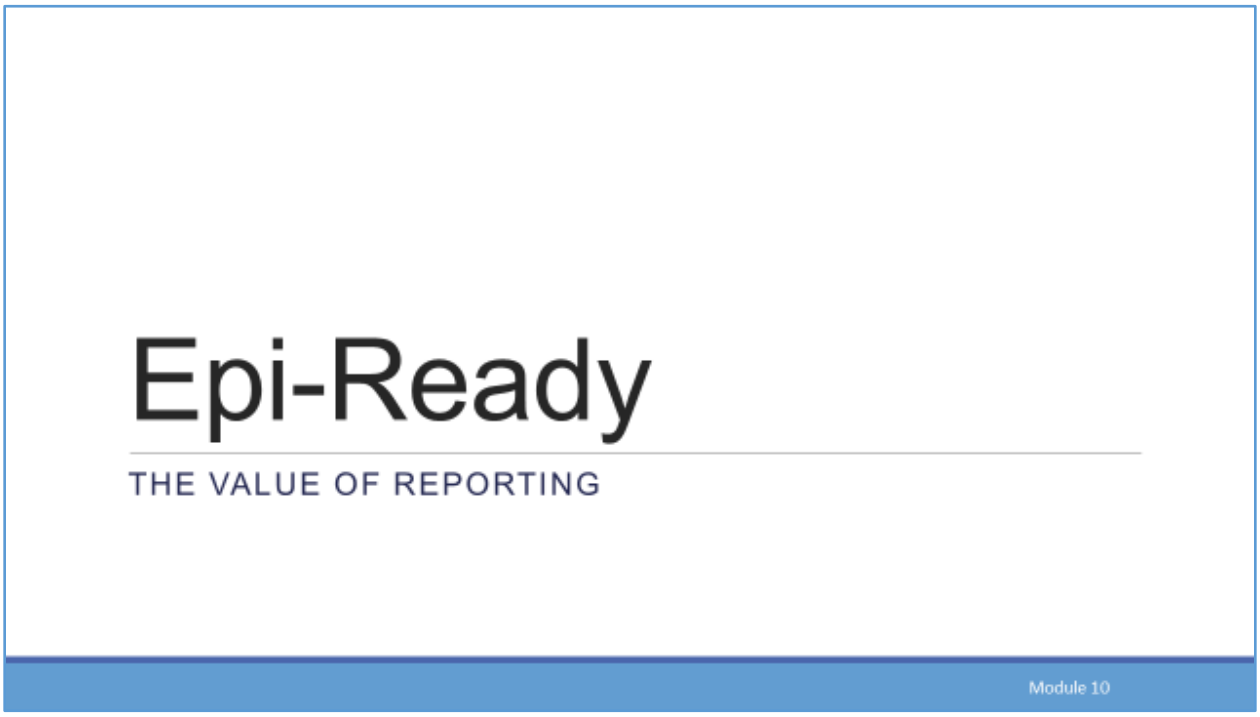
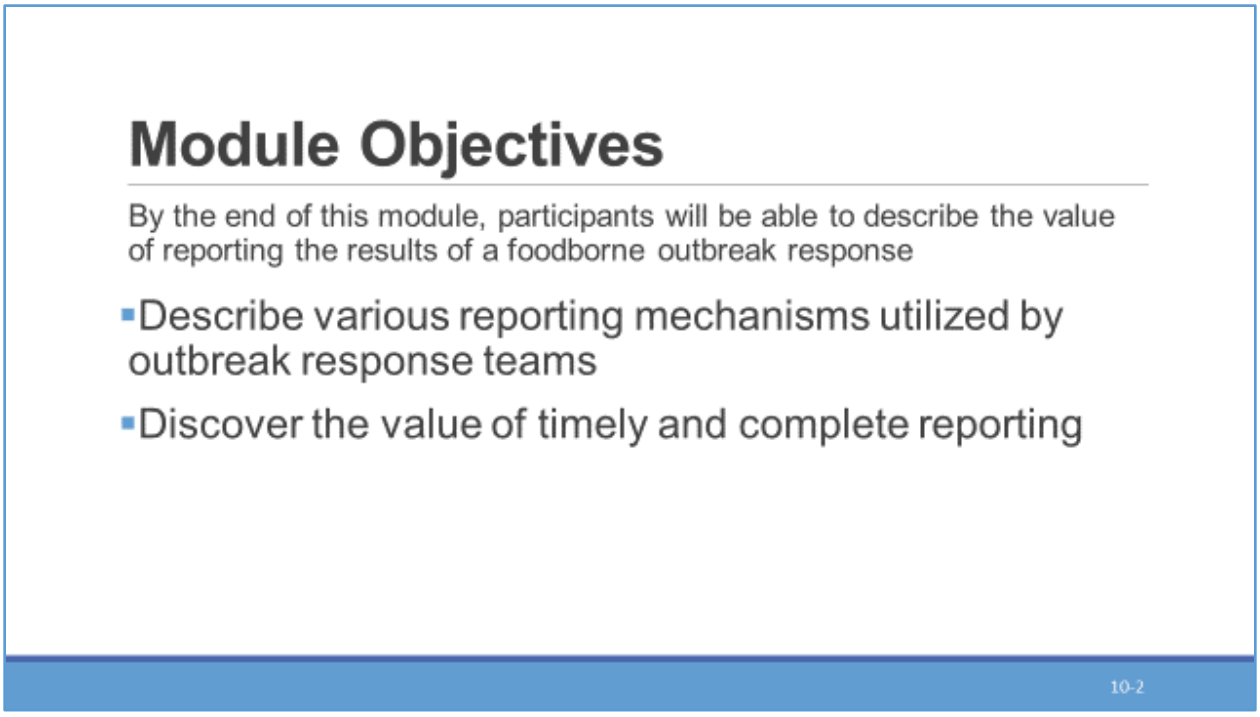
The Value of Outbreak Reporting



