Council to Improve Foodborne Outbreak Response (CIFOR)

Guidelines for Foodborne Disease Outbreak Response

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For Public Review

i. Foreword

The Council to Improve Foodborne Outbreak Response (CIFOR) *Guidelines for Foodborne Disease Outbreak Response* have been developed to aid governmental agencies that are responsible for preventing and managing foodborne disease. The *Guidelines* focus on agencies at the local and state level, since these organizations carry out the majority of foodborne disease outbreak investigations in the United States. However, the *Guidelines* are also intended to provide support to the federal public health and regulatory agencies that have critical roles in the country's food safety infrastructure.

The *Guidelines* describe the overall approach to foodborne disease outbreaks, including preparation, detection, investigation, control and follow-up. The *Guidelines* also describe the roles of all key organizations in foodborne disease outbreaks. While the document serves as a comprehensive source of information for individuals and organizations involved in foodborne disease, the *Guidelines* are not intended to replace existing procedure manuals. The *Guidelines* should be used as a reference document for comparison with existing procedures, for filling in gaps and updating site-specific procedures, for creating new procedures where they do not exist, and for providing training to program staff.

The CIFOR intends for the *Guidelines* to serve as a foundational resource for epidemiologists, laboratorians, environmental health specialists, and others involved in food safety programs. There are many governmental agencies -- local, state and federal -- that work in the area of foodborne disease outbreaks. This document hopes to harmonize the foodborne disease investigation work across all those agencies.

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

Chapter 1. Practical Guide to Foodborne Disease Outbreak Response

To be done -- Brief outline of the steps in a foodborne disease outbreak investigation, with page numbers that link to sections in the guidelines. To include a visual/graphic of the flow of an investigation.

Chapter 2. Fundamental Concepts of Foodborne Disease

> At either end of any food chain you find a biological system—a patch of soil, a human body—and the health of one is connected—literally—to the health of the other.
>
> Michael Pollan
> The omnivore's dilemma, 2006 [1]

2.0 Introduction

The past century has seen a significant transformation in the American diet--changes in what we eat, how that food is grown or raised, and how it arrives on our tables. Factors that have contributed to these changes include industry consolidation and globalization, health concerns and dietary recommendations as well as culinary trends. What and how we eat are directly related to the foodborne diseases we experience. This chapter provides an overview of the some of the factors responsible for trends in foodborne disease in the United States as well as a brief discussion of the most common microbial contaminants of food and how they cause disease.

2.1 Trends in Diet and the Food Industry

2.1.1 Dietary Changes and the Food Industry

We are no longer a nation of meat and potato eaters as evidenced by the most recent dietary recommendations from the United States Department of Health and Human Services and the United States Department of Agriculture (USDA) that stress the importance of a variety of fruit, vegetables and protein sources in the American diet. [2] From 1985 through 2005, the annual per capita consumption of fruit and vegetables rose from 89 to 101 pounds and 123 to 174 pounds respectively. [3] In 2006, the annual per capita consumption of seafood (fish and shellfish) was 16.5 pounds, compared with 12.5 pounds in 1980. [4] Demands for a broader variety of food have put pressure on a food industry that has accommodated Americans by moving away from locally grown and raised products to routine importation of items once thought of as out-of-season or considered too exotic for Americans to buy. The demand for ready-to-eat and processed foods has created a burgeoning international agribusiness that supports monoculture farming, mega-feedlots and the mass importation and distribution of foods.[1, 5]

Along with these changes in demand, technology has improved growing, harvest, packaging, handling and transportation practices, facilitating the year-round importation of far-way, fragile food items like raspberries from the Southern Hemisphere. Less stringent trade agreements with major fruit growing countries have also contributed to the growth of international imports: between 1990 and 2006, the dollar amount of annual imports of fresh fruits and vegetables into the United States rose from 2.7 to 7.9 billion; at the same time, the proportion of tropical fruits comprising those imports, primarily from Mexico and Costa Rica, increased from 7% to 15%. [3]

2.1.2 Changes in the Food Supply

The changing spectrum of what we eat and drink is not the only contributing factor to trends in foodborne disease--there is also how we eat: how the food is cultivated or raised, processed and distributed; how the food is prepared for eating, and by whom. Contamination of a food product can happen anywhere along the supply chain--as is often said--from farm to fork. Food production has become industrialized, with concentrated animal feeding operations and increasingly intense agricultural practices. The broadening distribution of food products has contributed to outbreaks of foodborne disease involving multiple states and even multiple countries. [6-16] Culinary trends that utilize undercooked or raw foods, particularly dairy, fish or shellfish products, may be contributing to an increase in infections and outbreaks caused by the micro-organisms associated with these foods. [17-23] Changes in agricultural, processing or packaging methods may facilitate bacteria contamination or growth, [6, 7, 14, 21, 24-32] while the routine use of antibiotics to promote the growth of livestock and poultry has increased the burden of human infections caused by drug-resistant bacteria. [10, 13, 33-36]

More and more Americans are eating their meals away from home and the majority of foodborne disease outbreaks are associated with eating in a restaurant or obtaining food at another commercial establishment. [37-39] Improper handling of food is a major source of contamination contributing to foodborne disease and the mistakes most commonly reported in foodborne outbreaks include:

(1) holding foods at improper temperatures for prolonged periods of time, which can promote the growth of micro-organisms,
(2) handling intrinsically contaminated products, such as raw chicken or eggs, which are frequently contaminated with the bacteria *Campylobacter jejuni* and *Salmonella enteritidis*, and contaminating ready-to-eat foods such as salads (cross-contamination),
(3) poor hand-washing practices,
(4) failure to adequately clean utensils and equipment and
(5) handling ready–to-eat foods with bare hands.[37, 38, 40-46]

Food workers infected with foodborne illnesses, a problem recognized since the era of Typhoid Mary[*], continue to be a source of microbial contamination, especially in restaurant-related outbreaks of norovirus, shigellosis, Hepatitis A infections and less frequently salmonellosis.[39, 42, 44]

In general, technology has improved food safety, but the changes in our food supply have not all been beneficial, as suggested by the increasing diversity and distribution of foods responsible for foodborne disease outbreaks in the United States. Outbreaks that were rarely seen prior to 1988, such as those associated with fresh produce, caused by Shiga-toxin producing *Escherichia coli* (STEC) or affecting multiple states are now frequently reported by the Centers for Disease Control and Prevention (CDC). [6, 7, 12, 14, 17, 32, 37, 40, 47-50] Multistate outbreaks require an extraordinary degree of coordination and cooperation between local, state/territorial and federal agencies responsible for public health and the oversight of food safety.

2.1.3 Trends in Food Product Recalls

Voluntary recalls of food products by their distributors or manufacturers usually occur for one of two reasons: either a problem is discovered in the course of routine inspection of the food, its processing or distribution, or the product is suspected or identified as the cause of human or

[*] Typhoid Mary, whose real name was Mary Mallon (born 1869), was the first person in the United States to be identified as an asymptomatic carrier of *Salmonella typhi*, the cause of typhoid fever. She was a cook in New York City where she infected 47 people, causing three deaths. She denied her role in causing the disease and continued to work as a cook. She was twice involuntarily quarantined by the New York City Health Department and died in quarantine in 1938. [ref]

animal disease. More than 90 voluntary recalls of food products associated with microbial contamination were reported by the USDA and the federal Food and Drug Administration (FDA) from February 2007 through February 2008. These recalls demonstrate the breadth of products and pathogens currently responsible for foodborne diseases in the United States. [15, 16]

During that period, many of the recalls were for contaminated meat, primarily ground beef and other beef products. But the recalls were not exclusively for meat products; they included shellfish, smoked fish, dried fish, frozen fish, and uneviscerated fish; fresh fruit, herbs and vegetables; canned vegetables; cheese and other dairy products; chocolate; ready-to-eat foods; frozen pizza; peanut butter; sesame seeds; tahini; tofu; and bottled water. The products were distributed locally, nationally or internationally and were sold not only by national chain retail stores and food services but at farm stands and small health food stores carrying organic and "natural" products. In other words, no one is completely protected from the risk of contaminated food.[15, 16]

Most of these recalls followed the identification of bacterial contamination of a food or beverage. However, in at least 20 instances, the contamination was associated with reported human illnesses, including 628 residents of 47 states infected with *Salmonella* after eating contaminated peanut butter.[14] The contaminating pathogens most commonly identified in these recalls were bacteria: *Listeria monocytogenes*, *E. coli* O157:H7 (STEC) and *Salmonella* species; the latter two were most frequently associated with reported foodborne outbreaks.

There were also recalls for products contaminated with viruses (e.g., norovirus in shellfish), parasites (e.g., *Cryptosporidium* in bottled water) and naturally-occurring toxins (e.g., *Clostridium botulinum*, *Staphylococcus aureus* and tetrodotoxin, produced by pufferfish).[15, 16] And the largest single food recall in the United States to date, a staggering 148 million pounds of beef, was initiated following the discovery that a California food processor was using disabled, or "downer," cows in beef production--a concern because of the theoretical risk that some of the cows may have been infected with the agent associated with bovine spongiform encephalopathy (BSE), or "mad cow disease." [51-53]

2.2 Surveillance of Foodborne Disease

2.2.1 Overview

Foodborne disease continues to be a significant cause of morbidity in the United States. In 1999, CDC estimated that foodborne diseases are responsible for 76 million illnesses in the United States each year, resulting in 325,000 hospitalizations and 5,000 deaths.[54] From 1998 to 2002, 6427 foodborne outbreaks were reported to CDC, resulting in at least 128,370 individual illnesses and 88 fatalities.[37] Although the national capacity for detection and tracking (surveillance) of foodborne disease has improved considerably in the past 20 years,[55] these statistics are just the tip of the foodborne disease iceberg for a number of reasons: (1) not all individuals seek medical attention for a brief bout of vomiting or diarrhea, (2) health care providers do not always obtain diagnostic tests for minor illnesses, (3) not all types of infections can be diagnosed with routine laboratory testing, and (4) laboratories and health care providers may fail to report the illness to their local public health agency. [56-59]

Our current knowledge of the trends in foodborne disease relies on the rapidity, accuracy and completeness of disease reporting by the healthcare system and on the disease investigations by local, state and territorial public health agencies, as well as on the flow of information from these agencies to the CDC's Enteric Diseases Epidemiology Branch and other groups at CDC.[23, 37, 55]

2.2.2 Surveillance and Investigation of Foodborne Disease

2.2.2.1 Overview

Disease surveillance is the backbone of communicable disease epidemiology and investigation of foodborne diseases is the bread and butter of many local, state and territorial public health agencies. As mentioned above, surveillance begins with an ill person who seeks medical attention. The health care provider sends a specimen (in the case of foodborne illness, this is usually a stool specimen) to the laboratory for the appropriate tests and the laboratory identifies the agent responsible for the patient's illness so they can be treated. The next step is crucial when the laboratory or health care provider notifies local public health of the illness. This is one link in the surveillance chain that is frequently overlooked. Once that individual's information goes to a public health agency, the illness is no longer an isolated incident, but is one detail in the sea of local data. It is combining the information in these separate reports that will alert an investigator to an outbreak.

In all states and territories, there are legal requirements to report certain diseases and conditions such as foodborne diseases to the local public health agency. In most states and territories, the law usually requires local public health agencies to report these diseases to the state or territorial public health agency. The requirements for what to report and with what urgency varies by state. States and territories, or sometimes local public health agencies, then send the information on to the National Notifiable Diseases Surveillance System, which is overseen by CDC. In the past, disease reports usually arrived by mail or facsimile transmission, but many agencies now encourage telephone reporting and have developed some form of electronic disease reporting locally. State public health laboratories also participate in national surveillance through programs such as the Public Health Laboratory Information System (PHLIS) and PulseNet.

Once collected and analyzed at any level, these surveillance data can reveal the burden of a particular disease or the presence and scale of a possible outbreak, and they may also provide clues to the source of the outbreak which can lead to control measures. Collected over time, surveillance data can identify disease trends and serve as a database that enables investigators to learn more about the diseases being tracked.

Traditional surveillance is "passive," meaning the investigator waits for a disease report to arrive from health care providers, laboratories and others requested or required to report these diseases to public health. As noted above, there are problems with this approach and efforts have been made at all levels of public health to overcome the challenges associated with disease reporting.

2.2.2.2 National Foodborne Disease Surveillance

On the national level, 1996 was a watershed year for foodborne disease surveillance in the United States. That year, the CDC, in collaboration with State Health Departments, FDA and USDA, established several programs to improve how foodborne diseases are tracked: (1) the Foodborne Diseases Active Surveillance System (FoodNet), (2) the National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet), (3) the National Antimicrobial Resistance Monitoring System-Enteric Diseases (NARMS), and (4) the Electronic Foodborne Outbreak Reporting System (EFORS).

FoodNet is an enhanced foodborne disease surveillance system, led and largely funded by CDC, with 10 participating sites covering a population of about 45 million people in the United States. FoodNet concentrates on cases of foodborne disease documented by laboratory testing and is an active surveillance system, as FoodNet site investigators contact area laboratories on a regular basis to maintain active reporting of cases of foodborne disease. FoodNet also serves as a platform for detailed epidemiological investigations into sporadic cases, which form the great bulk of all reported cases, and conducts surveys of the frequency of illness and exposures in the population and practices in clinical laboratories. The FoodNet reports provide valuable insight into the national incidence of, and trends in, foodborne and diarrheal diseases and has identified previously unrecognized sources of infection. [23, 34, 35, 52, 55, 56, 60-64] Foodnet also serves as a platform for evaluating new strategies for conducting epidemiologic investigations, including outbreaks.

PulseNet is a national network of local, state/territorial and federal laboratories coordinated by CDC. The name is derived from “pulsed-field gel electrophoresis,” or PFGE, a laboratory method used to look at the molecular fingerprint of bacteria. This laboratory test, which was developed and refined in the 1980’s, has revolutionized the investigation of foodborne disease outbreaks by identifying unique strains within a bacteria species. For example, there are many strains of *Salmonella*, each with their own unique PFGE pattern, or fingerprint. Because foodborne outbreaks are usually caused by a single strain of bacteria, investigators can identify the subgroup of persons infected with the same strain of *Salmonella* as a cluster of possibly related cases, to be considered separately from persons infected with other strains of *Salmonella*. That way they can focus their investigation on the correct group of individuals, and more quickly identify the source of an outbreak. Pulsed-field gel electrophoresis can also be used to characterize bacterial strains in food or the environment to determine if those strains match the pattern of bacteria responsible for an outbreak. [12, 27, 35, 65-68]

PulseNet has standardized the PFGE methods used by PulseNet laboratories to distinguish strains of STEC (*E. coli*), *Salmonella*, *Shigella*, *Listeria* and *Campylobacter.* In addition, PulseNet maintains an electronic database of PFGE patterns that enables investigators from participating sites to upload their pattern and compare it with patterns of bacterial strains circulating nationally. This capability has vastly improved investigators’ ability to rapidly detect even relatively small outbreaks occurring in multiple sites across the country. [69]

The National Antimicrobial Resistance Monitoring System-Enteric Diseases (NARMS) was developed to monitor antibiotic resistance patterns in foodborne disease bacteria present in people, animals and meat products. Data collected by this system has given investigators a better understanding of the interaction between the use of antibiotics for livestock and the patterns of antibiotic resistance in animals and humans who consume animal food products. [13, 34, 35, 64, 67, 70-72]

CDC has collected voluntary reports summarizing the results of foodborne outbreak investigations since the late 1960's, and has maintained a computerized database since 1973. In 1998, the format of reporting was changed, and more extensive efforts to close out annual reporting with each state were instituted. These enhancements have been so successful that the number of reported foodborne disease outbreaks doubled in 1998 as a result of better reporting by participating public health agencies. [37] In 2000, this was converted to web-based reporting in a system called EFORS. Beginning in 2009, this system will include modules for reporting waterborne outbreaks, and for enteric disease outbreaks, due to person-to-person contact and to direct contact with animals. The expanded system will be called the National Outbreak Reporting System (NORS).

2.3 Etiologic Agents associated with Foodborne Diseases

2.3.1 Overview

The causes of foodborne illnesses are myriad but can generally be grouped into those caused by micro-organisms and/or their toxins and those caused by inorganic compounds. Illness due to the ingestion of foods contaminated by inorganic toxins is relatively rare in the United States. Of the foodborne outbreaks with an identified etiology reported to the CDC from 1998 to 2002, 99.8% were caused by micro-organisms or microbial toxins and only 0.02% were caused by inorganic toxins.[37] Microbial causes of foodborne illness include bacteria, viruses, parasites, algae (organisms that produce toxins associated with certain fish and shellfish intoxications) and altered proteins known as prions (one of which causes BSE and the human variant Creutzfeldt-Jakob disease). Some of these agents produce their effects through direct infection of their hosts while others elaborate toxins that affect specific organs or organ systems and cause characteristic disease syndromes.[ref] The following discussion focuses on the microbial causes of foodborne illness.

In the most recent CDC surveillance summary of U.S. foodborne disease outbreaks (covering 1998 to 2002), bacteria accounted for 55% of reported outbreaks with an identified cause; the most common bacteria were *Salmonella, Clostridium perfringens,* STEC *(E. coli), Staphylococcus aureus, Shigella and Campylobacter* species*, Bacillus cereus* and *Vibrio* species*.* Although less common*, Listeria monocytogenes* and *Clostridium botulinum* were also important bacterial causes of foodborne disease. [37]

During the same surveillance period, viruses comprised 33% of the identified causes of foodborne disease outbreaks, increasing from 16% to 42% between 1998 and 2002. Noroviruses were the most common viral cause, followed by hepatitis A virus. Astro- and rotaviruses played a minor role in foodborne disease outbreaks, as did parasites, which accounted for 0.3% of outbreaks with identified etiologies, with *Cryptosporidium*, *Cyclospora* and *Trichinella* each comprising 0.1% of the reports. [37, 73, 74]

Micro-organisms have evolved numerous strategies for causing human disease. The microbes that can contaminate food include bacteria that can grow in food and manufacture toxins before ingestion (pre-formed toxins), or, once ingested, can reproduce exponentially in their host, causing damage with toxins produced within the host and/or by adhering to or invading cells. Signs and symptoms associated with some pathogens are characteristic of these strategies: the pre-formed toxins of *Staphylococcus aureus* and *Clostridium perfringens* cause a brief illness of rapid onset in which vomiting is prominent. The attachement, erosion and invasion of gastrointestinal tissue caused by *Campylobacter, Shigella and Salmonella* is marked by a longer incubation period followed by fever, abdominal pain and bloody diarrhea. The profuse, watery diarrhea caused by enterotoxigenic E. coli (ETEC) and *Vibrio* species is typical of bacteria that produce enterotoxins in the gastrointestinal tract. The severe diarrhea and exceptionally painful cramps of E. coli O157 infections are sometimes complicated by kidney and brain damage, all caused by the absorption of the Shiga toxins produced by the E. coli, which never themselves leave the gut.

The symptoms of foodborne diseases are not limited to nausea, vomiting, abdominal pain and diarrhea. Hepatitis A virus causes inflammation of the liver. Neurologic syndromes can be seen following the ingestion of botulinum toxin, chemical toxins associated with seafood, shellfish and mushrooms, and beef contaminated with the prion that causes BSE. Kidney and liver failure, severe muscle inflammation, and other complications may follow the consumption of toxic mushrooms. Parasites consumed in raw or undercooked meat, fish, snails or shellfish (e.g., *Angiostrongylus cantonensis, Anisakis simplex, Clonorchis sinensis, Paragonimus* species, *Toxoplasma gondii* and *Trichinella spiralis*) can invade the muscles, lungs, liver, central nervous system and other organs, causing a variety of symptoms. [19, 51, 75-78]

2.3.2 Pre-formed toxins

2.3.2.1 Pre-formed bacterial toxins

2.3.2.1.1 Bacillus cereus

Bacillus cereus is responsible for two different syndromes because it makes several toxins. Short incubation *B. cereus* is caused by an emetic toxin that contaminates food. It is characterized by the sudden onset of nausea, vomiting and abdominal cramps within 1-6 hours after ingesting contaminated food. Only about 30% of people have diarrhea, and fever is rare. Most people recover within 12 hours. The foods most commonly associated with short incubation *B. cereus* disease are fried rice, meat and vegetables that were inadequately reheated. [79] The second syndrome, long incubation *B. cereus* disease, is discussed below in section ***2.3.3.1***.

2.3.2.1.2 Clostridium botulinum

Clostridium botulinum is an ubiquitous soil bacteria that can remain dormant as a spore until ideal growth conditions allow it to reproduce and manufacture botulinum toxins. Those conditions are found in warm, moist, nutrient-rich non-acidic places with an absence of oxygen, which is toxic to Clostridia, conditions found in a can of food or a fermenting carcass. Botulinum toxins interfere with the release of acetylcholine from nerve endings and can cause life-threatening paralysis (botulism). The incubation period of botulism depends on the dose, but usually ranges from 12-36 hours after ingesting contaminated food. Patients are alert, have no fever, about 50% have nausea and vomiting and about 25% have diarrhea. Paralysis begins with nerves that control the face, neck, breathing and swallowing and progresses downward to the arms and legs. Patients can be treated with an anti-toxin, which prevents the progression of paralysis, but many require intensive care with mechanical ventilation, followed by prolonged hospitalization and rehabilitation. The foods most commonly associated with botulism are low-acid and packed under conditions that exclude air (anaerobic), typically through home-canning. These foods include canned vegetables, fruits, and preserved fish.[79]

2.3.2.1.3 Staphylococcus aureus

Staphylococcus aureus is an ubiquitous human skin organism primarily known for causing skin and soft tissue infections, but is also responsible for food contamination caused by several of its toxins. The sudden onset of vomiting and diarrhea without fever occurring within 1-6 hours of ingestion of contaminated food is characteristic of *S. aureus*. Symptoms typically resolve within 12 hours. Ready-to-eat foods at warm temperatures, such as ham, egg salad and cream pastries are usually contaminated by a food worker who is colonized or infected with enterotoxin producing straing of *S. aureus.*

2.3.2.2 Pre-formed non-bacterial toxins

2.3.2.2.1 Algae toxins

Tiny marine algae are responsible for several toxins that contaminate fish and shellfish, causing neurologic or systemic syndromes.

2.3.2.2.1.1 Amnesic shellfish poisoning

Amnesic shellfish poisoning (ASP) is a potentially serious, rare illness caused by domoic acid, which are produced by diatoms (marine algae). The diatoms are ingested by certain bivalves such as scallops, clams and mussels. When the contaminated bivalves are ingested by humans, it results in ASP. There are two separate syndromes caused by ASP–gastrointestinal and neurological. Gastrointestinal ASP, more common in people under 40 years of age, develops within 24 hours of the ingestion of domoic acid and includes nausea, vomiting, diarrhea and abdominal pain. The onset of neurological ASP occurs about 48 hours after toxin ingestion and includes headache, visual changes, confusion, short-term memory loss, weakness, seizures and coma. Patients recover within days or a severe neurological illness may result in permanent deficits. Bivalves contaminated with domoic acid are rare, but have been found throughout North American harvesting areas. [78]

2.3.2.2.1.2 Ciguatera

Ciguatera, a common fish poisoning, is caused by dinoflagellates (marine algae) that produce ciguatoxin, a contaminant of fish that ingest the dinoflagellates. Symptoms develop within 3-30 hours of intoxication and include facial tingling, headache, difficulty distinguishing between hot and cold, muscle pain and rash; the syndrome can progress to coma and death. Recovery can take from days to months, depending on the severity of the illness. The fish most likely to be contaminated are large, tropical reef fish such as barracuda, amberjack and grouper, usually caught by private individuals. Ciguatera has been reported from tropical and subtropical areas, including Hawaii and Florida. [78] [79] For this reason it is illegal to serve barracuda in Puerto Rico.

2.3.2.2.1.3 Neurotoxic shellfish poisoning

Neurotoxic shellfish poisoning (NSP) is caused by a dinoflagellate brevetoxin that contaminates bivalves that feed on the algae. The onset of NSP occurs within 3-6 hours of ingestion of the brevetoxin; symptoms include facial tingling, difficulty walking and breathing, dizziness, abdominal pain, headache and difficulty distinguishing between hot and cold temperatures. These symptoms usually do not last more than 48 hours. Brevetoxin is found in bivalves harvested in tropical waters and subtropical waters (including Florida) during warmer months.[78]

2.3.2.2.1.4 Paralytic shellfish poisoning

Paralytic shellfish poisoning (PSP) is caused by saxitoxin, made by dinoflagellates that are ingested by bivalves. The onset of PSP occurs within 30 minutes to four hours after ingestion of the toxin. Early symptoms include a tingling sensation around the mouth, face and extremities followed by headache, nausea, vomiting, diarrhea and weakness. The illness may progress to paralysis, respiratory failure and death. Depending on the dose of the toxin and the severity of illness, symptoms may last from hours to days. Saxitoxin is associated with bivalves harvested in temperate areas (including the Pacific Northwest and Northeast Atlantic) primarily during the warmer months. [78, 79]

2.3.2.3 Fish toxins

2.3.2.3.1 Escolar

Gempylotoxin is a toxin that occurs naturally in several species of fish, commonly known as escolar. The toxin is a poorly absorbed, waxy ester that can cause oily diarrhea. Escolar has been reported as the cause of clusters of diarrhea in several countries including the United States; some of the clusters have been complicated by scombroid poisoning. [80, 81]

2.3.2.3.2 Puffer fish

The fugu fish is a puffer fish eaten in Japan that is often naturally contaminated with tetrodoxin. Tetrodotoxin is one of the most potent poisons known and can cause a life-threatening illness if ingested. The symptoms of puffer fish poisoning begin 30 minutes to three hours after ingestion and include numbness of the face, arms and legs, vomiting, dizziness, a sense of impending doom, followed by paralysis, circulatory shock and respiratory failure. Symptoms resolve within 24 hours if the illness is not severe. The fugu fish is considered a delicacy in Japan, where careful preparation to remove the gonads, which have the greatest concentration, is required. The FDA restricts the importation of fugu into the United States to a single importer for use by trained, certified fugu chefs. [78] [82] Other puffer fish have recently been identified in Florida as the source of poisoning due saxitoxin, the cause of PSP. [97]

2.3.2.3.3 Scombroid (Histamine fish poisoning)

Scombroid is probably the most common intoxication caused by fish. In inadequately refrigerated fish, the bacterial breakdown of histadine produces histamine, as well as substances that inhibit histamine metabolism that together, cause the illness. A person who consumes the contaminated fish may describe the taste as “peppery” or may not notice anything at all. Intoxication is characterized by the onset within minutes to hours of symptoms of an allergic reaction: facial tingling and flushing, hives, headache, rapid heart beat and profuse sweating. Symptoms resolve in hours if mild or if the patient is treated with anti-histamines, though on rare occasions it has caused respiratory failure and death. The fish most commonly associated with scombroid are from the deep sea families *Scombridae* and *Scomberesocidae* (e.g., tuna and mackerel), but other fish may also be affected. Scombroid occurs worldwide in inadequately refrigerated fish. [78] [83]

2.3.2.4 Mushroom toxins

Edible mushrooms are raised as a commercial food product and some are foraged in the wild. Certain inedible mushrooms may be used for spiritual, cultural or recreational purposes, or may be consumed unintentionally when mistaken for an edible mushroom. There are limited data on the incidence of mushroom poisoning in the United States, and the involved species are rarely identified. A recent review of state and national poison control center data indicates that mushrooms account for less than 0.05% of all toxic ingestions. In 96% of mushroom poisonings, the mushroom species is unidentified. Children less than six years of age comprised 67-81% of the poisonings. Up to 50% of patients had no symptoms following ingestion, 6-15% had mild symptoms, less than 5.0% had moderate symptoms, 0.2-0.3% were severely ill and 0.03% of those poisoned died. Fatal mushroom poisoning in the United States is most commonly associated with amatoxin-producing species (e.g., *Amanita* and *Galerina*). There are a multitude of syndromes caused by mushroom toxins, and in general, they can be classified as neurotoxic, gastrointestinal, allergic or multisystem with early, late or delayed onset. Early onset (less than six hours following ingestion) syndromes include hallucinations and delirium caused by neurotoxic *Psilocybe* species*;* immune-mediated hemolytic anemia followed by renal failure, caused by *Paxillus involutus;* and gastrointestinal symptoms caused by several mushroom species. Late onset (6-24 hours) syndromes include liver toxicity caused by amatoxin-producing species and kidney toxicity caused by *Amanita* species. Delayed onset (more than 24 hours) syndromes include kidney toxicity caused by *Cortinarius* species and muscle toxicity caused by *Russula* and *Tricholoma* species. All of these species are found in North America. [77]

2.3.3. Bacterial toxins formed in vivo

In vivo toxin formation occurs after the ingestion of a microorganism.

