
	Implement prevention and control measures.
Epidemiologist	Contact health care providers of cases.
	Interview cases and controls.
	Obtain stool samples from cases and controls.
	Establish case definition.
	Characterize cases by person, place, and time.
	Calculate attack rates, by time.
	Develop hypothesis of outbreak.
	Calculate odds ratio or risk ratio.
	Summarize information to identify suspected agent.
Public health laboratory	Test stool specimens.
	Test food or implicated food item.
	Subtype all isolates.
	Summarize and explain lab reports.

Source: Adapted from Council to Improve Foodborne Outbreak Response.[13]

[a]Communication with other team members should be maintained throughout the investigation.

the state department of agriculture and/or other federal food safety agencies during foodborne illness outbreaks within states.

Outbreaks that are widespread, include a large number of people, or have unusual cases usually involve multiple state and/or federal agencies. The CDC, US Food and Drug Administration, US Department of Agriculture's Food Safety and Inspection Services (FSIS), and sometimes the Environmental Protection Agency may become involved with a local or state outbreak. This is usually initiated through the request or by invitation of the state epidemiologist. LHDs and state health departments can also request federal agency expert consultation, technical support, and/or laboratory support without having the agency directly involved.[15]

Foodborne illness outbreaks often require investigative individuals and/or agencies that work outside the LHD. For example, while most state and local health departments have authority over food inspection of restaurants, the US Department of Agriculture has specific authority over inspecting meat- and poultry-processing establishments. Memorandums of Understanding and information-sharing agreements should be in place with selected agencies so that communication is open during foodborne incidents.

Maintaining open communication and sharing of information for public health–related events are important. For this reason, CDC's Epidemic Information Exchange (Epi-X) serves as a tool that provides rapid communication that connects public health professionals whenever there is a need to exchange preliminary information and respond to health threats. Other valuable communication forums on foodborne illness and emerging public health threats include ProMED-mail, National Antimicrobial Resistance Monitoring System, PulseNet, and others that can be found at the Web site list at the end of the chapter.

Prepare Standard Operating Procedure and Outbreak Kit

Before a foodborne illness has even been reported, it is prudent to have a knowledgeable investigative team and an established protocol in place so that EH staff can take action at a moment's notice. In the event of an outbreak, a standard operating "outbreak" protocol (SOP) should be available that includes food sampling guidelines to help avoid any unnecessary confusion and to help guide the investigative team with duties and responsibilities. (Examples of SOP and guidelines can be found at the end of this chapter.) Before the investigative team heads into the field, an "outbreak kit" with equipment and forms should be on hand and ready to go. At a minimum, the foodborne illness outbreak toolkit should contain these items:

- Investigation guidelines;
- Agency and laboratory phone numbers and contacts;
- Business cards;
- Investigative forms;
- Large cooler, blue ice packs;
- Sterile wrapped sampling spoons (minimum 15);
- Sterile specimen containers (e.g., WhirlPak bags; minimum 15);
- Nonsterile zip-lock bags;
- Disinfection and sterilizing agents;
- Alcohol swabs and swab test kits;
- Properly calibrated temperature-measuring devices;
- Pens, pencils, paper, calculator;
- Laptop or electronic device; and
- Sterile gloves, hand sanitizer, alcohol wipes.

Ready-made, foodborne illness standard questionnaires and templates for collecting data and information are available from CDC, and a variety of other credible sources should also be included. It is important to maintain outbreak kits' sterility and check expiration dates of sterilized equipment. All contact and phone numbers of key agencies, medical care participants, hospitals, and laboratories should also be included.

It is important to consider the following:

- Make sure members of the investigative team are trained and competent in carrying out the basic functions of each respective area.
- Create and adopt an SOP manual for outbreak investigations for the office; include a flow chart on procedures and contact information of other agencies likely to be involved.
- Review the SOP on a scheduled routine basis to ensure team members are aware of their roles and that communication remains clear and open.
- Identify a team leader who is an effective communicator and works well with others.
- Communicate and coordinate with other agencies and establish contacts in advance of a potential outbreak.
- Make yourself knowledgeable about the most common foodborne illnesses and diseases.
- Consult in advance with persons in the laboratory concerning protocols for collecting, shipping, labeling, and other details of food and human biological samples.
- Include a library of information on enteric diseases and foodborne pathogens references that can be easily accessed by the investigative team.

Report a Potential Foodborne Illness

The foundation of a successful foodborne illness investigation begins with the prompt handling and/or referral of a food-related complaint. By initially gathering the proper information and quickly recognizing the problem, an investigator can work toward the prevention and spread of further illness.[6] Upon receiving a complaint, alert, or referral of a suspicious food or food-related illness, the SOP should be initiated that sets staff into a procedural motion to act swiftly and promptly. Whenever a foodborne illness is reported (e.g., via referral, alert, or complaint), a record or log should be maintained to gather appropriate information. The initial call or referral should collect key information from the complainant including the names of other persons at the event, whether ill or not, so that follow up can be done. Record date and time of onset of first symptoms, location, number of persons who became ill, and name of the suspected food. The Environmental Health Specialists Network Foodborne Illness Complaint Form is a good tool for capturing this information (see the Consumer Foodborne Illness Complaint Form available at: https://www.cdc.gov/nceh/ehs/ehsnet/resources/index.htm).

Other things to consider are to ask if the complainant has seen a physician and if any tests (e.g., stool sample) have been done. It is also important to gather meal consumption information from at least 72 hours before the onset of symptoms. This information should be passed immediately to the LHD medical director so that options can be weighed. Because administrative staff persons may be the first line of contact for a food-related illness report, it is important to include them in monthly outbreak meetings and discussions. The savvy administrative professional can usually provide good insight or information. Ensure that the person is properly trained to ask questions and follow outbreak protocol. LHDs should report cases of outbreaks to their respective state health department office as required. State health departments are requested to report all waterborne disease outbreaks and enteric disease outbreaks associated with food, contact with environmental sources, infected persons or animals, or unknown modes of transmission through the state administrator of the NORS.

