United States Government Accountability Office

Report to the Chairwoman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives

October 2020

FOOD SAFETY

CDC Could Further Strengthen Its Efforts to Identify and Respond to Foodborne Illnesses

Accessible Version

GAO-21-23

GAO Highlights

Highlights of GAO-21-23, a report to the Chairwoman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives

Why GAO Did This Study

CDC has estimated that each year, one in six people in the United States gets a foodborne illness, 128,000 are hospitalized, and 3,000 die. CDC data show increases in the number of reported multistate foodborne illness outbreaks—groups of two or more linked cases in multiple states—in recent years. Such outbreaks are responsible for a disproportionate number of hospitalizations and deaths, compared with single-state outbreaks.

GAO was asked to review CDC's response to multistate foodborne illness outbreaks. This report examines (1) CDC's roles and responsibilities, (2) challenges that CDC faces and the extent to which it has addressed these challenges, and (3) the extent to which CDC evaluates its performance. GAO reviewed agency documents and data; conducted site visits and case studies; and interviewed federal, state, and local public health officials, as well as representatives of stakeholder groups.

What GAO Recommends

GAO is recommending that CDC (1) develop a plan to respond to the increasing use of CIDTs, (2) make publicly available its decision-making framework for communicating about multistate foodborne illness outbreaks, and (3) implement all the elements of a performance assessment system. CDC concurred with all three recommendations.

View GAO-21-23. For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

October 2020

FOOD SAFETY

CDC Could Further Strengthen Its Efforts to Identify and Respond to Foodborne Illnesses

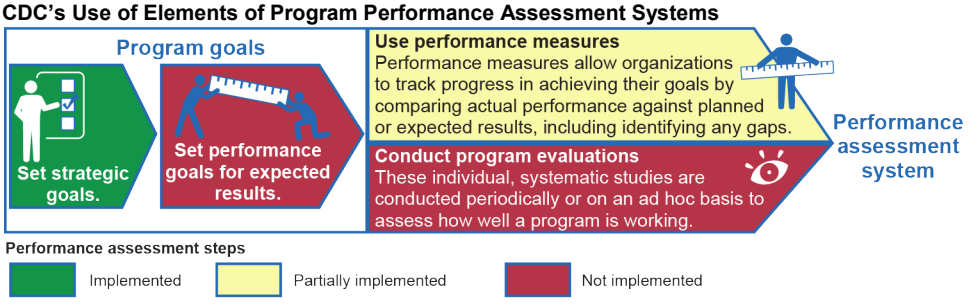
What GAO Found

The roles and responsibilities of the Centers for Disease Control and Prevention (CDC) during a multistate foodborne illness outbreak include analyzing federal foodborne illness surveillance networks to identify outbreaks, leading investigations to determine the food causing the outbreak, and communicating with the public. CDC also works to build and maintain federal, state, territorial, and local capacity to respond to foodborne illness outbreaks by awarding funds to state and local public health agencies and through other initiatives.

In identifying and responding to multistate foodborne illness outbreaks, CDC faces challenges related to clinical methods and communication, and it has taken some steps to respond to these challenges. One challenge stems from the increasing clinical use of culture-independent diagnostic tests (CIDTs). CIDTs diagnose foodborne illnesses faster and cheaper than traditional methods, but because they do not create DNA fingerprints that can specify a pathogen, they may reduce CDC's ability to identify an outbreak. A CDC working group recommended in May 2018 that CDC develop a plan to respond to the increasing use of CIDTs. By developing a plan, CDC will have greater assurance of continued access to necessary information. CDC also faces a challenge in balancing the competing needs for timeliness and accuracy in its outbreak communications while maintaining public trust. CDC has an internal framework to guide its communications decisions during outbreaks, and it recognizes that stakeholders would like more transparency about these decisions. By making its framework publicly available, CDC could better foster public trust in its information and guidance during outbreaks.

CDC has taken steps to evaluate its performance in identifying and responding to multistate outbreaks. Specifically, CDC has developed general strategic goals (see fig.) and taken initial steps to develop performance measures. However, CDC has not yet established other elements of a performance assessment system—an important component of effective program management.

CDC's Use of Elements of Program Performance Assessment Systems



Source: GAO. | GAO-21-23

In particular, CDC has not set specific performance goals, used performance measures to track progress, or conducted a program evaluation of its multistate foodborne illness outbreak investigation efforts. By implementing all elements of a performance assessment system, CDC could better assess its progress toward meeting its goals, identify potentially underperforming areas, and use that information to improve its performance.

