Module Objectives

By the end of this module, participants will be able to recognize a multijurisdictional or complex outbreak response and identify the appropriate methods of response.

- Recognize when a response is complex and requires a change in routine response activities
- Describe the characteristics of a multijurisdictional outbreak response
- Based on the outbreak response characteristics, identify additional resources necessary to meet the demands of the response

Performance Objective

By the end of this module, participants will be able to recognize a multijurisdictional or complex outbreak response and identify the appropriate methods of response.
Enabling Learning Objectives
By the end of this module, the instructor shall accomplish the following learning objectives in support of the performance objective:

- Recognize when a response is complex and requires a change in routine or normal response activities.
- Describe the characteristics of a multijurisdictional outbreak response.
- Based on the outbreak response characteristics, identify additional resources necessary to meet the demands of the response.

Local Outbreak Response

In years past, almost all outbreaks were detected and investigated at the local level. Investigations were conducted by local public health departments or food regulatory agencies operating at the local level. Outbreaks of this nature may be detected through the identification of a pathogen above baseline levels by the healthcare system (providers and clinical laboratories) or through complaints. There was very little opportunity to link cases to other jurisdictions. Localized outbreaks are generally associated with an event or a retail food establishment. Outbreaks of this nature are generally caused by a food-handling error(s), resulting in contributing factor(s) to foodborne illness. The number of cases associated with these localized events could range from 2 to several hundred.

The ability to form an effective response is related to the number of trained responders available in a jurisdiction. The number of trained responders may be proportional to the size of the agency and the emphasis placed on responding to outbreaks. Localized outbreak responses occur frequently.
Recall from slide 8-3 that response to a local outbreak generally involves the local health department and/or food regulatory agency. Complex responses require resources that exceed the capacity of the local response agencies. Some examples of complex outbreaks are:

- Multijurisdictional outbreaks
- Very large outbreaks
- Outbreaks associated with a very severe pathogen
- Outbreaks associated with a novel pathogens and food vehicles
- Outbreaks associated with intentional contamination
The effectiveness of the response is often determined by epidemiologic, laboratory, and environmental investigators at all levels of government working together. The complexity of the outbreak is not always associated with how many jurisdictions are impacted but is generally indicated by the need for resources over and above a jurisdiction’s capacity.

Some of the characteristics of a complex outbreak are: the need of additional core-discipline personnel, the need of non-conventional personnel, and the need for investigational capacity not available within the jurisdiction.
The complexity of a multijurisdictional response may be lost on the local responder but anytime cases are identified in multiple jurisdictions there is a coordinated response. A response in multiple jurisdictions within the same state will usually be coordinated by a state health department or agriculture agency. The epidemiologic response to multistate outbreaks are often coordinated by the CDC. Most multijurisdictional outbreak responses are initiated by laboratory investigators linking cases by advanced molecular detection methods. Multijurisdictional response methods provide the capacity to identify foodborne illnesses associated with commercially-distributed foods often at the ingredient level.

Instructional Note

Mention to participants that case count maps are provided to demonstrate the ability of the system to detect small numbers of cases over a large geographic area is the result of the PulseNet system. The Salmonella Mbandaka outbreak sickened over 100 people in 33 states. The E. coli O157:H7 outbreak linked to eating raw cookie dough sickened 72 persons in 30 states. The Salmonella Typhimurium outbreak linked to dried coconut sickened 14 in 8 states.
Prior to the 1990s, very few outbreaks involving multiple jurisdictions were detected and investigated in a coordinated fashion. It was not until the widespread use of advanced molecular detection methods throughout the United States that multijurisdictional outbreaks were detected and responses coordinated. Molecular subtyping, also referred to as DNA fingerprinting, began with the development of pulsed-field gel electrophoresis (PFGE) in the mid-1980’s. It gained prominence when it was used to identify the causative agent of an \textit{E. coli O157:H7} outbreak associated with the consumption of undercooked hamburger in 1993. In support of this detection method for foodborne illness cluster identification, PulseNet was launched in 1996. Advanced molecular detection methods have evolved to the use of whole genome sequencing, which will eventually take the place of PFGE.