Module Objectives



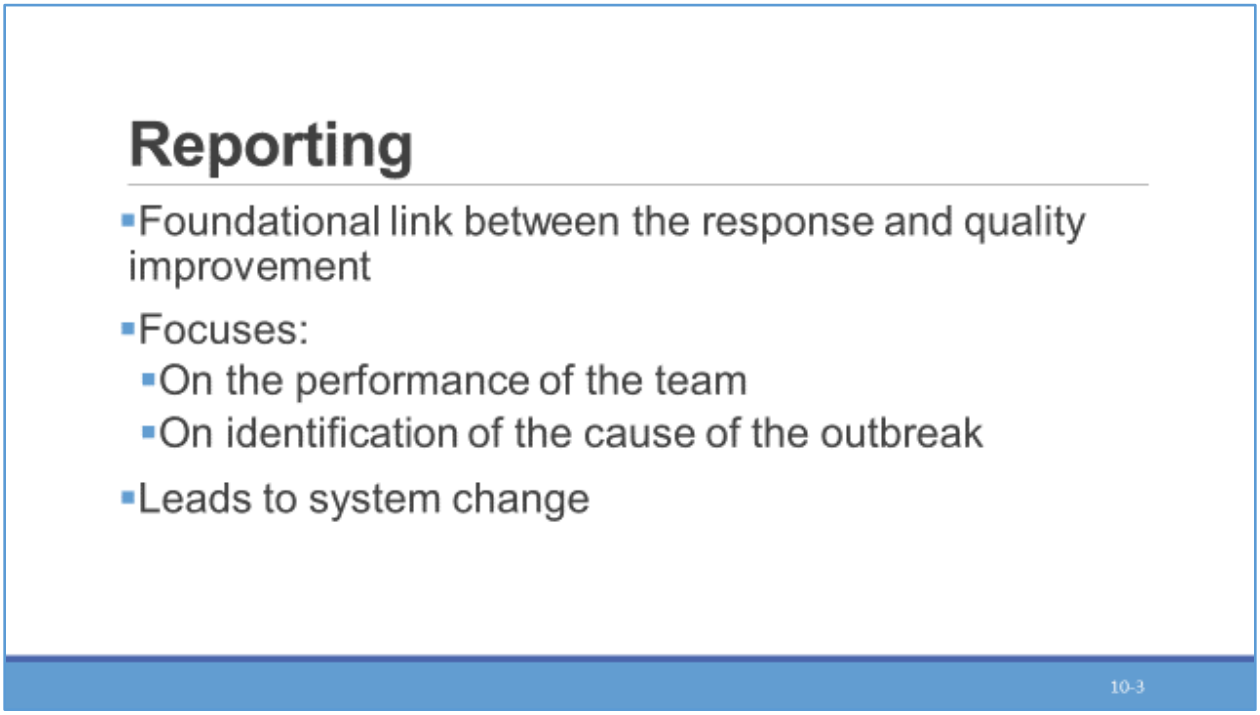
Performance Objective

By the end of this module, participants will be able to describe the value of reporting the results of a foodborne outbreak response.

Enabling Learning Objectives

By the end of this module, the instructor shall accomplish the following learning objectives in support of the performance objective:

- Describe various reporting mechanisms utilize by outbreak response teams
- Discover the value of timely and complete reporting



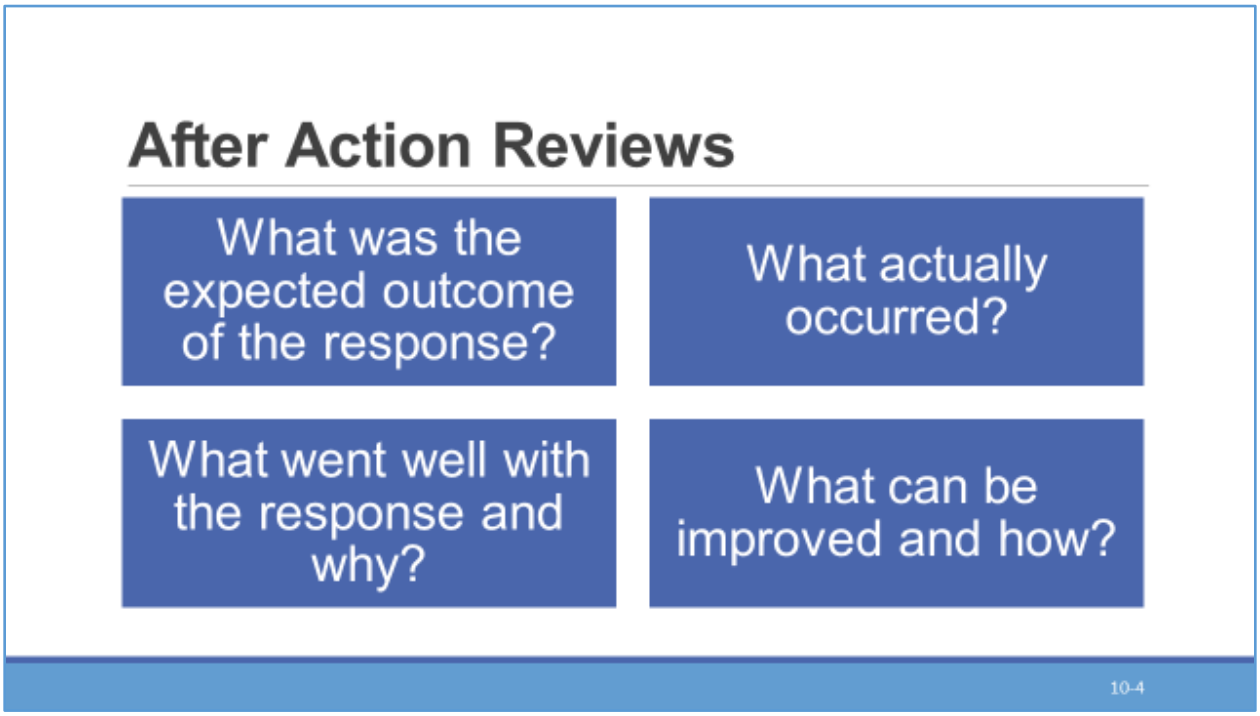
Reporting the outcome(s) of an outbreak response provides a foundational link between the response and quality improvement. Reporting is a means to record the findings of the evaluation process, a process necessary for performance improvement. There are various mechanisms that are utilized to report on the outcomes of a foodborne outbreak response. Reporting may focus on the performance of the team, or it may focus on the identification of the cause of the outbreak – leading to system change.