2.3.3.1 Bacillus cereus

Long incubation *Bacillus cereus* disease is caused by a toxin formed in vivo, and the incubation period of 6-18 hours distinguishes it from illness caused by the toxin of short incubation *B. cereus.* Diarrhea and abdominal pain are the predominant symptoms. Although nausea may occur, fever is rare. Symptoms usually resolve within 48 hours, but may persist for weeks. Foods associated with this *B. cereus* syndrome include cooked rice, meat, vegetables and milk kept at improper temperatures. [79]

2.3.3.2 Clostridium botulinum

When *Clostridium botulinum* spores are ingested and produce botulinum toxin in vivo, usually in an infant (or rarely in older children or adults with an altered gastrointestinal tract), infant botulism can occur. Infant botulism is characterized by weakness, poor feeding, constipation and loss of muscle tone ("floppy baby"). Infants are treated, not with the equine antitoxin used to treat foodborne botulism, but with human botulinum immune globulin or BIG, which prevents progression of the illness. Similar to adult botulism, the symptoms may last months. Although the disease has been associated with the ingestion of contaminated honey, other foods have not been implicated and most cases likely have an environmental source. [79]

2.3.3.3 Clostridium perfringens

Clostridium perfringens produces at least five toxins after ingestion by a host. The toxin thought to be primarily responsible for foodborne illness is Toxin A, produced in the intestine when dormant *C. perfringens* spores from contaminated food begin to reproduce. Toxin A causes abdominal pain and diarrhea after an incubation period of 8-16 hours. Nausea can occur but vomiting and fever are rare and symptoms resolve within 24 hours. *Clostridium perfringens* is associated with contamination of meat and gravies that have been inadequately reheated. [79]

2.3.3.4 Enterotoxigenic Escherichia coli

Enterotoxigenic *Escherichia coli* (ETEC) are strains that produce intestinal toxins (enterotoxins) following ingestion of contaminated food. These toxins cause the sudden onset of abdominal pain and watery diarrhea without fever after an incubation period of 1-3 days. Nausea and vomiting are uncommon and symptoms usually resolve within 3-7 days. These strains of *E. coli* are the leading cause of travelers' diarrhea and result from the ingestion of undercooked meat or other foods, fresh fruits and vegetables, however, outbreaks have been reported that occurred in the United States. [37, 79]

2.3.3.5 Shiga-toxin producing Escherichia coli
Shiga-toxin producing *Escherichia coli* (STEC) produce a toxin (known as Shiga- or verotoxin) that is absorbed in the intestine and causes damage to intestinal and kidney blood vessels. The most serious manifestation of this toxin results in a syndrome of hemorrhagic colitis that combined with kidney failure, is known as hemolytic uremic syndrome (HUS). The classic and most common serotype causing hemorrhagic colitis and HUS is *E. coli* O157:H7, but similar illnesses have been reported with other serotypes of *E. coli*. The incubation for STEC infections is 3-8 days. Patients initially have abdominal pain and watery diarrhea that becomes bloody, but typically have no fever. An uncomplicated infection usually lasts 1-12 days, but in a small proportion of patients, HUS may develop 5-10 days after the onset of diarrhea. Children and the elderly are most at risk for HUS, which can be fatal or result in serious, permanent kidney damage. Initially identified as the cause of outbreaks associated with undercooked or raw ground beef, STEC has more recently been recognized as an environmental organism that can be found in areas where livestock are kept, resulting in a broad range of contaminated vehicles. Though the most frequent source is undercooked beef, outbreaks have also been associated with petting zoos, contact with farm animals, swimming in or drinking contaminated water, and consumption of contaminated raw dairy products and fresh produce. [7, 12, 28-32, 37, 49, 63, 65, 79, 84, 85]

2.3.3.6 Vibrio cholerae non-O1
Vibrio cholerae non-O1 produces an enterotoxin that causes severe watery diarrhea and abdominal cramps, usually without nausea, vomiting or fever. The incubation period is 1-3 days and the illness may last 2-7 days. Infections with *Vibrio cholerae* non-O1 are rare in the United States, but have been associated with raw or undercooked shellfish, including shellfish from the waters of the Gulf Coast. [79]

2.3.3.7 Vibrio cholerae O1 or O139
Vibrio cholerae O1 or O139 produce cholera toxin, an enterotoxin that causes severe dehydrating, watery diarrhea, often accompanied by severe electrolyte disturbances, vomiting and painful muscle cramps, but with little fever. The incubation period of cholera is 1-3 days and the illness may last 2-7 days. Rapid and vigorous replacement of lost fluid and electrolytes is lifesaving. Cholera is associated with the consumption of contaminated water, food and raw or undercooked shellfish. In the United States, locally acquired cases have been reported following consumption of shellfish from the Gulf Coast. However, the vast majority of infections in the United States are acquired during international travel. [79]

2.3.4 Bacterial tissue invasion

2.3.4.1 Campylobacter

Campylobacter jejuni is the second most commonly reported bacterial cause of foodborne illness in the United States after Salmonella. *Campylobacter* causes damage by invasion of intestinal cells, and after an incubation period of 18 hours to five days, there is fever, abdominal pain and watery, occasionally bloody, diarrhea that typically lasts five days. Campylobacter is ubiquitous in poultry and can infect cattle as well; infection occurs most commonly following the consumption of undercooked chicken or turkey, and sometimes following consumption of raw milk. [79]

2.3.4.2 Listeria

In the high risk person, with immunodeficiency or advanced age, or in the fetus of a pregnant woman, *Listeria monocytogenes* can cause fever, bacteremia, meningitis, shock and death, with onset of symptoms up to several weeks after exposure. In the normal host, a very high dose of *Listeria monocytogenes* can cause diarrhea, abdominal pain and fever with an incubation period of nine hours to two days. Listerisosis is rarely reported as a cause of foodborne outbreaks, as most people exposed to lesser doses of Listeria have no symptoms at all. *Listeria monocytogenes* infections are most commonly reported among immunocompromised individuals or pregnant women, who are at risk for miscarriage. In the immunocompromised, *L. monocytogenes* invades intestinal cells and enters the bloodstream, causing sepsis and infections in the central nervous system. Listeria organisms can slowly multiply in some foods at refrigerator temperatures. Outbreaks of *Listeria monocytogenes* infection are typically associated with the consumption of ready-to-eat meats, such as deli meats and hot dogs, and with raw dairy products. [79]

2.3.3.3 Salmonella non-Typhi

Salmonella serotypes other than Typhi are the most commonly reported cause of foodborne disease and foodborne disease outbreaks. *Salmonella* invades cells of the intestine and also produces enterotoxins and other factors that cause cellular damage. In severe infections and in immunocompromised persons, Salmonella can spread through the blood stream to distant parts of the body causing localized infections. Salmonellosis has an incubation period of 12 hours to five days; fever, abdominal cramps, and watery diarrhea predominate, but there may be nausea and vomiting and the diarrhea may be bloody; severe infections can include high fever, sepsis, meningitis, urinary symptoms and infection of joints, aorta, and other organs. Nearly half of reported cases of salmonellosis are hospitalized. Uncomplicated salmonellosis typically lasts 2-7 days. Complicated infections can last much longer, and antimicrobial treatment can be lifesaving. Salmonella of may different serotypes have reservoirs in many different animals, and more than 2,500 serotypes have been described. *Salmonella* infections typically follow the consumption of contaminated, undercooked eggs, meat, raw dairy products and produce, as well as consumption of contaminated water, and contact with infected animals (such as reptiles, baby chicks and ducks). [79]

2.3.4.4 Salmonella Typhi

Salmonella Typhi infection (or typhoid fever) is an extremely rare cause of foodborne illness in the United States, and is almost always associated with an international source. *Salmonella* Typhi causes classic typhoid or “enteric” fever that results from invasion of intestinal cells, surrounding lymph nodes and bloodstream. This syndrome may also be caused by other Salmonella serotypes, including Paratyphi A, B and C; the reservoir for all of these is the infected human. Typhoid fever is a systemic illness characterized by high sustained fever, headache, abdominal pain and constipation rather than diarrhea. Without antibiotic treatment mortality may be greater than 15%, due to intestinal perforation. Even with appropriate antibiotic treatment, the illness lasts for weeks, and a small proportion of cases can become chronic carriers. Outbreaks in the United States have been related to international travel, carrier food workers, imported fruit, and, on one occasion, sexual transmission. [86-88]

2.3.4.5 Shigella

Shigella species cause invasion of the cells of the intestine and also produce enterotoxins and/or other factors that cause cellular damage. Shigellosis has an incubation period of 1-2 days, followed by fever, vomiting, abdominal cramps and watery diarrhea, which may be bloody; the illness lasts 2-7 days. Approximately 40 serotypes have been described, the most common of which (*Shigella sonnei*) causes the mildest illness. The reservoir is the infected human. *Shigella* outbreaks are associated with the consumption of contaminated, cold foods such as potato or egg salads and produce. [40, 79]

2.3.4.6 Vibrio parahaemolyticus

Vibrio parahaemolyticus causes invasion of the cells of the intestine and produces enterotoxins and/or other factors that cause cellular damage. Vibriosis has an incubation period of two hours to two days, followed by fever, abdominal cramps and watery diarrhea; nausea and vomiting are not typical; the illness lasts 2-5 days. Vibrio are free-living in warm, brackish coastal waters. Outbreaks of vibriosis are associated with the consumption of contaminated, raw or undercooked bivalve shellfish. Sources of contaminated shellfish include the coastal waters of the Gulf and Pacific in western states. [18, 79, 89, 90]

2.3.4.7 Yersinia

Yersinia enterocolitica causes invasion of the cells of the intestine and may also produce enterotoxins. Yersiniosis has an incubation period of 1-2 days, followed by fever, abdominal cramps and diarrhea, which may be bloody; nausea and vomiting are uncommon. Yersiniosis may also cause swelling of the lymph nodes surrounding the intestines (mesenteric lymphadenitis), a syndrome that may be mistaken for appendicitis. The illness lasts 1-3 weeks. Like *Listeria*, *Yersinia enterocolitica* can multiply slowly at refrigerator temperatures. The principal reservoir is the pig. Outbreaks of yersiniosis are associated with the consumption of contaminated milk and undercooked pork products. [79]

2.3.5 Viruses

2.3.5.1 Hepatitis A

Hepatitis A is a systemic illness caused by a virus that targets the liver. The incubation period of hepatitis A ranges from 15-50 days, which can make it difficult to pinpoint a source. Hepatitis A can be asymptomatic, especially in children. Most adults will have an illness characterized by fatigue, headache, fever, abdominal pain, diarrhea, nausea and vomiting and loss of appetite, followed in more serious infections by jaundice (dark urine, light stools and yellow coloration of the skin and eyes caused by abnormal liver function). The symptoms last from weeks to months and, rarely, patients with severe infection may have extensive liver damage that requires a liver transplant. The reservoir is the infected human. Hepatitis A has declined in the United States as a result of childhood immunization, but outbreaks continue to occur, usually as a result of contaminated produce or infected food workers who handle ready-to-eat foods. [37, 43, 44, 91]

2.3.5.2 Noroviruses

Noroviruses are the most common infectious cause of diarrhea, and as diagnostic tests for norovirus have improved, it is increasingly reported as a cause foodborne outbreaks. The incubation period for norovirus infection is 24-48 hours, beginning with nausea and abdominal pain. Vomiting or diarrhea usually predominate and fever is fairly common; the illness resolves within 48 hours. The reservoir is the infected human. Norovirus outbreaks are associated with ready-to-eat foods contaminated by an infected food worker or with consumption of raw or undercooked shellfish. [10, 37, 39, 44, 74, 92-94]

2.3.5.3 Other viruses

Foodborne outbreaks caused by other viruses, such as astrovirus and rotavirus, are rarely reported. [37]

2.3.6 Parasites

2.3.6.1 Cryptosporidia

Cryptosporidium parvum and *C. hominis,* protozoans, are well known as water contaminants, but are occasionally reported as a cause of foodborne outbreaks. The incubation period of cryptosporidiosis is 2-28 days; the most common symptoms are abdominal pain and watery diarrhea, but nausea, fever, fatigue and loss of appetite may occur. The length of illness ranges from 2-26 days, but may persist in immunocompromised individuals. Reservoirs are documented in ruminant animals and in humas. Cryptosporodiosis outbreaks have occurred following the consumption of unpasteurized apple cider. [26, 44, 95]

2.3.6.2 Cyclospora

Cyclospora cayatenensis is a protozoan occasionally reported as a cause of foodborne disease. The incubation period of cyclosporiasis is 1-11 days and the most common symptom is persistent watery diarrhea but abdominal pain, nausea, fever and fatigue may also be present. The reservoir is unknown. Outbreaks of cyclosporiasis have been associated with fresh berries and other produce imported from several countries and infected food workers. [7, 8, 44, 47]

2.3.6.3 Giardia

Giardia lamblii is a protozoan most frequently associated with waterborne illness. Giardiasis has an incubation period of five days to four weeks and is characterized by persistent, watery diarrhea, abdominal pain, bloating and loss of appetite. Outbreaks have been associated with infected food workers. [44; Mintz, 1993 #379]

2.3.6.4 Toxoplasma

Although *Toxoplasma gondii* is a common foodborne illness, outbreaks are infrequently reported because most individuals with toxoplasmosis are asymptomatic. The incubation period of toxoplasmosis is 6-10 days; symptoms, if present, include fever, fatigue, swelling of lymph nodes, sore throat, night sweats and rash. Although usually mild, the symptoms may last for months. In immunocompromised individuals, toxoplasmosis can be extremely serious, with central nervous system and eye damage, and in a pregnant woman, the infection can lead to serious developmental and physical defects in her newborn. Foodborne *Toxoplasma gondii* is most commonly associated with raw or undercooked meat, and clusters of illness in North America have been reported following consumption of raw game and goat's milk. [96: McDonald, 1990 #381]

2.3.6.4 Trichinella

Trichinella spiralis is a roundworm and though formerly common is now an uncommon cause of foodborne illness in the United States. The incubation period of trichinosis is 1-6 weeks, but may be longer. The initial symptoms include diarrhea, nausea, vomiting and abdominal pain caused by ingestion of the worm. Within several weeks, fever, fatigue, muscle pain, swelling around the eyes and rash appear, related to worm larvae forming cysts in muscles and organ tissues. The symptoms can last for months and cause serious complications, including heart failure. *Trichinella* species are a worldwide zoonosis of carnivores, and are particularly common in garbage fed pigs. Outbreaks of trichinosis in North America have been associated with consumption of raw or undercooked wild swine or other game. [79]

2.3.7 Prions

Prions are abnormal proteins believed to be the cause of diseases of animals and humans known as transmissible spongiform encephalopathies, or TSE. Following an incubation period of many years, TSE cause gradual and irreversible degeneration of the brain that leads to dementia, failure to thrive and death. The transmissibility of TSE by ingestion has been demonstrated in animals and humans.

Animal TSE affect sheep and goats (scrapie), mink (transmissible mink encephalopathy), deer and elk (chronic wasting disease) and cattle. Bovine spongiform encephalopathy (BSE), or "mad cow disease," was recognized in the United Kingdom in the 1980's and affected more than two million cattle. Since then, BSE has been reported throughout Europe, in Israel, Japan, Canada and two cases have been reported from the United States, in Washington State and Alabama.

Human prion diseases are extremely rare, and the majority occur spontaneously or result from a genetic defect. Creutzfeldt-Jakob disease (CJD) is the most common human prion disease, and typically affects individuals 55 years of age or older. This TSE has been transmitted from person-to-person via contaminated neurosurgical equipment, transplantation of corneas and the ritual ingestion of human flesh. In the United Kingdom in the 1990's, a syndrome very similar to CJD was identified in several young adults. This syndrome, which was distinguished from CJD by the youth of the victims, the noticeable psychiatric features and a more rapid progression, was named variant CJD and the source was soon suspected to be the consumption of ground beef derived from cows with BSE. The origins of BSE are unclear, but it is believed to be the outcome of feeding cattle animal protein contaminated with brain tissue, presumably from a cow with a spontaneous case of TSE.

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Comments on Chapter 2

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 3. Planning and Preparation

3.0 Introduction

The primary goal of a foodborne disease outbreak investigation is to identify the processes that let to food contamination or pathogen transmission and to implement control measures as quickly as possible to prevent further illness. Good planning and preparation help to accomplish this goal. A second goal is to understand the reasons for the occurrence well enough to prevent similar ones in the future. Including the right expertise in the investigation, and sharing the results rapidly can accomplish this goal.

The early days of an investigation are critical. Ideally an agency should have everything ready and should spend as little time as possible getting things organized. This chapter describes the roles of the major organizations involved in foodborne disease outbreak response and highlights the resources, processes and relationships that should be put in place before an outbreak occurs.

3.1 Agency Roles

3.1.1 Overview

A foodborne disease outbreak may be managed solely by a single local health agency or may become the shared responsibility of multiple local, state and federal agencies. The nature of the outbreak, including the type of pathogen, the suspected or implicated vehicle, the number and location of individuals affected, and the geographical jurisdictions involved in the outbreal will drive the types of agencies that need to be involved. This section describes the roles and responsibilities of each type of agency, the resources it typically has available, and the contributions it can make to outbreak investigation and response. Each agency's response plan should include contact information for relevant external agencies, and should cover contact, communication and escalation procedures for working with those agencies.

3.1.2 Local, State and Federal Agencies

3.1.2.1 Local Health Agencies

- Roles and Responsibilities

  Conducts surveillance; receives potential foodborne disease complaints; maintains and routinely reviews log of complaints; conducts routine communications with local health care professionals; conducts routine inspections of food preparation premises and investigations resulting from complaints; implements control measures to stop outbreaks; educates food workers on preventing foodborne disease outbreaks; provides information to the public and the media; serves as liaison with local industry representatives

- Available Resources

  Vary by agency, but may include expertise in epidemiologic and environmental outbreak investigation and response; and health information and promotion information for dissemination to the public. Extensive knowledge of local populations and community businesses, health care providers and organizations and other resources.

- Contributions to Outbreak Investigation and Response

  Detection of foodborne diseases; identification of local outbreaks; knowledge of suspect facilities (e.g., facility inspection reports, previous complaints); knowledge of affected communities; knowledge of local health care professionals and diagnostic practices

3.1.2.2 State Agencies – Health Department

- Roles and responsibilities

  Conducts surveillance; identifies local and statewide outbreaks; coordinates multi-jurisdictional outbreaks; provides advanced laboratory testing, including molecular fingerprinting in PulseNet; supports or directs environmental, laboratory, and epidemiologic investigations with advanced expertise; providing health education and promotion materials; maintains tools for collecting and analyzing outbreak associated information; provides public information; provides legal support for outbreak investigation and control; promotes statewide policies to increase food safety; serves as liaison with other state and federal agencies.

- Available resources

  Expertise in epidemiologic and environmental outbreak investigation and response (including traceback investigations); expertise in specific disease agents; advanced laboratory testing with expertise in microbial analyses and identification; health information and promotion information (often in multiple languages) for dissemination to the public; and additional staff to aid in outbreak investigations.

- Contribution to outbreak investigation and response

  Epidemiologic, environmental and laboratory support for local health agencies; coordination of multi-jurisdictional outbreaks.

3.1.2.3 State Agencies -- Agriculture Department

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

- Roles and responsibilities

  Ensures good manufacturing practices in commercial food operations; tests dairy, meat and food products for microbial contamination; conducts plant inspections following an outbreak; and coordinates food recalls. Also consults with health departments in outbreak investigations to aid the investigations (e.g. with knowledge of food production and distribution that may contribute to the success of the investigations) and to direct plant inspections by thoroughly understanding the epidemiologic, environmental, and laboratory data

- Available Resources

  Expertise in food manufacturing and distribution; staff to conduct plant inspections and specialized testing of dairy, meat and food products; expertise in regulatory tracebacks

- Contribution to outbreak investigation and response

Supporting investigations that involve commercially distributed food products through consultation with health department investigators, plant inspections, traceback investigations, and food recalls

3.1.2.4 Federal Agencies -- Centers for Disease Control and Prevention

- Roles and Responsibilities

  Conducts or coordinates national surveillance for illnesses due to pathogens commonly transmitted through food and for outbreaks of foodborne diseases of any cause; leads and supports the national surveillance networks, Foodnet, PulseNet and EFORS; maintains clinical, epidemiological, and laboratory expertise in pathogens of public health importance; develops and implements better tools for public health surveillance; provides consultation, assistance and leadership in outbreak investigations; improves and standardizes laboratory testing methods for foodborne disease organisms; provides advanced laboratory testing; coordinates multi-jurisdictional outbreaks where appropriate; provides training in methods; coordinates and collaborates with international surveillance, communication and training methods.

- Available Resources

  Experts (or trainees) in clinical, epidemiological and environmental health aspects to assist with cluster evaluation and outbreak investigations; advanced laboratory capacity (including resources to develop new testing methodologies); surge capacity to assist in large outbreaks; tools for collecting and analyzing outbreak-associated information; training programs; educational materials for the public.

- Contribution to Outbreak Investigation and Response

  Assistance in single jurisdiction outbreaks upon request of the jurisdiction; Leadership, coordination and logistics support and coordination for multi-jurisdictional outbreaks; centralized data collection and analysis for large multi-state outbreaks; assistance in outbreaks resulting from new or rare disease agents or from new modes of transmission of known disease agents; advanced laboratory testing; availability of additional personnel and other resources to aid local and state health agencies; conduit to other federal agencies

3.1.2.5 Federal Agencies -- Food and Drug Administration

- Roles and Responsibilities

  Regulates the safety of most foods, except for meat, poultry and pasteurized egg products that are regulated by the FSIS in USDA; regulates food additives and food labelling for FDA regulated foods; oversees seafood Hazard Analysis and Critical Control Point (HACCP) regulations; oversees imported food products; conducts research into foodborne contaminants; inspects food processing plants; conducts food industry post-market surveillance and compliance; oversees regulatory traceback investigations of the food products it regulates; publishes the Food Code.

- Available Resources

  Twenty District Offices located in five regions, providing coordination, field investigators, laboratory support, technical consultation, regulatory support, and media relations. FDA's Center for Food Safety and Applied Nutrition (CFSAN) provides policy, technical, and scientific support to foodborne disease outbreak investigations. Also provides education materials for the public.

- Contribution to Outbreak Investigation and Response

  Once an FDA regulated product is strongly suspected, identifying source of product and extent of its distribution; testing product obtained from commerce or production; conducting traceback and factory investigations; preventing further exposure to contaminated product; and initiating regulatory action including recalls if indicated. The FDA also assists the Federal Bureau of Investigation when deliberate contamination of food is suspected, supporting the investigation by providing technical, investigatory and laboratory support for products regulated by the FDA.

3.1.2.6 Federal Agencies -- U.S. Department of Agriculture/Food Safety and Inspection Service

- Roles and Responsibilities

  Ensures that the nation's commercial supply of meat, poultry and pasteurized egg products is safe, wholesome and correctly labelled and packaged through a national program of inspection, investigation and enforcement activities; provides data analysis, advice and recommendations on food safety; responding to foodborne illnesses, intentional food contamination and major threats to the Food Safety Inspection Service (FSIS)-regulated products including conducting recalls for contaminated meat and poultry products; conducts audits to determine the equivalency of foreign food safety systems and re-inspecting imported meat, poultry and egg products; develops public information and education programs for consumers

- Available Resources

  Approximately 7,600 inspection program personnel in more than 6,000 federally-regulated establishments nationwide coordinated by 15 district offices; three field laboratories including the Outbreaks Section of Eastern Laboratory in Athens, Georgia; field investigators with expertise in inspection, traceback, and enforcement activities; personnel with expertise in food safety science; educational materials and guidance for consumers.

- Contribution to Outbreak Investigation and Response

  Assistance, traceback coordination and epidemiologic consultation during investigations involving FSIS-regulated meat, poultry and egg products; ability to take enforcement and regulatory control actions against food manufacturers and distributors; assistance in working with international food manufacturers and distributors; consultation to public health and state agriculture agencies

3.1.3 Other Agencies

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

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

3.1.3.1 Tribes

- Jurisdiction

  Varies by tribal organization, but in general the tribes have complete sovereignty and are completely autonomous. Investigations may be conducted by tribal health staff, Indian Health Services (IHS) staff, or state or local health departments, but non-tribal entities can only become involved in an investigation at the request of the tribe. There is no legal requirement for reporting a foodborne disease outbreak to any public health officials. Control measures are typically implemented by IHS staff in cooperation with tribal government, but can only be implemented when authorized by tribal government.

- Relationships

  Outbreaks may be detected by IHS staff or by tribal members and reported to the IHS. IHS notifies the appropriate state and local health departments. Some tribes may also notify the local or state health department or the CDC. State and local health department staff need to develop relationships with IHS public health staff, tribal health staff (if any), and tribal leadership in tribal areas within or adjacent to the public health agency's jurisdiction. During an outbreak there should be communication not only between state or local health department and IHS in an outbreak but also directly with tribal government. IHS has developed tribal epidemiology centers to provide regional epidemiology capacity for multiple tribes. These centers are run by tribal boards, and focus their activities on health issues selected by the boards. They may become involved in outbreak investigations and are a good place to promote routine communication. IHS is a good source of information on how to coordinate public health issues with tribes.

- Resources for Outbreak Investigation and Response

  IHS has many public health staff including sanitarians and public health nurses at clinics on many tribal lands. These individuals most likely would be the ones dealing directly with an outbreak, and would request help from the IHS, the state or the CDC if needed. Some tribes have public health staff. Most tribes do not have public health laws or capacity to respond to outbreaks.

3.1.3.2 Military

- Jurisdiction

  Autonomous authority over all military bases, facilities (including food production/service facilities and health care service facilities), and vehicles. Public health responsibility is maintained by the particular branch of the military involved and also by the Department of Defense (DOD).

- Relationships

  Military public health personnel communicate with local and state health agencies for outbreaks that may involve civilian populations. Local and state health agencies should establish communication with the public health staff of any military facilities within or adjacent to their jurisdiction before any outbreaks occur. Coordination with other branches of the military and with other federal agencies occurs through the Foodborne Outbreak Response Coordinating Group.

- Resources for Outbreak Investigation and Response

  Military agencies conduct training in food safety and epidemiology; inspect and test food production/processing facilities and delivered food products; and coordinate these programs with other military and federal agencies. Preventive Medicine and Environmental Health Officers in each branch direct and conduct epidemiologic investigations of food borne disease outbreaks, and make recommendations. Veterinary Officers conduct traceback investigations. The DOD has officers trained in public health, environmental health, epidemiology, microbiology, toxicology, pathology, and food technology capable of providing coordination and support in outbreak investigations.

3.1.3.3 National Park Service

- Jurisdiction

  Three types: 1) exclusive federal jurisdiction in very large national parks; 2) concurrent jurisdiction with state and local agencies in the vast majority of parks; 3) proprietary – owned by the federal government but may be operated by local entity depending on support from local police, fire departments and others for services.

- Relationships

  Notifies relevant local and state health departments when an outbreak is suspected. Notifies appropriate federal agency if commercial product is suspected. Works closely with CDC. Relies on CDC or state health departments for laboratory testing. Local and state health agencies whose jurisdiction contains or is adjacent to a national park should establish communication with the NPS Office of Public Health before any outbreaks occur. Where appropriate, local and state health departments should include questions about visiting parks when they conduct interviews during an investigation, and to notify the NPS if a park may be involved.

- Resources for Outbreak Investigation and Response

  Epidemiology expertise including a medical epidemiologist in the NPS Office of Public Health; USPHS (U.S. Public Health Service) staff assigned to the NPS to conduct investigations (including regional public health consultants who are based around the country); park rangers who have extensive knowledge of their jurisdiction and the population that visits that jurisdiction; scientists in the NPS system with a wide range of expertise (veterinarians, water specialists, etc); contractors who run park operations on behalf of the NPS.

3.1.4 Other Potential Outbreak Settings

3.1.4.1 Other Federal Lands

- Jurisdiction

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

3.2 Outbreak Investigation and Control Team

3.2.1 Overview

The responsibility for conducting foodborne outbreak investigation and implementing control measures falls on a team of individuals who each contribute different knowledge and skill sets. Depending on the size and scope of the investigation, the size of the team may vary from one or two to hundreds. In smaller investigations, individuals may wear many hats concurrently. A team is more likely to effectively and efficiently respond to the outbreak if they combine their strengths and work collaboratively.

The team members' roles are defined by their assigned tasks as well as their knowledge and skills . Job titles alone may not provide an accurate indication of who does what. Members may come from different programs within an agency or from different agencies. Membership in the outbreak response team may vary depending on the specifics of the outbreak – for example, different disease organisms or different outbreak settings may require different skill sets or agency associations. In many investigations, roles are defined relatively informally, and they may change as the investigation unfolds.

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

Most importantly, team members should work closely together as a team, not in isolation. The roles are not mutually exclusive – epidemiologists can help laboratorians, laboratorians can help environmental health specialists, etc. Furthermore, the work of one team member often builds on that of the others. The team cannot succeed without a strong working relationship and ongoing, effective communication between its members.

3.2.2 Core Team Member Roles

Keep in mind that many of these roles may be played by the same individual(s), depending on the size of the investigation.

3.2.2.1 Team Leader

- Responsibilities

  Sets and enforces priorities; coordinates all activities associated with the investigation; serves as the point of contact regarding the investigation; coordinates content of messages to the public; communicates with other organizations involved in the investigation; and makes recommendations to agency decision-makers on course of action

- Desirable Skills

  Should include organization of investigation information; general knowledge of all elements of an outbreak investigation and the roles of each team member; specific expertise with outbreak investigation methods and with foodborne infections;

understanding of roles of all agencies involved in investigation; ability to communicate; and leadership skills

3.2.2.2 Epidemiologic Investigator

- Responsibilities

  Identifies and interviews cases; develops hypotheses and strategies to test them; interviews both case-patients and healthy controls; plans epidemiologic studies; collects and analyzes investigation data, using statistical analyses or in collaboration with a statistician; collects clinical specimens; coordinates testing of clinical specimens; and consults with environmental and laboratory investigators

- Desirable Skills

  Should include rapidly assessing the situation using available data; interpreting surveillance information; designing epidemiologic studies (e.g., case-control studies, cohort studies, and surveys) and developing questionnaires; conducting epidemiologic studies; conducting interviews, including hypothesis generating interviews; with assistance from the laboratory investigator, identifying appropriate clinical tests for suspect pathogens; and analyzing and interpreting data using standard epidemiologic methods as defined in the Applied Epidemiology Competencies including measures of association and tests of statistical significance (reference).

3.2.2.3 Environmental Investigator

- Responsibilities

  Investigates food preparation sites including sites involved with growing, raising, processing, packaging, or preparing food; collects environmental and food samples; arranges for testing of samples; coordinates food sampling, management and testing procedures with Laboratory Investigator; interviews food workers and managers; reviews food preparation and handling records; reviews food inventory and distribution records, food flow and identifying contributing factors; and consults with epidemiologic and laboratory investigators. May also interview cases, collect stool samples, and conduct traceback investigations.

- Desirable Skills

  Should include investigating food preparation processes; conducting interviews; and collecting food and environmental samples. To be successful, the environmental investigator must know about the causative agent (e.g., likely sources, optimum growth conditions, inhibitory substances, means of inactivation), factors necessary to cause illness (e.g., infectious dose, portal of entry), and the implicated vehicle (e.g., physical and chemical characteristics of the vehicle that might facilitate or inhibit growth, methods of production, processing, preparation)

3.2.2.4 Laboratory Investigator

- Responsibilities

  Conducts necessary laboratory analyses of clinical specimens and environmental samples; interprets test results and suggesting follow-up testing; reports results;

coordinates testing between laboratories; and advises other team members on laboratory testing, including collection, handling, storage and transport of specimens.

- Desirable Skills

  Will vary with the suspect outbreak agent(s) but may include classical or molecular microbiology, and organic, inorganic, or radiochemistry. The laboratory investigator should be familiar with optimal specimen or sample types, transport and storage conditions including chain of custody, available testing methodologies, and relevant laboratory-based networks (e.g., PulseNet).

3.2.2.5 Public Information Officer

- Responsibilities

  Develops general and specific messages for the public through the media; responds to media inquiries or identifies the appropriate spokesperson; coordinates communication with multiple agencies.

- Desirable Skills

  Should include preparing health education messages and press releases using best practices in health education and risk communications; speaking and presentation skills.

3.2.2.6 Additional Team Members

Additional team members with other expertise may be needed, depending on the unique characteristics of the disease or outbreak. Such individuals may include statisticians, to assist in the design of investigation studies and questionnaires, and analysis of data in large or complex outbreaks; health educators, to help craft communications for the public; Statisticians, to analyze data in large or complex outbreaks; and health care providers, to administer prophylactic medications.

3.2.3 Outbreak Investigation and Control Teams -- Model Practices

The following section lists model practices for outbreak control teams. While these are all recommended, it is recognized that full implementation all these practices may not be possible in many jurisdictions due to resource limitations and competing priorities. Implementing as many as possible and as completely as possible will improve the effectiveness of outbreak control teams.

3.2.3.1 Emergency Response Unit

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

3.2.3.2 Additional Support for Large-Scale Outbreaks

Some outbreaks are too large for a single agency to manage independently. Preparations can be made in advance to help mitigate the impact of a large-scale outbreak and to assure effective response.