The ability to detect pathogens at the subtyping level has resulted in linking foodborne illnesses and resolving outbreaks – many caused by contamination or other contributing factor prior to distribution. Slide 8-4 provides some example of multistate outbreaks that would likely gone undetected without the PulseNet system of cluster detection. The \textbf{Salmonella Mbandaka outbreak associated with Kellogg’s Honey Smacks Cereal} sickened over 100 people in 33 states. The outbreak strain was identified in a sample of unopened Kellogg’s Honey Smacks cereal collected from a retail location in California and in samples of leftover Kellogg’s Honey Smacks cereal collected from the homes of ill people in Montana, New York, and Utah. The \textbf{E. coli O157:H7 outbreak linked to eating raw refrigerated, prepackaged cookie dough} sickened 72 persons in 30 states. Of the 72 identified cases, 34 were hospitalized and 10 developed hemolytic uremic syndrome (HUS). The \textbf{Salmonella Typhimurium outbreak linked to dried coconut} sickened 14 in 8 states and the District of Columbia. Even though only a few of cases were identified; the epidemiologic, laboratory, and product tracing evidence was convincing enough that the manufacturer recalled the product.
Significance of Multistate Outbreaks

- Make up only 3% percent of all foodborne outbreaks of known etiology reported
- Have a significant public health impact
  - Make up 12% of illness
  - 42% of hospitalizations
  - 50% of deaths

Source: Surveillance for Foodborne Disease Outbreaks in the United States, 2015 Annual Report (CDC)

Multistate outbreaks comprise only a small proportion of all outbreaks identified in the United States. In the 2015 annual report of the Surveillance for Disease Outbreaks, only 3% of all outbreaks reported with a known etiology were multistate. Even though multistate foodborne outbreaks comprise only 3% of all outbreaks identified, they account for 12% of illness, 42% of all hospitalizations, and 50% of all deaths.

Leading Pathogens of Multistate Outbreaks

- 58% caused by *Salmonella* spp.
- 28% caused by Shiga toxin-producing *E. coli*
- 10% caused by *Listeria monocytogenes*

** Product tracing investigations led to product recall in 63% of multistate investigations conducted between 2010 - 2014.

Source: CDC FDSS
A study of multistate outbreaks in the United States from 2010 to 2014 compiled from CDC's Foodborne Disease Outbreak Surveillance System identified the leading pathogens in the outbreaks as Salmonella (58%), Shiga toxin-producing E. coli (28%), and Listeria monocytogenes (10%). The foods most commonly implicated in multistate outbreaks were fruits (14%), vegetable row crops (13%), beef (11%), and seeded vegetables (8%). 73% of the outbreaks identified during this 2010-2014 period prompted a product tracing investigation. Product tracing investigations led to product recall in 63% of the multistate investigations.

The successful investigation of a multistate outbreak involves response team members from all disciplines at all levels of government working together. The ability to detect almost all multistate outbreaks lies with a robust surveillance network of local, state and federal public health professionals. Working with healthcare providers, epidemiologic investigators identify and investigate illness suspected to be foodborne in origin. Clinical specimen collection leads to the identification of pathogen and large local public health and state public health laboratory systems utilize advanced molecular detection methods such as WGS to link cases of disease throughout the country. State and federal epidemiologic investigators often support the efforts of local agencies and may, in certain instances, provide direct response activity. Activities of the epidemiologic and laboratory investigator are coordinated with the environmental investigator to link the pathogen to a food and source of the illness. The response system is complex but when all response partners are functioning optimally, illness can be linked to other cases and the investigation can lead to finding the source of illness and mitigating additional illness. A notable investigation leading to resolution is the Listeriosis outbreak associated with Blue Bell Ice Cream.
This Listeria outbreak lasted almost five years as clinical specimens were linked by advanced molecular detection in all 10 hospitalized cases in 4 states. Of the 10 cases, 3 died. It should be noted that most of the cases were identified retrospectively through the review of the PulseNet database as the investigation started to reveal cases associated with a source.

Instructional Note

The following series of slides recount the Listeria outbreak associated with Blue Bell ice cream that lasted approximately five years. Mention to participants that many of the cases were identified retrospectively after the food sampling revealed Listeria in the product. The environmental assessment conducted by the FDA and the “root cause assessment” conducted by Blue Bell revealed Listeria contamination in the Oklahoma and Texas facilities and believed the bacteria colonized in the facilities. This is considered by all responders to be a very complex outbreak response.
The South Carolina Department of Health and Environmental Control isolated *Listeria* from Blue Bell single service ice cream products during routine sampling. Based upon the South Carolina findings, the Texas Department of State Health Services identifies *Listeria* from the same two products.