After-Action Review

The after-action report is a report that contains the debriefing or structured review evaluating the activities associated with an exercise or an actual response. Use of the terminology “After Action Report” is generally associated with a formal process required by the Department of Homeland Security (DHS)-Federal Emergency Management Agency (FEMA) or the Public Health Emergency Preparedness (PHEP) Cooperative Agreement but the underlying principles of the report should never be lost by the response team. More important to team performance is to focus on the review and realize the report and improvement plan is the outcome of a thorough and well documented review.

An **after-action review** (AAR) is a professional discussion of an event, focused on individual and team performance standards, that enables participants to discover what happened, why it happened, and how to sustain strengths and improve on weaknesses.

Adapted from a definition by the Department of the Army



After-action reviews may use a format that is agency-specific or be a generally accepted format. The content of the review must consider any reporting requirements. The AAR should be centered of four questions:

- What was the expected outcome of the response?
- What actually occurred?
- What went well with the response and why?
- What can be improved and how?

The AAR should be an open and frank professional discussion involving all response team members. The focus of the review should be on results and identify how to sustain what went well and develop recommendations on how to improve on results that did not meet expected outcomes. Ground rules should be established. The following is “a” set of ground rules that can be a basis for establishing ground rules at after-action review meetings:

- Active participation: it is important for everyone to participate and no one dominates
- Everyone's views have equal value
- Listen to understand, this is how solutions emerge
- Be responsible and avoid blaming
- There are no right or wrong answers
- Be open to new ideas
- Be creative in proposing solutions to barriers
- Build consensus where possible
- Commitment to identifying opportunities for improvement and recommending possible improvement approaches
- No record of the discussion will be distributed without the agreement of all participants
- Quotes will not be attributed to individuals without permission
- Stay on schedule; honor time limits

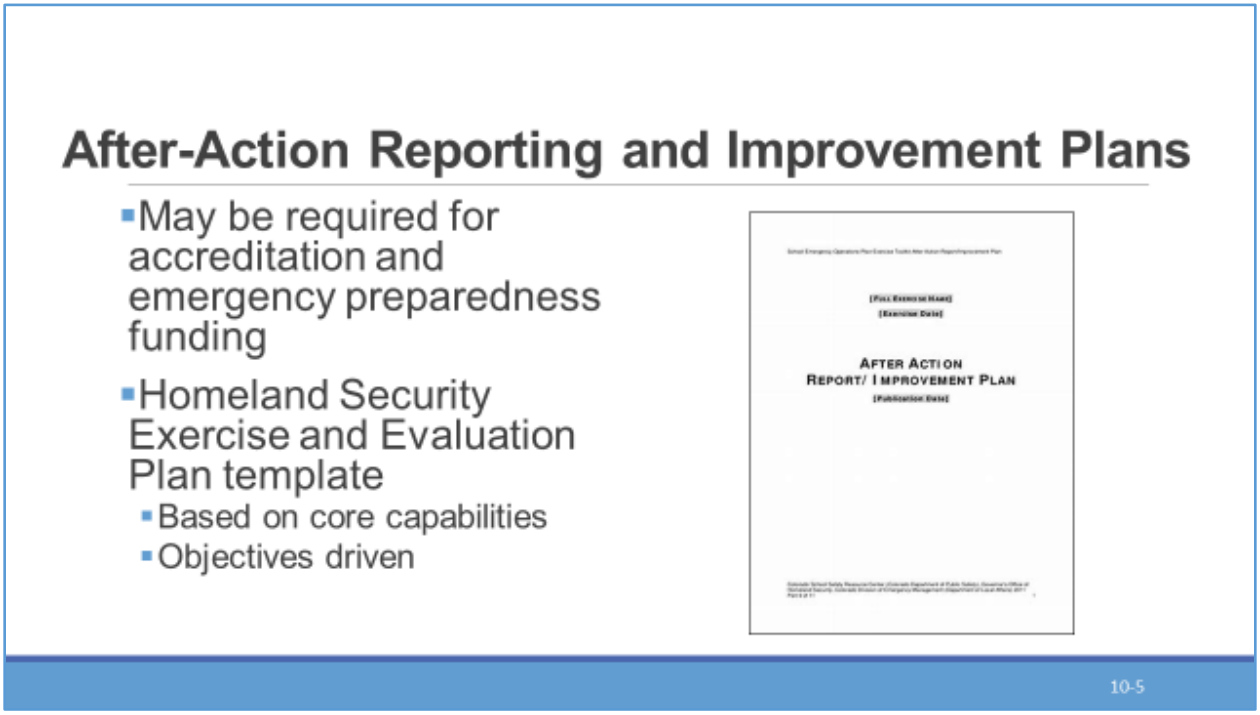
Large, formal after-action reviews may require a facilitator. A facilitator should be someone familiar with the subject matter but did not participate on the response. An outside facilitator is less likely to get caught up in the content of the conversation and can encourage all team members to participate in the conversation. If an external facilitator is unavailable, a team member may be able to fill the role of facilitator but it is important that they participate in the discussion as both facilitator and team member and it is clear when each of the roles are being conducted.

The after-action review requires planning and information gathering. A significant amount of detail must be provided to what occurred during the response. Subjects to be covered during the review should include:

- Perception of the event
- Technical performances of each participating discipline
- Communication – internal with the team and external risk communications
- Coordination of the activities
- Procedural adherence
- Stress and fatigue impact to responders
- Safety concerns
- Organizational issues or cultural challenges that may have impacted team performance