It is important to consider the following:

- It is essential that all food-related complaints and reported illnesses be properly logged and given top priority.
- Review the food complaint log on a weekly basis and report information to the district office, regional epidemiologist, or other appropriate agencies.
- Outbreaks often require involvement by other agencies (e.g., Department of Agriculture) and/or personnel. It is important to develop working relationships with others.

Verify and Confirm Diagnosis

One of the first tasks that should be considered before heading into the field is to verify the existence of the outbreak. This is done by gathering information and verifying the diagnosis of clinical findings of any reported cases through hospitals, laboratories, physicians, or other reports. This is important to (1) ensure the disease has been properly identified and (2) rule out laboratory error as the basis for the increase in reported cases.[8]

Next, interview the persons making the reported complaint. The data and information gathered from the interview process are critical as they provide the ideal opportunity to identify a common location or activity. The interview also provides the chance to get the list of food and nonfood history (exposures) and estimate incubation periods. If you are not comfortable asking clinical-type questions, ask a clinician for assistance. This can be done either over the phone or by talking directly face to face with those involved in the outbreak. The interview is critical to helping provide clues to the clinical features of the illness and useful for developing the hypotheses. It can help answer questions about exposures and what they they think caused the illness or help with finding other people that may have gotten ill. Customized and standard interview forms can be generated with Epi Info or downloaded from PulseNet or other sources. A sample questionnaire can be found on the Washington State Department of Health Web site (Foodborne Illness Case Investigation Worksheet available at: https://www.doh.wa.gov/Portals/1/Documents/5100/420-020-ReportForm-FoodOutbreak1.pdf).

When interviewing the affected person, follow common-sense rules of being professional and courteous. Exhibit concern and empathy and communicate a sense of urgency with the person you are interviewing. Reports of suspected foodborne illness by anyone should be verified by taking a thorough case history and, if possible, reviewing clinical information including laboratory results from analyzed samples. It is helpful to have physicians or other medical professionals assist with verification. Interview persons involved as soon as possible and use interviewer techniques that capture the person's recall of exposure to the food or drink product.[6] Obtaining a food history of more than the past four or five days is probably unrealistic, but the investigator should strive to get this information as part of the interview. As part of the investigative interview, some commonly asked questions should include things such as whether meals were shared and what or which specific foods and beverages were consumed.

It is important to consider the following when one is interviewing the affected persons:

- Interview and collect information related to demographics, signs, and symptoms. Use hospital records and laboratory records when possible.
- Gather information about all foods, water, and ice consumed within the past 72 hours that preceded the illness.
- Get information about the location where the person consumed food, sources of water, and ice. Include if the person has been traveling and note any unusual places.
- Obtain any clinical specimens (i.e., fecal) and food specimens where possible. In rare cases, blood samples may be taken from an affected individual by an appropriately trained person if botulism or infectious agents are suspected. If food samples are available, collect, label, and hold in refrigeration. If a commercial product is suspected, obtain the original container or package. This can be used to track a lot number for back tracing to the processor.
- Communicate with other team members, including the laboratory, to ensure that they are aware of the proper protocol for mailing specimens of the collected food or biological samples.
- It is important to establish that the outbreak is real by examining how the cases were diagnosed and by determining what the baseline rate of disease was previously. For reportable diseases, baseline rates of disease (i.e., the usual or expected rate) can be determined from surveillance data, and one can compare rates during the previous month or weeks with the current rates of disease.

Laboratory Testing and Human Samples

Laboratory testing is important to an outbreak investigation and can provide verification of the diagnosis. It is not necessary, nor is it feasible, to confirm the diagnosis of all cases, but verification of a subsample is important. It is also important to verify that laboratory results are consistent with the signs and symptoms that were reported.

For bacterial diseases, DNA fingerprinting through pulsed gel field electrophoresis (PGFE) can be extremely helpful in establishing that affected individuals were exposed to the same strain of bacterium and, presumably, from the same source. PGFE can be particularly useful as a way of connecting cases that are geographically far apart—for example, during multistate outbreaks. Once PGFE is conducted, the data are entered into PulseNet, an electronic database created through a collaboration between CDC and the Association of Public Health Laboratories. Guidelines for human specimen collection can be found at https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/specimen-collection.html.

It is important to consider the following:

- Meet and discuss with the laboratory director before an outbreak event to facilitate improved communication and sampling protocol.
- Practice interviewing.
- Download Epi Info and practice foodborne illness outbreak exercises.
- When establishing an outbreak, notify other involved agencies, regional epidemiologists, and state health agencies about the outbreak.
- Exhibit genuine concern for persons who are affected. Be sincere and cordial and ensure the person that privacy will be maintained. Parental consent must be obtained before interviewing persons younger than 18 years.
- Be aware and sensitive to any language and/or cultural barriers.

Construct Case Definition and Identify Cases

Following personal interviewing and data gathering, a *case definition* needs to be established. A case definition is a standard set of criteria that should be used to classify whether an ill person should be considered as being a case associated with the outbreak. A case definition consists of clinical criteria and usually specifies limitations on time, place, and person.[8] This usually presents itself as information that is being gathered from the investigation and classified as someone with illness signs and/or symptoms that meet the defined criteria. This also helps to narrow the suspected contamination source. Case definition criteria must be specific and not be open to interpretation, such as this example adapted from the Centers for Disease Control and Prevention[16]:

- Clinical information such as symptoms or laboratory results (e.g., the presence of a fever >101°F and jaundice for hepatitis A or the presence of elevated immunoglobulin M anti–hepatitis A antibodies in an outbreak of hepatitis A).
- Personal characteristics of the cases (e.g., individuals in a certain age group).
- Limits with respect to the location of the case (e.g., residing or working in the Lyndale neighborhood).
- A specified time period for this particular outbreak (e.g., during March and April 2016 or among people who attended a specific luncheon).