Contents

Abbreviations

CDC	Centers for Disease Control and Prevention
CIDT	culture-independent diagnostic test
COVID-19	Coronavirus Disease 2019
ELC	Epidemiological and Laboratory Capacity Cooperative Agreement
FDA	Food and Drug Administration
FoodNet	Foodborne Diseases Active Surveillance Network

FSIS	Food Safety and Inspection Service
GPRA	Government Performance and Results Act of 1993
HHS	U.S. Department of Health and Human Services
SEDRIC	System for Enteric Disease Response, Investigation, and Coordination
USDA	U.S. Department of Agriculture

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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October 21, 2020

The Honorable Rosa DeLauro
Chairwoman
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
House of Representatives

Dear Madam Chairwoman:

Although the U.S. food supply is generally considered safe, foodborne illness remains a common and costly public health problem. Foodborne illness sickens approximately one in six people in the United States (48 million people) each year, leading to 128,000 hospitalizations and 3,000 deaths, according to the most recent estimates from the Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services (HHS).[1] Foodborne illnesses occur when people consume contaminated food, such as produce, meat, poultry, or processed products. Food may become contaminated in different ways, such as when vegetable crops are irrigated with contaminated water or when food is improperly handled in a restaurant. According to CDC, when a larger number of people than expected have the same foodborne illness in a given time period and area, it is called a "cluster." When an investigation shows that sick people in a cluster have something in common to explain why they all got the same illness, CDC calls the group of illnesses an "outbreak." Outbreaks can be large or small and can affect people in a single state or in multiple states.

Although multistate outbreaks make up a small proportion of total outbreaks, they cause a disproportionate number of hospitalizations and deaths among reported foodborne illness outbreaks.[2] In addition, while

[1]Elaine Scallan, et al., "Foodborne Illness Acquired in the United States—Major Pathogens," *Emerging Infectious Diseases,* vol. 17, no. 1 (January 2011); and Elaine Scallan, et al., "Foodborne Illness Acquired in the United States—Unspecified Agents," *Emerging Infectious Diseases*, vol. 17, no. 1 (January 2011). As of July 2020, CDC officials said that they were working to update these estimates.

[2]GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed,* GAO-16-425 (Washington, D.C.: May 2016).

only a small proportion of foodborne illnesses are confirmed by laboratory testing and reported to public health agencies, CDC data show an increase in the number of reported multistate foodborne illness outbreaks, from 28 in 2014 to 58 in 2018. In the past, CDC has cited several potential contributors to the reported increase, including greater centralization of food processing practices, wider food distribution, and improved identification and investigation methods. In this context, concerns have been raised about CDC's ability to identify and respond to multistate foodborne illness outbreaks. According to CDC officials, many of CDC's subject matter experts on foodborne illness were deployed or working full time on the agency's response efforts to the Coronavirus Disease 2019 (COVID-19) pandemic in the spring of 2020, and some states may have resource constraints on their ability to interview ill people in an outbreak of foodborne illness. At the same time, however, the COVID-19 pandemic seems to have reduced the likelihood that individuals will seek medical care for a foodborne illness, and CDC has received fewer reports that would allow it to detect possible outbreaks than in past years. As a result, CDC officials said that the agency has had sufficient staff resources to investigate recent possible outbreaks that have been detected.

CDC is the lead federal agency for addressing public health, and its National Center for Emerging and Zoonotic Infectious Diseases is responsible for the prevention and control of a wide range of infectious diseases, including foodborne illnesses. CDC partners with the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and HHS's Food and Drug Administration (FDA). FSIS is responsible for the safety of meat, poultry, and processed egg products; FDA is responsible for virtually all other food. FSIS and FDA monitor the safety of food products by conducting facility inspections, sampling foods, and monitoring consumer complaints. They also respond to outbreaks of foodborne illnesses by, among other things, participating in the investigation of the suspect food and by conducting investigations to determine how contamination occurred and, if applicable, which products should be recalled.[3] For more than 4 decades, we have reported on the

[3]We have previously reported on the challenges FDA and FSIS face in managing recalls and reducing pathogens in regulated food products. See, for example, GAO, *Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening,* GAO-12-589 (Washington, D.C.: July 26, 2012); and *Food Safety: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products,* GAO-18-272 (Washington, D.C.: Mar. 19, 2018).

fragmented federal food safety oversight system, which has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. We added federal oversight of food safety to our High Risk List in 2007, where it remains today.[4]