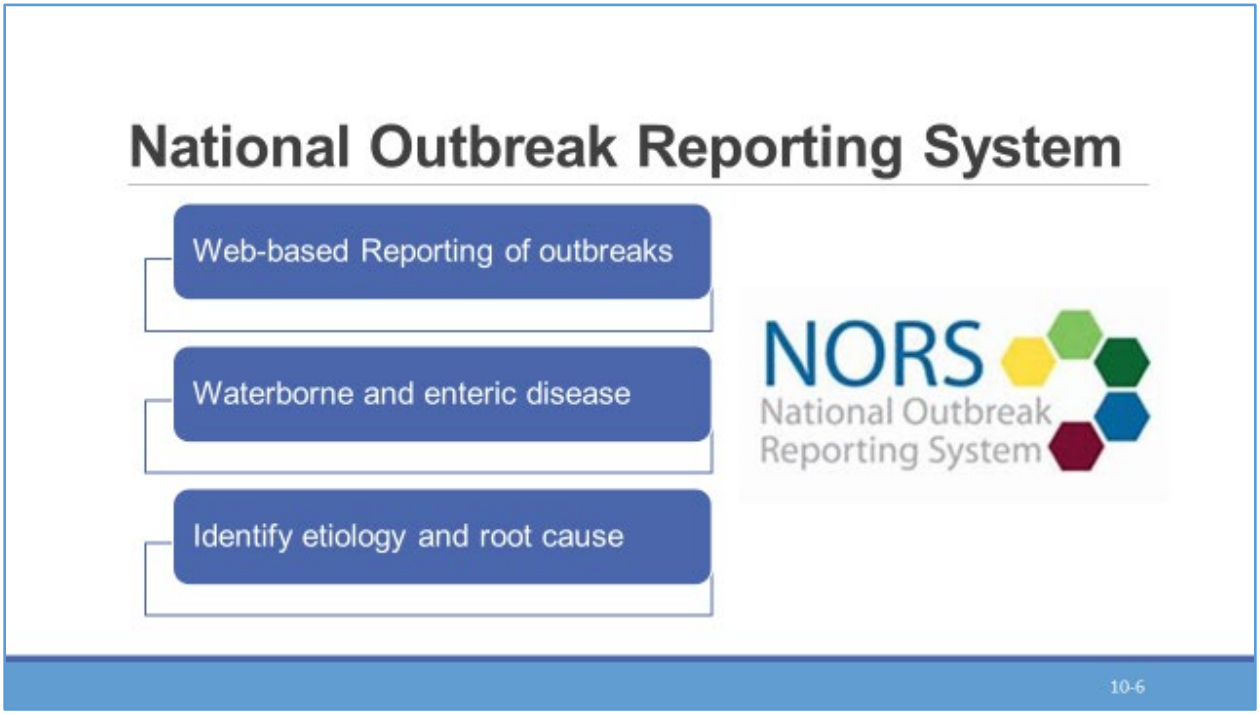
The AAR meeting site should be comfortable and private – away from work areas. An agenda centered on the four questions above with additional detail must be sent in advance of the meeting. Be aware of busy work schedules and stay to the schedule set by the agenda.

After-Action Reporting and Improvement Plans



Reporting the findings of the after-action review is an important aspect of continuous quality improvement. Since most foodborne outbreaks have a public health component in the response, and accreditation and emergency preparedness funding is integrally linked to response activities, the template developed by DHS-FEMA is a tool that can be used for reporting. The template for reporting was developed under the Homeland Security Exercise and Evaluation Program (HSEEP). The HSEEP was developed to evaluate exercises but it provides the framework to report for any foodborne outbreak response. The report focuses on core capabilities and is objective driven. The Public Health Preparedness Capabilities for public health response activities have been developed by the CDC and can be found at: https://www.cdc.gov/phpr/readiness/00_docs/DSLR_capabilities_July.pdf. This document defines 15 capabilities with detail provided for functions associated with the capability and performance measure (if developed). FEMA's core capabilities as established in the National Preparedness Goal organize 32 goals into the five mission areas of: prevention, protection, mitigation, response, and recovery. The following table presents FEMA's core capabilities by mission areas. The FEMA document can be found at: https://www.fema.gov/core-capabilities.

Reporting to CDC

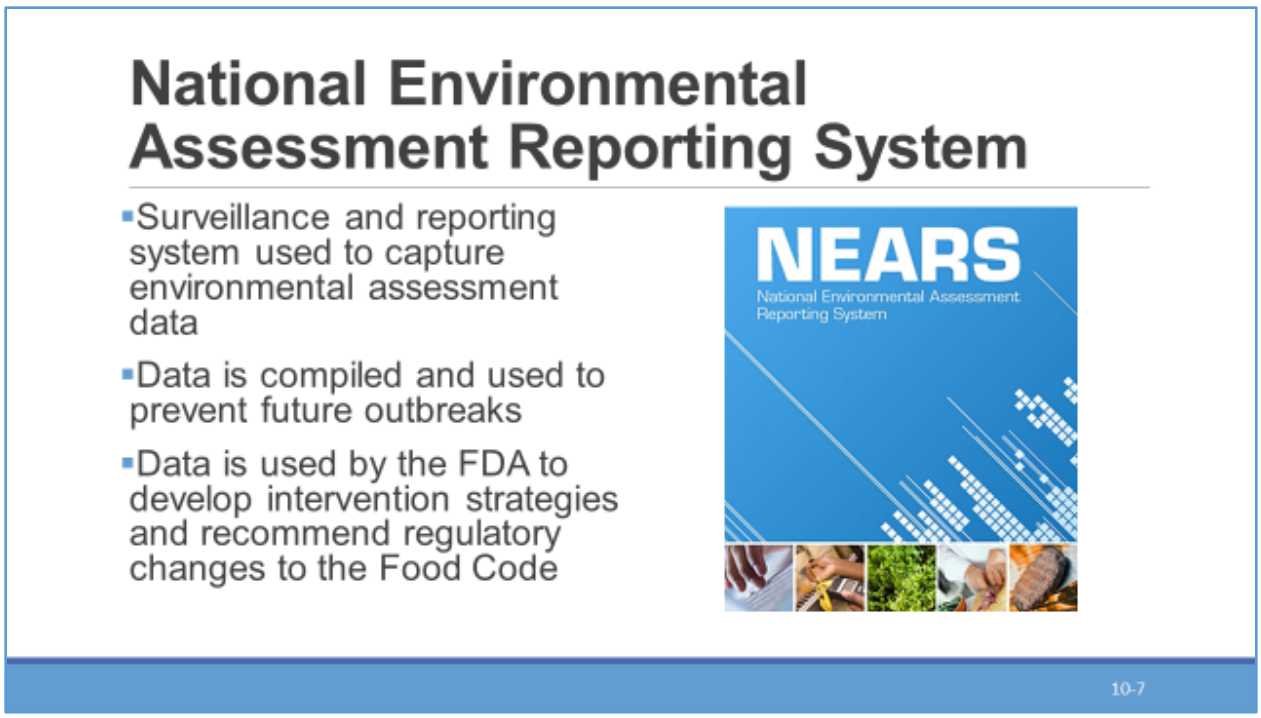


The National Outbreak Reporting System (NORS) is a passive, web-based reporting system established by the CDC in 2009. It replaced e-FORS (the electronic Foodborne Outbreak Reporting System) and other systems dating back to the 1960s. NORS is used by local, state, and territorial health departments in the United States to report all waterborne, foodborne and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to CDC. NORS is intended to enhance the information available to quantify, describe, and understand these types of outbreaks at a national level.