Establishing a case definition can be tricky, particularly in the initial phases of the investigation. Sometimes investigators will use a loose definition early on to help them identify the extent of the outbreak. However, as the investigation progresses to the analytic stage, studies to test hypotheses, a more specific definition should be used to reduce misclassification that would bias the results. In the early stages, a case definition might be broader and less specific to make sure all potential cases (or "possible" cases) are identified. Later on, the definition might include more specific clinical or laboratory criteria that will enable the team to categorize individuals as "possible," "probable," or "confirmed" cases. Investigators often group cases by placing them into one of these three categories[17]:

- Confirmed cases: These are usually laboratory-confirmed cases (e.g., persons who attended a church supper on May 19, 2011, who had *Salmonella* isolated from a stool culture). Confirmed cases are best, because they are the most definitive.
- Probable cases: These usually have characteristic clinical features of the disease, but lack laboratory confirmation (e.g., persons with bloody diarrhea who attended a church supper on May 19, 2011, but without laboratory confirmation).
- Possible cases: These have some of the clinical features (e.g., abdominal cramps and diarrhea [at least three stools in a 24-hour period] who attended a church supper on May 19, 2011).

Note: The CDC also makes well-established case definitions available.[18]

Finding Additional Cases

Once a case definition has been established, there should be a focused effort to find and identify as many other cases as possible in order to accurately establish the magnitude and scope of the outbreak. For foodborne outbreak investigations in group settings (such as an assisted living facility) it may be relatively easy to identify cases.

However, in non–group settings, such as restaurants, or food-recall situations, an active surveillance approach may be needed. Such strategies may include searching for cases in hospitals; contacting school nurses, family members, or friends of cases; or searching for cases in other facilities and institutions. As cases are identified, it can also be useful to ask them if they know of others who are similarly affected (e.g., family members and acquaintances).

Passive surveillance methods of identifying additional cases are less aggressive and may include relying on self-reporting of cases or relying on doctor or laboratory reports. Occasionally, investigators will try to identify cases by posting notices in the media. These serve the dual purpose of alerting the public about potential hazards and identifying possible cases that have already become ill. For more information on case finding, see *Case Finding and Line Listing: A Guide for Investigators.*[19]

Perform Descriptive Epidemiology: Person, Place, and Time

Identifying and gathering information on persons with the disease is an important step for systematically "describing" some of the key characteristics of those persons involved in the outbreak. Epidemiologists call this *descriptive epidemiology*. Descriptive epidemiology can provide useful clues that can be turned into hypotheses. These clues can inform the development of the hypotheses that can be tested later with appropriate analytic methods. Such questions may inform why some groups (e.g., age, gender, or other personal characteristics) are at particular risk.

Descriptive epidemiology uses the data gathered from the investigation to summarize and describe characteristics including "person, place, and time" elements of the investigation. In other words, it covers the personal characteristics of the cases, changes in disease frequency over time, and differences in disease frequency according to location.[8] By systematically organizing the data to describe the characteristics of person, place, and time, the investigating team can learn more about who is affected and the extent and patterns of disease in the community. This information is valuable because it can be easily turned into tables, graphs, and maps that can be shared and communicated with others. It can also help identify possible sources of the outbreak while formulating a testable hypothesis that can be used later for analytical epidemiology (to test associations). The next paragraphs describe more about the importance of defining and characterizing person, place, and time in the investigation.

Person

Personal characteristics such as age, gender, and occupation are factors that can strongly influence a person's susceptibility to a pathogen and can provide clues into how a disease may be spread. For example, with regard to age, the immune systems of both very young and older persons make them more susceptible to illness and certain infections. To further explain, a senior citizen who is immunocompromised and has other underlying medical conditions may be more vulnerable to an airborne pathogen such as norovirus than a middle-aged person with a strong immune system. Differences in race, ethnicity, socioeconomic status, and access to health care are also factors that can influence the risk of disease and illness.

Place

The geographical extent, location of the cases' home residence, places visited, and where the event may have occurred provide etiologic clues about the foodborne pathogen. For example, if reported illnesses are spread across the community, the agent may point to a restaurant or, perhaps, a commercially distributed food product from a local grocery store. If the health problem is limited to an isolated event, such as a catered wedding, it is likely to be caused by a point source. Cluster maps or spot maps provide visual clues for pinpointing case locations and how the pathogen may have been transmitted to other cases.

Time

A key factor for conducting outbreak investigations is having knowledge of specific time periods, such as day of week and time of day when a person experienced onset of illness. Having this information can help identify incubation periods and assist the team in understanding potential causative agents for controlling an outbreak. An *incubation period* is the time period from exposure to the causative agent until the appearance of the first signs or symptoms of illness. For example, the incubation period for norovirus-associated gastroenteritis is between 12 and 48 hours with median period of approximately 33 hours. The EH practitioner should become familiar with onset time and incubation periods of foodborne agents (Table 13-1).

Epidemic or "Epi" Curves

One of the best clues for helping establish the causative organism is by using the incubation period to construct an *epidemic curve*. An epidemic or "epi" curve is a constructed histogram or a time graph that displays the number of new cases over time according to their date of onset. Epi curves can help categorize and "visualize" foodborne illness outbreak events. Interpreting the epi curve can provide important information, because the shape of the curve can provide clues about the potential source of the outbreak. From the line listing of case data, the elements of person, place, and time can be used to construct an epi curve by drawing the element of time (e.g., day, week, month) of onset on the x-axis and the number of cases on the y-axis. Date of *onset* is when the person first experienced conditions or symptoms of illness. With this information, the shape of the epi curve can assist the investigative team with (1) identifying the time course of the epidemic, (2) estimating a probable time of exposure, and (3) drawing inferences about the epidemic pattern (e.g., causative agent, mode of transmission). Epi curves can easily be drawn by hand. However, Epi INFO, a free software program from CDC, is an excellent tool to use for constructing epi curves.