- Identify individuals within the agency or from other organizations such as other branches of government, university students, volunteers such as a Medical Resrve Corp, etc, who would have a minimal set of skills or knowledge and be wiling to help conduct interviews or provide other support during a large-scale outbreak.

- Develop a contact list and contact protocol for contacting these individuals when needed. Ensure that the list includes after-hours and weekend contact information, and update it at regular intervals.

- Develop training and job description(s) for these individuals. If possible, provide on-the-job training to these individuals specific to the tasks they have been asked to do and their role in the overall investigation. Such training could occur shortly before performing the necessary task.

3.2.3.3 Agency-Specific Response Protocol and Other Resources

At a minimum, the outbreak control team should have specific, pre-identified protocols to follow and should be trained in those protocols. The team also needs access to additional resources that can help answer questions and provide key information for decision-making during an outbreak. These protocols and resources should be assembled before an outbreak occurs.

- Prepare a response protocol, based on the CIFOR guidelines but customized for the agency's needs with specific information relevant to the agency

- Prepare a list of contact people in the agency (names, contact numbers, etc) including back-ups, as well as contact people in external agencies (state, adjacent local health, and federal agencies). Ensure that the list includes after-hours and weekend contact information, and update it at regular intervals.

- Assemble a reference library (including online resources) with information on foodborne disease, enteric illnesses, and control measures. Where possible include resources in electronic form that can be accessed via laptop computers during investigations. Review and update the contents of this reference library on a regular basis.

- Assemble a list of resource persons with expertise in specific disease agents and investigation methodologies.

3.2.3.4 Training for Team

On-going training is critical for outbreak control team members. The training should include general continuing education as well as specific training in the agency's outbreak response protocols and the member's team role. For a larger agency with a large number of outbreaks, this may take the form of on-the-job training. For a smaller agency with a limited number of outbreaks, special training opportunities should be arranged.

- Ensure that all team members have a common understanding of the primary goal for outbreak response, which is to implement control measures as quickly as possible to prevent illness.

- Provide team members with continuing education and training opportunities (referenced in Appendix ___ of these guidelines).

- Exercise teams together to assure that each team member understands and can perform his or her role according to the agency-specific protocols and understands the roles/responsibilities of other team members. These exercises can also identify likely problem areas and gaps in resources before an outbreak occurs.
- Conduct regional training with multiple agencies, including table-top exercises. This can help identify problems that may arise during a multi-jurisdictional outbreak.
- Make training interesting, covering not just methods and statistics but also what happened to the people in the outbreak and the investigation.
- Outbreaks themselves provide training opportunities. If an agency does not have frequent outbreaks, team members may be able to assist in the response to outbreaks in other jurisdictions. This can help promote learning and also provide valuable insights that an agency can use to refine its own protocols.
- Conduct a debriefing following each outbreak. These debriefings can be used to identify lessons learned and to refine the agency's response protocols.
- Foodborne disease outbreaks provide a good training ground for any epidemiologic investigation. Involving other agency staff in investigations, even if their regular job is not related to food safety, can both enhance the investigation and render these staff better prepared to assist in future investigations.

3.3 Necessary Resources

3.3.1 Overview

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

3.3.2 Recommended Resources

3.3.2.1 Administrative Staff

- Support personnel to make phone calls, answer incoming calls from concerned members of the public, enter data into a database, copy paperwork, etc.
- Legal personnel to review agency procedures, control measures, confidentiality, and public health orders

3.3.2.2 Equipment (Figure 3.1)

Figure 3.1 Outbreak Investigation Equipment.

- Sterilization equipment for sample collection tools
- Temperature checking probes
- Equipment to determine food characteristics (e.g., pH, water content, sugar content)
- Conference call capabilities/equipment
- Multiple phone lines available
- Computers, laptops, software (e.g. data entry, statistical), portable printers, paper, graph paper, pens, clipboards

3.3.2.3 Supplies

Note -- Foodborne outbreak investigation kits should be maintained in ready-to-use condition, with sampling containers implements kept sterile. Conduct an inventory at least twice a year (preferably quarterly), replace missing and expired materials and re-sterilize existing equipment. Detailed information on kits and sample lists are included at the CIFOR Clearinghouse.

- Clinical Specimen Kits
    - Stool specimen kits, including instructions and stool hats
    - Blood drawing kits
- Food Sample Containers and Inspection Equipment (Figure 3.2)

Figure 3.2 Food and water sampling kit supplies.

- Sterile sample containers (e.g., plastic bags, wide mouth plastic and glass jars with screw caps, bottles, whirlpack bags) and mailing instructions
- Sterile and wrapped sample collection implements (spoons, scoops, tongue-depressor blades, spatulas, swabs, knives)
- Sterilizing and sanitizing agents (e.g., 95% ethyl alcohol, sodium or calcium hypochlorite, alcohol swabs)
- Refrigerants (e.g., ice packs), thermometer (0-220ºF), insulated containers
- Labeling and sealing equipment (e.g, fine-point felt tip marking pen, roll of adhesive or masking tape, waterproof labels/tags, sample forms)
- Clothing (e.g., disposable plastic gloves, hair restraint, laboratory coat)
- Personal protective equipment (gloves and masks)

3.3.2.4 Outbreak Investigation Documents (Figure 3.3)

Figure 3.3 Outbreak Investigation Documents.

Note: These and other sample documents are available from the CIFOR Clearinghouse.

- Chain of custody forms
- Food illness complaint worksheets
- Sample case report forms
- Oregon and Minnesota Foodborne Disease Questionnaires [available at http://www.cdc.gov/foodborneoutbreaks]

3.3.2.5 Reference Materials

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

3.4 Complaint Processing

Establish a formal process for receiving complaints from members of the public. A standard process should be used for collecting information, including use of a standard intake form. As much information as possible should be collected on the initial call. Ideally all illness complaints should be received or processed by a single individual, so that patterns can be identified quickly. Individuals receiving calls and any back-up staff should be trained to give appropriate instructions to the callers. Further detail on complaint processing systems is included in Chapter 4.

3.5 Records Management

3.5.1 Overview

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

3.5.2 Recommended Records Managements Practices

3.5.2.1 Information collection and sharing

- Identify standard forms, including illness complaint forms, disease-specific report forms, and trawling interview questionnaires, for recording information about potential cases (examples of such forms are available through the CIFOR Clearinghouse). These forms may need to be modified depending on the specifics of the outbreak.
- Train staff in the use of standard forms to assure consistency across the investigation team.
- Determine how and what information from forms and questionnaires can be properly and efficiently shared within the investigation team
- *Determine when and how to communicate with the person/organization in charge of the facility implicated in an outbreak.*

3.5.2.2 Data tracking and analysis

- Establish an enteric illness log or database to track all illness complaints. A database with templates for rapid data entry and analysis will streamline the data management process.
- Identify the tools that will be used for analysis of outbreak data (EpiInfo, etc). Ensure that staff are trained in the use of these tools.

- Assure that appropriate electronic records management procedures are in place, including routine data back-ups, off-site redundant storage, and disaster recovery procedures.

3.6 Communication

3.6.1 Overview

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

3.6.2 Communication -- Model Practices

The following section lists model practices for communication. While these are all recommended, it is recognized that full implementation of all of these practices may not be possible in many jurisdictions due to resource limitations and competing priorities. Implementing as many as possible and as completely as possible will improve the effectiveness of communication.

3.6.2.1 Contact Lists

Establish and frequently update a contact list (primary phone numbers and alternates, 24 hour numbers, home numbers, pagers, email, fax, and addresses)

- Core outbreak control team members
- Other officials inside agency such as the chief of the epidemiology unit, director of the public health laboratory, and the agency director
- Critical contacts in other governmental agencies
- Key food industry contacts
- Key health care provider contacts
- Key media contacts

Ensure that the contact list is updated at least twice yearly. This is usually much more difficult than expected, and will require tenacity, but it is critical for mobilization of resources in emergencies.

3.6.2.2 Communication between the agencies and units comprising the Outbreak Control Team (e.g. between epidemiology, environmental health and laboratory)

- Ensure that all who may be involved in outbreak response know who the other members of the team are

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

3.6.2.3 Communication with Other Local, State and Federal Authorities

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

3.6.2.4 Communication with Local Organizations, Food Industry and Other Professional Groups (Including Health care providers)

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

3.6.2.5 Communication with the Public

- Create templates for communications with the public (press releases, fact sheets, etc), focusing on the most common foodborne diseases. Sample materials are available at the CIFOR Clearinghouse.
- Create and test web-based tools for communication with the public (blast emails, survey instruments, etc).
- Periodically issue foodborne disease prevention messages to the public to reduce illness and to assure that the public knows who to communicate with (which is often their primary care provider) and where information will come from when a foodborne disease outbreak occurs.
- Establish standard channels of communication (web-site, telephone number, etc) and use those same channels each time there is a public health issue where the public may be seeking information. Make sure the public knows the source or that it is published in a place the public is likely to consult.

3.6.2.6 Communication with the Media

- Identify an agency lead on media interactions, ideally someone trained as a public information officer. Establish procedures for coordinating communication with the media.
- Obtain media training for key agency spokespersons.
- Identify contact persons from major local media outlets.
- Periodically hold a media education event, to teach any new media professionals in the community's media market about public health and foodborne disease outbreak response.
- Find out about routine deadlines and timeframes for reporting news through major local media outlets (e.g., how late can they receive a press release to have a story appear in the evening paper?)
- Establish standard channels of communication (web-site, telephone number, etc) and use those same channels each time there is a public health issue where the public may be seeking information.

3.7 Planning for Recovery and Follow-up

3.7.1 Overview

Part of preparing to respond to an outbreak is planning for the recovery and follow-up stages. Ensure that your agency's protocols include actions that will be taken when the outbreak is over. Having standardized processes for recovery and follow-up will help to guarantee that the appropriate actions are taken for each outbreak and that investigation difficulties are identified and rectified before the next outbreak.

3.7.2 Recommended Preparations for Recovery and Follow-up

- Establish standard protocols for what actions must be taken or results that must be achieved before an implicated facility or food source can return to normal operations.

- Establish standard protocols for monitoring an implicated facility or food source if monitoring post-outbreak should be deemed necessary.
- Establish a process for creating after-action reports following investigations with lessons learned and action items for follow-up.

3.8 Legal Framework

An outbreak response team will have more confidence in its ability to respond to and control an outbreak if it is sure that the necessary legal framework is in place. This includes local and state statutes and regulations to support surveillance, detection, investigation, and control activities. Chapter 10 in these guidelines provides detailed information on legal issues that may be encountered and how an agency can develop a legal framework to support its foodborne disease control activities.

3.9 Escalation

3.9.1 Overview

While a single agency is likely to be able to independently manage most outbreaks that it encounters, there will be many outbreaks where the agency will need to and should ask for help. In addition, many outbreaks that an agency encounters will become part of a multi-jurisdictional investigation.

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

Always remember that even an apparently local outbreak may be the "herald event" that is part of a much bigger problem. This is especially true of an outbreak that appears to be associated with a facility that is part of a regional or national chain, or when the suspect food is in general commercial distribution. Other indications of multi-jurisdictional outbreaks are listed in Chapter 8.

3.9.2 When to Ask for Help

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

3.9.3 How to Obtain Help

- Steps in asking for help will vary depending on which agency is asking for help and for what purpose.
- At the local level, call State Epidemiologist or his/her surrogate. Most state epidemiology offices have a 24-hour number and someone on 24/7 call.
- At the state level, call the most appropriate office at the CDC, or the CDC emergency response number, which is staffed 24/7. The emergency response staff will contact the appropriate office at the CDC.
- If the suspected product is under the jurisdiction of one of the food regulatory agencies, contact that agency using their 24-hour contact number.

3.10 Incident Command System

3.10.1 Overview

Increasingly agencies that are responding to a public health emergency, occasionally including foodborne disease outbreaks, may consider using an Incident Command System (ICS) to help coordinate response. Agencies that are implementing an ICS need to determine what types of events or outbreaks will trigger the use of such a system. Most foodborne disease outbreaks do not need a formal ICS response, while a large-scale outbreak or an outbreak clearly related to intentional product tampering could benefit from it. If an ICS structure is to be used, it should be incorporated into the agency's foodborne disease outbreak response protocol.

The role of an ICS response in outbreak investigations is variable and not without controversy. Even within a single investigation, some agencies may utilize an ICS structure while others do not.

3.10.2 Definition of ICS

The ICS was originally developed in the 1970's to coordinate activities to control wildfires in California. The system has been expanded and integrated into the Federal Emergency Management Agency's National Incident Management System to aid intra- and interagency coordination, especially during large-scale emergency events that involve multiple jurisdictions. The ICS features a clearly defined chain of command with common nomenclature for key management positions; defined management sections; and a modular organizational structure; and uses specifically defined emergency response function roles. Some agencies involved in the investigation and response to foodborne disease outbreaks may implement ICS for the management of their response before other agencies do. All agencies will need to work together to ensure that such responses are carried out in the most effective way possible. Chapter 7 within these Guidelines on multi-jurisdictional outbreaks provides additional guidance in coordinating response to widespread outbreaks.

3.10.3 Context for Use

3.10.3.1 Small Scale Event (limited outbreak, only affecting a small population within the local health agency's jurisdiction)

- If desired, an agency can define roles and responsibilities for the outbreak investigation and response team within the context of the ICS command structure and can use that structure to assure appropriate communication and coordination within the agency.

3.10.3.2 Large Scale Event (multi-jurisdictional, involving widespread population across multiple states and/or a commercially distributed product)

- Local health agency outbreak response team becomes a unit within a regional or national ICS command structure; this defined structure expedites communication and decision-making.

3.10.4 Training

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

3.10.5 References

K. Qureshi, KM Gebbie and EN Gebbie. 2005. *Implementing ICS within Public Health Agencies.* University at Albany, SUNY. http://www.ualbanycphp.org/pinata/phics/guide/default.cfm

Comments on Chapter 3

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 4. Foodborne Disease Surveillance and Outbreak Detection

4.0 Introduction

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

One of the primary functions of foodborne disease surveillance and investigation of the outbreaks detected is to detect problems in our food and water production and delivery systems that might otherwise have gone unnoticed. Rapid detection and investigation of outbreaks along with follow-up action and continued surveillance:

- Allows prevention of ongoing transmission,
- Allows determination of the circumstances leading to causes of contamination, so that future outbreaks can be prevented altogether, and
- Provides a basis for evaluation of control and prevention efforts.

Broader goals of surveillance include defining the magnitude and burden of disease, providing a platform for applied research, and facilitating better understanding of foodborne disease epidemiology.

Unlike food monitoring programs, which seek to identify problems in food production so they can be corrected before illness occurs, foodborne disease surveillance activities cannot by definition prevent initial cases of disease. Nevertheless, surveillance represents the most sensitive tool available for identifying failures anywhere in our food supply systems. While food monitoring must concentrate on monitoring the effectiveness of risk reduction procedures at critical control points, the range of potential contaminated food vehicles that could be detected by foodborne disease surveillance includes all food or other substances consumed in the surveillance area, contaminated at any point in the chain from production to consumption. Foodborne disease surveillance complements regulatory and commercial monitoring programs by providing primary feedback on prevention program effectiveness.

Over the years, foodborne disease surveillance, coupled with outbreak investigation, has remained among the most productive public health activities, resulting in the recall of hundreds of millions of pounds of contaminated products and prompting numerous large and small changes in our food production and delivery systems. Indeed, most of the improvements in food safety that have occurred in the last 100 years are the direct or indirect result of outbreak investigations (ref). However, current surveillance practices are widely variable and unevenly resourced, and have in general exploited only a fraction of the system's potential.

4.1 Overview

Disease surveillance methods are used to identify clusters of enteric illness. Investigation methods (Chapter 5) are then used to identify exposures the cluster of ill persons have in common that distinguish them from healthy persons. Although in practice multiple approaches may be involved in detecting individual enteric disease outbreaks, there are three general methods for detecting such outbreaks: pathogen-specific surveillance, notification/complaint systems, and syndromic surveillance. These three methods will be described in detail in the following sections, and are summarized below and in **Table 4.1**.

a. **Pathogen-specific surveillance**: Health care providers and laboratorians report individual cases of disease when selected pathogens such as *Salmonella enterica* or *E. coli* O157:H7 are identified in specimens from patients. This type of surveillance also includes specific clinical syndromes with or without laboratory confirmation, such as hemolytic uremic syndrome or botulism. Exposure information is gathered by case interviews after the case is reported. Data and pathogens collected as part of food, animal, or environmental monitoring programs enhance this type of human disease surveillance. The national PulseNet system is an example of pathogen-specific surveillance.

b. **Notification/complaint systems**: Suspect disease clusters or independent complaints are identified and reported by healthcare providers or by the public, and exposure information is acquired by case interviews.

c. **Syndromic surveillance**: This type of surveillance generally involves systematic (usually automated) gathering of data on non-specific health indicators that may reflect an increase in disease occurrence, such as Immodium® use, ER visits for diarrheal complaints, or calls to poison control hotlines. Exposure information is not routinely collected.

This chapter reviews key features, strengths and limitations of of the above methods of outbreak detection, and provides recommendations for increasing the effectiveness of each. These guidelines are focused on foodborne disease, but many of the agents spread by food can also be spread by water, person-to-person transmission, animal-to-person transmission, or by other mechanisms. Therefore, outbreaks are not considered as “foodborne” until determined to be so during the investigative phase.

Table 4.1: A Comparison of Foodborne Disease Surveillance Systems

Type of surveillance--->	**Pathogen-specific**	**Notification, Complaint**		**Syndromic**
		Group notification	**Independent complaint**	
Inherent speed of outbreak detection	Relatively slow	Fast	Fast	Potentially fast[1]
Sensitivity to widespread, low level contamination events (best practices used)	High	Intermediate	Intermediate	Low[2]
Types of outbreaks (etiology) that system can potentially detect	Limited to clinically suspected or laboratory confirmed diseases under surveillance	Any[3]	Any, although effectiveness limited to agents with short incubation periods[3]	Limited to syndromes (or indicators) under surveillance

Initial outbreak signal (at public health level)	Cluster of cases in space or time with common agent	Report of group illnesses recognized by health care provider, laboratory, or the public	Multiple independent reports with common exposures in space or time or unique clinical presentation	Trend in health indicator different from expected, space/time clusters of diagnosed cases
Number of cases needed to create initial signal	Low to moderate	Low	Low to moderate	High[4]
Signal: Noise	High (after interview of case and collection of 5 day food history) Even higher when combined with subtyping	High (after interview of case and collection of 5 day food history)	Low to moderate (after interview of case and collection of 5 day food history)	Low[5,6]

[1] An advantage in speed is mainly limited to non-specific health indicators (pre-clinical and clinical pre-diagnostic data). A follow-up investigation is required, including comparison with standard surveillance before public health action can be taken.

[2] Sensitivity is higher for rare, specific syndromes such as botulism-like syndrome.

[3] While outbreaks may be detected without an identified etiology, linking multiple outbreaks to a common source may require agent information.

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

[5] Exposure histories are not typically obtained.

[6] A high signal to noise ratio means that even a small number of cases stand out against a quiet background. A low ratio means that it is hard to perceive a cluster of cases or events because they aer lost in the many other similar cases or events happening at the same time, like a weak radio signal lost in a lot of static noise. The signal to noise ratio is lowest for non-specific health indicators, such as Immodium® use or visits to the emergency room with diarrheal disease complaints. The ratio increases with increasing specificity of agent/syndrome information. For highly specific, rare syndromes, such as “botulism-like” syndrome, the signal to noise ratio would approach that of pathogen-specific surveillance.

4.2 Definitions

Surveillance: The systematic collection, analysis, interpretation, and dissemination of data for public health action.

Foodborne disease: Any disease caused by consumption of food. Although some agents are more likely to be transmitted by food than others, the identification of foodborne, waterborne, or person-to-person transmission requires investigation. Furthermore multiple modes of transmission may be involved in any single outbreak.

Foodborne disease surveillance: Surveillance of diseases or conditions which may be foodborne. Thus, all diseases of enteric origin potentially may be tracked by this mechanism, including diseases such as noroviru which involve a substantial amount of person-to-person transmission, listeriosis which may have a diarrheal stage but is generally detected by blood culture or botulism which presents as neurological disease.

Cluster: An unusual aggregation of similar health events, generally grouped together in time or space. A cluster may be seen as the occurrence of cases of disease in excess of what is usually expected for a given period of time. A cluster may, or may not reach the status of an "outbreak." The use of the term is particularly common in describing the results of subtype-based surveillance, which may detect a cluster of infections caused by similar microbial strains.

Outbreak: The occurrence of two or more cases of a similar illness shown by an investigation to result from a common exposure such as consumption of a common food. An outbreak is a cluster with a clear association between cases, with or without a recognized common source or known disease agent. Single cases of certain serious conditions, such as gastrointestinal anthrax, botulism, or cholera elicit an outbreak-like response.

Sporadic case: A case that is not linked epidemiologically to other cases of the same illness. Note that single sporadic cases of extremely rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera merit a detailed investigation as soon as possible, as though they were outbreaks, in order to prevent any further cases from occurring.

Trawling questionnaire: This term commonly refers to interview forms designed to capture a wide range of exposures. They are sometimes called "hypothesis-generating" or trolling or shotgun questionnaires. These forms may be designed with embedded questions focused on disease-specific hypotheses, which may serve to consolidate the hypothesis generation and testing processes into a single step. For instance, the trawling questionnaire for an outbreak of E. coli O157:H7 may contain questions about standard transmission mechanisms for this agent such as hamburger consumption, day-care attendance, recreational pool use, animal exposures, and other exposures identified in previous outbreaks which function as a priori hypotheses.

Reportable Conditions (notifiable diseases): The list of diseases based on state laws or regulations that should be reported by health care providers (e.g., health care providers, laboratories, hospitals) to local or state health agencies. The list of notifiable diseases and legal obligation for reporting differs from state to state. States can report notifiable diseases to the CDC, which maintains a list of nationally notifiable diseases, but compliance is voluntary. The CDC reports selected diseases to the World Health Organization in compliance with International Health Regulations.

PulseNet: PulseNet is an international surveillance network made up of national, state and local public health and food regulatory agency laboratories that conduct standardized molecular subtyping of foodborne disease pathogens ("DNA fingerprinting") and maintain centrally accessible databases of patterns. PulseNet also functions as a communication hub for laboratories involved in food and foodborne disease monitoring.

EFORS: Electronic Foodborne Outbreak Reporting System. A secure web-based reporting system that allows state health departments to report foodborne disease outbreaks to the CDC electronically. EFORS is being subsumed into the National Outbreak Reporting System (NORS) which will include outbreaks due to all transmission routes including waterborne, person-to-person, and animal contact.

Foodnet Atlas of Exposures: The results of periodic population-based surveys undertaken at selected sites in the U.S. The survey collects information on exposures that might be associated with foodborne illnesses and can be used to estimate the background rate of different food exposures in the community.

4.3 Pathogen-Specific Surveillance

4.3.1 Purpose

To systematically collect, analyze, and disseminate information on cases of laboratory-confirmed illnesses or well-defined syndromes as part of prevention and control activities. One important goal of pathogen-specific surveillance for foodborne disease (but not the only goal) is to identify clusters of cases that may be caused by a common food source in order to interrupt ongoing transmission to develop and prevention strategies.

4.3.2 Background

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

4.3.3 Case Reporting and Laboratory Submission Process

Most diseases included under pathogen-specific surveillance are reportable diseases. State or local health agencies establish criteria for voluntary or mandatory reporting of infectious diseases, including those that may be foodborne. These criteria describe which diseases to report, to whom, how, and in what timeframe. For this type of surveillance, diseases are defined by specific laboratory findings, such as isolation of *Salmonella enterica*, or by well-defined syndromes, such as hemolytic uremic syndrome. Diseases are primarily reported by laboratories, medical staff (e.g., physicians, infection control practitioners, medical records clerks), or both. Reporting can be by telephone, mail, fax, through a secure web-site, or automatically via reports that are generated from an electronic medical record or laboratory information system. In addition, isolates or other clinical materials are forwarded from laboratories serving primary healthcare facilities to public health laboratories for confirmation and further characterization, as required by state laws or regulations or requested by the local jurisdiction. The CDC works with the states to compile national surveillance data. See **Table 4.2** for a list of nationally notifiable diseases that can be foodborne. Requirements for individual states can be found at: http://www.cste.org/nndss/reportingrequirements.htm

Table 4.2: Selected Nationally Notifiable Diseases Which May Be Foodborne

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

From CDC. Nationally Notifiable Infectious Diseases. United States 2007, Revised http://www.cdc.gov/epo/dphsi/phs/infdis2007r.htm

4.3.4 Epidemiology Process

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

Cases may be interviewed one or more times in this process in order to gather information on potential exposures, as well as additional clinical and demographic information. The scope of these interviews may vary during an investigation and may cover basic descriptive information and exposures of primarily local importance, such as attendance at a day care facility, extensive hypothesis generating "trawling" questionnaires, or medical follow-up information.

Agent, time, and place factors are examined individually and in combination to identify potentially significant clusters or trends. Clusters of unusual exposures reported by cases, abnormal exposure frequencies, or unusual demographic distributions (e.g., predominance of cases in a particular age group) may be identified in this process. Clusters of cases are examined as a group, and may be further investigated if a common exposure seems likely.

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

Questionnaire data are not the sole source of information available to investigators, who should also take advantage of product distribution data or noteworthy "coincidences" as they are identified. The most successful investigators develop and consider information from as wide a variety of sources as possible.

4.3.5 Public Health Laboratory Process

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

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

National notification or inquiries may be conducted via the PulseNet system if multi-jurisdictional outbreaks are suspected. Since this type of surveillance depends on primary diagnosis in hospital or clinical laboratories, the Public Health Laboratory may play a role in laboratory quality improvement or monitoring.

In the individual case of botulism, and occasionally in an individual case of other infections, testing food or other environmental specimens is useful (e.g. pet reptiles in a case of Salmonella infection or frozen ground beef in the case of an E. coli O157:H7 infection), but it is otherwise not advised. Without strong epidemiologic data, microbiological screening of food to investigate clusters is generally unproductive and it is always resource intensive. However, this approach is occasionally warranted when there are not too many suspect foods, reasonable samples are available, and other approaches do not appear to be working.

4.3.6 Environmental Health Process

Initial foodborne disease complaint reports are often received by food safety programs. Accurate and complete data collection from such complaints can help elucidate the nature and extent of a potential outbreak, and even give clues that may point toward specific pathogens. Environmental Health Specialists are the “front line” point people in the field investigation of food borne outbreak responses. Their roles are critical to the overall investigation and information gathered in the field can lend itself to identifying what specific pathogens may potentially be involved in an outbreak.

In addition, each jurisdiction’s food code requires the person in charge of a regulated food establishment to report certain illnesses in food workers to the local or state food safety program. At times such reports precede laboratory confirmation reports or reports from physicians through typical communicable disease reporting mechanisms.

Increasingly data gathered as part of environmental and food monitoring programs is augmenting human disease data for detection of outbreaks. For instance, PFGE patterns from food regulatory activities are now part of the PulseNet database, and have complemented human disease data in detecting or rapidly solving foodborne disease outbreaks. The review of HACCP records or other documentation during routine inspections can also provide meaningful insight into potential pathogen-specific outbreaks. Time/temperature logs, corrective action logs, and other records can identify specific breakdowns in pathogen control that lead to foodborne illness outbreaks. In addition, potentially important food may be collected by environmental health staff early in the investigation process, while it is still available. Such food should be properly stored for testing after further implicating epidemiologic information is available.

4.3.7 Strengths of Pathogen-Specific Surveillance for Outbreak Detection

a. When combined with specific exposure information, pathogen-specific surveillance is arguably the most sensitive single method for detecting unforeseen problems in our food and water supply systems caused by the agents under surveillance. The specificity of agent or syndrome information combined with specific exposure information obtained by interviews makes it possible for small numbers of cases to be positively associated with exposures.

b. Permits detection of widespread disease clusters initially linked only by a common agent. Most national and international foodborne disease outbreaks are detected in this manner.

4.3.8 Limitations of Pathogen-Specific Surveillance

a. Works only for those diseases detected by routine testing and reported to a public health agency.

b. Relatively slow, since it requires that (1) patients seek medical attention, (2) tests are ordered, (3) samples are collected, transported and tested, (4) isolates are forwarded to public health laboratories for further characterization, (5) cases are interviewed and data analysed, and (6) clusters are investigated.

c. Relatively resource intensive.

4.3.9 Key Determinants of Successful Pathogen-Specific Surveillance

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

4.3.9.1 Sensitivity of case detection

Surveillance represents a sampling of the true population of affected individuals, as most cases of foodborne disease are not diagnosed and reported. **The completeness of the reporting and isolate submission processes affects the number and size of outbreaks detected.** If the percentage of cases reported or isolates submitted is low, the total number of cases per outbreaks will need to be higher before detection by surveillance is likely. As described below, greater sensitivity (more cases) is required to identify outbreaks due to agents or exposures that are common in the population. These impacts might be mitigated by increasing the specificity of the agent/case definition or exposure information. Furthermore, if the sensitivity is low pathogen-specific surveillance may not be truly representative of all cases, since patients may not seek out medical care, primary care providers may not collect specimens or order the correct test, and the infections may be asymptomatic.

4.3.9.2 Prevalence of the agent and specificity of agent classification

The more common the agent, the more likely it is that sporadic (unrelated) cases will be misclassified with outbreak cases. This has the effect of obscuring trends and diluting outbreak measures of association (type 2 probability error, or the possibility of missing an exposure-disease association when one truly exists). Consequently a larger number of outbreak cases is needed to significantly associate illness with exposure.

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

Increasing the specificity of strain classification is useful only to a point. Since truly associated cases with different subtypes (or no subtyping at all) may also be eliminated from the study, increasing strain classification stringency may become problematic when the number of cases is small. For this reason standard PulseNet protocols provide multiple steps for testing agent specificity that may be used to define cases.

4.3.9.3 Sensitivity of case interviews – timing

For pathogen-specific surveillance, the chance that a true outbreak exposure will be identified during the interview process depends in part on the length of time between illness reporting and case interview. For surveillance that is based on reported illnesses associated with specific events, where menus are often available, the event itself largely (but not entirely) defines the denominator of potential exposures. However, the set of exposures that needs to be considered in pathogen-specific surveillance is usually open-ended, including all exposures of all cases in a timeframe appropriate to the disease.

The lack of a specific list of exposures such as a menu makes prompting cases during the interview more difficult. Furthermore, cases identified through pathogen-specific surveillance are interviewed longer after the exposure than cases reported as part of specific events. **As a result of these factors, greater attention must be paid to interview timing and content**.

4.3.9.4 Sensitivity of case interviews - content

In pathogen-specific surveillance, the interview form itself must include a broader range of potential exposures than interview forms for event-driven investigations. The most sensitive and specific interview:

1. Includes questions about specific exposures, such as a broad range of specific food items and non-food exposures previously associated with the pathogen,
2. Prompts cases to further describe exposures, such as requesting brand information and place of purchase or consumption, and
3. Allows cases to identify unanticipated exposures through open-ended questions ("at which restaurants did you eat?").