NORS is a system to report outbreaks. Clusters of illness where no source is identified are not reported to NORS as well a single confirmed cases of botulism or other toxin poisoning as they do not meet the definition of a foodborne outbreak.

The fundamental reasons to respond to an outbreak associated with food is to stop the outbreak and apply the lessons learned to prevent future outbreaks. At the heart of NORS is the determination of the etiology and root cause of the outbreak. When foodborne outbreak reports are submitted to NORS, the information may lead to a better understanding of why foodborne illness occurs and result in changes to the food safety system. CDC has developed the NORS Dashboard, a web-based tool available to the public for searching and accessing data from NORS. The NORS Dashboard helps you learn about reports of outbreaks of foodborne, waterborne, and enteric (intestinal) diseases spread by person-to-person contact, environmental contamination, animal contact, and other means. The dashboard may be accessed at: https://www.cdc.gov/nors/data/dashboard/index.html.

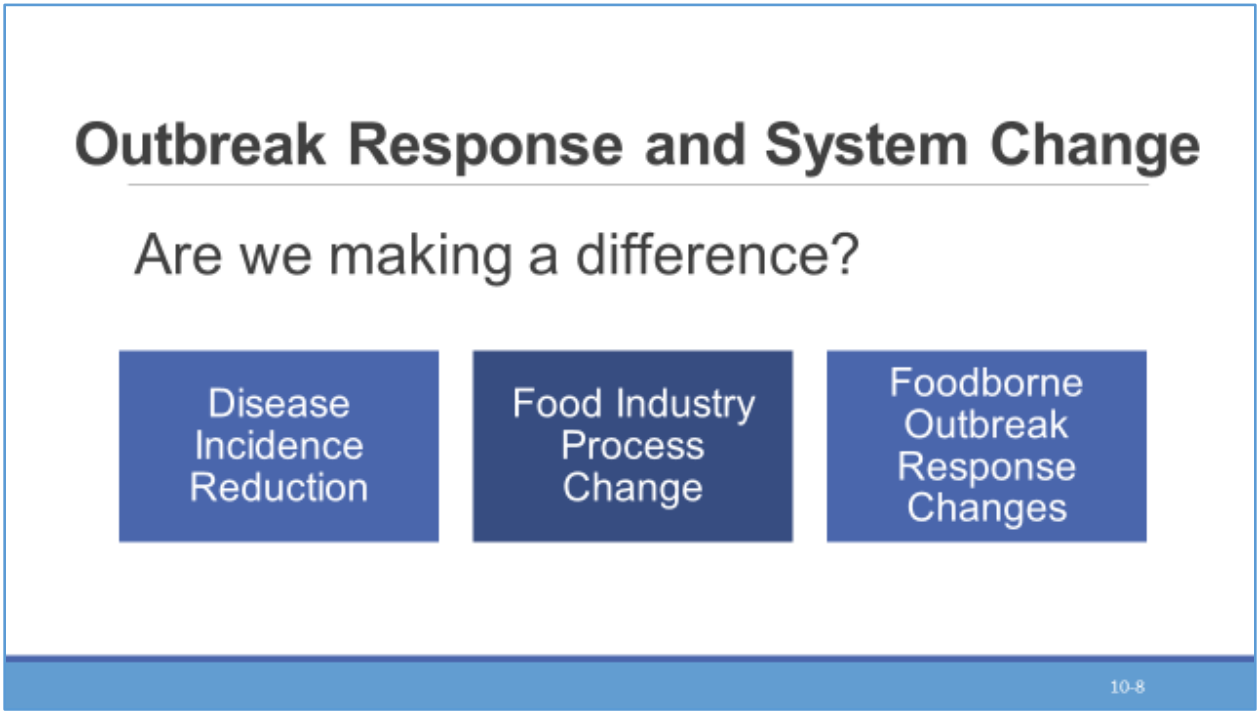
For a better understanding of how to fill out a NORS form, the Colorado Integrated Food Safety Center of Excellence has developed a training video. The video can be found at: https://www.youtube.com/watch?v=3QmNcPvrO3c.



The National Environmental Assessment Reporting System (NEARS) is a program of the CDC's National Center for Environmental Health. NEARS is a surveillance and reporting system that captures the environmental assessment data from foodborne outbreak investigations. The data is compiled and used to prevent future outbreaks. Reporting to NEARS provides access to data that can be used for food safety policy initiatives within a specific jurisdiction or add to the body of knowledge necessary for the FDA to develop intervention strategies and recommend regulatory changes to the Food Code.