The primary types of epidemic curves associated with outbreaks are shown in Figure 13-3 and are as follows:

- Common source
  - Point source
  - Continuous source
  - Intermittent source
- Propagated (person-to-person)
- Mixed (a mixture of common source and propagated)

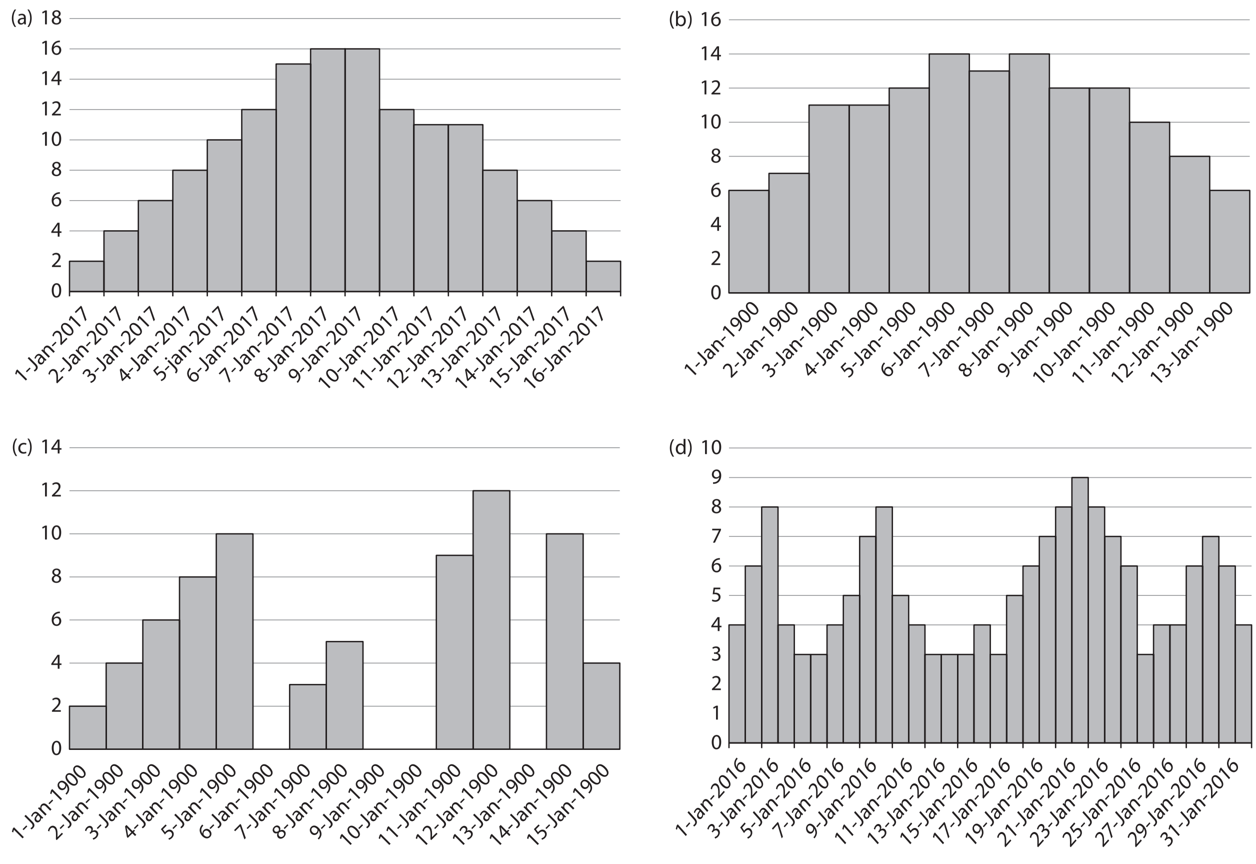


Figure 13-3. Examples of Different Types of Epidemic Curves: (a) Point Source; (b) Continuous Source; (c) Intermittent Common Source; and (d) Propagaged (Person-to-Person)

The common *point source* outbreak is one in which a group of persons are all exposed to an infectious agent or a toxin from the same source at one point in time. As shown in Figure 13-3a, the epi curve is noted by a steep upslope, a gradual downslope, and a width approximating the average incubation period of the pathogen. With a *point-source outbreak*, if the group is exposed over a relatively brief period, everyone who becomes ill does so within one incubation period.[8] For example, an epidemic of hepatitis A among patrons that had eaten green onions at a restaurant in Pennsylvania each had a point source of exposure.[20] Identifying and removing the exposure to the common source (e.g., the contaminated food) causes the epidemic to rapidly decrease. In general, common-source epidemics tend to result in more cases occurring more rapidly and sooner than person-to-person epidemics.

Another common source is the *continuous-source* epi curve. This curve implies that there is an ongoing source of contamination. As shown in Figure 13-3b, the curve may rise to a peak and then flatten, widen, and fall; however, cases may continue to appear after the incubation period has passed. The last common-source curve is the *intermittent common-source* outbreak. This curve often displays a pattern of sporadic nature of exposure. It may have peaks and valleys over the duration of the outbreak (Figure 13-3c).

A *propagated outbreak* results from one infected person to another person. Host-to-host or person-to-person contact epidemics tend to rise and fall more slowly than common-source epidemics (Figure 13-3d). Transmission can be either direct (e.g., fecal–oral contact) or indirect (e.g., eating foods contaminated by a sick food handler with norovirus, a highly contagious enterovirus).

It is important to consider the following:

- If the causative organism has not been identified, the epi curve may help enable you to calculate the incubation period.
- The overall shape of the epidemic curve will be determined by the incubation period and will help identify whether it is a common-source or propagated epidemic.
- Download CDC Epi Info software and work through the Oswego case-finding exercise; create epi curves by using the supplied data.

Develop, Evaluate, and Test Hypotheses

As early as the data collection process begins, the team should begin putting the pieces of the puzzle together to formulate an idea or develop a hypothesis of the potential source and cause of the outbreak. Making educated guesses or forming a hypothesis based on the available information and clues that have been collected also helps determine whether others, such as outside agencies, need to be involved and what measures need to be taken to control the outbreak. When developing the hypothesis, the team should consider factors such as the causative organism or agent, who are the people at risk, what is the transmission vehicle, and the timeframe of interest.