Kansas state health officials identify four cases from the same hospital infected with *Listeria* that had indistinguishable PFGE patterns. These PFGE patterns were indistinguishable from the
Listeria isolated from ice cream samples in South Carolina and Texas. Investigation of the hospitalized patients strongly suggest that the Listeria infections were acquired in the hospital. All four cases consumed milkshakes made with Blue Bell ice cream.

**Listeria Outbreak - Sequence of Events**

- Blue Bell removes implicated product made on the production line and closes their Texas facilities.

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**Listeria Outbreak - Sequence of Events**

- Kansas Department of Health and Environment isolated the outbreak strain of *Listeria* from an unopened, single-service container of ice cream.
- Sample of the same product from the company’s Oklahoma facility yielded *Listeria* that was indistinguishable from each other but different from other sampling conducted previously.
- The next day, Blue Bell issued a recall of single-service ice cream cups manufactured at the Oklahoma facility.
Kansas Department of Health and Environment isolated the outbreak strain of Listeria from an unopened, single-service container of ice cream. A sample of the same product from the company's Oklahoma facility yielded *Listeria* that were indistinguishable from each other (Kansas-Oklahoma) but different from sampling conducted previously. The next day, Blue Bell issued a recall of single-service ice cream cups manufactured at the Oklahoma facility.

**Listeria Outbreak - Sequence of Events**

- CDC identifies six people from Arizona (1), Oklahoma (1), and Texas (4) with *Listeria* infection with indistinguishable isolates compared to the sample taken from the Oklahoma facility.
- Information from one of the cases in Texas reported they consumed ice cream in the hospital prior to developing listeriosis.
- CDC issues an advisory that consumers not eat any products made at the Oklahoma facility.
- Blue Bell reported that they had voluntarily suspended operations at their facility in Oklahoma.

The CDC and coordinating laboratories identified six people from Arizona (1), Oklahoma (1), and Texas (4) with *Listeria* infection with indistinguishable isolates as compared to the sample taken from the Oklahoma facility. Information from one of the cases in Texas reported they consumed ice cream in the hospital prior to developing listeriosis. CDC issues an advisory that consumers not eat any products made at the Oklahoma facility. Blue Bell reported that they had voluntarily suspended operations at their facility in Oklahoma.
The CDC reported that whole genome sequencing (WGS) confirmed that three of the four isolates from the people in Texas were nearly identical to the Listeria strains isolated from the ice cream from the Oklahoma facility. The fourth isolate was later determined not to be part of the outbreak by WGS.

Listeria Outbreak - Sequence of Events

- Blue Bell voluntarily recalled all products made at all three of their facilities.
- Recall was announced after sampling by the company revealed that Chocolate Chip Cookie Dough Ice Cream half gallons produced on March 17, 2015, and March 27, 2015, contained Listeria.
Blue Bell voluntarily recalled all products made at their facilities in Texas, Oklahoma, and Alabama. Recall was announced after sampling by the company revealed that Chocolate Chip Cookie Dough Ice Cream half gallons produced on March 17, 2015, and March 27, 2015, contained Listeria.

The FDA releases findings from recent inspection at all three Blue Bell facilities. The items listed below were taken directly from the inspections:

- “Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.”
- “Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food.”
- “The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials.”
Prior to the outbreak, Blue Bell Creameries was the fourth largest ice cream manufacturer in the United States. The Oklahoma and Alabama facilities were reopened in July and September 2015, respectively. The corporate headquarters facility in Texas reopened approximately one year after closure. Lay off of 1,450 of 3,900 workers, Furloughed 1,400 workers, Kept afloat by $125 million loan.

"This was a complex multistate outbreak investigation of listeriosis" - CDC

The response to the Blue Bell outbreak is a good example of the need for additional resources over and above what is available at the local jurisdictional level. Without advanced laboratory methods and the utilization of epidemiologic and environmental capacities at the state and federal levels, foodborne illness associated with contamination of Blue Bell ice cream products may have continued for some time after the source was identified and control measures implemented, reducing ongoing illness and deaths.