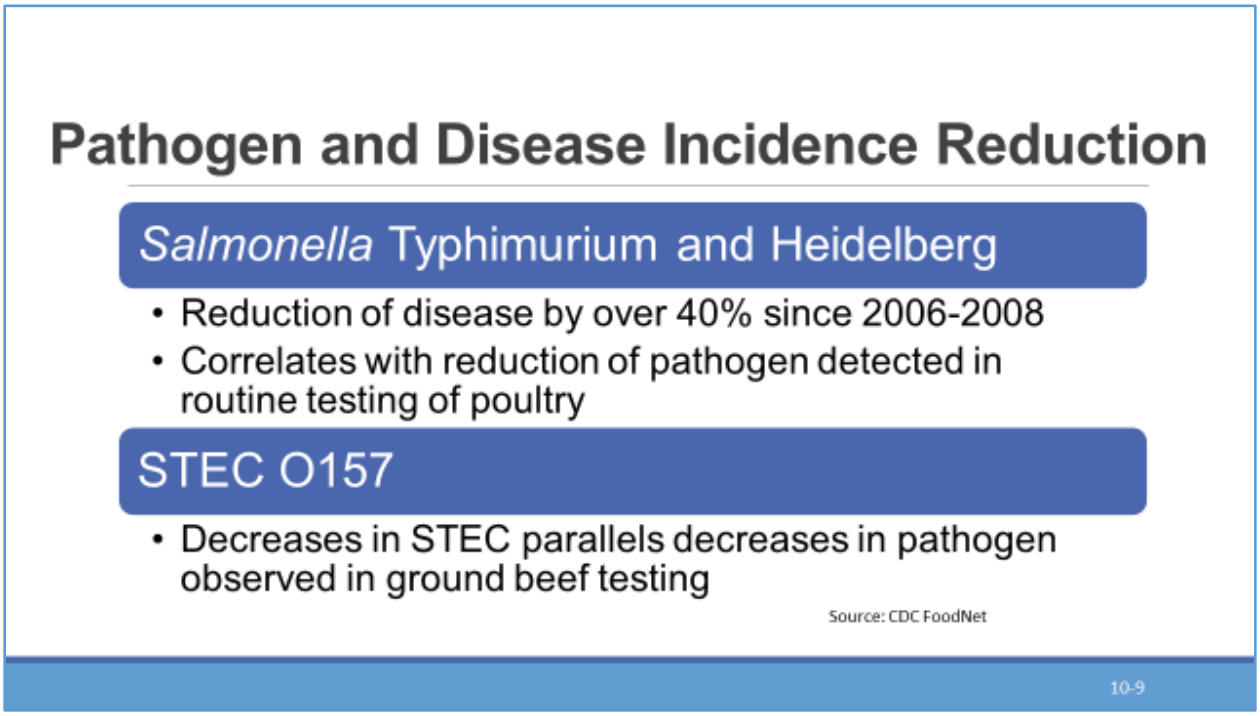
Although considered national surveillance systems, the reporting to PulseNet, CaliciNet, and CryptoNet provide valuable information as a result of the systematic collection and molecular characterization of pathogens in circulation in the United States. These systems provide an increased capacity to identify traditional and novel epidemiological links, risk factors, outbreak sources that would otherwise go undetected without the diligence of these highly-effective surveillance systems.

Improving Food Safety through Foodborne Outbreak Response



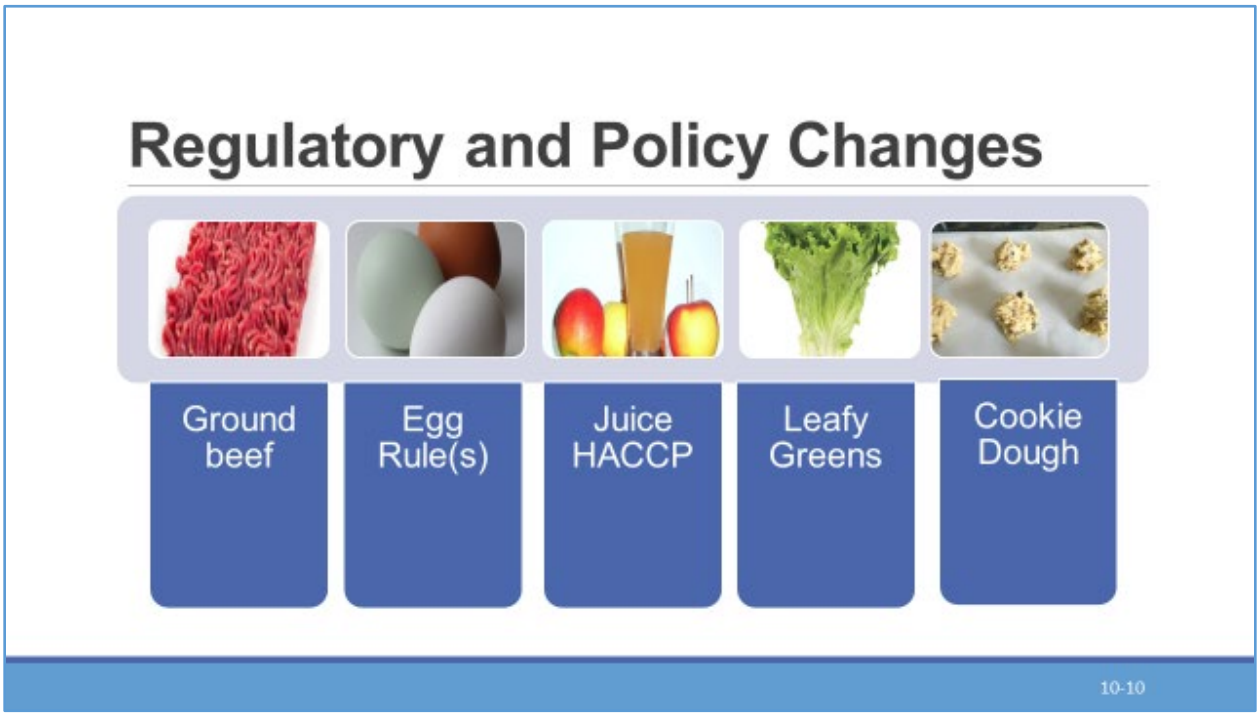
Measuring improvement of the food safety system is a difficult task. Measures could include process changes within the public health system, outcomes such as incidence of pathogen and disease reduction, or process changes within the food industry due to the response outcomes.

Pathogen and Disease Reduction



Understanding the change in incidence of foodborne illness lies within data of the Foodborne Disease Active Surveillance Network (FoodNet). FoodNet monitors laboratory-identified cases of foodborne illness due to nine pathogens that commonly cause foodborne illness. Even though foodborne illness for *Campylobacter*, *Listeria*, non-O157 Shiga toxin–producing *Escherichia coli* (STEC), *Yersinia*, *Vibrio*, and *Cyclospora* increased in 2017 as compared to 2014-2016 data, the incidence of infections with *Salmonella* serotypes Typhimurium and Heidelberg have decreased by over 40% since the 2006-2008 reporting period. These *Salmonella* serotypes have generally been associated with infection as a result of contaminated poultry. This reduction in illness correlates with the reduction of *Salmonella* identified by the routine testing of poultry. This reduction is likely the result of the enhanced control measures of depopulating and vaccination. Comparing illness associated with Shiga toxin-producing *E. coli* O157 between 2017 and 2006-2008, the incidence of disease has decreased. This decrease parallels the decreases observed in raw ground beef samples analyzed by the USDA Food Safety and Inspection Service (FSIS). Pathogen reduction by changes in the food industry will be explained in more detail in the next section.