After considering these factors, a written hypothesis should be able to be developed. A written hypothesis helps bring clarity to the question the investigative team is trying to answer. Things to consider in the process of writing the hypotheses include using experiences learned from previous outbreaks, examining in detail the incubation or onset times between food consumption and illness of the cases, reviewing the microbiology and epidemiology of the pathogen, interpretation of the laboratory results, information generated from the interviews, and other possible causal relationships.[8,15]

After a hypothesis has been developed, the next objective is to evaluate and analytically test the hypothesis. In an outbreak field investigation, hypotheses are typically evaluated by comparing the hypotheses with established facts, such as a combination of environmental evidence, laboratory science, and epidemiology, and/or by using analytic epidemiology to quantify relationships and assess the role of chance.[8] The first technique is more likely to be used when the evidence (e.g., clinical, laboratory, environmental, and/or epidemiologic) clearly supports the hypothesis—for example, a reported outbreak describing an abrupt and acute gastrointestinal illness among a group of softball team players where no food was involved, but all players that drank water from a water cooler got ill shortly following a game. Investigators hypothesized that the water was the vehicle and the drinking water cooler was the source. All stool samples from the players were laboratory confirmed positive for giardiasis. Upon further investigation, the water in the cooler was traced back to the source, an unregulated drinking water well that tested positive for microscopic parasites.

In the second method, when the evidence may not be as straightforward and interview data or information from the cases is lacking, investigators may use analytical epidemiology to test a hypothesis about the *causal relationship* between the exposure and the illness. One of the hallmark features of testing hypotheses and looking for causal relationships is the method of comparison. By comparing patterns of exposure (e.g., foods eaten) of cases with patterns among noncases or unexposed persons, we can better determine these relationships.[8] Although the EH practitioner may rely on the assistance of an epidemiologist to help perform this part of the investigation, it is important to understand and acquire the basic epidemiology skills to carry out this function.

Measures of Risk and Disease Frequency

To quantify the relationship between illness and exposure, we can use ***measures of risk*** to estimate the statistical strength of the relationship between our comparison groups and the variables of interest. In other words, if we want to know whether a certain exposure (e.g., food eaten) is linked with a given illness, we can use measures of risk to estimate the relationship. The two measures of risk commonly used in field epidemiology outbreaks are the *relative risk* and *odds ratio*. The type of study, or study design, determines which measure of risk to use for the analysis. Two common types of studies used in foodborne illness outbreaks are the *retrospective cohort study* and the *case–control* study. The relative risk is commonly used for the retrospective cohort study and the odds ratio is used for case–control studies.

However, before moving further into discussing measures of risk, let us first describe *disease frequency measures*. Disease frequency measures describe how common an illness or other health event is among a group or population at risk. This is usually the first step that precedes the more in-depth calculation. For example, after interviewing and collecting information on symptoms (illness) and food consumption (exposure) from individuals at a picnic outbreak, the investigator wants to initially determine what proportion of the group were ill. By calculating the proportion of people who were ill, we are able to estimate the probability, or risk, of getting an illness or disease compared with the consumption of specific foods. This is called an *attack rate* or *risk*. An attack rate is synonymous with the terms incidence proportion and cumulative incidence. It is a disease frequency measure that tells us the proportion of people who become ill in the group or a population who were initially free of the disease. An overall attack rate is defined as the total number of ill cases divided by the total number in the group (including cases and noncases). For example, in an outbreak of salmonellosis among 200 attendees at a church wedding, 50 became ill. We would calculate this as

$$\frac{50\ (\text{Total Ill};\ a)}{200\ (\text{Total Attendees};\ a+b)} \tag{1}$$

or

$$\text{Risk} = \text{“Attack Rate”} = (50/200) \times 100 = 0.25 \times 100 = 25.0$$

However, to narrow down the choices and identify which specific food item may be the culprit, we would need to calculate a “food”-specific attack rate for each specific food item. For example, 109 persons out of the total wedding group ate chicken salad, 35 of whom developed severe stomach cramps. The risk, or food-specific attack rate of illness among persons who ate the chicken salad, would be as follows:

$$\frac{35\ (\text{Ill Who Ate Chicken Salad};\ a)}{109\ (\text{Total Who Ate Chicken Salad};\ a+b)} \tag{2}$$

or

$$\text{Risk} = \text{“Food-Specific Attack Rate”} = (35/109) \times 100 = 0.321 \times 100 = 32.1\%$$

This attack rate provides good information that tells us that the proportion of people who consumed the food product (i.e., those persons who were exposed) who fell ill.

Table 13-3. Example of a Food-Specific Attack Rate Table

Food Item	Exposed (Ate Food)			Unexposed (Did Not Eat Food)			Difference in Attack Rate
	Ill	Total	Attack Rate	Ill	Total	Attack Rate	
Hamburger	8	53	15%	14	30	47%	–32%
Beans	14	30	47%	6	14	43%	+4%
Iced tea	20	22	91%	56	60	93%	–2%
Lettuce	19	40	48%	1	4	25%	+23%
Tomato	6	10	60%	14	34	41%	+19%
Chicken salad	**18**	**22**	**82%**	**2**	**22**	**9%**	**+73%**
Ice cream	56	60	93%	20	22	91%	+2%
Apple pie	17	25	68%	12	17	71%	–3%
Hot dog	34	50	68%	17	20	85%	–17%

However, before we reach a conclusion, we must continue by calculating attack rates for those persons who did not get ill (those persons who were unexposed). Comparison is fundamental to epidemiology and the same rules apply here. Using a food-specific attack rate table, we would calculate food-specific attack rates for both groups—ill (exposed) and ill (unexposed)—and compare differences between the attack rates to identify the most likely food product responsible for the outbreak. As shown in the example in Table 13-3, the greatest difference in attack rates between the exposed and unexposed people is highest (73%) for the chicken salad. In general, a higher attack rate among a food-specific item indicates that a food or beverage item is strongly suspicious for being the contaminated product. The difference column is also known as excess risk or *attributable risk* and is more commonly calculated in cohort studies. Although we have estimated our attack rate, we cannot stop there; we need to calculate another measure of risk to estimate the power of the relationship between the actual exposure and illness. To determine which risk measurement to use, we need to describe the types of epidemiologic studies that are most appropriate given the situation, as described in the next section.

Types of Epidemiologic Studies

The most common types of epidemiologic study design approaches for field investigations of foodborne illness outbreaks are the *case series reports, retrospective cohort study*, and the *case–control study*. The study type that will be used will depend primarily on the number of individuals exposed (those ill), the availability of control individuals (not ill), and the availability of resources.