There are a number costs associated with obtaining this mix of exposure data. The interview requires more highly trained personnel than with simple lists of exposures, takes longer, and inherently is less amenable to rapid data entry. As

with any process, cost must be balanced with benefit for individual situations and jurisdictions.

The sensitivity and specificity of the interviews can be greatly enhanced by adding questions about exposures as they become recognized as potentially important suspect vehicles. During the cluster investigation process, interviews can be further enhanced by adding suspect exposures to interviews, and re-questioning previously interviewed cases about newly identified suspect exposures. (see "Dynamic Cluster Investigation Model;" below).

4.3.9.5 Frequency of the (ultimately implicated) exposure

The more common the exposure the more difficult it is to demonstrate significant association with illness. This signal to noise problem is analogous to the issue of agent classification. In case-control studies, more cases are required to establish a significant difference with controls (the "signal") when a high proportion or frequency of the population is exposed (high "noise" exposure). **The effective frequency of the exposure can be reduced by increasing the specificity of the exposure information.** For example, hamburger consumption is a high frequency exposure in the U.S., but a particular brand of hamburger from a particular store is likely to be a low frequency exposure.

4.3.9.6 Specificity of exposure information

Gathering specific exposure information through properly designed interviews and using it as part of the definition of the exposure strengthens measures of association in much the same manner as using more specific agent definitions. Both controls and misclassified cases are more likely to be considered "non-exposed" as more specific exposure information is used. For example, in the 2005 outbreak of E. coli O157:H7 associated with pre-packaged lettuce, progressively more specific exposure definitions strengthened the association with the common source. These definitions included: (1) "lettuce", (2) "pre-packaged lettuce salad", (3) "Brand A pre-packaged lettuce salad". (ref. Minnesota Department of Health upublished data)

4.3.9.7 Overall speed of the surveillance and investigation processes

As described in section 4.3.8 above, time delays are inherent in pathogen-specific surveillance. **The usefulness of pathogen-specific surveillance at preventing ongoing transmission of disease from contaminated food, especially perishable commodities, is directly related to the speed of the process.**

Once an outbreak investigation is underway, epidemiologists should be on a "war footing" until the situation is resolved, with obvious implications for evening and weekend efforts. Avoid delegating interviews and other critical activities to people who don't appreciate the sense of urgency.

4.3.10 Routine Surveillance - Model Practices

The following section lists model practices for routine surveillance programs. The practices in this section are listed in priority order, with those at the beginning of the list providing a more aggressive approach to investigating cases than those later in the list. The practices used by an agency may vary based on the needs of a particular outbreak, pathogen priority (i.e, seriousness of the related illness) and an agency's resources. For example, an E. coli O157:H7 cluster warrants very aggressive case identification and investigation in order to minimize serious illness and death. A cluster of suspect norovirus may be investigated with less aggressive approaches or not investigated at all.

4.3.10.1 Reporting and isolate submission

Encourage health care providers to test patient specimens as part of the routine diagnostic process for possible foodborne diseases. Increase reporting and isolate submission by clinical laboratories and health care providers through (a) education about the value of reporting and the mechanisms to report, (b) regulatory action (such as modifying reporting rules to mandate isolate submission), (c) laboratory audits, and (d) providing easier methods for compliance, The last mechanism includes automated or web-based reporting, isolate transport systems, making reporting more consistent across reporting areas, and limiting the initial amount of information requested. Education of physicians, laboratorians, and medical records clerks may be facilitated by workshops or conferences, newsletters, electronic health alerts, and regular feedback from public health agencies.

4.3.10.2 Isolate characterization

Confer with the laboratory to determine subtyping methods available for the pathogen under study. Conduct real-time laboratory characterization. Tests such as PFGE and serotyping are ideally performed concurrently to reduce turnaround time, which permits more timely detection and investigation of clusters. Recommended turnaround times are described in the APHL/CIFOR "yardstick" project (add URL when available). Results should be posted to national databases as quickly as possible.

4.3.10.3 Case interviews

Quality exposure information is normally difficult to obtain, and is often the key limiting factor of pathogen-specific surveillance. **Given sufficient resources, all laboratory-diagnosed cases of potentially foodborne disease are interviewed when first reported using a trawling interview form as soon as case reports or laboratory isolates are received, when mental recall is the greatest.**

Obtain an exposure history consistent with the incubation period of the pathogen that has been identified. Table XX shows the incubation periods for the most common foodborne disease pathogens.

- Table XX – to be done

The interview should:

- Include specific questions about exposures as a priori hypotheses to be tested (including specific food items that have been linked to previous outbreaks),
- Prompt interviewees to provide additional details such as brand and place of purchase or consumption for some of the highest likelihood exposures, and
- Include broad open-ended questions to capture exposures that may not have been considered.

Examples of trawling questionnaires can be found at the CIFOR clearinghouse (http://www.naccho.org/toolbox/program.cfm?id=2). Other strategies that gather the same types of exposure information in an appropriate timeframe, such as use of a brief preliminary interview when the case is first reported followed by more extensive interviews when clusters are identified also may be effective. However, the increased time between initial case identification and collection of detailed exposure information may negatively impact recall and the timeliness of outbreak source identification.

Where use of a trawling questionnaire with all cases as they are reported is not practical given available resources, detailed interviews are typically conducted at the cluster evaluation stage (see 4..3.xxx below). In some jurisdictions, brief questionnaires are administered as soon as possible after cases are reported, and more extensive trawling questionnaires are administered when clusters or exposures warranting follow-up are identified. While the use of open-ended questions increases both the sensitivity of exposure detection and the specificity of the exposure information, it complicates electronic data entry and analysis. This is a problem for those jurisdictions that rely on electronic data entry at the local public health level for rapid communication with the state.

In general, to help improve food recall when collecting a food history for an outbreak not associated with a specific event:

- Question subjects as soon as possible after reporting.
- Do not share information on suspected food items or working hypotheses with study subjects. However, do ask specifically about suspect item(s), as described in the dynamic cluster investigation model.
- Encourage the subject's memory by having them elaborate on where they ate, with whom they ate, and events associated with the meals. Ask the subject 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.
- 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.
- If the subject uses a grocery store shopper card and gives permission, it is possible to get purchase records for a specified time period. Some grocery chains are very cooperative with these requests; others are not.

4.3.10.4 Data analysis

Continuously examine laboratory and interview data to detect and investigate clusters.. **Compare disease agent frequencies at multiple classification levels (species, serotype or other subtype, more stringent subtype) and in subgroups of the population (defined by selected demographic characteristics) to historical frequencies and national trends.** This is facilitated by daily, automated laboratory reporting and analysis systems, and by continuous monitoring of national databases and listserves, such as PulseNet (including food, veterinary, and environmental entries), EpiX, and the Foodborne Outbreak listserve. Compare exposure data to those obtained through interviews of group and independent complaints (see section below) or to those presented in the Atlas of Exposures. Storage of interview data in an electronic database may facilitate this process.

4.3.10.5 Communication

Improve communication and cooperation within and between local, state, and federal public health agencies. States vary greatly in the roles of local and state public health agencies. **Poor coordination within and between agencies limits the effectiveness of pathogen-specific surveillance.** Establish and use routine procedures for communicating between epidemiology, laboratory and environmental health branches within an agency, and between local and state agencies. Communication between states is also important and can be facilitated by rapid posting of subtyping results to PulseNet and discussion on epi listserves such as the Foodborne Outbreak listserve and EpiX.

4.3.10.6 Obtain and store suspect food

Suspect food should be secured while it is available. Test after epidemiological implication using standardized methods (required by regulatory agencies). **Note:** Food testing has different inherent limitations than clinical diagnostic testing, and demonstration of an agent in food is rarely possible or necessary before taking public health action.

4.3.11 Cluster Evaluation -- Model Practices

The following section lists model practices for evaluation of clusters once a cluster is detected, or cluster follow-up. The practices are listed in priority order, with those at the beginning of the list providing a more aggressive approach to evaluating even very small clusters than are those later in the list. The practices used by an agency may vary based on pathogen priority and on the needs of a particular outbreak and on an agency's resources. It is important to triage the clusters to focus resources on the most important ones. For example, a cluster of *E. coli* O157:H7 warrants very aggressive cluster evaluation of even small clusters in order to minimize serious illness and death. A large cluster of norovirus infections may be evaluated with less aggressive approaches, or not investigated at all.

4.3.11.1 Use a dynamic cluster investigation process to generate hypotheses

In a frequently used investigation process, extensive hypothesis-generating interviews are conducted with a sample of cases from an identified cluster that contains numerous cases. Then hypotheses are generated and tested by a case-control or other study. **In the Dynamic Cluster Investigation model, initial cases within a recognized cluster are interviewed routinely following a disease report with a detailed exposure history questionnaire, as described in 4.3.10.1**. **Then as new possible 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.**

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 be uniformly identified with the original questionnaire, specific questions regarding the newly suspect exposures should be added to the questionnaire for future use. The re-interviews of previously interviewed cases, combined with interviews of new cases in the cluster, can result in rapid definition 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, it is important to test the various hypotheses with a case control study in the ensuing investigation. See **Figure 4.1** for a visual representation of this process.

Not only can questions about specific exposures be added to the interview form as they are identified, questions may be removed as exposures are ruled out to streamline the process. For example, after the first eight or ten cases have been interviewed, it is usually appropriate to drop items that have not been mentioned by any cases. This typically shortens long trawling questionnaires by 50-80%, freeing up time for more detail about the remaining products of interest. In this way the initial trawling questionnaire is modified to become the case-control investigative form.

As epidemiological investigation information is being gathered, any hypothesis or patterns should be shared immediately with environmental health specialists in the field as it can guide food sampling and result in more complete interviews of food workers and managers.

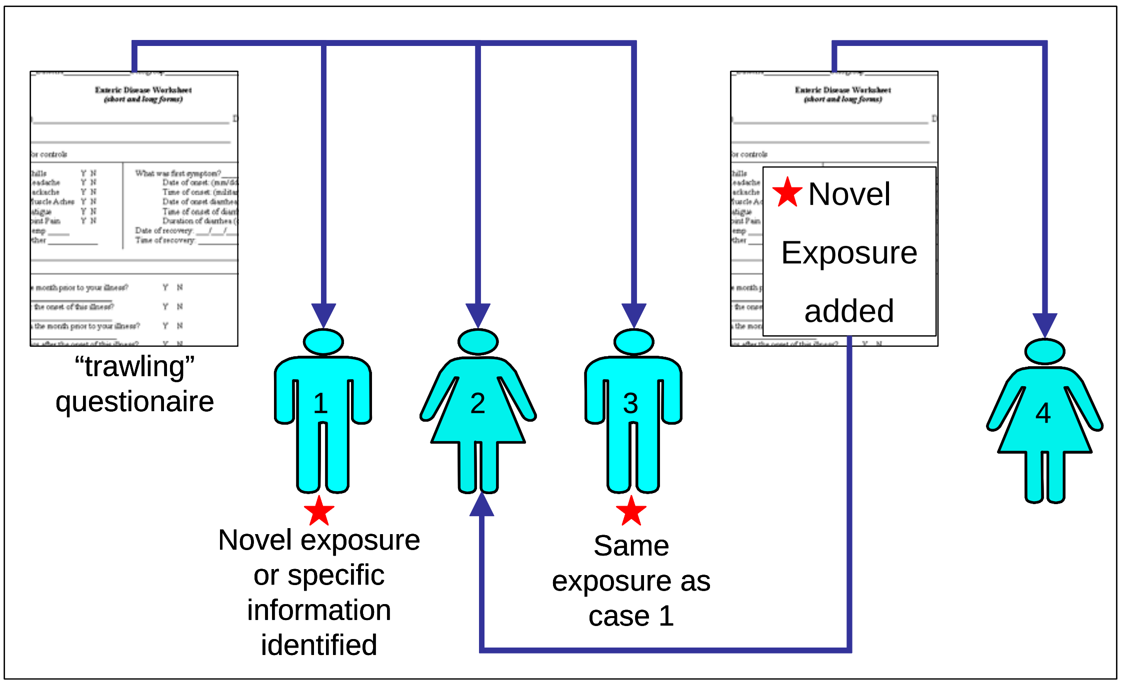

Figure 4.1: Dynamic Cluster Investigation. In this model, cases are interviewed with a detailed exposure history questionnaire. Ideally, this will involve walking cases through a long list of specific shopping and eating venues and specific food items, supplemented by open-ended efforts to reconstruct meals eaten during the 5 days before onset of illness or providing grocery store, restaurant, and/or brand information for foods), as well as specifically prompting the case regarding exposures that should be considered as a priori hypotheses to be tested (such as specific food items that have been linked to previous outbreaks). In this manner, specific exposures shared by multiple cases may surface that are 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 be uniformly ascertained with the original questionnaire, specific questions should be added to the questionnaire for future use, and to systematically re-interview cases to uniformly assess exposure to the suspicious sources discovered during the investigation process.

Dynamic cluster investigation increases the sensitivity and speed of outbreak identification and resolution in several ways.

a. **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 consumption history, and more likely to remember when questioned about specific exposures that have been identified by other cases. For example, in the 2007 multi-state 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 consumed, and highly likely to remember when asked specifically if they consumed the particular snack.

b. **Compressed timeframe:** This process also increases recall, and the likelihood of meaningful intervention because of its shortened timeframe. Standard methods may involve sequential attempts at hypothesis generation, followed by hypothesis testing. In this model, these processes are essentially compressed in a nested manner.

4.3.11.1.1 Dynamic cluster investigation without routine interviewing of cases

For those agencies that cannot interview cases routinely with a trawling questionnaire, interviews initiated at the cluster identification phase can still be conducted in a dynamic fashion, as described above. Questionnaires should contain both specific and open-ended questions. Interviewing all cases when clusters are small eliminates the need for sampling schemes used to investigate large clusters that have developed over time, and reduces recall bias. When interviewing with trawling questionnaires is initiated only in response to a cluster, investigation priority setting and cluster definitions are greater issues than when cases are routinely interviewed.

If investigators use the trawling questionnaire on cases only after a cluster is identified, they can either 1) use the results for hypothesis generation with subsequent testing of those hypotheses in a controlled study or 2) they can use the trawling questionnaire on an appropriate set of controls, thereby combining hypothesis generation and hypothesis testing.

4.3.11.1.2 Standard cluster investigation

The conventional cluster investigation process includes (1) waiting until a sizable number of cases are identified, making it obvious that a common source outbreak is occurring, (2) conducting hypothesis generating interviews with with trawling interviews of a subset of these cases, and (3) 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 focus the list of exposures identified during hypothesis generation:

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

The FoodNet Atlas of Exposures can help put the findings from hypothesis-generating interviews into perspective. (See below.)

4.3.11.2 Conduct case-to-case comparison studies

In jurisdictions that routinely conduct interviews using trawling questionnaires, case-to-case comparison studies offer a convenient screening tool for potentially significant exposures as part of cluster investigations. **Cases with microbial agents other than the agent under investigation 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.

Case-to-case comparison studies are especially useful for retrospective study, as the comparison group can be chosen from cases in the appropriate time period. This type of study has inherent bias towards the null (i.e., finding no association between an exposure and a disease). This problem is most severe for exposures which are very common in both the agents associated with cases and agents associated with illness in the comparison group. For instance, it may be difficult to identify chicken as the vehicle in a cluster of *Salmonella* Enteritidis cases by using cases of salmonellosis due to *S*. Heidelberg as a comparison group, since chicken is a common vehicle for both serotypes. Therefore, negative results should be interpreted with caution. **The potential for bias can be reduced by obtaining more specific exposure information, increasing agent specificity, using larger comparison groups (such as using all Salmonella cases instead of a single serotype, which dilutes the impact of bias), age matching and good temporal matching.** The best way to eliminate this bias is to use a healthy control group.

4.3.11.3 Use the FoodNet Atlas of Exposures

Exposure frequency data may 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 U.S. The Atlas of Exposures includes information on exposures that might be associated with foodborne illnesses and can be used as a crude estimate of the background rate of different food exposures in the community to highlight increased rates of exposure among cases. They can even be compared in a statistical fashion using a standard binomial model (e.g. the one available at http://healthoregon.org/acd/keene/cfm).

For example, bagged spinach was first identified as the source of the 2006 *E. coli* O157:H7 outbreak based on only six structured interviews (with five reporting consumption of bagged, pre-washed spinach). FoodNet survey data suggested that only about 17% of the US population recalled eating any kind of fresh spinach within a given week. This comparison was stronger as Oregon was one of the sites included in the Atlas, confirming the significance of these findings. Combined with information from other states conducting case investigations and reaching similar conclusions independently, 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, initial surveys do not always yield such obvious associations with a single food item, but they may still yield suggestive findings that can be tested in a controlled study. For example, use of a modified shotgun questionnaire 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 was then readily identified as the source of the outbreak. [ref. Bill Keene, personal communication].

Because the Atlas is based on surveys taken in selected sites at certain times, care must be used in extrapolating the findings 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 move investigations along quickly. For example, although not included in the FoodNet surveys, the significance of finding five of five SE cases reporting consumption of shelled almonds of a single brand was readily apparent not only to epidemiologists but to regulators and the distributors as well, particularly as the SE subtype had previously been implicated as the etiology of a large international outbreak traced to shelled almonds.

4.3.11.4 Perform additional agent subtyping

At a minimum, clinical laboratories in the affected region can be contacted and asked to rapidly submit all of a particular category of pathogen to the State Laboratory for subtyping. Guidelines are available on the PulseNet web board. **Additional subtyping may be indicated (1) when a common exposure is being considered, or when the available exposure information is non-specific, (2) when the subtype is common in a particular community, and (3) when alternate hypotheses are being considered (such as the presence of two concurrent outbreaks with different vehicles).**

4.3.11.5 Obtain and store food (see 4.3.10.6 above)

4.3.11.6 Increase surveillance

At a minimum, actively search for additional cases by contacting health care providers and laboratories or by sending out public notices. Additional cases can be found through reviews of laboratory reports, employee or school absentee records, chart reviews at hospitals or physician's offices, death certificates, requests to health care providers, surveys of known cases or the population affected, and requests for cases through the news media. The identification of additional cases is important since the initial cases might be biased in some way (i.e., not be representative of all cases of the disease), and additional cases increase statistical power.

4.3.12 Multi-Jurisdictional Considerations for Pathogen-specific Surveillance

Since pathogen-specific surveillance does not depend on geographic clustering, it is more sensitive to detection of widespread, low-level contamination events than are outbreaks reported by notification. Outbreaks detected by this method tend to span multiple jurisdictions. See Chapter 7 for Multi-jurisdictional Investigation Guidelines.

4.3.13 Indicators/Measures for Pathogen-Specific Surveillance

The success of pathogen-specific surveillance at detecting and resolving common source outbreaks depends on multiple interrelated processes. Key indicators which can be used for program assessment and improvement can be found in Chapter 8. Indicators specifically related to pathogen-specific surveillance include:

- For local health departments (to be added from Chapter 8)
- For state health departments (to be added from Chapter 8)

4.4 Notification/Complaint Systems

4.4.1 Purpose

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

4.4.2 Background

Receiving and responding to reports of disease in the community has been a basic function of public health agencies since their inception. However, although surveillance of consumer complaints has been well established in industry for years, its application in public health is fairly recent.

4.4.3 Event/Complaint Reporting

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

a. Reports from any individual or group who observes a pattern of illness affecting a group of people

b. Independent reports concerning illness in single individuals

Examples of the former are reports of illness among multiple individuals attending the same restaurant or wedding and reports of unusual patterns of illness from health care providers, such as multiple patients with bloody diarrhea in a short timespan. Health agencies also accept independent complaints of suspect foodborne disease. Group illness and independent complaints may be used together, and linked with data obtained through pathogen-specific surveillance. In contrast to pathogen-specific surveillance, reporting does not require identification of a specific agent or syndrome.

4.4.4 Epidemiology Process

Notification of health events or independent complaints may occur at the local, regional, state or national levels. Reporting of “unusual clusters of disease” by healthcare providers is mandated in some jurisdictions. For unusual disease clusters, reports are triaged, occurrence of the same disease is confirmed, data analyzed, investigations are initiated, and control measures are taken as appropriate. For reports of group illness associated with an event or venue, the investigation generally involves obtaining lists of attendees, confirming that ill persons are suffering from the same disease, obtaining menus, undertaking case interviews, performing a cohort or case control study, and collection of food and patient specimens (see Chapter 5 on Investigation). Outbreaks detected in this manner may be linked to other outbreaks or to other cases in the community by a variety of processes such as PulseNet or eFORS, and communication conducted via Epi-X or OutbreakNet.

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

4.4.5 Public Health Laboratory Process

Laboratory activities are not essential for primary detection of outbreaks by this process, but are essential for determining etiology, linking separate events during the investigation, and monitoring the efficacy of control measures (see Chapters 5 and 6). For instance, an outbreak associated with a particular restaurant may come to the attention of authorities solely on the basis of a report by a customer who observed multiple cases among fellow patrons. Laboratory testing and identification of *Salmonella* Typhimurium in the cases may result in additional testing and restrictions for workers found to be carriers, or connection between this outbreak and other outbreaks due to a contaminated commodity.

4.4.6 Environmental Health Process

Routine environmental health activities such as restaurant inspections may uncover unreported cases of employee illnesses or consumer complaints. Attention given to the health of food service workers during inspections can serve as an early indicator of widespread viral-based illnesses. For instance, a jaundiced employee noted during a routine environmental health inspection could alert epidemiologists to consider a link between seemingly unrelated Hepatitis A cases. Food illness complaints frequently come first to food inspection programs within local environmental health agencies. Therefore it is critical that all complaint intake systems, regardless of where they are located in an organization, utilize standardized formats for collecting complaint information, so that all complaint data can be analyzed for patterns and shared between epidemiology and environmental health staff. Training of food managers and workers should include information on the importance of reporting of any unusual patterns of illness among workers or customers and food code requirements for communicable disease reporting.

While routine restaurant inspections may trigger a foodborne disease investigation, it is important to note that routine inspections are not the same as investigations. An environmental investigation conducted as part of a foodborne disease outbreak investigation is far more detailed and focused on identifying potential causes of a known disease outbreak. Further information on environmental investigations is found in Chapter 5.

4.4.7 Key Determinants of Successful Notification/Complaint Systems

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

4.4.7.1 Sensitivity of case/event detection

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

4.4.7.2 Background prevalence of disease - group complaints

The likelihood that cases of sporadic, unrelated illnesses are included in groups reported as having probable common exposures is dependent on the background prevalence of the disease or complaint. For instance, unrelated cases with diarrhea may be grouped inadvertently with true outbreak cases, since at any one time a significant proportion of the population is “normally” experiencing diarrhea. **Inclusion of misclassified cases (i.e., cases not associated with the outbreak) hinders the detection of associations between exposures and disease, thus decreasing the likelihood of discovering a common source.** When reported clusters are of small size, the possibility that the reported cluster is due to coincidence rather than causal association must be considered (type I probability error -- i.e., the detection of an association between an exposure and a disease where one in truth does not exist.). With unusual syndromes such as neurological symptoms associated with botulism or ciguatera fish poisoning, the likelihood of misclassification and type 1 probability error is low. The system specificity may be increased by identification of a specific agent or disease marker, or by increasing the specificity of the symptoms (e.g., bloody diarrhea or diarrhea of a longer duration) or exposure information.

4.4.7.3 Sensitivity and specificity of case interviews – group complaints

Case interviews for group complaints capture two types of information:

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

Since exposures associated with group events are relatively limited in number and can be described specifically, recall tends to be good (see articles on accuracy of food histories in an outbreak associated with an event by Mann, 1981 and Decker, 1986), and timing is less an issue than it is with pathogen-specific surveillance or independent complaints. Nonetheless, the more specific exposure-related questions are, the better recall will be. For example, cases asked if they “ate German potato salad” at a particular event are more likely to remember than if they were asked if they ate “salad,” or simply asked to list what they consumed in a trawling questionnaire. Interviews of food preparation staff adds another layer of valuable information, as ingredients are often added which cases are not likely to recall, and which would not be included in a standard questionnaire. A good example is the 1998 international outbreak of shigellosis associated with parsley, which was added as a garnish to restaurant-served meals.

The second type of information gathered in this type of outbreak, independent food histories, has the same broad exposure denominator and recall challenges as pathogen-specific surveillance. The problems may be even greater since there are no exposures previously associated with that pathogen to go on. Hence, interviews must be done promptly for this aspect to be effective.

To improve recall of foods eaten at a particular meal or event:

- Provide the person collecting the food history with an overview of the meal or event and how foods were served so they know as much as study subjects do.
- Question subjects as soon as possible after the implicated meal or event.
- Do not share information on suspected food items or working hypotheses with study subjects.
- Provide the subject with a list of the foods available at the meal or event. When possible, get menus from those who prepared (or organized) the meal rather than relying on recall by initial cases or meal attendees.
- Organize the list of foods to facilitate recall (e.g., by the order in which courses were served or by their position on the buffet table).
- Provide a description of each food item since names may not indicate what the item looked like or the main ingredient.
- Ask subjects to focus on the appearance of their plate or the physical setting of the buffet.
- Ask the subject to think about other cues within the meal (e.g., appearance of servers at the buffet table or the timing of speeches).

Enlist the help of dining partners or the person who prepared the meal.

4.4.7.4 Background prevalence of disease and the quality of exposure information - independent complaints

Unlike pathogen-specific surveillance, where agent information is used to link cases and exposure information is used for hypothesis generation and testing, complaint systems use exposure information to both link cases and generate hypotheses (unless symptoms are unique and by themselves will link cases). **The lack of dependency on specific agent information allows outbreaks to be detected due to any cause, known or unknown. On the down side, the lack of agent specificity means that all cases with similar symptoms are evaluated as a group, which gives surveillance of independent complaints an intrinsically less favourable signal to noise ratio than pathogen-specific surveillance, especially for common non-specific complaints, such a diarrhea.** Furthermore, since most people associate illness with the last meal consumed before onset of symptoms, the reliability of independent complaints without a full interview would be expected to be greatest for outbreaks due to agents with short incubation periods, such as those caused by *Staphylococcus aureus* enterotoxin or heavy metals. The specificity of this type of surveillance can be increased by routine follow-up interviews for exposure histories, and by routine examination of exposure data. Given the ubiquity of calicivirus infections, one should pay particular attention to exposures in the 24 to 48 hourse before onset whenever a Norwalk-like illness is reported.

4.4.8 Strengths of Notification/Complaint Systems for Outbreak Detection

i. Since detection does not depend on identification of an agent, this system is able to detect outbreaks due to any cause, known or unknown. As such, this is one of the best methods for detecting non-reportable pathogens and new or emerging agents.

ii. Event related notifications only -- The size of the cluster is less important for detecting this type of outbreak than for pathogen-specific surveillance, since other factors (such as convergence of two otherwise unrelated individuals at a particular event) are used to link cases. However, small size does limit the ability to draw significant associations with exposures.

iii. Notification and complaint surveillance systems are inherently faster than pathogen-specific surveillance, since the chain of events related to laboratory testing and reporting is not required.

iv. Individual outbreaks identified by this method may be linked together or linked to seemingly sporadic cases to detect widespread events when combined with laboratory confirmation and subtyping. Examples include the parsley-associated shigellosis outbreak of 1998 or the 2006 lettuce associated *E. coli* O157:H7 outbreak in restaurants serving Mexican foods.

v. Event-related notifications only -- Recall of exposures by cases is usually good for reported events, as specific exposures associated with the event can normally be determined, and included in the interview.

vi. Reports do not depend on a visit to a healthcare provider, making this system potentially more sensitive to outbreaks where the illness is of short duration or where symptoms are mild.

4.4.9 Limitations of Notification/Complaint systems

i. Notification of illness in groups is in general less sensitive to widespread low-level contamination events than is pathogen-specific surveillance, since recognition by an individual of a person-place-time connection between cases is required.

ii. The value of complaints about single cases of possible foodborne disease in detecting outbreaks is limited by the exposure information used to link cases, and by the lack of specific agent or disease information to exclude unrelated cases. The illness of complainants may or may not be foodborne, and illness presentation may or may not be typical. For any true outbreak, the absence of an agent makes misclassification of cases more likely. This dilutes the association between true outbreak cases and exposures.

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

4.4.10 Notification/Complaint Systems -- Model Practices

The following section lists model practices for notification and complaint systems. The practices are listed in priority order, with those at the beginning of the list providing a more aggressive approach to identifying cases than those later in the list. The practices used by an agency may vary based on suspected pathogen and on an agency's resources. For example, reports of bloody diarrhea may warrant very aggressive case identification and investigation in order to minimize serious illness and death. An cluster of potential norovirus infections may be detected and investigated with less aggressive approaches, or not investigated at all.

4.4.10.1 Interviews related to independent complaints

A detailed 5 day exposure history is essential for independent complaints, since common exposures are the sole linking mechanism. While it may be possible to identify outbreaks caused by agents with short incubation periods based on initial complaints only, the signal to noise ratio would be low, and investigations would tend to be non-productive.

When beginning an investigation based on independent complaints, the best approach is to collect a 5-day exposure history. However, as more information is collected, this approach can be modified. The complaint and subsequent interviews can lead to a hypothesis about the pathogen that leads to a different time frame for the exposure history (e.g., vomiting as symptoms leads to a different hypothesis and exposure history timeframe than bloody diarrhea).

4.4.10.2 Interviews related to reported illnesses in groups

Some "complaints" are tantamount to outbreak reports. When someone calls to say that eight to twelve people who ate together at a restaurant got sick a day or two later, that merits a different response than someone calling with an isolated report of diarrhea.

Focus interviews on the event that the members of the group have in common. However, be aware that there may be more than one event in common, so explore that possibility with members of the group. For example, an outbreak associated with a wedding reception might actually result from the rehearsal dinner the night before which involved many of the same individuals. The interview process should also include other potential exposures, either for the interviewee or for others that the interviewee may come in contact with, such as day care attendance, employment as a food worker, or ill family members.

4.4.10.3 Obtain clinical specimens and food samples related to group illness

Obtain clinical specimens from cases that are part of group illnesses, and collect and store but do not test food from the suspect group event (if the presumed exposure involves food). Health departments may also choose to collect specimens from independent complaints or encourage patients to seek health care. Appropriately store food, but generally only test food after epidemiologic implication. Standard testing methods must be used at a minimum for regulated products (products such as pasteurized eggs or commercially distributed beef which are regulated by federal agencies). The collection of food samples can be done as part of the process of removing suspect food from service.

Note: Food testing has inherent limitations and demonstration of an agent in food is not always possible or necessary before taking public health action. **Microbial or toxin detection in food is most important for outbreaks involving pre-formed toxins such as enterotoxins of *Staphylococcus aureus* or *Bacillus cereus*, where detection of toxin or toxin-producing organisms in cases is frequently problematic.** It is also important for organisms such as *S. aureus* and *Clostridium* *perfringens,* which are normal flora in the human intestinal tract and which may confound interpretation of culture results.