The remainder of the module will identify additional outbreaks that are considered complex in nature and additional resources are required to effectively respond.
Very Large Foodborne Outbreaks

Large numbers of cases associated with a foodborne outbreak may require additional core discipline staff to assist with response activities. These outbreaks may be associated with an event and cases may be dispersed to other jurisdictions. Coordination is necessary when cases reside in other jurisdictions. There are several well-documented large outbreaks. A 2004 outbreak associated with a norovirus infection sickened 1252 employees and guests at the Flamingo Las Vegas hotel.
Outbreaks Associated with Severe Pathogens

Outbreaks Associated with Severe Outcomes

- Illness associated with high morbidity and mortality
- Requires crisis and risk communication methods
- May require subject matter experts

*E. coli* O104:H4 outbreak associated with sprouted fenugreek seeds from Egypt

Illness associated with **severe pathogens have high morbidity and mortality**. Due to the severity, healthcare systems may be adversely impacted. The **use of crisis and risk communication methods may be necessary** to keep the public informed of response efforts to mitigate fear and confusion. Outbreaks of this nature may **require subject matter expertise not available in all jurisdictions**.

A very notable outbreak associated with a severe pathogen was a large outbreak of **Shiga toxin-producing *E. coli* O104:H4 in Germany in 2011**. Originally implicating Spanish cucumbers, the investigation led to sprouted fenugreek seeds as the culprit. **There were 2,987 cases of illness, 855 cases of hemolytic-uremic syndrome (HUS), and 53 deaths**. HUS is a condition caused by the abnormal destruction of red blood cells. The damaged red blood cells clog the filtering system in the kidneys, which can lead to life-threatening kidney failure.
Outbreaks Associated with Novel Pathogens and Food Vehicles

Novel Pathogens and Food Vehicles

- Identified by advanced molecular laboratory detection methods
- May require subject matter expertise not available in local jurisdictions
- Leads to a better understanding of pathogens

Novel pathogens and food vehicles leading to foodborne illness requires identification by advanced molecular laboratory detection methods. It generally takes response team partners with subject matter expertise to determine the root cause of illness. Understanding the root cause of illness and novel food sources associated with outbreaks lead to a better understanding of the characteristic of pathogens and their viability in foods.

Instructional Note

Mention to participants that there are 3 examples of novel pathogens and food vehicles in the participant’s manual. They are: *Salmonella* infection associated with organic sprouted chia powder, STEC O121 and STEC O26 associated with flour as the vehicle for foodborne illness, and Moringa Leaf powder used in RAW Meal Organic Shakes and Meal Replacement products as the source of a foodborne outbreak associated with a novel pathogen – *Salmonella Virchow*. 
In 2014, a foodborne outbreak investigation was conducted involving *Salmonella* infection associated with organic sprouted chia powder. A total of 31 cases in 16 states with outbreak strains of *Salmonella* Newport, *Salmonella* Hartford, and *Salmonella* Oranienburg. There were an additional 49 cases in Canada. Several recalls were associated with this outbreak as this sprouted chia seed powder was an ingredient in many products. Ingredient-level response activities can be complex and require all response partners to provide information to assist with identification of the source of illness. The final epi curve and case count map are provided below.
A multistate outbreak investigation associated with STEC O121 and STEC O26 revealed flour as the vehicle for foodborne illness. Epidemiologic, laboratory, and product tracing led to the source of the outbreak – a General Mills facility in Kansas City, Missouri. This outbreak lasted at least 9 months and demonstrated that a shelf-stable product such as flour can harbor viable pathogens of foodborne illness.
Moringa Leaf powder used in RAW Meal Organic Shakes and Meal Replacement products was the source of a foodborne outbreak associated with a novel pathogen – *Salmonella* Virchow. This outbreak caused 33 people to become ill in 23 states. This outbreak investigation reaffirms the ability of *Salmonella ssp.* to remain viable in foods with low water activity. This outbreak also highlights the growing popularity of meal replacement products and the associated risk as a ready-to-eat food.
Outbreaks Associated with Criminal Intent

Intentional Contamination

- *Shigella dysenteriae* type 2 infection caused by a laboratory worker, 1997
- Arsenic contaminated coffee served at a Lutheran Church in New Sweden, Maine, 2003
- Nicotine contaminated meat in Michigan, 2003
- Mouse poison and hand sanitizer in Michigan, 2016

Although not a regular occurrence, foodborne illness has occurred as a result of intentional contamination of food. **Intentional contamination of food is a criminal act and foodborne outbreak response teams will have a new partner – law enforcement.** The following is a list of notable intentional contaminations of food:

- *Shigella dysenteriae* type 2 infection caused by a laboratory worker resulted in 12 illnesses. Shigella was introduced onto muffins and doughnuts placed in the staff breakroom. This outbreak occurred in October, 1997.
- Arsenic contaminated coffee served at the Gustaf Adolph Lutheran Church in New Sweden, Maine hospitalized 15 and caused one death. A congregation member left a suicide note claiming responsibility. This outbreak occurred in May 2003.
- In 2003, a man sprinkled an insecticide called Black Leaf 40, which has a main ingredient of nicotine, on 200 pounds of meat at a supermarket, causing approximately 100 illness associated with nicotine poisoning in Michigan. The person contaminating the meat was an employee of the supermarket. As cited in the MMWR published on this incident, “This investigation involved the private sector (i.e., the food retailer) and five government agencies, including local and state public health departments, the state agriculture department, and two federal agencies.”
- In 2016, a man was arrested for sprinkling a combination of mouse poison, hand sanitizer and water on produce in grocery stores in Michigan. State authorities listed at least 15 other stores in other cities, including Flint and Midland, that might have been affected. Health officials in Michigan said that the man also admitted to contaminating some produce stacked in stands. **The incident was investigated by local and state law enforcement officials as well as the FBI.**
Horizontal scaling, or **scaling out**, is a means to add response team partners at the same **level of jurisdiction**. Generally, when a local response team scales out, the team will recruit from within their agency and add more epidemiologic, laboratory, or environmental investigators to the response. In certain circumstances, there may be another agency operating at the same level of government that may be a source of response team members. This may be the case with municipal and county health departments or agricultural departments operating at the local jurisdictional level.
Vertical scaling, or **scaling up**, will add response team members from agencies that operate above the local level of government. Vertical scaling may add core discipline members, non-conventional team members, or add investigational capacity not available within the jurisdiction. **An epi-aid from the CDC may add core response team members to conduct the same activities as the initial response team** or it may add subject matter expertise lacking at the local response level. Another example of **adding lab capacity would be to use the LRN and FERN.**
In the participant’s manual, read and discuss the scenarios presented.

Based upon your jurisdiction, state whether the scenario presented is a complex outbreak and why.

Provide the response team partners that would be necessary for a successful response.

Record responses in the space provided in the manual.

Instructional Hint

This activity will reinforce concepts presented for a complex outbreak response. Responses will change based on the jurisdiction but general responses expected will be provided as instructional notes.
**Scenario 1**
On Tuesday, May 8th, a local health department is notified by the local hospital lab that they have identified 10 cases of *Salmonella* detected by CIDT. Preserved stool is being sent to the state public health lab for confirmation and subtyping. Eight of the cases are males, ranging in age from 21 to 28. Information on the cases are available on the electronic lab reporting system.

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**Instructional Hint**
The date of onset and the gender and age of the cases may lead some participants to consider this a possible complex outbreak response. These cases may have been associated with an event (Cinco de Mayo) and there may be many more cases yet to present. More investigational capacity may be necessary.

**Scenario 2**
There now appears to be at least 50 people identified by laboratory analysis or with symptoms associated with salmonellosis. Most cases state that they attended a Cinco de Mayo event downtown. There were numerous food vendors at the event. The state public health lab has identified *Salmonella enterica* Hvittingfoss, a subtype of *Salmonella* identified infrequently in that part of the country. Hospitalization rates are 50%.
Complex Outbreak? Why or why not?

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Instructional Note

50 cases with high hospitalization rates will prompt most jurisdictions to consider this a complex outbreak response. Partners would include laboratory at the local, state and federal levels and possibly the need for additional epidemiologic support. Since there was an event identified and multiple vendors, environmental health staff may be in the field attempting to gain information about the event and the vendors.

Scenario 3
As the investigation continues, many of the cases ate at “The Taco Wagon”. Environmental investigators gained information that Pico de gallo and other accompaniments were provided on a table. Two people noticed a suspicious person hanging around the table. A sketch of the person has been provided to the cases.
Meeting the Demands of a Complex Outbreak

Module 3 described many of the partners available and the tools necessary to respond to a complex outbreak. During a response to a complex outbreak, the response team will have to identify and engage new partners. The ability to expand and add new partners is considered scaling. Horizontal and vertical scaling is terminology used by outbreak response teams to add new members. It is also used in the information technology world and has similar meaning.
Summary

Recognize when a response is complex and exceeds normal operating conditions

Describe the characteristics of a multijurisdictional outbreak response

Identify additional resources necessary to meet the demands of the response

Coming Up Next

Effective Team Response – Strategies and Tactics