Case Series Reports

Case series reports are used to describe an aspect of a condition or illness, typically when the number of exposed individuals is small, usually one or several cases. With case series, all exposed individuals reporting illness are symptomatic and there is no control group. Case series primarily describe person, place, and time, but because the case number is limited, do not include any analysis. The benefits of case series reports are that they are relatively straightforward, are easy to understand, and can be written up in a short period of time and readily communicated to others who need to know information to make decisions.

Retrospective Cohort Study

In the *retrospective cohort study*, the investigator contacts each member of the defined population (e.g., party guests), determines each person's exposure (i.e., consumed) to possible food and beverages, and notes whether the person became ill or experienced ill health symptoms. Retrospective studies are typically used when one is investigating small, well-defined groups at events, when the entire group can be identified and interviewed about illness and exposure—for example, an outbreak of gastroenteritis among wedding party guests for which a complete list of guests is available.

One of the most common epidemiologic analytical procedures for examining the relationship between exposure and illness among two groups is the two-factor analyses method, or more commonly the 2 × 2 table. The 2 × 2 table can identify relationships that can be cross-tabulated by putting the disease status at top (e.g., ill vs. well) and the exposure status along the side.

Following the calculation of the attack rate, investigators commonly calculate the *relative risk*, also called the *risk ratio* (RR), to measure the attack rate in the exposed group against the attack rate in the unexposed group. This provides the measure of risk (discussed earlier) between the exposure (e.g., the specific food item) and the illness or disease. The formula for the risk ratio is as follows:

$$\frac{\text{Attack Rate (Risk) in the Exposed Group}}{\text{Attack Rate (Risk) in the Unexposed Group}} \tag{3}$$

or

$$\text{Risk Ratio} = (a + b)/(c/(c + d))$$

Risk Ratio:

	Ill	Well	Total	Risk (Attack Rate)
Exposed (ate food)	a	b	a + b	a/(a + b)
Unexposed (did not eat food)	c	d	c + d	c/(c + d)
Total				

The interpretation of the measures of association of the risk ratio is as follows:

- RR = 1.0; risk is the same among those exposed and unexposed.
- RR > 1.0; risk is higher among those exposed.
- RR < 1.0; risk is lower among those exposed.

Keep in mind that for each environmental exposure (i.e., specific food or beverage consumed) a separate hypothesis should be generated and analytically tested.

The methods for calculating odds ratio and relative risk are described briefly in the next paragraphs. However, the reader is referred to the epidemiology references at the end of the chapter for more detailed information on how to calculate and interpret results. Also, Epi Info will provide confidence intervals and *p* values, which are very useful for determining statistical significance.

Case–Control Study

In the *case–control* approach, the group of individuals at risk cannot be identified or a complete list of guests or cases may not be available—for example, a community-wide outbreak of individuals who have eaten at a suspected local restaurant or purchased food from a popular neighborhood bakery. A case–control study approach compares exposures among ill persons (cases/patients) with non-ill persons (controls). However, in a case–control study, the investigator does not know the true size of the exposed and the unexposed groups, so there is not a denominator to calculate an attack rate or risk. Therefore, a sample of both case-patients and a comparison group of persons without disease ("controls") are asked about their exposures. Using the information about disease and exposure status, the investigator can then calculate an *odds ratio* (OR), sometimes called the *cross-product ratio*, to quantify the relationship between exposure and disease. With case–control data, the relative risk can be approximated by the odds ratio and is calculated as follows:

$$\text{(4)} \qquad \frac{(\text{Number of Exposed Cases} \times \text{Number of Unexposed Controls})}{(\text{Number of Exposed Controls} \times \text{Number of Unexposed Cases})}$$

or

$$\text{Odds Ratio} = ad/bc$$

Odds Ratio:

	Case (Ill)	Control (Well)	Total
Exposed (ate food)	a	b	a + b
Unexposed (did not eat food)	c	d	c + d
Total			

When the case–control method is being used, people selected as "controls" must not have the disease being studied but should represent the population in which the cases occurred. In other words, they should be similar to the cases except that they do not have the disease. Why is this important? Because the controls provide the level of exposure you would expect to find among the case-patients if the null hypothesis were true.[8] If exposure is much more common among the case-patients than among the controls (i.e., the observed exposure among case-patients is greater than expected exposure provided by the controls), then exposure is said to be associated with illness.[7] The interpretation of the measures of association of the odds ratio are as follows:

- OR = 1.0; odds of exposure are the same among ill and non-ill persons.
- OR > 1.0; odds of exposure are higher among those who are ill.
- OR < 1.0; odds of exposure are lower among those who are ill.

Unfortunately, analysis of your hypotheses may not always reveal an answer or the "smoking gun" of the outbreak. If this is this case, reconsider, refine, and re-evaluate your hypotheses. For example, consider other modes of transmission or look for common links among cases.

It is important to consider the following:

- The CDC software program Epi Info is an ideal tool to assist for calculating analysis.
- Use each outbreak investigation as a research opportunity to learn more about the disease, mode of transmission, and host factors, and for staff to gain experience.
- Confidence intervals and *p* values are important to use when one is interpreting measures of risk.

Conduct an Environmental Health Assessment

The timing of the EH assessment as part of the outbreak investigation depends largely on the specifics of the situation and the available information.[6,17] As shown in Figure 13-2, it may be appropriate to start the EH assessment early, after constructing the case definition. For instance, multiple suspected reports of symptoms from ill patients at a nursing home facility may initiate an immediate EH assessment. In other situations, the EH assessment may begin after case illness/symptom interviews have been conducted, laboratory information has been received, and a common location has been established—for example, after receiving widespread and varying food history and symptoms and/or reports among those reporting illnesses.

Regardless of each situation, EH practitioners should remain cognizant that they may need to act promptly so that the opportunity for collecting food specimens or products best reflects the conditions at the time of the outbreak. Also, control measures can be implemented to stop further spread of the outbreak. However, a word of caution: acting too quickly and making hasty decisions without consulting with others or having most of the facts can create unnecessary tension and anxiety among team members and others involved, including those experiencing illness and food owner/managers of the affected facility.