4.4.10.4 Establish etiology through laboratory testing

While knowing the etiology is not essential for primary linkage of cases, as it is for pathogen-specific surveillance, **information about agents is important for understanding the outbreak and for rational intervention, and facilitates establishing linkage to other outbreaks or sporadic cases via PulseNet and EFORS.**

4.4.10.5 Regularly review interview data

Review interview data regularly to look for trends or commonalities. **Compile interview data in a single database, and examine daily for exposure clustering.** Use of exposure data obtained through pathogen-specific surveillance interviews increases the sensitivity of both surveillance systems. Complaints may be made to multiple agencies so it is important to have a robust method of sharing information.

4.4.10.6 Improve inter-agency cooperation and communication

Improve cooperation between agencies that receive illness complaints, e.g. agriculture agencies, facility licensing agencies, poison control centers, etc. Regularly communicate with these agencies and ensure that they have current contact information for your staff.

4.4.10.7 Compare information received to national databases

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

4.4.10.8 Simplify reporting process

To increase surveillance sensitivity, the reporting process should be made as simple as possible for the public, such as providing a single telephone 24/7 toll-free number or a web site. Such systems allow callers to leave information which can be followed up at a later time by public health staff.

4.4.10.9 Increase public awareness of reporting process

Reporting can be promoted by routine press releases in the media that educate the public about food safety and also advertise the number to call for illness reports. Also use a telephone number that can easily be remembered or found in the telephone directory.

4.4.10.10 Centralize reporting or report review process

Set up the reporting process so that all reports go through a single individual or that a single individual routinely reviews reports. Centralization of the reporting or review process increases the likelihood that patterns will be detected.

4.4.10.11 Maintain contact with other organizations that may receive complaints

Consumer complaints may be submitted to multiple organizations, such as poison control centers, regulatory agencies or grocery stores. **Identify the organizations that may receive complaints in your community and maintain routine contact with them.** Ideally, set up a database that all can access and review.

4.4.11 Multi-Jurisdictional Considerations for Notification/Complaint Systems

Outbreaks discovered through notification/complaints may span multiple jurisdictions, as evidenced by the 1998 parsley-associated shigellosis and the 2006 multi-state lettuce associated *E. coli* O157:H7 outbreak in Taco restaurants. See Chapter 7 for Multi-jurisdictional Investigation Guidelines.

4.4.12 Indicators/Measures

Key indicators have been developed to assess the surveillance processes and overall success of surveillance programs. Key indicators which can be used for program assessment and improvement can be found in Chapter 8. Indicators specifically related to notification/complaint systems include:

- For local health departments (to be added from Chapter 8)
- For state health departments (to be added from Chapter 8)

4.5 Syndromic Surveillance

4.5.1 Overview

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

4.5.2 Background

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

4.5.3 Reporting

Syndromic surveillance typically relies on automated extraction of health information:

1. Pre-clinical (i.e., not depending on access to health care, consequently less specific and potentially less useful) -- School and work absenteeism, nurse help lines, over-the-counter drug sales, complaints to water companies, calls to poison control centers
2. Clinical pre-diagnostic -- ER chief complaint, ambulance dispatch, lab test orders
3. Post-diagnostic data, such as hospital discharge codes (ICD-9/10)

4.5.4 Epidemiology Process

Alerts triggered by the syndromic surveillance system are evaluated by epidemiology or emergency preparedness groups. The effectiveness of syndromic surveillance for detection of outbreaks has not been demonstrated. Presumably, cases would be interviewed and exposures determined if an alert were determined likely to represent a true outbreak.

4.5.5 Laboratory Process

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

4.5.6 Strengths of Syndromic Surveillance

i. In theory, syndromic surveillance has the potential to identify clusters of disease before definitive diagnosis and reporting, thus generating a faster signal than can be expected with pathogen-specific surveillance.

ii. As with notification/complaint systems, outbreaks can potentially be detected due to any cause, known or unknown. Included are clusters of cases identified with discharge diagnoses that include specific agents not part of standard surveillance.

iii. Syndromic surveillance should be able to detect very large, undiagnosed events, such as widespread diarrheal disease. For example, the massive 1993 outbreak of cryptosporidiosis in Milwaukee would likely have created a significant syndromic surveillance signal. Outbreaks of this magnitude are also likely to be rapidly detected by other means.

iv. Several long-term trends have been revealed by the New York City syndromic surveillance program that might not have been detected otherwise.

v. Most syndromic surveillance systems have been built with automated electronic data transfer. This infrastructure should be useful for other types of surveillance and public health activities.

4.5.7 Limitations of Syndromic Surveillance

i. Lack of specificity for most syndromic surveillance indicators in the area of foodborne disease makes for an unfavourable signal to noise ratio, meaning that only the largest events would be detected and many false positive signals are to be expected. Responding to false positive signals is a major drain on an agency's resources.

ii. Evaluating a signal usually means cross checking it with routine surveillance reports, which means that it cannot replace routine surveillance.

iii. More specific signals, such as discharge diagnoses, are also less timely, and do not appear to offer advantage over standard surveillance methods.

iv. The usefulness of syndromic surveillance has not been demonstrated for foodborne disease. After examination of 2.5 million patient records in its first year of operation, the NYC surveillance system identified 18 diarrhea or vomiting alerts in three outbreak periods. Five institutional outbreaks were identified during one of these periods, but It is not clear that the data were of sufficient specificity to allow for public health intervention (Heffernan, 2004; DAS, 2005, Besser 2005).

v. The cost of developing syndromic surveillance systems is substantial, and if it occurs at the expense of maintaining or upgrading routine surveillance, the final outcome is degraded rather than enhanced surveillance.

4.5.8 Key Determinants of Successful Syndromic Surveillance Systems

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

4.5.8.1 Specificity and speed

While the potential speed of syndromic surveillance is its chief strength, speed is inversely proportional to the specificity of the indicator disease information. Preclinical information such as over the counter (OTC) drug sales is generally available sooner and is less specific than clinical, pre-diagnostic signals (such as laboratory test orders). Pre-diagnostic signals are in turn available sooner and are less specific than post-diagnostic signals (such as hospital discharge data).

Lack of specificity at any level results in both type 1 probability error (the suggestion that there is an association between a signal and a significant health event, when in fact there is not) and type 2 probability error (the lack of signal suggests that a disease event is not occurring, when it in fact is). **Less specificity means that that more cases are needed to overcome background noise, and that false positive alerts are likely.**

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

1. The diagnoses similarly requires agent identification,
2. Standard investigation would likely be required for public health action, and
3. Identification of the illness may precede discharge.

Signals from rare, specific syndromes without laboratory confirmation, such as botulism-like syndrome, should be as effective as pathogen-specific surveillance. This is the basis for the national botulism surveillance program at CDC, which provides emergency clinical epidemiological and microbiological consultation, and antitoxin treatment for suspect cases of botulism, because of the extremely serious nature of that illness, and the possibility that one case may herald other cases from the same exposure (ref bot handbook).

4.5.8.2 Personal information privacy issues

In a survey on implementation of syndromic surveillance systems, more than 50% of respondents reported some or substantial problems caused by real or perceived patient confidentiality concerns and the Health Information Portability and Accountability Act (HIPAA). Respondents noted that many people did not understand HIPAA and so tended to give minimal patient information. Questions were also raised about whether syndromic surveillance falls under the same regulations as diagnosis related disease reports. For example, it is not always clear that health departments have the legal authority to collect these data. Most respondents were using current disease reporting regulations to cover syndromic surveillance. Many respondents felt that there is a need for more specific syndromic indicators in order to incorporate them into regulations. **Most agencies that had implemented a syndromic surveillance system were using deidentified data. This slows down investigations of positive signals from the surveillance system.** Drociuk D. et al, 2004.

4.5.9 Practices for Improving Syndromic Surveillance

Since the usefulness of syndromic surveillance for detection of foodborne disease events has not been demonstrated, it is not that clear additional investment is warranted, especially if systems compete for resources with under-resourced standard surveillance systems. If an agency is implementing or seeks to improve a syndromic surveillance system, the following practices should be considered:

i. Better electronic and process integration with standard surveillance systems may improve usefulness.

ii. Syndromic surveillance data are most useful when corroborated with data from multiple sources (eg, rise in OTC diarrheal medicines with rise in ER chief complaints of diarrhea). As historical data accumulate, it may be possible to fine-tune detection algorithms to reduce false positive signals.

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Comments on Chapter 4

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 5. Investigation of Outbreaks

5.0 Introduction

Many of the agents responsible for outbreaks of foodborne disease may also be transmitted by other routes such as waterborne, zoonotic, and person-to-person transmission. It is not always possible to determine the route of transmission by identifying the agent or by the clinical presentation of the outbreak. Thus, identifying the route of transmission is an important objective in many outbreak investigations and is critical for implementing effective control measures (see chapter 6, Control Measures).

5.1 Characteristics of Outbreak Investigations

5.1.1 Importance of Speed and Accuracy

Speed and accuracy are the two most important qualities of all outbreak investigations. The outbreak 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:

1. **"Removing the pump handle**" - Stopping an outbreak in its tracks and preventing illnesses is the most obvious goal of outbreak investigations. From this perspective, there are three types of outbreaks.

    - A one-time event, such as a specific food preparation error or ill food worker. By the time these outbreaks are recognized, the event may be over. However, assuring that an ill worker does not continue to spread disease or preventing secondary spread of cases from person-to-person or future outbreaks from the same or similar food safety problems might be possible.

    - Widespread distribution of a perishable commodity, such as spinach or tomatoes. In these outbreaks, product may still be in the marketplace when the outbreak is detected. Thus, the faster the source can be identified, the more likely you will be to prevent illnesses from exposure to the source. Given the large quantities of contaminated product involved in these events, even a limited recall could have a significant public health benefit.

    - 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 can be identified and the effectiveness of any recall will be directly related to the size of the outbreak attributed to the source.

2. **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 thus the opportunity to prevent future outbreaks will be lost.

3. **Identifying new hazards** - New agents, new food vehicles, and new agent-food interactions and other unsuspected gaps in the food safety system are identified by outbreak investigations. 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 them to change their procedures.

4. **Maintaining the public's confidence** - Foodborne outbreaks undermine the public's confidence in the food supply and in the public health system that is established to ensure food safety. Rapidly identifying outbreaks, determining their source and limiting their scope are all critical to restoring confidence in our food supply and food safety system. On the other hand, inaccurate results also undermine public confidence and harm food producers who were not the cause of the outbreak. For example, strawberries from California were implicated as the source of a multi-state outbreak of cyclosporiasis that was actually due to raspberries from Guatemala. Media reports based on the erroneous epidemiology conclusions let to millions of dollars in lost strawberry sales, even though the error was rapidly corrected. This situation likely could have been avoided if investigators had considered results from other investigations occurring at the same time 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. Section 6.6.1 has additional discussion of the importance for collecting sufficient information before taking action.

5. **Empowering the public** – While releasing premature and incorrect conclusions to the public can be a disaster, and sounding the alarm bell too often can lead to warning fatigue, it is a mistake to withhold or delay the release of information that the public may need to protect themselves. Public health agencies have an obligation to get information to the public or others who need to know as quickly as possible. A rule of thumb is "Do you want your mother or grandmother to know about this hazard?"

5.1.2 Principles of Investigation

5.1.2.1 Initiation of outbreak investigations

Outbreak investigations are frequently initiated by consumer complaints to environmental health programs, health provider reports to communicable disease programs, or by the detection of unusual clusters in isolates submitted to the public health laboratory. **Preliminary investigations will need to assess the epidemiologic context of the reported illnesses to determine whether they may be part of an outbreak.**

Outbreaks are typically detected through three general methods: pathogen-specific surveillance, notification/complaint systems, and syndromic surveillance. (See Chapter 4). Preliminary investigations will need to assess the epidemiologic context of the reported illnesses to determine whether they may be part of an outbreak.

5.1.2.2 Investigation Leadership

Outbreaks are defined by epidemiology and the results of investigations should explain the timing of the outbreak, the location, and the individuals. Leadership of the investigation should reflect the focus of investigation activities and may change over time.

During the course of the investigation, the focus of activities may shift between 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
- Regulatory investigation of food production sources and distribution chains
- Environmental evaluation of food production, processing and service facilities
- Communication of investigation findings to the public and the food industry

5.1.2.3 Investigation Processes

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 that require close communication and coordination among members of the outbreak control team. Maintaining close communication and coordination among members of the investigation team is the best way to ensure that concurrent activities do not interfer with each other and that important investigation steps are not forgotten.

Hypothesis generation should begin during the earliest stages of the investigation. To narrow the focus of an investigation and use investigation time and resources most effectively, investigators should begin to generate hypotheses during the earliest stages of the outbreak investigation, and refine them as information is received. Key steps in this process include:

- Review previously identified risk factors and exposures for the disease
- Examine the descriptive epidemiology of cases to identify person, place, or time characteristics that may suggest a particular exposure
- Interview in detail the affected persons or a sample of the affected persons to identify unusual exposures or commonalities among cases. As noted in Chapter 4, standard use of a trawling questionnaire with all cases or potentially foodborne diseases as they are reported might expedite hypothesis generation during this phase of the investigation.

Based on this information the 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 modification of the hypothesis as more information is obtained. For example, an outbreak that involves a high proportion of cases among pre-school aged children may suggest exposure to a food product marketed to young children, such as a cereal product or snack food. The identification of a specific product, such as a particular vegetable powder-coated snack, by several cases should prompt the re-interview of other cases to identify unrecognized exposures to the product. Concordance of exposures could lead directly to product testing and recall, and/or to a more focused epidemiologic study to establish the association.

Use standard forms for data collection where possible. Standard data collection forms for collecting exposure histories facilitate comparison of exposures across jurisdictions and aid in the investigation of multi-state outbreaks. Similarly, using standard forms for environmental investigations will provide comparable data for investigations that may involve multiple establishments. In addition, using standard forms will allow investigators to become proficient with the forms and reduce the amount of effort spent on development of and training staff on new forms during the course of the investigation.

Good forms take a great deal of time to develop and format. Thus, it is critical to develop templates *before* the crisis so they can be rapidly deployed.

Protect the privacy of individuals, patients and their families. All outbreak investigations involve collection of private information from individuals that must be protected from public disclosure to the extent allowed by law. Investigators need to be familiar with relevant state and federal laws and practices including the Health Information Portability and Accountability Act (HIPAA).

5.2 Outbreak Investigation Procedures

5.2.1 Conduct a Preliminary Investigation (See also, Chapter 4: Outbreak Detection and Surveillance)

Following the 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.

5.2.1.1 For complaints of illness attributed to a particular event or establishment

Interview cases associated with the complaint(s) to obtain details of illness history and possible exposures and to answer the following questions:

- 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 illnesses being attributed to the same exposure?
- Are all of the illnesses similar in nature (suggesting all are the same disease)?
- Could these illnesses be reasonably explained by other common exposures?

The following guidelines are suggested for the exposure histories:

- If the etiologic agent is unknown, collect a 72-hour exposure history
- If the etiologic agent is unknown, but diarrhea is a predominant symptom, collect a 5-day exposure history
- If the etiologic agent is known, collect an exposure history consistent with the agent.
- If more than one person is ill, focus on exposures common to all or most of the ill persons because there are often cases that don't “fit”, perhaps due to imperfect recall.

If multiple illnesses consistent with the reported exposure cannot reasonably be explained by other common exposures, they may represent an outbreak. The potential outbreak should be investigated to identify the agent and mode of transmission.

5.2.1.2 For case clusters identified through pathogen-specific surveillance

The following questions should be answered:

- Based on previous history, 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 (age, sex, ethnicity, etc) or geography suggest a common source?
- Do cases share any unusual exposures?

To answer these questions, determine the specificity of the cluster definition and interview cases associated with the cluster to obtain details of illness history and possible sources of exposure. For uncommon *Salmonella* serotypes, such as S. Wandsworth, the cluster may be defined by serotype alone. For common serotypes such as S. Typhimurium or for *E. coli* O157:H7, subtyping by pulsed-field gel electrophoresis (PFGE) or other method may be required to define a cluster. While increasing the stringency of strain characterization can increase the predictive value of the cluster definition, this should not be done at the cost of delaying the start of an investigation of a suspected outbreak. See section 4.3.9.2 for further information.

Specific exposure information is also important to cluster investigations. Exposure histories consistent with the incubation period for the etiologic agent, if known, should be collected. Of note, although the published incubation period for salmonellosis is 12-72 hours, recent investigations suggest that the incubation period may be substantially longer in some patients, Therefore, for outbreaks of *Salmonella infection*, interviews should cover four to five days before onset of symptoms. For *E. coli* O157:H7, interviews should cover at least seven days and preferably ten. The identification of an unusual exposure among most cases in a cluster may be critical to tipping the scale towards early public health intervention even before exposure data are available from control subjects.

If the number of cases in a cluster clearly exceeds an expected value, or if the demographic features or known exposures of cases suggest a common source, the cluster may represent an outbreak. The potential outbreak should be investigated to identify the source and mode of transmission.

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

Outbreak investigation and control team leaders should be alerted as soon as the potential outbreak has been identified. Descriptive features of the outbreak setting should be reviewed along with relevant background information regarding the etiologic agent, establishment, or event.

5.2.2.2 Assess the priority of the outbreak investigation

Based on the outbreak setting and descriptive epidemiology, **outbreak investigation and control team leaders should assess the priority that should be given to the outbreak.** Highest priority for investigation should be given to outbreaks that:

- Have a high public health impact:
    1. Severe or life-threatening illnesses such as *E. coli* O157:H7, HUS or botulism

2. Affect populations at high risk for complications of the illness (e.g., infants, elderly, or immunocompromised persons)

3. Affect a large number of persons

- Appear to be ongoing:

  1. Outbreak may be associated with food service establishment in which ill food workers or adulterated food provide a continuing source of infection

  2. Outbreak may be associated with commercially distributed food product that is still being consumed

5.2.2.3 Assemble and brief the outbreak investigation and control team

Based on the priority given the outbreak, outbreak investigation and control team leaders should assess the availability of staff to conduct the investigation. **In particular, assure the presence of adequate staffing to conduct case interviews 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 membership of the outbreak control team, and their individual role in the investigation.

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

5.2.2.4 Establish goals for the investigation

The overall goal of an outbreak investigation should be to rapidly obtain sufficient information to support implementing specific interventions that will abate the outbreak, or to determine that no specific interventions are warranted. Secondary goals should include identifying and documenting the agent, vehicle, source of contamination, and factors contributing to the occurrence of the outbreak. To achieve these goals, specific objectives need to be established for the epidemiologic investigation, the environmental health investigation, and the public health laboratory.

For outbreaks associated with events and establishments, it may be necessary to identify the agent as well as the mode of transmission, vehicle, source of contamination and contributing factors. **A key goal will be to determine whether the outbreak is ongoing, if conditions leading to the outbreak still exist, or if it was a one-time event.**

For outbreaks identified through pathogen-specific surveillance, the agent will be characterized, although further characterization (e.g., subtyping by PFGE) of the agent may needed. Thus it will be necessary primarily to identify the mode of transmission, vehicle, source of contamination and contributing factors. **A key goal will be to determine the size and scope of the outbreak, and if it is ongoing.**

All outbreaks present opportunities to increase our knowledge of the epidemiology and control of foodborne diseases. Whenever possible, unanswered questions about the etiologic agent, the mode of transmission, or contributing factors should be identified and included in the investigation to add to the public health knowledge base.

5.2.2.5 Select Investigation Methods

Most foodborne outbreaks require coordinated investigations by epidemiology, environmental health and the public health laboratory. Each involves specialized methods that are adapted to the outbreak circumstances.

Regardless of the exact methods, investigators will undertake the following steps:

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

The order of these steps varies from outbreak to outbreak. Depending on the outbreak, some of the steps may be undertaken simultaneously. Some may not be undertaken at all. Occasionally other steps will be added.

The following tables describe these key steps and potential methods used during the epidemiologic, environmental health, and the public health laboratory iinvestigation of two major types of foodborne outbreaks: those associated with events or establishments, and those identified by pathogen-specific surveillance. The table format highlights the major objectives of the investigation to help ensure coordination between epidemiologists, environmental health specialists and laboratorians in meeting the objective. The assignment of investigation responsibilities 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, the roles defined in the outbreak response team, and available resources.

The following table summarizes key steps and potential methods for investigation of **outbreaks associated with events or establishments:**

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

Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health Laboratory**
Identify 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 patients. • Establish case definition based on confirmed diagnosis or clinical profile of cases. • Obtain stool from patients.	• Interview food workers to determine illness. • Obtain stool from ill or all food workers. • Obtain samples of implicated and suspect food items and ingredients • Determine if setting or food item suggest a likely pathogen.	• Contact clinical laboratories that may have performed primary cultures on cases. • Test stool samples to identify agent. • Test samples of implicated food items to identify agent. • Subtype all isolates as soon as possible after they are received.
Identify persons at risk	• Obtain list of persons attending event from event organizer. • Interview persons who attended the event or patronized the establishment to determine attack rates, by time. • Contact health care providers to identify additional persons seeking medical care.	• Obtain list of reservations for establishment, credit card receipts, or guest lists for events.	• Contact clinical laboratories to identify additional stool specimens being cultured.
Identify mode of transmission and vehicle	• Interview identified cases and controls or well meal companions regarding all common exposure sources and calculate odds ratios for specific exposures • Interview persons with identified exposures to determine attack rates and relative risks of specific	• 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	• Test implicated food and environmental samples to confirm presence of agent. • Subtype all isolates as soon as possible after they are received. • Conduct applied food safety research to determine ability of agent to survive or multiply in

Table 5.1. Investigation methods for outbreaks associated with events or establishments.			
Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health Laboratory**
	exposures.	• Obtain samples of implicated food. • Obtain environmental samples from food contact surfaces or potential environmental reservoirs.	implicated vehicle and how vehicle may have become contaminated.
Identify source of contamination	• Combine descriptive and analytical epidemiology results to develop a model for the occurrence of 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 the point of preparation or service. • If no contamination event identified, trace source of ingredients of implicated food item, back through distribution to the point where a contamination event can be identified, or to the source of production if no contamination events can be identified during distribution.	• Evaluate results of all outbreak-associated cultures to highlight possible relationships between isolates from clinical, food and environmental samples. • Conduct applied food safety research to determine how vehicle may have become contaminated.
Identify contributing factors	• Summarize available information to identify confirmed or suspected agent. • Summarize available information to identify confirmed or suspected food vehicle.	• Evaluate results of environmental investigation, given identification of agent and results of epidemiological investigation, to identify factors that likely contributed to the occurrence of the outbreak.	• Summarize available information regarding culture results from clinical, food and environmental samples.
Determine potential for ongoing	• Based on agent, incubation period, and likelihood of secondary spread, create epi	• Implement control measures to prevent further exposures: 1. Verify that all food workers who	• Assess status of completed and pending cultures to identify gaps that may suggest a

Table 5.1. Investigation methods for outbreaks associated with events or establishments.			
Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health Laboratory**
transmission, need for abatement procedures	curve and evaluate to determine whether additional cases may still be occurring. • If the outbreak appears to be ongoing, review potential abatement procedures.	pose a risk for transmission have been excluded. 2. Verify that potentially contaminated foods have been properly disposed. 3. Verify that food contact surfaces and potential environmental reservoirs have been adequately cleaned and sanitized. 4. Train staff on safe food handling practices. 5. Modify the food production/preparation processes. 6. Modify the menu. • If any of these measures cannot be verified, review additional abatement procedures, or if further exposure appears likely, alert public or close the premises.	potential for ongoing transmission.

The following table summarizes key steps in the investigation of **outbreaks identified by pathogen-specific surveillance:**

Table 5.2. Investigation methods for outbreaks identified by pathogen-specific surveillance.			
Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health 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 settings, cases are interviewed as soon as they are reported and before an outbreak has been recognized. • Establish case definition, based on characteristics of agent that led to detection of the outbreak. • Characterize cases by person, place and time and evaluate this descriptive epidemiology to identify pattern that may be associated with particular food items or diets. • Compare "trawling questionnaire" exposure frequencies against known or estimated background exposure rates, such as those found in the FoodNet Atlas of Exposures, to identify suspect food item. • Interview non-ill community controls or non-outbreak associated cases to obtain detailed exposure information to	• Contact restaurants identified by multiple cases to verify menu choices, identify ingredients, and identify distribution source for fresh produce items, or other commodities of interest. • Obtain samples of suspected food items. • Conduct rapid source tracing to determine if a suspect food vehicle from multiple cases has a 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 may have become contaminated.

Table 5.2. Investigation methods for outbreaks identified by pathogen-specific surveillance.			
Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health Laboratory**
	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 pre-packaged food items. • Analyze exposure information comparing cases to relevant comparison group (e.g., non-ill controls or non-outbreak-associated cases) to implicate food item, or non-food exposure source.		
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 physician’s offices to identify potential cases. • Ask known cases if they know of others who are similarly ill. • Depending on the nature of the outbreak, additional steps such as reviewing employee or school absences, reviewing death certificates, surveying the population affected, or making a direct request to the public might be warranted.	• Review foodborne illness complaints to identify undiagnosed cases that could be linked to the outbreak. • Contact restaurants visited by multiple cases to identify employee illnesses and/or occurrence of foodborne illness complaints from patrons.	• Contact clinical laboratories to identify additional stool specimens being cultured. • Speed up referral and subtyping of the outbreak pathogen.

Table 5.2. Investigation methods for outbreaks identified by pathogen-specific surveillance.			
Investigation Step	**Epidemiology**	**Environmental Health**	**Public Health Laboratory**
Identify source of contamination	• Combine descriptive and analytical epidemiology results to develop a model for the occurrence of the outbreak.	• Trace source of implicated food item or ingredients, back through distribution to the point where a contamination event can be identified, or to the source of production if no contamination events can be identified during distribution. • Conduct environmental assessment of likely source of contamination.	• Evaluate results of all outbreak-associated cultures to highlight possible relationships between isolates from clinical, food, and environmental samples. • Conduct applied food safety research to examine likely sources of contamination.
Identify contributing factors	• Summarize available information to identify confirmed or suspected food vehicle.	• Evaluate results of environmental investigation, given identification of agent and results of epidemiological investigation to identify factors that likely contributed to the occurrence of the outbreak.	• Summarize available information regarding culture results from clinical, food and environmental samples. • Provide background statistics on pathogen prevalence.
Determine potential for ongoing transmission, need for abatement procedures	• Create and evaluate the epi-curve to determine whether additional cases may still be occurring. • If the outbreak appears to be ongoing, continue surveillance and review potential abatement procedures.	• Verify that food workers who may have been infected during the 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 the food production/preparation processes. • Modify the menu.	• Assess status of completed and pending cultures to identify gaps that may suggest a potential for ongoing transmission.

Obtaining detailed exposure histories using a standardized "trawling questionnaire" that contains exposure-specific questions, supplemented with open-ended probing, is critical to rapidly and accurately identifying the mode of transmission and vehicle. Several approaches can be taken to collect and use this detailed exposure information. Some investigators will use such interviews with a limited number of cases as "hypothesis-generating" interviews. A subset of food items or exposures identified by multiple cases can then be evaluated in a formal case-control study. Some investigators interview all foodborne disease cases as they are reported with the trawling questionnaire or use it with all cases after a cluster is recognized. The same trawling questionnaire can be used to interview controls and be directly incorporated into a case-control study. If there are sufficient cases to have adequate statistical power, exclude the initial hypothesis generating case from the formal study. There have been no formal evaluations to determine whether the benefits of having a more focused case-control study offsets the additional time required to conduct and analyze hypothesis-generating interviews and develop and administer an outbreak-specific questionnaire. It depends on the specificity of the hypothesis compared to the way the relevant question is phrased on the trawling form.

In practice, novel or unanticipated exposures frequently surface during case interviews. Re-interviewing cases to assess these exposures as they arise can help to rapidly identify a likely source (see Dynamic Cluster Investigation Model, section 4.____). Obtaining very detailed information on exposures can facilitate implementation of control measures (see Chapter 6) by demonstrating association based on frequencies of exposure among cases or by reducing the numbers of controls necessary to demonstrate an association in a case-control study.

5.2.2.6 Coordinate investigation activities

Whether the outbreak is restricted to a single jurisdiction or involves multiple jurisdictions, notification and updates should be provided to other interested agencies following the Guidelines for Multi-jurisdictional Investigations.

Arrange for outbreak control team leaders to meet daily and provide regular updates to 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.** Results of interviewing 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 food worker interviews and food preparation reviews may 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 only food items prepared 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, there may be a premium placed on conducting patron interviews rapidly. However, the focus of outbreak activities is likely to shift to food worker interviews, environmental evaluations of the establishment, and review of food preparation procedures as the investigation progresses.

During investigation of outbreaks detected by pathogen-specific surveillance, it is particularly important that the public health laboratory immediately forward case information to epidemiologists for every new potentially outbreak-associated case that is received. This will ensure rapid enrollment of new cases in the outbreak investigation studies. Similarly, as information regarding exposures in restaurants and other licensed facilities is obtained from cases, that information should be forwarded rapidly to environmental health specialists. This will ensure rapid identification of commodity ingredients and their distribution sources.

During the early stages of the investigation, the efforts to identify the mode of transmission and food vehicle will require close coordination of the outbreak team under the leadership of epidemiology. After identification of a likely food vehicle, efforts to identify the source of contamination and contributing factors will require engagement of local, state, and/or federal food programs.

5.2.2.7 Compile results of investigation and re-evaluate goals for investigation (see also Chapter 6 -- Control Measures)

Results of outbreak investigations should be compiled in a manner that allows for readily addressing the original goals for the investigation. Background information on the outbreak should include the outbreak setting, the timing and manner of detection, and an explicit statement of the goals of the investigation.

Epidemic curves should be prepared and updated daily to visually depict the beginning and end of the outbreak. Continued motion of successive epidemic curves day by day over time is a clear indication that the outbreak is still going on. Time scales for the epidemic curve should be selected 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. It is often helpful to generate an accompanying time line of the events in the investigation, as they are happening.

Results should be compiled to demonstrate how each goal was achieved, or if the goal was not achieved to demonstrate why. For example, in an investigation of an outbreak of vomiting and diarrhea at a restaurant, the steps taken to identify the agent should be documented. 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, identification of the methods used to culture or test the specimens, and results of the tests.

Novel questions or opportunities to address fundamental questions of foodborne disease transmission may develop during the course of the outbreak investigation. The opportunity to address these issues may require a re-evaluation of the goals of the investigation.

Encourage a post-outbreak meeting among investigators to assess lessons learned and compare notes on final findings. This is particularly important for multi-agency investigations, but is also important for single agency investigations.

5.2.2.8 Document investigation findings, conclusions and recommendations

Every outbreak investigation should be documented in a standardized manner to facilitate inclusion in state and national outbreak databases. Use a standardized form to collect basic information (e.g. CDC's form 52.13 or its equivalent). These forms should be routinely reviewed and summarized (e.g. in annual outbreak summaries). Summary data should be reported nationally to the NORS database.

More significant investigations demand a more complete narrative report and, potentially, publication in a peer-reviewed journal. Written reports should include the following:

- o **Background**- including date of the event, date the investigating agency was notified, and a description of how the agency was notified.
- o **Methods**- including other agencies involved in the investigation, investigation methods used, case definition, number of people exposed, number interviewed, number ill, number of stools collected, and pathogens tested for in stools.
- o **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, 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.
- o **Conclusions**- including etiologic agent, discussion of transmission route, contributing factors, justifications for conclusions and limitations of the study.
- o **Recommendations**- including all specific recommendations for abatement of this outbreak and prevention of similar future outbreaks.