Regulatory and Policy Changes within the Food Industry



There are some very notable decreases in certain pathogens associated with foodborne illness. As mentioned in the previous section, illness associated with certain serotypes of *Salmonella* and Shiga toxin-producing *E. coli* O157 have seen statistically-significant reductions. These reductions in illness can be attributed to changes in processes to make food safer. This section will discuss some of the notable outbreaks and investigations that have led to changes in the food industry.

Shiga toxin-producing *E. coli* O157

A discussion of the illness associated with Shiga toxin-producing *E. coli* O157:H7 (STEC O157) always starts with one event: the 1993 foodborne outbreak associated with the Jack in the Box

restaurant chain. Over 650 were ill and four children died as a result of this outbreak. This outbreak, certainly a sentinel event, precipitated media coverage, lawsuits and changes in the federal regulation regarding STEC O157 in ground beef. The resultant FSIS regulation deemed STEC O157 an adulterant, a dramatic change from their previous position regarding bacteria in raw meat. Primed to survive the outbreak, Jack in the Box established the systematic approach to ensure food safety in their restaurants as well as with their food suppliers. In the restaurants, they implemented Hazard Analysis and Critical Control Points (HACCP), a system of food safety established by NASA and Pillsbury in the late 1950s. Jack in the Box also implemented testing for STEC O157 in their supply chain and dropped suppliers with *E. coli* positives samples, markedly reducing the amount of *E. coli* positive samples. Jack in the Box forced slaughter houses to change their processing to establish proper methods of skinning, washing the carcasses and removing the organ without disrupting the intestines. These industry changes sparked changes in the regulatory approach to STEC O157. In 1997, FSIS implemented "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems" (PR/HACCP). This HACCP-based inspection model was implemented system-wide throughout the beef, pork and poultry industries.

As foodborne illness associated with beef products wane, outbreaks of STEC O157 associated with leafy greens have become more prevalent. In 2006, a fresh, bagged spinach outbreak resulted in 199 persons ill, 102 hospitalizations and 31 cases with Hemolytic-uremic syndrome (HUS). As a result of this outbreak the California Department of Food and Agriculture (CDFA) and the leafy greens industry created the California Leafy Green Products Handler Marketing Agreement (LGMA), which has resulted in improved food safety practices for growers and handlers. A similar program was created in Arizona. Under these programs in California and Arizona, almost 95% of all leafy greens are produced under the LGMA program. This equates to 50 billion servings of lettuce annually. Although LGMA certification is voluntary, it is widely accepted as an association that protects public health through creating a culture of food safety on the farm. LGMA establishes strict food safety practices and requires regular audits by CDFA.

Despite the best efforts of the leafy green industry, an outbreak in 2018 of STEC O157 associated with romaine lettuce sickened 100, with a hospitalization rate of close to 50% and four cases of HUS. An April 29, 2018 Forbes Article titled "*E. coli* Outbreak in Romaine Lettuce Underscores Need for Change and Technology" discusses the romaine lettuce outbreak.

<u>*Salmonella* in Poultry Products</u>

In July of 2009, the FDA established the Final Rule: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation. By the implementation of this rule in 2010, the FDA expected to prevent 79,000 illnesses associated with *Salmonella* infection, a 60% reduction in *Salmonella* Enteritidis (SE) infections from eggs. This final rule, and other incremental rules that preceded, significantly changed the safety standards associated with shell eggs.

In 2008, the CDC reported that SE accounted for 20.1% of all serotyped *Salmonella* infection in the United States. Even more remarkable is the rate of SE isolates reported to CDC increased from 0.6 per 100,000 population in 1976 to 3.6 per 100,000 population in 1996. Between 1985 and 2002, a total of 53 percent of all SE illnesses identified through CDC outbreak surveillance are attributable to eggs. Where a vehicle of transmission was identified, 81 percent of outbreaks and 79 percent of illnesses identified through outbreaks were attributed to eggs. Most of the

attributed illness during this period occurred before 1995 (73%) with the resultant decline attributed to egg quality assurance programs (EQAPs) requiring refrigeration of eggs at retail establishments.

By this final rule, the FDA made the following food safety changes:

- Shell eggs being held or transported are required to be refrigerated at or below 45 degrees Fahrenheit (°F) ambient temperature beginning 36 hours after time of lay.
- Shell egg producers must conduct environmental testing for SE when laying hens are 40 to 45 weeks of age and 4 to 6 weeks after molt.
- Shell egg producers must conduct egg testing for SE when an environmental test is positive for SE.
- Shell egg producers must maintain a written SE prevention plan and records documenting compliance with the requirements in the plan.

(Federal Register/Vol. 74, No. 130/Thursday, July 9, 2009/Rules and Regulations)

Similar strategies have been employed to reduce the prevalence of *Salmonella* in poultry meat (broiler industry). Measures are harsh as it relates to control of *Salmonella* in poultry. High levels of biosecurity (cleaning and disinfection) in poultry and food processing plants is important to avoid disease outbreaks and the possible slaughter of entire flocks. FSIS requires strict *Salmonella* and *Campylobacter* testing and intervention as established in the Federal Register Notice entitled, *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection.

Juice HACCP

"Odwalla Will Pasteurize Its Apple Juice"

Los Angeles Times December 5, 1996

Breaking from a culture of the wholesome, fresh squeezed, and pressed juices, Odwalla began distributing flashed-pasteurized apple juice. This process change was a direct result of the 1996 outbreak of illness associated with *E. coli* O157:H7. This STEC accounted for more than 60 illnesses and left a 16 month-old female dead. As a result of this outbreak, Odwalla's stock dropped 90% and the company lost $11.3 million. The outbreak also led to a $1.5 million fine imposed on the company and the requirement of strict sanitary controls.)

This outbreak led to significant changes in the industry commencing with Labeling of Juice Products (Federal Register, July 8, 1998) and HACCP Procedures for the Safe and Sanitary Processing and Importing of Juice (Federal Register January 19, 2001). Further modification of the Juice HACCP occurred in 2017 as a result of the passage of the Food Safety Modernization Act (FSMA). Low-acid juices have very little means of complying with this rule without pasteurization to achieve the required "5-log pathogen reduction" specified in the rule.