Naturally, the EH practitioner should carry out the EH assessment of the outbreak investigation. An experienced EH investigator will have a trained eye and the necessary skills for evaluating outbreaks including knowledge of food safety, worker hygiene, and operating practices. However, it is important to keep in mind that an EH assessment of a suspected establishment or facility in an outbreak investigation differs from a food service inspection, a facility plan review, or a Hazard Analysis and Critical Control Points (HACCP) risk assessment.[20] The EH assessment component is focused more on food safety issues that occurred as a result of past events that were primarily related to the implicated food item including the preparing and serving of food products that led to the outbreak. The EH practitioner must make a conscious effort to focus on how the disease agent, host factors, and environmental conditions that led up to the illness interacted. This can be facilitated by reconstructing past events, identifying contributing factors, identifying environmental antecedents, and considering effective interventions.[21]

Develop an Environmental Investigation Profile

Before heading into the field, the prudent EH practitioner will have consulted with other members of the team. Several things to consider include gathering available outbreak information on the causative agent and a review of any prior records in the office of past or recent food service inspections that may shed light on previously noted violations or problems, such as food temperatures. Consult with other EH inspectors or agencies that may have a relationship with or food history inspection knowledge of the facility.

Upon arrival for the initial site visit (of a facility), ask to meet with someone in authority, (e.g., owner, administrator, or food manager). Taking this initial step projects professional courtesy and is a way to establish a relationship. Similarly to a detective looking for clues, the EH practitioner should focus the EH site investigation assessment on reconstructing past events, focusing on implicated food(s) in the timeframe preceding the event, identifying contributing factors, antecedents, and other activities that may have contributed to the outbreak.

When investigating the cause of the outbreak, it is necessary to examine all aspects of the food service operation with an emphasis on events leading up to the time of exposure to the suspected food items. An establishment's standard practices directly correlate with the establishment's control over pathogens that contribute to foodborne illness. Important measures such as the amount of food safety knowledge, the extent to which employees practice safe food handling methods, and the degree by which critical pathogen control steps are documented all reflect the establishment's ability to produce safe food. A comprehensive field investigation may provide an overall picture of the day-to-day activities that promote safe food production or contribute to an atmosphere that can lead to a foodborne illness outbreak.

In some cases, epidemiologic study analyses will indicate consumption of one or more possible dishes associated with illness in the outbreak. In other cases, a pathogen may be isolated from clinical samples of ill persons or suspected on the basis of clinical symptoms. To accurately assess the establishment's ability to control pathogens, the EH practitioner should focus on foods and processes that could be the source of the suspected pathogen without forming biases. For instance, if the suspected pathogen is *Salmonella*, scrutiny should be given to menu items involving chicken, but other possible sources (such as eggs, raw and undercooked meat and poultry, and cross-contamination) should not be ignored. The EH practitioner should strive to gain an understanding of the many different practices that occurred during the time period before the outbreak that could have been the source of the exposure.

Specific EH foodborne outbreak investigative guidelines, food codes, and procedures may vary with individual health authority agencies and jurisdictions. However, there are many excellent resources on guidelines and procedures for conducting foodborne illness investigations that the reader is referred to at the end of this chapter. An example of guidelines for conducting an EH assessment as part of a foodborne illness outbreak can be found at Appendix 13A.

It is important to consider the following:

- Provide opportunities for EH practitioners to shadow other seasoned EH practitioners and epidemiologists on outbreak investigations.
- Seek out opportunities for training and expertise on food production, HACCP, and traceback investigations.

Implement Control and Prevention Measures

The prevention of further spreading of illness should be the top priority of any outbreak investigation. Several measures can be taken early in the investigation that can reduce the possibility for new illnesses, regardless of the specific vehicle for proliferation. Any of these nonspecific control measures can be implemented when a facility has been implicated in an outbreak but a specific food has not been identified. Once the pathogen has been identified, specific control measures should be taken followed by a corrective action or reporting plan to ensure future food safety. More specific and in-depth details on EH guidelines for control and prevention measures are referenced at the end of this chapter.

Communicate the Findings

CIFOR recognizes that most outbreaks are considered over when two or more incubation periods have passed with no new cases.[6] As the investigation concludes, it is important to communicate findings back to authorities and to those responsible for implementing control and prevention measures. Communications should be both in oral and written reports. When multiple agencies are involved, the group should identify one spokesperson representative for all agencies to address the media.[6] The lead spokesperson can ensure that all information being released is accurate and that any highly sensitive information is safeguarded.[14] The formal written report should follow standard scientific guidelines and should include an introduction, background, methods, results, discussion, and recommendations. Further readings on risk communication are suggested at the end of this chapter.

It is important to consider the following:

- Establish and use routine procedures for communicating messages among epidemiologists, laboratories, health care providers, other EH branches, and local, state, and federal agencies.
- Develop and update contact lists and establish relationships with key individuals and groups, including internal and external organizations to your department and the media.
- Create templates for communicating (e.g., press releases, fact sheets) that focus on the most common foodborne diseases and how and where to report a foodborne illness.[6]

CONCLUSIONS

The control and prevention of foodborne illnesses and diseases are an essential component of the EH practitioner's duties and responsibilities to safeguard the community's health. Knowing the components of a foodborne illness outbreak and how to respond are essential elements to the profession. Communicating the health risks associated with improper food safety to others plays an important role in this process.

The information provided in this chapter provides a general overview of a foodborne illness outbreak from the perspective of the EH practitioner. For more information, entire books have been published and are available, as well as an abundance of other free information from local, state, and federal government Web sites. National organizations such as the National Environmental Health Association and CIFOR also provide training opportunities that are extremely beneficial. For more information, a list at the end of the chapter has been provided to assist the reader or lead the reader to other helpful sources for conducting a foodborne illness outbreak.