5.2.2.9 Distribute report

Copies of the report should be made available to all persons involved with the investigation, including:

- Investigation team members and their supervisors
- Health department officials and press officers
- Health care providers who reported cases
- Laboratorians who performed tests

Copies of the report should also be distributed to those responsible for implementation of 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
- Organizations or regulatory agencies that might develop/implement policies and regulations for which the investigation might have implications.

The usefulness of EFORS depends on the quality and quantity of information submitted to it. Make every effort to complete both **Part 1: Basic Information**, and **Part 2: Additional Information**, and submit the completed forms to EFORS as soon as possible. In addition, investigators are encouraged to submit preliminary reports of outbreaks while the investigation is ongoing. If submitted in a timely fashion, these reports can help identify potentially related outbreaks occurring in multiple places at the same time and facilitate further investigation of the outbreaks.

5.3 Multi-Jurisdictional Considerations for Outbreak Investigations

Our country's increased reliance on large-scale food distribution systems and international food sources has increased the likelihood that outbreaks will occur in multiple jurisdictions. Local and state health agencies always need to be sensitive to the fact that any outbreak may rapidly escalate to a regional or national event. Chapter 7 in these guidelines focuses on the extra steps that need to be taken to address multi-jurisdictional outbreaks.

5.4 Indicators/Measures

Key indicators have been developed to assess investigation processes and the overall success of outbreak investigations. Key indicators which can be used for program assessment and improvement can be found in Chapter 8. Indicators specifically related to outbreak investigations include:

- For local health departments (to be added from Chapter 8)
- For state health departments (to be added from Chapter 8)

Comments on Chapter 5

Other information that should be added:

Information that doesn’t really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 6. Control Measures

6.0 Introduction

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

Specifically, the objectives of control measures are to:

- Prevent additional exposures
- Alert the public and tell them how to protect themselves

In addition, the investigation into the circumstances likely to have led to the contamination of the food will lead to more long-term prevention efforts. The objectives of this phase of the investigation are:

- Prevent future outbreaks due to the same uncorrected practices
- Identify policy changes or practice changes that will prevent future outbreaks from similar causes

Rapid response is key. Rapidly assess available information to identify suspect food or facilities, and get people into the field immediately. Contaminated food may be served at the next meal or an ill employee may repeatedly contaminate food products. Practices that led to the outbreak are likely to continue unless there is an intervention. It is possible that the source of the outbreak is a nationally distributed food product and that a recall may be necessary to prevent additional illnesses across the country.

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

The two major types of foodborne disease outbreaks – food service establishment-based and processor/producer-based -- require two different types of control measures. Control measures appropriate for restaurants or institutional kitchens may not be appropriate for a processor/producer problem, but early in an investigation you probably don't know the real cause of the problem. There can be benefit in going to a restaurant to find potential problems, even if they are not related to the outbreak. However, looking for local causes may not be relevant for a system-wide outbreak and may even be distracting. The control measures will vary based on the setting and the time, and may change as more information is known.

Communication is critical in determining what control measures to implement, and when to change an intervention's focus. Field staff implementing control measures must be in constant communication with epidemiologists and laboratorians who may uncover a different potential cause for the outbreak. Field staff may also gather information that can lead the epidemiologists in a new direction.

6.1 Information-Based Decision-Making

6.1.1 Collecting Sufficient Information for Taking Action

6.1.1.1 Concurrent interventions and investigations

Implementing control measures can occur concurrently with conducting investigations. It is not necessary to wait for laboratory results, confirmed medical diagnosis, or the results of all interviews before implementing initial control measures. Sometimes, non-specific control measures can be implemented immediately to prevent further transmission of disease, regardless of the type of disease (see Section 6.2.1 below).

Sending at least two investigators to a food establishment implicated in an outbreak is best. One investigator is needed to make certain that food about to be served is safe (no suspect leftovers are served, foods are at proper temperature, food was prepared with no bare hand contact, no food workers are ill preparing food, etc). While the first investigator is focused on immediately preventing additional illness, the second conducts the investigation (obtains the menu for everything served to those reporting illness, identifies those who prepared suspect items and how the foods were prepared, what other groups were served the same foods, etc) For more detail on investigation steps, see Chapter 5.

6.1.1.2 Information that can implicate a food or an establishment

A wide variety of information can be used to help implicate a food or an establishment, including:

- Interviews with or reports from the public that mention a common food or establishment. Specifically look for:
    - Common symptoms or signs
    - Frequent public observations of problems with the food or establishment (e.g. reports that hot and/or cold foods were lukewarm when served)
    - Common timeframes of consumption or onset of symptoms.
- Facility history of problems (e.g. reports that hot and/or cold foods were lukewarm when served) or past outbreaks
- Information from health care providers who have seen multiple patients all reporting a common exposure.
- Information from food establishments who have received multiple reports of illness associated with the establishment or a food item.
- Cases with the same PFGE pattern or a rare serotype all associated with a particular establishment or food.
- Food testing indicating the presence of pathogens, toxins or chemicals at levels that can cause illness.
- Ill food worker from whom a reportable pathogen has been isolated.

- Inspectional findings of imminent hazards to health, such as sewage leaks, no refrigeration, no electricity, food temperature violations, or hygiene violations.
- Analytic epidemiologic investigation implicating an establishment (results of case-control or cohort, or hypothesis generation). This is often the strongest information all available.

6.1.1.3 Considerations when implementing control measures

Interventions such as recalling food or closing food premises can have major legal or economic consequences just as inaction or delayed actions can have significant public health consequences. **The outbreak control team must balance potential consequences against the likelihood that any actions taken will prevent further cases of disease.** Issues to be considered when deciding whether to move ahead with an intervention include:

- **The balance between consequences of taking action and not taking action** – For example, one is more likely to take action if the illness is serious/life-threatening (e.g., botulism or *E. coli* O157:H7), the population affected is at high risk for serious complications, and if exposure is thought to be on-going. One must also consider the potential impact on business/industry. Is it a minor inconvenience or will it have resounding and lasting effects on the business? Will the actions affect only one business or an entire industry? What is the burden on the involved public of taking action?
- **The quality of information** – What is the quality of information on which the decision is being made? Does it include results of a controlled study, e.g., case-control study or cohort study? If a controlled study was undertaken, was the study well-designed and executed and of sufficient size to detect differences? What is the likelihood of information or selection bias or confounding? Is there consistency between the findings of different studies, e.g., several case-control studies undertaken at different sites, or between epidemiologic, environmental, and microbiological studies? Is there biological plausibility for the implicated source? Is the implicated source new or novel?

The considerations cited above can add confidence to decision-making, but no one person should do this alone. **Decisions about implementing an intervention or waiting require the input of the entire investigation team**, including epidemiology, laboratory, and environmental health specialists.

6.2 Control of Source

6.2.1 Non-Specific Control Measures

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

- Holding the leftovers
- Stopping bare hand contact

- Emphasizing handwashing
- Monitoring of time/temperature control of food products
- Excluding any ill employees
- If there is the possibility of norovirus, prohibiting serving of uncooked foods

In deciding what control measures to implement, check the history of the establishment to see if there have been outbreaks associated with this facility before. What is their history of correcting violations? If they have a history of serious hazards, a history of not correcting violations, and lack credibility, this may warrant closure as they have demonstrated they cannot be trusted to implement needed control measures to prevent additional illness.

While taking these first actions, be sure to collect samples for laboratory analyses. Discarding the suspect food can help stop the outbreak, but isolating the etiologic agent from the food provides additional evidence that the food was the source. Contact your public health laboratory to find out how much food to collect.

6.2.2 Specific Control Measures – Model Practices

When a specific food or foods have been implicated, specific control measures can be implemented. While these control measures are all recommended, it is recognized that full implementation all these practices may not be possible in many jurisdictions due to resource limitations and competing priorities. Implementing as many as possible and as completely as possible will improve the effectiveness of the control measures.

The control measures to be implemented will vary depending on whether the implicated food is associated with one facility or multiple facilities. The outbreak response team must first make an initial determination as to whether a single facility or multiple facilities are involved.

6.2.2.1 Foods associated with a single facility

6.2.2.1.1 Removing food from consumption

- Ask that the owner discard or embargo all implicated food. If there is not yet any implicated food, but there is an implicated facility, ask that the owner discard or embargo all food where there is biological plausibility for linkage to the outbreak. Reserve some samples for testing.
- If the owner will not discard or embargo the food voluntarily, the agency may need to issue a public health order to require action. This will vary by jurisdiction, as some may be able to embargo food without a public health order. In investigation and enforcement matters it is usually preferable to issue a hold or embargo order in writing so that the expectation of holding the food is clear. This will prevent the owner from destroying the food before the investigation is complete.
- Fully document the information received that led to the decision (whether to remove or not remove) and also the process used to make the decision.

6.2.2.1.2 Cleaning and Sanitizing

- Ensure that the facility or facilities performs a thorough cleaning and sanitization, followed by microbial verification of the effectiveness of this cleaning and sanitation process. This would include disassembling all equipment, retraining staff on proper equipment cleaning and maintenance procedures, etc. This is particularly important if norovirus is suspected.

6.2.2.1.3 Training

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

6.2.2.1.4 Modifying a food production/preparation process

- Assure that food production/preparation processes are appropriate and adequate to prevent further contamination of food or survival and growth of microbes already present in food.
- Modify processes if needed to reduce risk such as changing a recipe, changing a process, reorganizing preparation processes, changing storage temperatures or modifying instructions to consumers. Ensure that sufficient scientific expertise exists to evaluate the proposed times, temperatures, pH, water activity level, etc, for controlling the pathogen of interest.
- Conduct follow-up monitoring to assure that no further contamination is occurring.
- Put in place a HACCP system or preventive controls.

6.2.2.1.5 Modifying the menu

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

6.2.2.1.6 Removal of infected food worker

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

6.2.2.1.7 Closing food premises

- If there are multiple problems present in the facility, and if the owner is unable or unwilling to take immediate corrective action, it may be necessary to close the premises.
- A good test is to ask oneself the questions – If this place is not closed, is it highly likely more people will become ill? Would I let a family member eat there?
- If the food premises are in an institution where there are no alternatives for residents, the outbreak response team should work with the institution staff to either identify options for bringing in food, or leave food premises open but eliminate high risk items from the menu.

- Local regulations need to be followed when requiring closure of food premises. Reopen only when risk factors have been eliminated and testing indicates that the problem has been eliminated.

6.2.2.1.8 Communication with the public

- If the outbreak involves only one facility, determine whether public notification is necessary. Factors to consider include:
    - Is any kind of medical treatment necessary for individuals who may have been exposed to the disease? If so, public notification is critical.
    - Is it necessary to encourage public reporting of suspect illness in order to determine the scope of the outbreak? If so, public notification may be appropriate.
    - Is the outbreak short-term so that there is no further risk to the public? If so, public notification is generally not necessary.
- A key consideration is whether there is still risk of exposure. Remember that people take food home from restaurants, so public notification may still be appropriate.
- Prepare communication following the agency's risk communication protocols. Seek assistance from the agency Public Information Officer, or PIO at another agency if the one with jurisdictional responsibility does not have this resource.
- If the facility owner will not act voluntarily, other source control measures include cease and desist orders, permit action and hearing in front of a judge.

6.2.2.2 Multiple facilities or single product distributed at multiple locations

If there are multiple facilities or multiple reports from consumers consistent with an outbreak caused by a single product at multiple locations, decide whether to remove the suspect food from access for human consumption. This decision is almost always made by the retailer initially – local, state, and federal regulators should first meet together to coordinate, then contact the retailer to "persuade". See Table 6.1 for factors to consider when determining whether to remove food from the market.

Table 6.1 Factors to consider when determining whether to remove food from the market

- Does the available information justify removing food from the market? Remove the food if:
    - Definitive lab results have shown that the outbreak pathogen is present in the product.
    - There is a strong epidemiological association between the illness and eating that food, even if the pathogen has not been isolated from it.
    - Epidemiologic association is not strong, but pathogen is so hazardous that the risk to the public is very high.
- Is the product still on the market?
- Is the product likely to be in the homes of consumers?
- Is there an ongoing risk to consumers?
- Fully document the information received that led to the decision (whether to remove or not

6.2.2.2.1 Procedures for removing food from the market

Once a decision is made to remove food from the market, the goal is to remove it as quickly and efficiently as possible. Foods with short shelf lives (fresh produce, meat, dairy products) may already have been disposed of and are generally consumed within seven to ten days. Foods with longer shelf lives will likely still be around. Try to prevent additional exposure by making sure suspect food is not served.

If the decision is made to remove the product from the market, contact the manufacturer about the decision and get their cooperation. Ask retailers to voluntarily remove the product from their shelves and distributors to voluntarily withhold the product from distribution. The manufacturer may decide to issue a food recall.

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

The following recommendations for industry and retail establishments can help assure that the recall is effective (refer to AFDO Recall Guide):

Before a recall is announced:

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

After a recall is announced:

- Quickly remove recalled contaminated product from commerce at the site and notify customers.

- Notify customers through the regulatory agencies and news media as needed.
- Post signs at the point of sale to advise consumers of the recall.
- Put in place fail-safe systems that do not allow sale of recalled products (e.g. cash register flags recalled products and prohibits sale). Assure that stores have clearly defined storage areas and handling processes for recalled products. This may include denaturing or other process to assure that foods are not resold.
- Put in place systems for safe handling and/or disposal of recalled products to avoid cross contamination to other products, accidental restocking, diversion and the creation of other hazards. Consider the possibility of homeless individuals removing discarded product from the trash.

To improve the effectiveness of recall measures, health departments can:

- Develop a list of control measures to immediately put in place once an outbreak or illness related recall has been identified.
- Identify industry needs and develop guidance for how to interact with health/agricultural officials conducting an investigation. Provide 24/7 contact numbers and e-mails for regulators.
- Develop guidance for how to deal with the news media.
- Develop guidelines for mitigating impact.
- Develop templates/message maps/community information sheets for common foodborne agents to have ready to use in case of an outbreak.

Regulators who are responsible for retail food facilities MUST have a means to notify all food facilities in their jurisdiction immediately through e-mail, blast fax, phone calls. It is highly recommended that there be sub-categories so that notices can be targeted to specific facilities (e.g. notices of a seafood recall sent specifically to seafood restaurants). Failing to have such a system is not an acceptable practice. This process should include food bank donation centers and other sites that may have received food donations.

If any of the distributors or retailers refuse to remove the food, it may be necessary to issue a public health warning and order to require action. The appropriate agency for taking this action will depend on the type of food and disease organism (e.g., for a highly dangerous condition like botulism, food seizure is appropriate to assure that suspect food is removed immediately and completely from the market).

Monitor to assure that product is completely removed. This often requires very close cooperation with local, state and federal agencies on recall effectiveness checks. If the product is not being immediately removed, determine why (Did the distributor notify retailers of the recall? Did the manufacturer notify the distributor?

Did notifications occur but no action was taken? Was returned recalled product diverted and sold somewhere else?).

6.2.2.2.2 Communication with the public

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

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

If the manufacturer has refused to do a recall, the firm should be advised promptly that public health agencies or regulators may issue their own notice to the public and that the notice may include the message that the firm declined to conduct a voluntary recall. **The message to the public should describe the available information and provide clear actions for the public to take.**

The means of notifying depends on the public health risk, and may include press releases, fax, radio, television, telephone, email and/or letters. Notification may be initiated by the manufacturer, public health agencies, regulatory agencies, retail food establishment or all four. These releases should be coordinated and include consistent messages to avoid confusing the public.

Attempt to reach all members of the population at risk, including non-English speaking and low-literacy populations.

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

Provide only objective, factual information about the outbreak. Do not give preliminary, unconfirmed information.

If press releases are to be issued by retailers or manufacturers, they should be reviewed and approved before release by relevant local, state, or federal officials. Manufacturers often seek guidance on what to say in press releases, and public health agencies can provide needed information. If a specific food is implicated, such as a particular brand of bagged baby spinach, the press releases need to inform consumers that the local jurisdiction is interested in obtaining these products from those households that may still have them.

Public health agencies should issue their own press releases, even if the affected industry or business is also issuing a release. Offer to review the release being prepared by the industry or business, and if time allows give affected parties an opportunity to comment on your releases. However, avoid prolonged negotiations about the wording of press releases.

6.2.2.2.3 Post-recall reporting by the business

If a business or manufacturer conducts a recall, they should prepare interim and final reports about the recall. The contents of these reports are used to determine if further recall actions are necessary.

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

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

6.3 Control of Secondary Transmission

6.3.1 Information for Health Care Providers

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

6.3.2 Information for the Public

Any outbreak is an opportunity or "teachable moment" to reinforce basic food safety messages to the public, and also to provide information to the public on how to contact the appropriate authorities to report suspected foodborne illnesses.

6.3.2.1 Personal protection from disease outbreak

- Handwashing is the single most important measure to protect an individual's own health and to protect other people.
- At home or when attending a social gathering (potluck dinners, etc) avoid eating food that has not been handled properly (hot food has not been kept hot, cold food has not been kept cold).

6.3.2.2 Proper food preparation

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

6.3.2.3 Advice on personal hygiene

- Avoid preparing food for others until free of diarrhea or vomiting.

- Thoroughly wash hands with soap and warm water after defecation and urination, and before preparing or consuming food. Also wash hands after changing diapers, assisting a child at the toilet, and handling animals or animal waste.
- If someone in the household has diarrhea or vomiting, clean toilet seats, and flush handles, and wash hand basin taps and toilet door handles with disinfectant after use. If young children are infected these cleaning procedures must be undertaken on their behalf. If norovirus is involved, clothes, towels and linens soiled with vomitus or stool should be washed promptly at the highest temperature the item will allow.

6.3.3 Exclusion of Infected Persons from Settings Where Transmission May Occur *(including food preparation, health care, daycare settings)*

Persons with an enteric illness can shed viruses or bacteria for weeks after symptoms have ended. Infected skin lesions can also serve as a reservoir for pathogens that can be transmitted to food when there is bare hand contact.

If an individual has been ill and is considered to be a possible source of pathogens, the individual can be restricted to specific areas and tasks where there will be minimal risk of transmitting the disease. Note that even if given duties not involving food preparation, workers infected with norovirus can transmit infection to others and must wash their hands carefully.

If it is not possible to restrict the individual, it may be necessary to exclude the individual from the facility until all likelihood of shedding pathogens has passed. Testing the person to assure there is no further risk may be necessary. Individuals who are no longer ill with vomiting or diarrhea can usually return to work without testing if they practice good personal hygiene and are adequately supervised. Consult your local ordinances or state statutes for specific requirements for returning to work.

According to the 2005 FDA Food Code, available at http://www.cfsan.fda.gov/~dms/fc05-toc.html, food workers with diarrhea and vomiting should be excluded from the work place for at least 24 hours after symptoms resolve. If there is a medical diagnosis of norovirus, the food worker must wait at least 48 hours after symptoms resolve before returning to work. Approval to return to work may be required from the local or state health department

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

6.3.4 Infection Control Precautions

Work with the facility operator to create a risk-control plan or consent agreement, so that the operator knows exactly what steps need to be taken and has committed to bring the situation into control and to prevent further outbreaks. The risk control plan or agreement may include actions that are above and beyond those required by regulation (e.g., extra temperature checks and logging of temperature, mandatory glove usage by all food workers, routinely asking staff before they start their shift whether they've had diarrhea or vomiting in the last 24 hours). Ideally both epidemiology and environmental health specialists are involved in creating this plan or agreement. An important aspect of the plan is to 1) include employee training and 2) provide adequate oversight to assure employees are following proper procedures.

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

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

Reinforce the following:

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

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

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

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

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

6.3.5 Prophylaxis

Have processes set up with area hospitals, physicians, local health departments, specialty clinics or other health care providers to provide prophylaxis if needed. Have plans in place (and have tested those plans) for large-scale prophylaxis if necessary.

Develop processes for identifying and communicating with persons who may need prophylaxis. Depending on the organism, this may include giving special consideration to protecting risk groups:

- Certain groups are at higher risk of severe illness and poor outcomes from foodborne disease than others, including infants, pregnant women, and immunocompromised individuals. Safe food preparation practices and hand washing particularly need to be emphasized to these groups.
- There may also be a need to issue specific advice, such as advising pregnant women and immunocompromised individuals against consuming unpasteurized dairy products or other products potentially containing *Listeria.*
- Individuals with underlying chronic hepatitis B or C may need to be advised to be vaccinated against Hepatitis A.

6.4 Communication

6.4.1 With Other Members of the Investigation and Control Teams

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

Keep the owners/managers of the implicated establishment informed and notify them that they must report any new reports of illness or other new information learned that could have an impact on the investigation.

Illness complaints may also be reported to retail food chains or the manufacturer concerning a commercial product. These illness complaints must be reported to the appropriate food regulatory agency. Such reports may lead to the initial identification of an outbreak or the expansion of a recall if it is learned that additional product codes are also associated with illness.

6.4.2 With Agency Executives and Other Agencies

Ensure that agency heads routinely receive information about the status of the outbreak investigation and clean-up

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

6.4.3 With the Public

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

Recognize that the public gets news from multiple sources – the Internet, television, radio, and newspaper. Use all available sources to get information out. Know the typical deadlines for area news outlets, and try to work within those timelines if at all possible when releasing information out.

If the public is not receiving needed information from the public health agency, they will get it from other sources (which may not be very accurate). It is important for the public health agency to be seen as and to act as the most reliable source of information on a foodborne disease outbreak.

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

It is important to recognize that key terms (e.g., risk, bacteria, etc) may seem to be common terms but in fact are often misunderstood. A standard format for reporting risk information should be adopted. Communications about foodborne disease risks should be routine (meaning, the same process should be used each time). This will help make the process more familiar and reduce concerns over the message.

In communication planning, adopt standard scripts for reporting complex procedural information about what is happening in the investigation and what people should do. Messages that are to be used with the public should be tested first with representatives of the target population.

6.4.4 With the Industry

Contact the firm or firms directly linked to an outbreak as soon as possible, and tell them as much as possible. Give them advice on potential control measures for the outbreak, such as voluntary recall of an implicated product. This communication can be complicated by the fact that an enforcement action may result from the investigation, but it is still important to be honest and forthright with the regulated firms. Large firms often have their own staff who understand a lot of this and know what decisions to make. Some medium sized and many small firms do not have this kind of expertise and therefore need more guidance. Different state and local governments have different laws and policies in these situations. **Understand your own legal framework so you know how to interact with firms that may be linked to an outbreak.**

The food industry has many trade associations. Some overlap but in general there are associations for every segment of the food industry. **State, local and federal agencies need to have existing working relationships with these associations BEFORE the outbreak occurs.** At the time of the outbreak it is very helpful if government reaches out to the appropriate associations with information on the outbreak and with actions that the members should take to prevent spread of the current problem or similar problems from happening in their firms.

Outbreaks can be a teachable moment for the food industry. When the press is carrying stories about an outbreak communication within the industry is lively, often with misinformation. Food safety and public health agencies need to work to dispel these misconceptions before they lead to other problems. These agencies also need to explain what they are doing in response to the outbreak and to show the public that that they can have faith in eating the implicated product in the future, once the problems have been addressed.

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

6.5 End of Outbreak

6.5.1 Determining When an Outbreak is Over

Most outbreaks can be considered over when two or more incubation periods have passed with no new cases occurring. This arbitrary rule may not apply to clusters with a very low attack rate; cases from some sources may appear intermittently for years.

6.5.2 Determining When to Remove Restrictions

Remove restrictions when there is no further risk to the public

- Risk factors in the facility have been eliminated
- Ill food workers have recovered and are no longer shedding pathogens
- Tests show that no further contamination is present
- Employees have been taught how to avoid a problem

- Managers agree to provide appropriate oversight

6.5.3 Post-outbreak Monitoring

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

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

Maintain communication with the implicated facility(ies) to let them know if additional information becomes available.

Increase the number of routine inspections at the implicated facility(ies) to assure that they are complying with all required procedures. Old unsafe practices are often hard to change and it may take one month or more using new practices before they become routine. Consider customized training to support the desired behavior change. Look to see if long-term behavioral change has occurred. If the inspection program is fee-based, consider charging more for the additional inspections that are needed when a facility is implicated in an outbreak.

6.6 Debriefing

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

A formal debriefing meeting should cover the following topics:

- Identify the cause of the outbreak and what can be done to prevent additional outbreaks at this and other facilities.
- Identify the long-term and structural control measures and plan their implementation
- Assess the effectiveness of outbreak control measures and difficulties met in implementing the control measures
- Assess whether further scientific studies should be conducted
- Clarify resource needs, structural changes or training needs to optimize future outbreak response
- Identify the factors which compromised the investigations and seek solutions
- Identify necessary changes to current guidelines and development of new guidelines or protocols as required
- Discuss any legal issues which may have arisen

6.7 Outbreak Report

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

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

For a large outbreak, the final report should be more comprehensive, with information provided by all team participants. Such a report should be disseminated to all participating organizations. Sample outbreak reports are available on the CIFOR Clearinghouse web site.

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

6.8 Future Studies and Research

The outbreak investigation findings may point to the need for future research. For example, investigators may determine that for certain pathogens in certain foods, standard control measures don't seem to be very effective. Such observations should be considered for in-depth study, either by the public health agency or by research centers. **Identifying issues that need follow-up research is an important way to improve the practice of foodborne disease outbreak response.**

6.8.1 Publication of Outbreak Results

If there was something unusual about the outbreak (unusual exposure, presence of a pathogen in a food where it had not previously been seen, etc) the report should be disseminated more widely (EpiX, MMWR or other national forum, peer reviewed journals).

If there were important lessons learned (new investigation methods that proved particularly helpful, control measures that seemed particularly effective, actions taken that seemed to shorten the outbreak, etc) this information should be published in an appropriate national forum.

6.8.2 Education

An outbreak may identify the need for broad education efforts of the public, the food preparation industry, or health care providers. Public service announcements may be necessary to remind the public about food preparation precautions. Food worker and food manager training may need to be modified to address specific concerns. Managers need to provide oversight to make sure food workers are trained and are using recommended procedures. Health care providers may need continuing education efforts focused on diagnosing, treating or reporting foodborne diseases. Such action can help prevent future outbreaks or reduce the number of cases or the severity of illness when an outbreak occurs.

6.8.3 Policy Action

Information gained during an outbreak may identify the need for new public health or regulatory policy at the local, state or federal level. It may be necessary to establish different inspection practices, source controls, or surveillance procedures, or to establish more control over the recall process. Reports of past outbreaks should be analyzed to determine whether the need for new policy is supported by multiple outbreaks. Other public health and environmental health agencies should also be consulted to see if there is concurrence on the need for new policy. If there is agreement on the need for new policy, the issue should be presented to the appropriate jurisdictional authority using the appropriate policy development processes.

6.9 Multi-Jurisdictional Considerations for Control Measures

While control measures are typically implemented at the local level, outbreaks that are multi-jurisdictional require extensive coordination between agencies to assure that control measures are implemented consistently and are effective. See Chapter 7 for Multi-jurisdictional Investigation Guidelines.

6.10 Indicators/Measures

Key indicators have been developed to assess control measures and the overall success of efforts to halt outbreaks. Key indicators which can be used for program assessment and improvement can be found in Chapter 8. Indicators specifically related to control measures include:

- For local health departments (to be added from Chapter 8)
- For state health departments (to be added from Chapter 8)

Comments on Chapter 6

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 7. Special Considerations for Multi-Jurisdictional Outbreaks

7.0 Introduction

7.0.1 Definition

A multi-jurisdictional foodborne disease event is one that requires the resources of more than one local, state, territorial, tribal, or federal public health or food regulatory agency to detect, investigate, or control.

A multi-jurisdictional investigation may involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

7.0.2 Purpose

These CIFOR multi-jurisdictional guidelines are intended to help improve communication and coordination between agencies at all levels of governmental organization investigating multi-jurisdictional outbreaks.

The guidelines are proposed to help agencies identify multi-jurisdictional outbreaks and to increase the speed of investigation and control of outbreaks. Specifically the guidelines have the following objectives:

1) Provide a definition of when an outbreak may be considered a multiple jurisdictional outbreak,
2) Establish a framework for rapidly assessing whether multiple jurisdictions are affected by a given foodborne disease event,
3) Promote early and effective communication and coordination among agencies involved in multi-jurisdictional investigations,
4) Detail specific actions that may need to be carried out in a multi-jurisdictional outbreak,
5) Provide guidance on how to manage the transition between the phases of an outbreak investigation during which leadership of the investigation changes, and
6) Provide guidance on post-outbreak debriefing and dissemination of findings.

7.0.3 Scope

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

For ease of reading, these guidelines focus on relationships between local, state, and federal levels. Although Territories, Tribal lands, and the District of Columbia represent independent administrative structures, with unique legal standing, the general principles of multi-jurisdictional investigations articulated in these guidelines should be useful for health officials in these areas as well.

7.1 Background

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

In 2001, the National Food Safety System (NFSS) Project, Outbreak Coordination and Investigation Workgroup published guidelines for improving coordination and communication in Multi-state Foodborne Outbreak Investigations. The NFSS multi-state guidelines were specifically developed to address the challenges of coordinating large and complex foodborne outbreak investigations among multiple states and federal public health and food regulatory agencies.

Since the development of these guidelines, the terrorist attacks on September 11, 2001 have raised concerns regarding the potential for intentional contamination of food at all levels of the food system that would require interactions between agencies that have not previously worked together. In addition, large multi-state case clusters and foodborne disease outbreaks have continued to occur. For example, from 2002-2005, at least 6% of foodborne outbreaks reported to the CDC's Foodborne Outbreak Reporting System (EFORS) involved multi-state or multi-county exposures, or affected residents of multiple states or counties (Table 7.1). Furthermore, 40% of *E. coli* O157:H7 outbreaks and 25% of *Salmonella* or hepatitis A (HAV) outbreaks were multi-jurisdictional. The use of PulseNet as a tool for surveillance of *E. coli* O157:H7 and Salmonella has increased the ability to detect multi-jurisdictional outbreaks. Thus, for these most important foodborne pathogens, the need for multi-jurisdictional coordination should be anticipated during the earliest stages of the investigation.

The Council to Improve Foodborne Outbreak Responses (CIFOR) was created in 2006 to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CIFOR determined that one priority area would be to go beyond multi-state outbreaks by also developing guidelines for multi-jurisdictional outbreaks. Multi-jurisdictional guidelines are applicable to multiple states, but also include localities within a state and outbreaks involving multiple agencies. Table 7.2 describes the categories of multi-jurisdictional outbreaks.

Based on recent experiences with multi-jurisdictional investigations, there are two overriding concerns with communication and coordination of multi-jurisdictional investigations. The first is to establish criteria by which a local health agency may recognize that a foodborne outbreak under investigation is multi-jurisdictional, and to facilitate rapid communication of that fact to all affected agencies. The second is to establish effective means of integrating local agencies into large, multi-state investigations that are detected and coordinated on a national level.