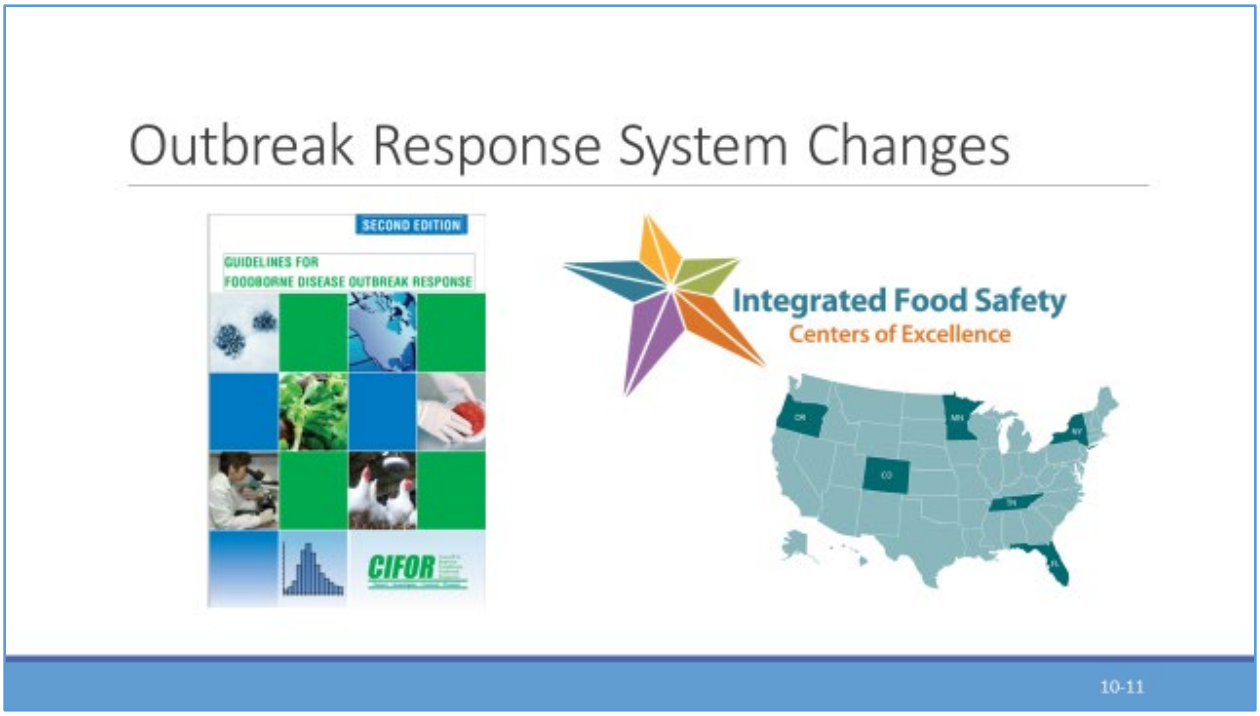
Cookie Dough and Raw Flour

From 2009 through 2017, there were 14 recalls of wheat flour and flour products as a result of contamination with *E. coli*. (http://ucfoodsafety.ucdavis.edu/files/271162.pdf). An investigation of an E. coli O121 and O26 outbreak from December 2015 until September 2016 causing 63

persons to become ill in 24 states revealed that flour from General Mills was the likely source. This outbreak investigation resulted in the recall of over ten million pounds of flour and flour-containing products. This outbreak and the several others mentioned has caused the FDA to issue a Consumer Advisory Notice generalizing not to eat raw dough products and the industry to consider flour as ready-to-eat food and establish preventative controls to reduce or eliminate pathogens in the product and label products as unsafe to consume prior to cooking. In November 2017, The FDA reinforced their position regarding raw cookie dough and targeted flour as the likely source of foodborne illnesses.

Changes with Foodborne Outbreak Response System

Since 2006, there have been significant changes to the foodborne outbreak response system. Initiatives such as CIFOR and the Integrated Food Safety Center of Excellence (CoE) focus on a cross-disciplinary approach to foodborne outbreak response and numerous projects of CIFOR (http://cifor.us/) and the Centers (https://www.coefoodsafetytools.org/AllCoEProducts.aspx) are available. Other initiatives with direct impact on improving foodborne outbreak response are FoodCORE and CORE Network. In 2009, the CDC funded a pilot project to improve state and local response to foodborne outbreaks. FoodCORE centers work together to develop innovative methods to detect, investigate and control multistate outbreaks. FoodCore has established performance metrics designed to demonstrate successes and identify gaps in response. These metrics are based on the principles of the CIFOR Guidelines. FDA's Coordinated Outbreak Response and Evaluation (CORE) Network was initiated in 2011. CORE brought together a full-time team with expertise in medicine, public health and science with a goal of improving efforts associated with detection, response, and prevention.



CIFOR was created in 2006 in direct response to a need to improve the response system from a cross-disciplinary approach as well as to identify and implement best practices in the field of foodborne outbreak response. In response to this need, CIFOR developed the "Guidelines for Foodborne Disease Outbreak Response". The *Guidelines* are a comprehensive source of information on foodborne disease investigation and control for local, state and federal health agencies. The *Guidelines* describe the overall approach to addressing foodborne disease outbreaks, including preparation, detection, investigation, control and follow-up and the roles of key organizations in foodborne disease outbreaks. The guidelines were updated to the second edition in 2014. The CIFOR have created numerous other tools and resources to enhance the foodborne outbreak response system. For more information about the CIFOR go to www.cifor.us.

The Integrated Food Safety Centers of Excellence were established under the authority of the Food Safety Modernization Act (FSMA), which was signed into law on January 4, 2011 to improve prevention, surveillance, and response to outbreaks of foodborne illness. In the legislation, CDC is charged with designating Integrated Food Safety Centers of Excell**ence** at state health departments, in association with a university system, to identify and implement best practices in foodborne disease surveillance and to serve as a resource for public health professionals at state, local, and regional levels. There are six CoEs, the five original of Colorado, Oregon, Tennessee, Minnesota and Florida established in 2012 and New York joining the program in 2015. The CoEs work to:

- **Strengthen** surveillance and outbreak investigations
- **Analyze** timeliness and effectiveness of responses
- **Train** public health staff in proven investigation techniques
- **Educate** future food safety workforce
- **Improve** capacity of information systems
- **Evaluate** and communicate best practices

The CoEs have developed numerous online training products and provide on-site training to states.

Summary

Coming Up Next