RESOURCES

Foodborne Illness–Related Terms

- Analytical epidemiology
- Attack rate
- Attributable risk

- Case–control study
- Case series
- Causal relationship
- Cluster
- Descriptive epidemiology
- Endemic
- Epidemic
- Epidemic curves
  - Continuous source
  - Intermittent source
  - Point source
  - Propagated source
- Incubation period
- Measures of frequency
- Measures of risk
- Odds ratio
- Outbreak
- Pandemic
- Pathogen
- Retrospective cohort study
- Risk ratio
- Surveillance

Societies and Organizations

- Association of State and Territorial Health Officials (ASTHO)
- Council of State and Territorial Epidemiologists (CSTE)
- National Association of County and City Health Officials (NACCHO)
- National Environmental Health Association (NEHA)

Foodborne Illness Outbreak Investigative Guidelines, Protocols, and Information

- Arizona Department of Health Services. *Foodborne and Waterborne Disease Outbreak Investigation Resource Manual*. Available at: http://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/disease-investigation-resources/foodborne-waterborne-disease-outbreak-manual.pdf.
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- Centers for Disease Control and Prevention. Foodborne illness outbreaks. Available at: https://www.cdc.gov/foodsafety/outbreaks/index.html.
- Colorado Department of Public Health and Environment. Outbreak investigation guidelines. Available at: https://www.colorado.gov/pacific/cdphe/outbreak-investigation-guidelines.
- Council to Improve Foodborne Outbreak Response. Available at: http://cifor.us.
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- New Mexico Department of Health. Publications. Available at: https://nmhealth.org/publication.
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- Oregon Health Authority. Outbreak investigation. Available at: http://www.oregon.gov/oha/ph/DiseasesConditions/CommunicableDisease/Outbreaks/Pages/index.aspx.
- Rhode Island Department of Health. Guidelines for investigating foodborne illness outbreaks. Available at: http://health.ri.gov/publications/guidelines/InvestigatingFoodborneIllnessOutbreaks.pdf.
- US Department of Agriculture, Food Safety and Inspection Service. Available at: https://www.fsis.usda.gov/wps/portal/fsis/home.
- US Food and Drug Administration. Multi-state foodborne illness investigative guidelines. Available at: https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM143338.pdf.
- Washington State Department of Health. Foodborne disease outbreaks. Available at: https://www.doh.wa.gov/Portals/1/Documents/5100/420-054-Guideline-FoodOutbreak.pdf.
- Western Australia Department of Health. Guidelines for the environmental health investigation of a food-borne disease outbreak. Available at: http://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/food/PDF/guidelines-for-the-environmental-health-investigation-of-a-food-borne-disease-outbreak1.pdf.
- World Health Organization. Foodborne disease outbreaks: Guidelines for investigation and control. Available at: http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf.

Foodborne Disease Outbreak Investigation Fillable Interview Questionnaires and Tools

- Centers for Disease Control and Prevention. National and state fillable forms in English and Spanish. Available at: https://www.cdc.gov/foodsafety/outbreaks/surveillance-reporting/investigation-toolkit.html.
- Centers for Disease Control and Prevention. Epi Info. Available at: https://www.cdc.gov/epiinfo/index.html.

Multistate Food Recalls and Alerts

- US Department of Health and Human Services. FoodSafety.gov. Available at: https://www.foodsafety.gov/about.

State and Federal Agencies with a Role in Food Safety

- Association of Public Health Laboratories. Available at: https://www.aphl.org.
- Centers for Disease Control and Prevention, Division of Foodborne, Waterborne, and Environmental Diseases. Available at: https://www.cdc.gov/ncezid/dfwed/edlb/index.html.
- Centers for Disease Control and Prevention, Division of Laboratory Sciences. Available at: https://www.cdc.gov/nceh/dls.
- Centers for Disease Control and Prevention. Epidemiology in the classroom. Available at: https://www.cdc.gov/careerpaths/k12teacherroadmap/classroom/index.html.
- Centers for Disease Control and Prevention. Foodborne Diseases Active Surveillance Network (FoodNet). Available at: https://www.cdc.gov/foodnet/index.html.
- Centers for Disease Control and Prevention. Guidelines for confirming cause of foodborne disease outbreaks. Available at: https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html.
- Centers for Disease Control and Prevention. PulseNet. Available at: https://www.cdc.gov/pulsenet/index.html.
- Centers for Disease Control and Prevention. Risk communication. Available at: https://www.cdc.gov/healthcommunication.
- Food Safety Inspection Service. Available at: https://www.fsis.usda.gov/wps/portal/fsis/home.
- US Department of Health and Human Services. State departments of public health. Available at: https://www.foodsafety.gov/about/state/index.html.
- US Food and Drug Administration. Available at: https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks.

Environmental Health Surveillance (Food-Related)

- National Antimicrobial Resistance Monitoring System. Available at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm. National Environmental Assessment Reporting System. Available at: https://www.cdc.gov/nceh/ehs/nears.
- National Outbreak Reporting System. Available at: https://www.cdc.gov/nors/index.html.
- ProMED-mail. Available at: https://www.promedmail.org.
- Environmental Health Services Network. Available at: https://www.cdc.gov/nceh/ehs/ehsnet/index.htm.

Useful Environmental Health Web Sites

- Assessment of Foodborne Illness Outbreak Response and Investigation Capacity in US Environmental Health Food Safety Regulatory Programs. Available at: https://neha.org/sites/default/files/publications/NEHA-Assessment-Foodborne-Illness-Outbreak-Response.pdf.
- Association of Public Health Laboratories. Available at: https://www.aphl.org/Pages/default.aspx.
- Food Safety News. Available at: http://www.foodsafetynews.com.
- US Food and Drug Administration. HACCP principles and application guidelines. Available at: https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm.

SUGGESTED READINGS

- American Medical Association, American Nurses Association–American Nurses Foundation, Centers for Disease Control and Prevention, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, Food Safety and Inspection Service, US Department of Agriculture. Diagnosis and management of foodborne illnesses: a primer for physicians and other health care professionals. *MMWR Recomm Rep*. 2004;53(RR-4):1–33.
- Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for foodborne disease outbreak response. Atlanta, GA: Council of State and Territorial Epidemiologists. 2009.
- Heymann DL. *Control of Communicable Diseases Manual: An Official Report of the American Public Health Association.* 19th ed. Washington, DC: American Public Health Association; 2008.
- Institute of Medicine, National Research Council. *Enhancing Food Safety: The Role of the Food and Drug Administration.* Washington, DC: The National Academies

Press; 2010. International Association for Food Protection. *Procedures to Investigate Foodborne Illness.* Boston, MA: Springer; 2011.
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