Table 7.1 Number of multi-state exposure, multi-state resident, multi-county exposure, and multi-county resident outbreaks by etiology, 2002-2005

Agent	Agent	No. Outbreaks	No. Outbreaks, Multi-state Exposure	No. Outbreaks, Multi-state Resident	No. Outbreaks, Multi-county Exposure	No. Outbreaks, Multi-county Resident
Confirmed Etiology		1903	43	34	122	31
	E. coli O157:H7	75	11	1	17	1
	Salmonella	448	24	10	65	14
	C. perfringens	90	0	1	1	2
	S. aureus	61	0	2	3	1
	Hepatitis A	24	1	0	5	0
	Norovirus	770	0	13	12	9
	Other	391	4	6	18	3
	Multiple	44	3[a]	1[b]	1[c]	1[d]
Suspect Etiology		1402	0	3	17	18
Unknown Etiology		1438	0	10	17	12
TOTAL		4743	43	47	156	61

[a]Three multi-state exposure outbreaks involving multiple etiologies; one *Salmonella* outbreak due to serotypes Anatum, Muenchen, Javiana, Thompson, and Typhimurium; another *Salmonella* outbreak due to Saintpaul and Typhimurium; and a third *Salmonella* outbreak due to Enteritidis, Kentucky, and Typhimurium

[b]One multi-state resident outbreak due to C. parvum and E. coli O111

[c]One multi-county exposure *Salmonella* outbreak due to serotypes Adelaide and Hadar

[d]One multi-county resident *Salmonella* outbreak due to serotypes Newport and Typhimurium

Table 7.2 Categories of multi-jurisdictional outbreaks
1. Outbreaks affecting multiple local health jurisdictions (City, County, Town, etc) within the same state.
2. Outbreaks involving multiple states.
3. Outbreaks involving multiple countries.
4. Outbreaks affecting multiple distinct agencies (Public Health, Food Regulatory, Emergency Management, etc).
5. Outbreaks, regardless of jurisdiction caused by highly pathogenic or unusual agent (e.g., botulism) that may require specialized laboratory testing, investigation procedures or treatment.
6. Outbreaks in which the suspected or implicated vehicle is a commercially distributed processed or ready-to-eat food contaminated prior to the point of service.
7. Outbreaks involving large numbers of cases that may require additional resources to investigate.
8. Outbreaks in which intentional contamination is suspected.

7.2 Key Indicators and Notification Steps

Following the recognition that a foodborne disease event requires multi-jurisdictional investigation, agencies that may be needed to participate in the investigation and agencies that may be otherwise affected by the event should be immediately notified. Key indicators of multi-jurisdictional foodborne disease events are summarized in Table 7.2 and Figure 7.1. Specific examples of these indicators and required notification steps are described below in Table 7.3. In some states, functions identified as occurring at the local level may be performed at the state level.

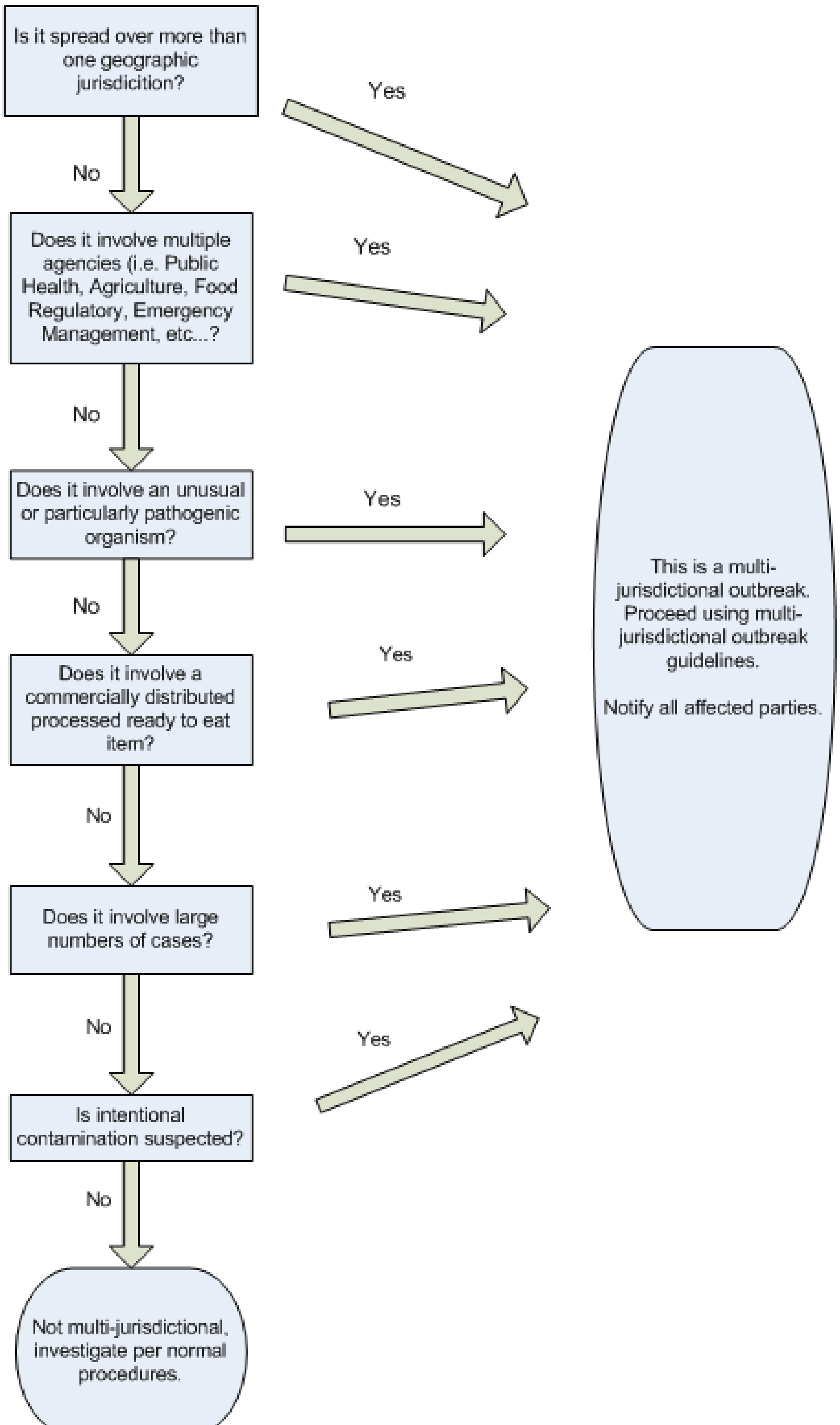
Table 7.3. Examples of key indicators and required notification steps.

Outbreak Detection	Key Indicator	Notification Steps
Local level	Commercially distributed processed or ready-to-eat food contaminated prior to the point of service suspected or implicated as the vehicle in the outbreak.	Immediately notify state health department, relevant state food regulatory agency, CDC, and FDA or FSIS (depending on product) and local and state reporting requirements.
	Fresh produce item contaminated prior to the point of service is suspected or implicated as the vehicle in the outbreak .	Immediately notify state health department, relevant state food regulatory agency, CDC, and FDA, depending on state and local reporting requirements.
	Ground beef is implicated in an outbreak of *E. coli* O157:H7 infections.	Immediately notify state health department, relevant state food regulatory agency, CDC, and FSIS, depending on state and local reporting requirements.
	Molecular subtype characteristics of etiologic agent matches the pattern of an agent independently associated with other foodborne disease outbreaks.	Immediately notify state health department, relevant state food regulatory agency, CDC, and FDA or FSIS, depending on product and state and local reporting requirements.
	Intentional contamination of food item is suspected or implicated.	Immediately notify state health department, relevant state food regulatory agency, CDC, and FDA or FSIS (depending on product) local law enforcement and FBI.
	Illnesses are associated with multiple restaurants/food service establishments, especially when those establishments are part of the same chain.	Immediately notify state health department, relevant state food regulatory agency, and CDC depending on local and state reporting requirements.
State Level	Increase of sporadic infections with common subtype characteristics identified across multiple	Immediately notify affected local agencies, CDC, state and federal food regulatory agencies.

Table 7.3. Examples of key indicators and required notification steps.		
Outbreak Detection	**Key Indicator**	**Notification Steps**
	jurisdictions.	
	Multiple common source outbreaks linked by common agent, food, or water.	Immediately notify affected local agencies, CDC, relevant state and federal food regulatory agencies.
	Microbiological food testing by state food regulatory agency prompts recall.	Immediately notify affected state and local public health agencies, CDC, relevant federal food regulatory agencies.
	Illnesses are associated with multiple restaurants/food service establishments, especially when those establishments are part of the same chain.	Immediately notify relevant state food regulatory agency, and CDC, depending on product and local and state reporting requirements.
Federal Level	Increase of sporadic infections with common subtype characteristics identified across multiple states.	Immediately notify affected state and local public health agencies, federal food regulatory agencies.
	Multiple common source outbreaks linked by common agent, food, or water.	Immediately notify affected state and local public health agencies, CDC, relevant state and federal food regulatory agencies.
	Microbiological food testing by, or reported to FDA or FSIS prompts recall.	Immediately notify affected state and local public health agencies, CDC, relevant state and federal food regulatory agencies.

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

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



7.3 Coordination of Multi-Jurisdictional Investigations

Following the notification of affected agencies, coordination of the multi-jurisdictional investigation may require the establishment of a coordinating office to collect, organize, and disseminate collective data from the investigation. Depending on the scope and nature of the multi-jurisdictional event, the coordinating office may be located at a local or state health or food regulatory agency, or at the CDC, FDA, or FSIS.

There are several principles that may guide the decision on where to locate the coordinating office in a given multi-jurisdictional investigation. The key issue is to avoid interagency conflict over coordination that may distract from the prompt conduct of the investigation.

1. **Outbreaks are most efficiently investigated as close to the source as possible.** In general, investigations should be coordinated at the level at which the outbreak was originally detected and investigated. This is likely to be where the bulk of relevant investigation materials will reside, which can facilitate organization and analysis of the data. This means that an outbreak involving several local health agencies may best be coordinated by a lead local agency. Similarly, investigation of a multi-state outbreak with most cases in one or a few adjacent states may best be coordinated by a lead state agency. Investigations of outbreaks of more widely dispersed sporadic cases may best be coordinated by the CDC.
2. **The coordinating office must have sufficient resources, expertise, and legal authority to collect, organize, and disseminate data from the investigation.** Many local agencies may not have sufficient resources to effectively coordinate a multi-jurisdictional investigation, or state rules may assign jurisdiction over multi-county investigations to the state health department. In these situations, the coordinating office should be located at the state level. In multi-state investigations, the coordinating office should be located at CDC if no individual state is prepared to do so. In multi-state investigations led by an individual state, CDC should provide support for the investigation in coordination with the lead agency.
3. **Outbreak investigations progress through phases of activity, and leadership of the investigation should reflect the focus of the investigation at the time.** Typically, the early stages of an outbreak investigation are dominated by epidemiologic efforts to characterize the outbreak by person, place, and time. Efforts to identify the mode of transmission and food vehicle begin to incorporate environmental health specialists and food regulators. Determining contributing factors, conducting regulatory tracebacks, and implementing control measures moves the investigation into the food regulatory realm. Transition of leadership within the outbreak team should be planned in advance by consensus and communicated to the entire outbreak control team. These phases of activity can be elaborated as follows:

    Investigation of human illness outbreaks should be coordinated within public health agencies. In addition to public health agencies having greater expertise and experience in conducting these investigations, rules governing the reporting and collection of information on human patients require that authorized public health agencies maintain and protect that information. While de-identified information may be shared across agencies, the redaction process may reduce the value of the available information for analysis.

    Investigations of food contamination events should be coordinated within food regulatory agencies. In addition to food regulatory agencies having greater expertise and experience with these investigations, rules governing the collection of product manufacturing and distribution information may dictate that authorized food regulatory agencies not share that information outbreak investigators in other agencies. If that information is important to the investigation, outbreak investigators should consider collecting that information directly, even if that means some duplication of effort.

4. **Sharing of information between public health and food regulatory agencies is critical to the effectiveness of multi-jurisdictional investigations.** The need to share information between public health and food regulatory agencies frequently challenges the legal authority of each party. However, the efficiency and effectiveness of multi-jurisdictional investigations can be greatly enhanced by rapid and open information sharing. For example, public health agencies need access to detailed product source and distribution data to conduct epidemiologic investigations and evaluate potential public health interventions. Similarly, food regulatory agencies need detailed case information and preliminary results of epidemiologic investigations to guide environmental assessments and traceback activities. Since these activities build on each other, it is critical to establish information sharing protocols during the earliest stages of the investigation.

5. **Identifying the source of a multi-jurisdictional outbreak represents a collaborative process between local, state and federal agencies and industry.** Individual food companies and trade associations should be engaged early on to help with the investigation. Including affected industries in the investigation can help improve exposure assessment and help industry respond sooner and more effectively.

6. **Releasing public information about the outbreak should be coordinated with the lead investigating agency, when feasible.** Although the public and press are not aware of most outbreak investigations, the results of investigations are public information. In addition, responding to media attention is important to address public concerns about the outbreak. Although individual agencies participating in the investigation may be obligated to respond to media inquiries, a coordinated communications plan can help provide a consistent message about the progress of the investigation, or the source of the outbreak. Coordinating communications with the media is particularly important when media attention is needed for public action to avoid exposure to a specific contamination source, such as a recalled food product.

7. **Most health departments have incident command systems that guide outbreak responses within the public health agencies. However, most multi-jurisdictional foodborne outbreak investigations do not require activation of incident command systems.** Incident command systems (ICS) are structures that provide for internal communications within a governmental system between primary event responders, public information officers, and security and safety officers and for external liaison with various organizations. Local, state and federal health and food safety agencies are increasingly developing and using ICS to guide their responses to foodborne disease events. In concept, these guidelines provide for communication and coordination between agencies involved with responding to a multi-jurisdictional foodborne outbreak in a similar manner. However, while the principles of multi-jurisdictional investigations may be similar to ICS responses, in many states and local jurisdictions, ICS are formal structures that are controlled by Public Safety Officials with no other jurisdiction for food safety or outbreak control. In these settings, activating ICS may initiate actions that could distract from the prompt conduct of the investigation.

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

8. **An after-action review should be conducted by the agency coordinating the investigation.** The coordinating agency should review the conduct of the investigation with collaborating agencies, should summarize the effectiveness of communication and coordination between jurisdictions, and should identify specific gaps or problems that arose during the course of the investigation.

9. **All multi-jurisdictional outbreak investigations should be reported as such to EFORS.**

7.4 Outbreak Detection and Investigation by Level

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

7.4.1 Outbreak detection and investigation at the local level

7.4.1.1 Detect outbreak

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

- Consumer complaint identifies group exposure with multiple illnesses.
- Multiple consumer complaints received regarding the same source.
- Health care provider reports group exposure with multiple illnesses.
- Sporadic case investigation identifies group exposure with multiple illnesses.
- Sporadic case cluster investigation identifies common source.

7.4.1.2 Ensure notification

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

- Affected and surrounding county, city health departments (Epidemiology, Environmental Health, Laboratory).
- State health department (Epidemiology, Environmental Health, Laboratory).

7.4.1.3 Provide coordination

During the course of the investigation, a local agency needs to **provide coordination** between the epidemiology, environmental health and laboratory components of the investigation.

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

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

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

Action: Ensure notification of the affected jurisdiction immediately.

Incident: Common source outbreak identified in one jurisdiction has cases that reside in two or more local jurisdictions.

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

These investigations are handled following **routine polices and procedures**, under **local agency leadership** unless otherwise specified by state procedures. The level of state involvement is a function of local/state protocols.

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

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

Action: Ensure notification of appropriate food regulatory agencies of likely contaminated food vehicle, **traceback** source to the point where contamination likely occurred, or determine if responsibility for the investigation needs to be transferred to a state or federal agency.

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

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

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

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

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

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

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

Action: Upload patterns to PulseNet.

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

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

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

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

These investigations **require information sharing and coordination** between multiple local agencies, under **local agency leadership** unless otherwise specified by state procedures. The state receives information and provides consultation. There is no activation of emergency management systems.

7.4.2 Outbreak detection and investigation at the state level

7.4.2.1 Detect outbreak

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

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

7.4.2.2 Ensure notification

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

- All local health departments likely to be affected by the outbreak or involved in the investigation
- The state food regulatory agency
- Other state health departments (regional counterparts, or potentially nationally via Epi-X, OutbreakNet, PulseNet or similar networks)
- CDC (ORST)
- Federal regulatory agency offices (e.g., FSIS, FDA, EPA), depending on the nature and status of the investigation

7.4.2.3 Provide coordination

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

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

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

Action: Upload patterns to PulseNet.

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

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

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

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

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

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

Action: Ensure notification of appropriate food regulatory agencies of the likely contaminated food vehicle in commercial distribution, **traceback** source to the point where contamination likely occurred, or determine if jurisdiction needs to be transferred to a federal agency.

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

Action: Establish the coordinating office (or an individual) for investigations to **collect, organize and disseminate** collective data. In cooperative investigations, raw data must be made readily available in a common format to interested participants from all participating agencies.

The resources of one or more local jurisdictions cannot adequately respond to these events following routine procedures. These investigations **require active participation** from multiple local agencies, typically under **state agency leadership**. The state provides response coordination, consultation and information sharing. Based on established procedures, there may be activation of emergency management systems at local level or possibly state level. Federal agencies are notified and involved depending on product type and distribution.

Multi-state outbreaks, and outbreaks associated with regionally or nationally distributed food products involve a **transition from state to national significance**. These outbreaks may require regional or national resources. While they **require active participation** from multiple local agencies, and state **response coordination,**

consultation and information sharing, they may require **federal agency leadership**, depending on the capabilities and willingness of the states involved. In a small number of events, there may be activation of emergency management systems at local and state levels, and possibly at federal level.

7.4.3 Outbreak detection and investigation at the federal level

7.4.3.1 Detect outbreak

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

- Common source outbreaks in multiple states linked by common agent, food, or water.
- Cluster(s) of sporadic infections with common subtype characteristics identified in multiple states.
- Regional or national increase of sporadic infections with common subtype characteristics identified.

7.4.3.2 Ensure notification

With initiation of an outbreak investigation, the CDC Outbreak Response and Surveillance Team (ORST) should **ensure notification,** and provide subsequent updates as appropriate**:**

- States, and local health departments, as appropriate (Epi-X, Foodborne Outbreak Listserve, OutbreakNet, PulseNet)
- Federal regulatory agency offices as appropriate (FSIS, FDA, EPA)

7.4.3.3 Provide coordination

During the course of the investigation, federal agencies need to **provide coordination** between the epidemiology, environmental health and laboratory components of the investigation at the federal level, and **ensure that federal** epidemiology, environmental health and laboratory **programs are communicating and coordinating** activities with their counterparts at both the state and local levels.

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

  Incident: Common source outbreaks in multiple states, linked by common agent, food, or water.

    Action: Ensure notification of all states, and local jurisdictions as appropriate, of results of outbreak investigations regarding agent and vehicle.

    Action: Ensure notification of appropriate food regulatory agencies of likely contaminated food vehicle in commercial distribution, **traceback** source to the point where contamination likely occurred.

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

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

  Incident: Case clusters in multiple states, regional or national increase of sporadic infections with common subtype characteristics identified.

Action: Ensure notification of all states, and local jurisdictions as appropriate, **distribute** summary data regarding cases, descriptive epidemiology, investigation protocols and standardized questionnaires.

Action: Request that local or state agencies **interview cases and controls** as soon as possible using standardized questionnaire to obtain detailed food exposure histories, including product brand and retail source. **Assess** the availability and willingness of local or state agency staff to conduct interviews in a timely manner. **Provide support** needed to ensure that **interviews are conducted in a timely manner**.

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

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

These outbreaks require activation of local, state, regional, and national resources to contain disease and protect human health. They **require active participation** from multiple local agencies, state **response coordination, consultation and information sharing**, and **federal agency leadership.** There may be activation of emergency management systems at local, state, and federal levels.

7.5 Multi-Jurisdictional Outbreak Investigation After-Action Reports and Reporting to EFORS

A conference call should be held among the involved organizations one to three months after the initial investigation is over to review lessons learned, and to update participants on findings and conclusions and actions taken.

An after-action report should be prepared by the lead agency(ies) coordinating the investigation, following the conference call. The report should summarize the effectiveness of communication and coordination between jurisdictions, and identify specific gaps or problems that arose during the course of the investigation. All participating agencies should have the opportunity to review and comment on the report before it is more widely distributed.

All multi-jurisdictional investigations should be reported by individual states to EFORS. The multi-jurisdictional nature of the investigation should be indicated by completion of appropriate data fields in the EFORS report form. Individual state reports will be consolidated as part of a multi-state outbreak report.

Comments on Chapter 7

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 8. Performance Indicators for Foodborne Disease Programs

8.0 Introduction

A long-standing goal of the CDC and national public health professional organizations has been to build state capacity for the detection and prevention of foodborne illness. In 1997, the CDC convened an expert panel to draft a core competencies report for foodborne outbreak and response, focusing on epidemiologic and laboratory capacity. The panel's report was entitled *Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program.* In 1999, as a follow-up to these activities, the CDC funded the Council of State and Territorial Epidemiologists (CSTE) and the Association of Public Health Laboratories (APHL) to conduct assessments of states' foodborne investigation capacity with the goal of providing background data by which to determine the priority areas for building food safety program support. Subsequently, CSTE's enteric diseases investigation timelines study (EDITS) was developed to objectively assess time intervals from disease onset to reporting to the CDC for the surveillance of foodborne diseases and investigation of foodborne outbreaks.

Surveillance and outbreak response is a key component of states' foodborne investigation capacity and is essential for the prevention and control of foodborne illness in the population. Multiple entities - more than 3,000 local health departments, more than 50 state and territorial health departments, and several federal agencies - interact in a complex system covering surveillance for, detection of, and response to enteric and other foodborne diseases.

The occurrence of large and multi-state foodborne outbreaks and concerns about bioterrorism have increased the need to rapidly detect and distinguish between outbreaks of foodborne disease and possible intentional contamination events. Evaluating the timeliness and effectiveness of foodborne disease surveillance is a key step towards assessing and improving the nation's capacity for foodborne disease surveillance and outbreak response.

The development of the CDC's Public Health Emergency Preparedness Goals has established a general framework and a few specific performance measures relevant to foodborne disease surveillance. However, there are no comprehensive national performance standards, measures or models for public health agencies to follow to assure that foodborne illness surveillance and outbreak detection and response systems are working at maximum efficiency.

8.1 Purpose and Intended Use

CIFOR has worked to develop measurable indicators of effective surveillance for enteric foodborne diseases and for response to outbreaks of such diseases on the part of state and local public health officials. These indicators are intended to be used by state and local public health agencies to evaluate the performance of their foodborne disease surveillance and control programs. Specific indicators and sub-indicators have been identified to support the overall objectives of the foodborne disease surveillance program. Metrics have been developed to standardize the evaluation of the indicators.

The use of standardized performance criteria and metrics serves several functions.

- They promote a common understanding of the key elements of foodborne disease surveillance and control activities across local, state, and federal public health agencies;

- They facilitate training of food program staff in the use and interpretation of the performance criteria; and
- They allow for the aggregation of data at state, regional, or national levels to evaluate program effectiveness and identify specific needs for improvement and additional resource investment.

The indicators are not intended to serve as performance standards. Where specific performance standards have been established (e.g., PulseNet turn-around-times, Draft Voluntary National Retail Food Regulatory Program Standards), meeting the performance standard has been adopted as a performance indicator. The development of performance standards depends on the availability of specific indicators such as these to provide a basis for program evaluation. However, defining the level of performance expected from foodborne disease surveillance and control programs goes beyond the scope of these Guidelines. Neither are the performance indicators intended to be used for comparing individual local or state programs with each other. The aggregation of data at state, regional, or national levels is intended to provide a comprehensive overview of foodborne disease surveillance and control programs, rather than providing a system for ranking them.

8.2 Performance Indicators

This chapter is organized in a series of tables. Tables 8.1 summarizes short, intermediate and long term objectives of a foodborne disease surveillance program. These objectives form the basis for developing the specific performance indicators. Tables 8.2 through 8.4 relate specific performance indicators, sub-indicators and metrics back to the foodborne disease surveillance program objectives. Tables 8.5 through 8.12 highlight the Top 10 Performance Indicators for Foodborne Disease Surveillance and Control and constituent programs at local and state levels. Table 8.13 summarizes available benchmark data derived from the EDITS program.

It is recognized that the roles and responsibilities of Foodborne Disease Surveillance and Control programs will vary by state, according to state law. The organization of these tables is meant to highlight key performance indicators by program function. Individual agencies that wish to evaluate their programs using these performance indicators should select indicators and metrics that best reflect their activities, regardless of where they fall in the document's table structure.

Overall Foodborne Disease Program Objectives and Indicators

Key Performance Indicators and Metrics for Program Evaluation

Table 8.1 Objectives of Foodborne Disease Surveillance Program

Short Term Objectives	Intermediate Objectives	Long Term Objectives
• Detect foodborne disease events of public health importance • Respond to events in a timely manner • Intervene when appropriate to prevent illness	• Determine etiology, vehicle and contributing factors of foodborne disease outbreaks. • Monitor trends to identify emerging foodborne diseases and food safety problems. • Increase knowledge of foodborne disease causes and abatement strategies.	• Prevent future outbreaks. • Reduce incidence of foodborne illness • Increase health of the general population.

Table 8.2 Short Term Objectives, Indicators, Sub-Indicators, and Metrics

Short Term Objective	Indicator	Sub-Indicator	Metrics
Detect foodborne disease events of public health importance	8.2.1 Foodborne complaints investigated	Process • The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes. (Draft Voluntary National Retail Food Regulatory Program Standard 5, part 1.d.) • Demographic information obtained • Food history obtained Outcome • Disposition, action or follow-up on complaint or referral report alleging food-related illness or injury within 24 hours. • Establishment investigated, where appropriate • Outbreak detected	Process • Draft Voluntary National Retail Food Regulatory Program Standard 5, part 1.d. met, yes/no • % of complaints that had complete demographic information • % of complaints that had food history obtained Outcome • % of reports resulting in disposition, action or follow-up within 24 hours. • Number of establishments investigated • Number of outbreaks detected

Short Term Objective	Indicator	Sub-Indicator	Metrics
Detect foodborne disease events of public health importance	8.2.2 Reported cases of specified foodborne illnesses interviewed	Process • Demographic information obtained • Exposure history obtained • Case onset date obtained • Date of report documented • Case report maintained in searchable database Outcome • Time interval from receipt of report to case interview • Need for public health intervention identified (e.g. exclusion of workers, conduct of investigation, etc)	Process • % of reported cases that had complete demographic information • % of reported cases that had food history obtained • % of reported cases that had an onset date • % of reported cases that had a report date • Searchable database maintained, yes/no Outcome • Median number of days between receipt of report to case interview • % of cases that had an intervention identified or ruled out.

Short Term Objective	Indicator	Sub-Indicator	Metrics
Detect foodborne disease events of public health importance	8.2.3 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	<u>Process</u> • Stool collection date obtained • Date of clinical laboratory finding obtained • Date of submission to PHL documented • Date of serotyping documented • Date of subtyping by PFGE documented • Isolate report maintained in searchable database <u>Outcome</u> • Reported cases with isolates submitted to PHL • Time interval from clinical laboratory finding to PHL submission. • Turn-around-time from submission to serotyping result • Turn-around-time from submission to subtyping result. • Subtype-clusters identified • For each type of agent, 90% of PFGE sub-typing data results are submitted to the PulseNet database within 4 working days (CDC preparedness goal).	<u>Process</u> • % of cases that had stool collection date • % of investigated cases that had date of clinical laboratory finding • % of cases that had a date of submission to PHL • % of cases that had PFGE subtyping date • Searchable database maintained, yes/no. <u>Outcome</u> • % of cases with isolates submitted to PHL • Median number of days from clinical findings being reported to receipt of isolate at PHL. • Median number of days between receipt of specimen to serotyping or subtyping results • Number of subtype clusters identified • CDC preparedness goal met, yes/no.

Short Term Objective	Indicator	Sub-Indicator	Metrics
Respond to events in a timely manner	8.2.4 Foodborne outbreaks investigated	Process • Cases interviewed to determine illness and exposure histories • Stool samples obtained from cases • Controls (non-ill persons) interviewed to determine exposure histories • Environmental health assessment of establishment conducted, where appropriate • Food flow documented • Food workers interviewed • Stool samples obtained from foodhandlers • Food or environmental samples obtained Outcome • Time from onset of symptoms to initiation of outbreak investigation • Turn-around-time from collection of stools samples to confirmed culture results • Turn-around-times from collection of environmental or food samples to confirmed culture results	Process • % of investigations that had cases interviewed • % of investigations that had stool samples collected from at least one case. • % of investigations that had controls interviewed to determine exposure history • % of investigations where an establishment was investigated if appropriate • % of environmental investigations that included: a food flow, food workers were interviewed, stool samples were collected from foodhandlers, food or environmental samples were taken Outcome • Median number of days from onset of symptoms of the first/index case to outbreak investigation • Median number of days from submission of stool samples to obtaining results. • Median number of days from submission of food or environmental samples to obtaining results. • % of foodborne outbreaks where a source was identified.

		• Foodborne outbreak source identified	
Short Term Objective	**Indicator**	**Sub-Indicator**	**Metrics**
Respond to events in a timely manner	8.2.5 Case-clusters investigated	Process • Cases interviewed to determine exposure histories • Controls or non-cluster cases interviewed to determine exposure histories Outcome • Time from cluster recognition to completion of case and control interviews • Cluster source identified	Process • % of cases clusters where at least half the cases were interviewed to determine exposure history • % of clusters that where controls were interviewed to determine exposure history Outcome • Median number of days from identification of a cluster to completion of all planned interviews • % of clusters where a source was identified

Short Term Objective	Indicator	Sub-Indicator	Metrics
Respond to events in a timely manner	8.2.6 Sentinel foodborne events investigated	<u>Process</u> • Event-specific data collected	<u>Process</u> • % of sentinel events where cases were interviewed • % of events where environmental samples were collected when appropriate • % of events where stool samples were collected when appropriate
Intervene when appropriate to prevent illness	8.2.7 Ill or infected foodhandlers identified and excluded		<u>Outcome</u> • Median number of days from initiation of investigation to implementation of intervention
	8.2.8 Deficient foodhandling practice identified and corrected		<u>Outcome</u> Median number of days from initiation of investigation to implementation of intervention
	8.2.9 Advisory issued regarding occurrence of outbreak and implicated source		<u>Outcome</u> Median number of days from initiation of investigation to implementation of intervention
	8.2.10 Contaminated food recalled and removed from marketplace		<u>Outcome</u> • Median number of days from initiation of investigation to implementation of intervention

Short Term Objective	Indicator	Sub-Indicator	Metrics
Respond to events in a timely manner and Intervene when appropriate to prevent illness	8.2.11 After-action reviews of outbreak investigations conducted within a mean of 60 days following conclusion of the investigation (CDC preparedness goal).		<u>Process</u> CDC preparedness goal met, yes/no.

Table 8.3 Intermediate Objectives, Indicators, Sub-Indicators, and Metrics

Intermediate Objective	Indicator	Sub-Indicator	Metrics
Determine etiology, vehicle and contributing factors of foodborne disease outbreaks.	8.3.1 Etiology of outbreak identified	<u>Process</u> • Clinical characteristics of outbreak characterized • Stool samples tested for likely agents • Food and environmental samples tested for likely agents <u>Outcome</u> • Etiology of outbreak identified	<u>Process</u> • % of outbreaks where clinical characteristics are described • % of outbreaks where at least one stool sample was tested for likely agents • % of outbreaks where food or environmental samples were tested for likely agents <u>Outcome</u> • % of outbreaks where the etiology was identified
	8.3.2 Vehicle of outbreak identified	<u>Process</u> • Suitable epidemiologic study conducted to identify vehicle • Informational traceback conducted to subtype exposure histories • Regulatory traceback conducted to confirm production source of implicated food vehicle • Isolates from case specimens and potential vehicles subtyped <u>Outcome</u> • Vehicle of outbreak identified	<u>Process</u> • % of outbreaks where a epidemiologic study was carried out to identify a vehicle • % of outbreaks where an informational traceback was conducted to help elucidate exposure histories • % of outbreaks where a regulatory traceback was conducted to confirm production source of an implicated food vehicle • %of outbreaks where subtyping of isolates from cases and potential vehicles was conducted <u>Outcome</u> • % of outbreaks where vehicle identified

<table>
<tr><th>Intermediate Objective</th><th>Indicator</th><th>Sub-Indicator</th><th>Metrics</th></tr>
<tr><td>Determine etiology, vehicle and contributing factors of foodborne disease outbreaks.</td><td>8.3.3 Contributing factors identified</td><td><u>Process</u>
Food preparation review of implicated food items conducted
Food preparation review guided by identification of suspected agent
Possible contributing factors to the illness, injury or intentional food contamination are identified in each on-site investigation report.
<u>Outcome</u>
Contributing factors identified</td><td><u>Process</u>
% of outbreaks where a food preparation review of food flow was done on implicated food item
% of outbreaks where a food preparation review of food flow was done, with specific agent suspected.
Draft Voluntary National Retail Food Regulatory Program Standard 5, part 2.a met, yes/no.
<u>Outcome</u>
% of outbreaks where contributing factors were identified.</td></tr>
<tr><td>Monitor trends to identify emerging foodborne diseases and food safety problems.</td><td colspan="2"><u>Process</u>
At least annually, the program conducts a review of the data in the complaint log or database and the illness and injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations and may suggest steps for illness prevention (Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a).
Routine review of cases of reported foodborne diseases for trends in emerging foodborne diseases.
Routine review of outbreak investigation findings for trends</td><td><u>Process</u>
Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a. met, yes/no.
Analysis of foodborne disease case reports, yes/no.
Analysis of outbreak reports, yes/no.</td></tr>
</table>

Increase knowledge of foodborne disease causes and abatement strategies	Results of outbreak investigation summaries incorporated into food safety training activities	Training activities updated on an annual basis, yes/no.

Table 8.4 Long Term Objectives, Indicators, Sub-Indicators, and Metrics

Long Term Objective	**Indicator**	**Sub-Indicator**	**Metrics**
Prevent future outbreaks.	8.4.1 Decrease in number of outbreaks attributable to previously identified sources and contributing factors		Change in number and % of outbreaks with specific sources and contributing factors, from baseline.
Reduce incidence of foodborne illness	8.4.2 Trends in the number of confirmed foodborne outbreaks	Outcome • Numbers of outbreaks reported to individual state health departments • Outbreaks per million population • Outbreaks per 1,000 reported cases of specified foodborne disease agents • Outbreaks in restaurants per 1,000 restaurants • Numbers of outbreaks reported to EFORS	Outcome • % of outbreaks reported to the state health department by year and type of agent, compared over time
	8.4.3 Trends in the incidence of specified foodborne illnesses	Outcome • Statewide annual summaries of reported foodborne diseases with trend analysis • FoodNet trend analyses	
Increase health	Beyond scope		

of population	of project		

Key Performance Indicators and Metrics for Program Evaluation

Table 8.5 Local Health Department: Overall Foodborne Disease Surveillance and Control Programs*

Performance Indicator	Sub-Indicator	Metric
8.5.1 Foodborne complaints investigated	Disposition, action or follow-up on complaint or referral report alleging food-related illness or injury within 24 hours.	% of reports resulting in disposition, action or follow-up within 24 hours.
8.5.2 Reported cases of specified foodborne illnesses interviewed	Case report maintained in searchable database.	Searchable database maintained, yes/no
	Time interval from receipt of report to case interview.	Median number of days between receipt of report to case interview.
8.5.3 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	Reported cases with isolates submitted to PHL	% of cases with isolates submitted to PHL
8.5.4 Foodborne outbreaks investigated	Time from onset of symptoms to initiation of outbreak investigation	Median number of days from onset of symptoms of the first/index case to outbreak investigation
8.5.5 Appropriate control measure initiated		Median number of days from initiation of investigation to implementation of intervention
8.5.6 Etiology of outbreak identified	Etiology of outbreak identified	% of outbreaks where the etiology was identified
8.5.7 Vehicle of outbreak identified	Vehicle of outbreak identified	% of outbreaks where the vehicle was identified
8.5.8 Contributing factors identified	Contributing factors identified	% of outbreaks where contributing factors were identified.

Performance Indicator	Sub-Indicator	Metric
8.5.9 Trends in the number of confirmed foodborne outbreaks	Numbers of outbreaks reported to EFORS	% of outbreaks reported to the state health department by year and type of agent, compared over time

*Includes functions that may be variously assigned to communicable disease or environmental health programs, depending on local jurisdiction.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.6 Local Health Department: Communicable Disease Program *

Performance Indicator	Sub-Indicator	Metric
8.6.1 Reported cases of specified foodborne illnesses interviewed	Demographic information obtained	% of reported cases that had complete demographic information
	Exposure history obtained	% of reported cases that had exposure history obtained
	Case onset date obtained	% of reported cases that had an onset date
	Date of report documented	% of reported cases that had a report date
	Need for public health intervention identified	% of cases that had an intervention identified or ruled out.
8.6.2 Foodborne outbreaks investigated	Cases interviewed to determine illness and exposure histories	% of investigations that had cases interviewed
	Stool samples obtained from cases	% of investigations that had stool samples collected from at least one case
8.6.3 Etiology of outbreak identified	Clinical characteristics of outbreak characterized	% of outbreaks where clinical characteristics are described
8.6.4 Vehicle of outbreak identified	Suitable epidemiologic study conducted to identify vehicle	% of outbreaks where an epidemiologic study was carried out to identify a vehicle
	Informational traceback conducted to subtype exposure histories	% of outbreaks where an informational traceback was conducted to help elucidate exposure histories

*Includes functions typically assigned to communicable disease programs, not included in overall foodborne disease surveillance and control program indicators.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.7 Local Health Department: Environmental Health Program *

Performance Indicator	Sub-Indicator	Metric
8.7.1 Foodborne complaints investigated	The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.	Draft Voluntary National Retail Food Regulatory Program Standard 5, part 1.d. met, yes/no
	Demographic information obtained	% of complaints that had complete demographic information
	Food history obtained	% of complaints that had food history obtained
	Outbreak detected	Number of outbreaks detected
8.7.2 Foodborne outbreaks investigated	Environmental health assessment of establishment conducted, where appropriate	% of outbreaks where an establishment was investigated if appropriate
	Food flow documented	% of environmental assessments that included a food flow
	Food workers interviewed	% of environmental assessments that included food worker interviews

Performance Indicator	Sub-Indicator	Metric
8.7.3 Ill or infected foodhandlers identified and excluded		Median number of days from initiation of investigation to implementation of intervention
8.7.4 Deficient foodhandling practice identified and corrected		Median number of days from initiation of investigation to implementation of intervention
8.7.5 Contributing factors identified	Possible contributing factors to the illness, injury or intentional food contamination are identified in each on-site investigation report.	Draft Voluntary National Retail Food Regulatory Program Standard 5, part 7.a. met, yes/no.

* Includes functions typically assigned to environmental health programs, not included in overall foodborne disease surveillance and control program indicators.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.8 Local Health Department: Public Health Laboratory*

Performance Indicator	Sub-Indicator	Metric
8.8.1 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	Stool collection date obtained	% of cases that had stool collection date
	Date of submission to PHL documented	% of cases that had a date of submission to PHL
	Date of serotyping documented	% of cases that had serotype date
	Date of subtyping by PFGE documented	% of cases that had PFGE subtyping date
	Isolate report maintained in searchable database	Searchable database maintained, yes/no.
	Turn-around-time from submission to serotyping result	Median number of days between submission of specimen to serotyping results
	Turn-around-time from submission to subtyping result.	Median number of days between submission of specimen to subtyping results
8.8.2 Foodborne outbreaks investigated	Turn-around-time from collection of stools samples to confirmed culture results	Median number of days from submission of stool samples to obtaining results.
8.8.3 Etiology of outbreak identified	Stool samples tested for likely agents	% of outbreaks where at least one stool sample was tested for likely agents
	Food and environmental samples tested for likely agents	% of outbreaks where environmental samples were tested for likely agents

*Includes functions typically assigned to public health laboratory programs, not included in overall foodborne disease surveillance and control program indicators.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.9 State Health Department: Overall Foodborne Disease Surveillance and Control Programs*

Performance Indicator	Sub-Indicator	Metric
8.9.1 Reported cases of specified foodborne illnesses interviewed	Case report maintained in searchable database.	Searchable database maintained, yes/no
8.9.2 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	Reported cases with isolates submitted to PHL	% of cases with isolates submitted to PHL
	Turn-around-time from submission to PFGE subtyping result.	Median number of days between submission of specimen to PFGE subtyping results
8.9.3 Foodborne outbreaks investigated	Time from onset of symptoms to initiation of outbreak investigation	Median number of days from onset of symptoms of the first/index case to outbreak investigation
8.9.4 Case-clusters investigated	Cluster source identified	% of clusters where a source was identified
8.9.5 Sentinel foodborne events investigated	Event-specific data collected	% of sentinel events with data collected
8.9.6 Appropriate control measure initiated		Median number of days from initiation of investigation to implementation of intervention
8.9.7 After-action reviews of outbreak investigations conducted within a mean of 60 days following conclusion of the investigation (CDC preparedness goal)		CDC preparedness goal met, yes/no
8.9.8 Trends in the number of confirmed foodborne outbreaks	Numbers of outbreaks reported to EFORS	% of outbreaks reported to the state health department by year and type of agent, compared over time

Performance Indicator	Sub-Indicator	Metric
8.9.9 Trends in the incidence of specified foodborne illnesses	Statewide annual summaries of reported foodborne diseases	Annual summary prepared, yes/no

***** Includes functions that may be variously assigned to communicable disease or environmental health programs, depending on local jurisdiction.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.10 State Health Department: Communicable Disease Program *

Performance Indicator	Sub-Indicator	Metric
8.10.1 Reported cases of specified foodborne illnesses interviewed	Time interval from receipt of report to case interview.	Median number of days between receipt of report to case interview.
8.10.2 Foodborne outbreaks investigated	Cases interviewed to determine illness and exposure histories	% of investigations that had cases interviewed
	Stool samples obtained from cases	% of investigations that had stool samples collected from at least one case
	Controls interviewed to determine exposure histories	% of investigations that had controls interviewed
8.10.3 Case-clusters investigated	Cases interviewed to determine exposure histories	% of case clusters where at least half the cases were interviewed to determine exposure history.
	Time from cluster recognition to completion of case and control interviews	Median number of days from identification of cluster to completion of all planned interviews
8.10.4 Etiology of outbreak identified	Clinical characteristics of outbreak characterized	% of outbreaks where clinical characteristics are described
8.10.5 Vehicle of outbreak identified	Suitable epidemiologic study conducted to identify vehicle	% of outbreaks where an epidemiologic study was carried out to identify a vehicle
	Informational traceback conducted to subtype exposure histories	% of outbreaks where an informational traceback was conducted to help elucidate

		exposure histories
Performance Indicator	**Sub-Indicator**	**Metric**
8.10.6 Trends in the number of confirmed foodborne outbreaks	Outbreaks per million population	Agent-specific outbreak rate determined

***** Includes functions typically assigned to communicable disease programs, not included in overall foodborne disease surveillance and control program indicators.

Key Performance Indicators and Metrics for Program Evaluation

Table 8.11 State Health Department: Environmental Health Program *

Performance Indicator	Sub-Indicator	Metric
8.11.1 Foodborne complaints investigated	Complaints maintained in searchable database.	Searchable database maintained, yes/no
8.11.2 Foodborne outbreaks investigated	Environmental health assessment of establishment conducted	% of investigations where an establishment was investigated if appropriate
8.11.3 Ill or infected foodhandlers identified and excluded		Median number of days from initiation of investigation to implementation of intervention
8.11.4 Deficient foodhandling practice identified and corrected		Median number of days from initiation of investigation to implementation of intervention
8.11.5 Source of outbreak identified	Regulatory traceback conducted to confirm production source of implicated vehicle	% of outbreaks where a regulatory traceback was conducted to confirm production source of an implicated food vehicle.
8.11.6 Contributing factors identified	Food preparation review of implicated food items conducted	% of outbreaks where a food preparation review of food flow was done on implicated food item
	Food preparation review guided by identification of suspected agent	% of outbreaks where a food preparation review of food flow was done, with specific agent suspected
8.11.7 Trends in the number of confirmed foodborne outbreaks	Outbreaks in restaurants per 1,000 restaurants	Restaurant specific outbreak rate determined

Performance Indicator	Sub-Indicator	Metric
8.11.8 Results of outbreak investigation summaries incorporated into food safety training activities		Training activities updated on annual basis, yes/no
8.11.9 Prevent future outbreaks	Decrease in number of outbreaks attributable to previously identified sources and contributing factors	Change in number and % of outbreaks with specific sources and contributing factors, from baseline

*****Includes functions typically assigned to environmental health programs, not included in overall foodborne disease surveillance and control program indicators.

Key Performance Indicators and Metrics for Program Evaluation

Table 9.12 State Health Department: Public Health Laboratory*

Performance Indicator	Sub-Indicator	Metric
8.12.1 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	Date of submission to PHL documented	% of cases that had a date of submission to PHL
	Date of serotyping documented	% of cases that had serotyping date
	Date of subtyping by PFGE documented	% of cases that had PFGE subtyping date
	Isolate report maintained in searchable database	Searchable database maintained, yes/no.
	Turn-around-time from submission to serotyping result	Median number of days between submission of specimen to serotyping results
	Subtype clusters identified	Number of subtype clusters identified
	For each type of agent, 90% of PFGE subtyping data results are submitted to the PulseNet database within 4 working days	CDC preparedness goal met, yes/no
8.12.2 Foodborne outbreaks investigated	Turn-around-time from collection of stools samples to confirmed culture results	Median number of days from submission of stool samples to obtaining results.
8.12.3 Etiology of outbreak identified	Stool samples tested for likely agents	% of outbreaks where at least one stool sample was tested for likely agents
	Food and environmental samples tested for likely agents	% of outbreaks where environmental samples were tested for likely agents

* Includes functions typically assigned to public health laboratory programs, not included in overall foodborne disease surveillance and control program indicators.

Table 8.13 Benchmark data established by EDITS

Short Term Objective	Indicator	Sub-Indicator	Metrics
Detect foodborne disease events of public health importance	8.13.1 Reported cases of specified foodborne illnesses interviewed	Process • Exposure history obtained • Case onset date obtained • Date of report documented Outcome • Time interval from receipt of report to case interview	Process • 49% of reported cases had some exposure history obtained • 66% of reported cases had an onset date • 42% of reported cases had a report date Outcome • 0 = Median number of days between receipt of report to case interview
	8.13.2 Isolates of specified foodborne pathogens submitted to the public health laboratory (PHL)	Process • Stool collection date obtained • Date of submission to PHL documented • Date of subtyping by PFGE documented Outcome • Reported cases with isolates submitted to PHL • Turn-around-time from submission to subtyping result.	Process • 82% of cases had stool collection date • 98% of cases that had a date of submission to PHL • 100% of cases that had PFGE subtyping date Outcome • 68% of cases had isolates submitted to PHL • 3 = Median number of days between submission of specimen to subtyping results.

Comments on Chapter 8

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Chapter 9. Legal Considerations for the Surveillance and Control of Foodborne Disease Outbreaks

9.0 Introduction

9.0.1 Public Health Protection and Surveillance

State and local health officials should familiarize themselves with applicable statutes and regulations and establish procedures for accessing and consulting with legal counsel for the agency.

9.0.2 The Role of State and Local Public Health Agencies in Surveillance

The primary role of local and state public health agencies is protection of the public's health. The authority for agencies to carry out this role is derived from the state's (or municipality's) broad police powers.

The essential parameters of modern public health law were established in the 1905 Supreme Court case *Jacobson v. Massachusetts.* The key issues defined in that case were:

- Individual liberties can be subject to community needs
- Police power of the state includes reasonable regulations to protect the public health and public safety
- Courts must defer to legislative basis for public health measures if supported by scientific evidence
- Public health measures cannot be arbitrary nor impose an unreasonable risk of harm to an individual

Detection of enteric disease and foodborne outbreaks is typically conducted and managed by local and state public health epidemiologists. State or local statutes tend to address disease surveillance in general and are usually not specific to the surveillance of foodborne diseases.

9.0.3 The Role of CDC in Surveillance

The CDC cannot mandate reporting of diseases and conditions. The CDC gathers data on nationally notifiable diseases and works with the Council of State and Territorial Epidemiologists (CSTE) to establish (and modify as needed) case definitions that are not legally binding. The CDC does not collect personal identifiers on routine surveillance data that it receives from the states.

The CDC laboratory may identify pathogens, confirm serotypes or molecular subtypes, or perform diagnostic assays and report the finding(s) to the appropriate state or local health department. Virtually all enteric disease specimens tested at the CDC laboratory were initially submitted for reference testing by state public health laboratories, which perform a preliminary work up.

By providing botulinum antiserum, the CDC learns of cases of botulism and verifies that the appropriate state or local health department is aware of them.

9.1 Legal Framework for Mandatory Disease Reporting

9.1.1 Statutes and Regulations

9.1.1.1 Authorization by Legislature

Generally the legislature gives broad statutory authority to the health department to collect information and require reports of conditions of public health significance, without specifying the exact diseases/infections.

In addition to broad authority, states typically have several disease-specific statutes, such as HIV/AIDS, TB, and Vaccine-preventable diseases, that authorize surveillance and control activities, and all states have statutes addressing the response to bioterrorism incidents

9.1.1.2 Regulatory Process for Maintaining and Updating List of Reportable Diseases

Every state has an oversight body or entity authorized to promulgate regulations (typically a Board of Health that is established by statute). Revisions or additions to the reportable disease list are implemented following a period where the proposed change is studied and public input is taken.

The list of reportable diseases/conditions and laboratory findings is maintained and updated by epidemiologists and health officers in state and local agencies, with review and approval by the oversight body. Required reporting of specific laboratory test results, as opposed to regulatory language of "any positive test for …" generally means that the list must be regularly updated.

Reportable disease regulations are established within the context of the basic public health compact. In return for allowing the government to collect without consent medical and personal information on selected conditions, the public requires the government to maintain confidentiality of the records and to prevent or minimize public health threats.

9.1.2 Reporting Processes

9.1.2.1 Timeframe and content of reports

Regulations usually specify the timeframe for reporting (e.g., within seven days, within 24 hours, immediately, etc.) and the information to be reported (e.g., diagnosis, personal identifying and locating information, date of onset/diagnosis, whether or not the case is suspected or confirmed).

9.1.2.2 Sources of reports

Regulations specify what entities are required to report. The usual sources of mandatory reports are:

- Laboratories
    - Hospital-based laboratories
    - National or regional commercial referral laboratories
    - Local or state health department laboratories
    - CDC laboratories
- Hospitals, e.g. hospitalized patients reported by infection control practitioners
- Emergency departments
- Office-based health care providers
- Long-term care facilities and/or nursing homes
- Schools and day care centers

An agency may also receive reports from other public health agencies, e.g., state-to-state.

The source of the report does not affect the legal status of the information—if it is required, it is protected by the statutes and regulations. Conversely, reports to the agency of illness that is not listed as a reportable condition may not be subject to disease surveillance regulations and confidentiality protections (see section ____ below).

9.1.2.3 Reporting methods

Any or all methods on the list below may be used within a given state or municipality. The specifics vary from one locale to another.

- Telephone
- Hardcopy/fax or mail
- Electronic batch reports sent by email
- Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies

9.1.2.4 Required submission of laboratory specimens

Some public health agencies have adopted regulations that require commercial laboratories to submit isolates of specific pathogens to a central state or local health department laboratory for further testing. One example would be a requirement that all *E. coli* O157:H7 isolates be submitted for PFGE testing. This requirement improves surveillance for foodborne disease as common subtypes may be identified. In some locales, the same goal is achieved by voluntary submission of specimens to the central referral laboratory.

9.1.3 Accessing Medical and Laboratory Records

Typically the broad authority to conduct surveillance includes authority to investigate and control diseases of public health significance, including review of relevant and pertinent medical and laboratory records and reports i.e., information that is not necessarily included in the basic case report

9.1.4 Enforcement

Because non-reporting by health care providers is common, redundant reporting systems have been established (e.g. salmonella infection is reportable by both physicians and laboratories) to ensure that a case will be reported one way or another.

Nonetheless, failure to comply with reporting regulations is punishable. This is rarely enforced because penalizing a doctor may not result in future compliance and may lead to reverberations throughout the clinical sector i.e., may be counter-productive to the system.

Penalties or sanctions, however, may be imposed if the lack of a report directly leads to an outbreak of disease (for example, a food worker with hepatitis A is not reported and therefore, IG is not administered in time to restaurant customers).

In most cases of non-reporting, the public health agency will explain the regulatory requirement and its rationale and ask for compliance in the future, rather than seeking penalties or sanctions.

Reporting is difficult to enforce with a laboratory or health care provider that is outside the agency's jurisdiction, such as state X seeks reports from a referral laboratory that is located in state Y.   Usually the lack of reporting in this situation is due to a misunderstanding of how to report.

Occasionally the laboratory will state that it is in compliance with the requirements of the agency in which it is physically located (which agency may require reporting to it or may not require reporting of the particular disease, infection, or laboratory result).

9.1.5 Protection of Confidentiality

Personally identifying information in disease reports and investigation records is confidential and exempt from disclosure in response to freedom of information requests. If personally identifying information can be redacted and no other exemptions from disclosure apply, such records may have to be released. In redacting personally identifying information, it is important to bear in mind that descriptors, such as age, sex, race/ethnicity, residence, and date of diagnosis may make it possible to determine the identity of the person if enough descriptors are provided. Preparing final outbreak investigation summary reports without any personally identifying information can speed up and simplify the process of releasing those reports to the attorneys or the media when they are requested.

Occasionally the public health agency must respond to a media inquiry in which the media has learned the name of a particular case-patient from another source. The agency's response to the media inquiry could lead to unintentional confirmation of the patient's name.

The public health agency generally is restricted from sharing personal identifying information with other government agencies without the consent of the reported person, except:

- Virtually every state has an exception for sharing information with law enforcement agencies when investigating a bioterrorism incident
- Many state statutes contain an exception for sharing information when, in the agency's judgment, it is necessary to protect the public health.
- There is often an expectation by state and local public health agencies that when they provide epidemiologic and laboratory data to federal food safety agencies (such as the FDA or the USDA), that they will receive from those agencies results of the product investigations; however, this is rarely the case, since the results of the investigations may contain trade secrets or confidential commercial information, be part of a legal enforcement action, or be part of a criminal case.

Typically the reporting statutes include a provision for punishment of government employees for a breach of confidential information held by the public health agency.

Health information that is protected by the Health Information Portability and Accountability Act (HIPAA) may be disclosed by the reporting source without individual authorization to a public health agency authorized by law to collect or receive such information, and this may include a contractor (e.g., academic institutions) to which a government agency has granted authority. This disclosure without individual authorization does not include disclosure of protected health information for research purposes.

The legal requirement to report relieves the reporting source (e.g. physician) of his/her fear that reporting is a breach of the privacy of the doctor-patient relationship. This can be explained to physicians and often results in better reporting.

9.2 Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

9.2.1 Sources of Surveillance Information

Reports of illness related to foods may come to the attention of the state or local health agency in a variety of ways:

i. Surveillance reports for enteric diseases, such as salmonella, shigella, campylobacter, etc.

ii. Request for botulinum antiserum

iii. Reports of food poisoning or gastrointestinal illness in defined groups, such as diarrhea and vomiting among residents of a nursing home or school or among attendees at a work-related meeting

iv. Enteric disease suspected of being caused intentionally

v. Complaints of alleged contaminated, adulterated, or improperly cooked food that is purchased from stores or in restaurants is reported voluntarily by the general public

vi. Syndromic surveillance using de-identified emergency department or pharmacy data.

9.2.2 Statutes and Regulations Governing Surveillance and Investigation

Confirmed or probable cases identified from items **i-iv** above are subject to the reporting statute(s) and regulations of the health agency, whereas items **v** and **vi** generally do not have as strong a level of legal protection as named case reports because they are either voluntary, unconfirmed disease reports (item v) or names are not collected and diagnoses are not confirmed (item vi).

The routine investigation of enteric diseases to determine the source of exposure, risk factors for infection, and contacts of a contagious case is usually considered part of surveillance activities that are authorized by state and local statutes.

CDC may participate in an investigation of an outbreak of enteric disease if invited by the state

9.3 Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

9.3.1 General

Because of (1) improvements in laboratory and communication technologies that can be used to link cases previously termed “sporadic” cases and (2) the globalization of the food production industries, more multi-state and international foodborne outbreaks are being discovered, thus changing the locus of outbreak investigations and control measures.

9.3.2 The Federal Role

The changes noted above have led to an increasingly direct, leading role in the control of foodborne diseases by several federal public health and regulatory agencies:

- Centers for Disease Control and Prevention
- Food and Drug Administration

- U.S. Department of Agriculture Food Safety and Inspection Service (FSIS)
- U.S. Environmental Protection Agency
- U.S. Departments of Justice and Homeland Security when there is suspicion of bioterrorism

These agencies exercise their authority over food safety at various stages along the farm-to-table continuum primarily by inspections:

- Safety of food, feed, and animals on the farm
- Plant and animal health on the farm, including animal vaccines
- Pesticide use on the farm
- Food processing
- Slaughter and processing of meat and poultry products and egg products
- Labeling, transportation, storage, and retail sale of food
- Cruise ships, trains, buses, airplanes (e.g. all interstate transportation) and the servicing areas for these transportation vehicles [21CFR 1240 and 1250]
- Coordination and collation of multi-state investigations

The FDA has jurisdiction over restaurants, groceries, and other retail establishments, but it generally defers to state and local health agencies to enforce their own requirements through inspections.

The primary legislation by which the FDA exercises authority over food is the Federal Food, Drug, and Cosmetic Act (FFDCA). A goal of the FDA is to prevent contamination of food product before distribution, but the legislation allows it to pursue:

- Voluntary compliance through the issuance of inspectional observations, untitled letters and warning letters.
- Civil action such as an injunction to prevent future violations of the FFDCA, i.e., continued distribution of adulterated food
- A seizure action to remove specific lots of adulterated food. [Note: FDA also asks the producer or distributor, as appropriate, to voluntarily recall an adulterated food].
- Criminal action against an individual or company that violates the FFDCA such as causing food to become adulterated by inadequate processing and handling of food.
- Since the Bioterrorism Act of 2002, the FDA has the authority to administratively detain certain food for up to 30 days [Note: administrative detention does not require a court order].

- The FDA's authority under the FFDCA is limited by the requirement for interstate commerce; however, under the Public Health Service Act, the FDA can regulate intrastate commerce in some circumstances.
- State agencies may in some instances be swifter than the FDA because they may require less evidence of problems prior to taking action than the requirements imposed on the FDA by its legislation.
- Amendments to the FFDCA in 2007 require the FDA to establish a reportable food registry for the reporting by individuals, companies, and local and state agencies of food that may cause serious adverse health consequences or death to humans or animals.

9.3.3 State and Local Public Health Agency Roles and Legal Authority

Environmental health specialists and epidemiologists should understand their respective roles and legal authorities for various public health actions and how and when they need to obtain expert legal counsel and upper level management support and decision-making.

In those instances in which improper food preparation and preparation at the local level results in foodborne disease, the broad authority of public health agencies to control epidemics and stop nuisances, as well as specific authority to inspect restaurants and ensure proper food safety, is used to:

- Close restaurants
- Issue statements to the public through the media
- Embargo, seize, and/or destroy contaminated food or require removal of contaminated lots from retail stores
- Require changes in food preparation
- Temporarily remove infectious persons from the workplace.

Agencies should review their current legal authority to ensure that these basic disease control measures can be applied when necessary to protect public health.

Such actions are usually initiated as agency administrative orders. The orders need to set a time limit and the conditions for removing the order. If necessary, an agency may seek enforcement through court orders.

9.4 Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution

9.4.1 Chain of Custody

Laboratory specimens must be collected and submitted using proper procedures to ensure the chain of custody of the specimen, defined by one author as "everyone handling the sample [or specimen] must be able to demonstrate it is, and has been, identified as coming from the person [or item] in question [in order] to be admissible and probative in court" (Lazzarini Z et al; Criminal law and public health practice; chapter in *Law in Public Health Practice, Second Edition*, edited by Goodman RA et al., 2007).

9.4.2 Collection of Evidence

Some investigations are initiated by public health officials but widen to other interests and agencies when it is realized that a public health event resulted from a potential criminal act. Government agents must conform to constitutional standards (e.g. Fourth and Fifth amendments to the Constitution) regarding the collection of evidence, especially in those situations that may require a joint investigation by public health and law enforcement.

9.4.3 Role of Data in Regulatory Action

Epidemiologic and laboratory data may provide strong evidence linking illness to consumption of a particular food, and this may result in a traceback investigation. When involving multiple states, this is typically led by federal regulatory agencies.

Because of the need to link epidemiologic data with product information in order to take actions that protect the public health, the roles of state and local public health agencies and the CDC must be coordinated with the roles of federal regulatory agencies.

Comments on Chapter 9

Other information that should be added:

Information that doesn't really need to be here:

Any needed corrections or things that you disagree with:

Any recommended changes to improve flow or readability:

Is this information that would be helpful to your organization?

Appendices

To Be Done

Appendix 1	Glossary
Appendix 2	Questionnaire design and administration
Appendix 3	Index of forms and materials available in CIFOR Clearinghouse
Appendix 4	Statistics references
Appendix 5	Procedures and equipment for specimen collection and transport
Appendix 6	Links to foodborne disease outbreak resources and training programs

Comments on Overall CIFOR Guidelines

Other information that should be added:

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