The federal food safety system is supplemented by states, localities, tribes, and territories, which may have their own laws and agencies to address the safety and quality of food. In all, more than 3,000 nonfederal agencies perform the great majority of government food safety activities.[5] Among other things, these agencies conduct illness surveillance; investigate and contain illness outbreaks; monitor the food supply for contamination; inspect restaurants, grocery stores, and food processing plants; and take regulatory action to remove unsafe or unsanitary products from the market.[6]

You asked us to review CDC's response to multistate foodborne illness outbreaks. This report (1) describes CDC's roles and responsibilities in identifying and responding to multistate foodborne illness outbreaks, including collaboration with federal, state, territorial, and local partners; (2) examines challenges CDC faces in identifying and responding to multistate foodborne illness outbreaks and the steps CDC has taken to address these challenges; and (3) examines the extent to which CDC evaluates its performance in identifying and responding to multistate foodborne illness outbreaks.

To describe CDC's roles and responsibilities in multistate foodborne illness outbreaks, we reviewed CDC and stakeholder documents describing the process CDC uses to investigate such outbreaks. We also conducted site visits to FDA's Southeast Food and Feed Laboratory, FSIS's Eastern Laboratory, and CDC laboratory facilities to observe how these laboratories analyze samples. To help illustrate CDC's roles and responsibilities in active investigations, we conducted four case studies of outbreak investigations completed from 2014 through 2019. We selected the four case studies based on the length of the investigation; the number

[4]For more information, see GAO, *High Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: Mar. 6, 2019).

[5]GAO-16-425.

[6]Illness surveillance is the ongoing and systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice, such as outbreak investigations.

of cases involved; the number of states involved; the pathogen involved; and the federal regulatory agency with which CDC coordinated during the investigation, among other factors. As part of the case studies, we interviewed officials from CDC, FDA, FSIS, and one state public health agency.[7] (See app. I for a more detailed discussion of the scope and methods of our review, and see app. II for more detailed descriptions of the investigation time lines for the outbreaks in our case studies.)

To examine challenges CDC faces in identifying and responding to multistate foodborne illness outbreaks and how CDC is responding to these challenges, we conducted a literature search in which we selected and reviewed 30 articles from the last 10 years related to the identification of and response to multistate foodborne illness outbreaks.[8] Using those studies, we identified challenges that CDC faces in identifying and responding to multistate foodborne illness outbreaks. We also interviewed a variety of stakeholders from consumer groups, industry associations, and professional associations representing food safety officials to get their views on challenges that CDC faces in identifying and responding to multistate foodborne illness investigations. We then interviewed CDC officials to discuss these challenges and their efforts to respond to them. Where applicable, we also drew on our four case studies of outbreak investigations to provide illustrative examples. We assessed the agency's actions against CDC criteria, recommendations from a CDC-led working group, and federal standards for internal control for information and communication.[9]

To examine the extent to which CDC evaluates its performance in identifying and responding to multistate foodborne illness outbreaks, we reviewed agency documents describing CDC's strategic planning and the performance measures CDC collects. We also reviewed our prior work on leading practices in performance management, such as the GPRA

[7]We contacted state officials to discuss the other three case studies, but these officials were unavailable because they were responding to the COVID-19 pandemic.

[8]The challenges we discuss in this report are not intended to represent all of the challenges CDC faces. The search terms we used to identify the studies included, but were not limited to, foodborne illness, *Salmonella*, Shiga toxin-producing *E. coli*, *Campylobacter*, *Listeria*, detect, address, respond, manage, challenge, detection, identification, and outbreak.

[9]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 2014).

Modernization Act of 2010,[10] as well as on key elements of program performance assessment systems.[11] We then compared CDC strategic planning documents with these criteria to determine the extent to which CDC has these elements in place. We also interviewed CDC officials to obtain their views on how they measure their performance.

We conducted this performance audit from March 2019 to October 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[10]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRA stands for the Government Performance and Results Act of 1993; Pub. L. No. 103-62, 107 Stat. 285 (1993). Although these requirements apply to departments (e.g., HHS), we have previously reported that they can serve as leading practices at other organizational levels, such as component agencies (e.g., CDC) for performance management. See, for example, GAO, *Coast Guard: Actions Needed to Enhance Performance Information Transparency and Monitoring*, GAO-18-13 (Washington, D.C.: Oct. 27, 2017); and *Motor Carriers: Better Information Needed to Assess Effectiveness and Efficiency of Safety Interventions*, GAO-17-49 (Washington, D.C.: Oct. 27, 2016).

[11]See, for example, GAO, *Program Evaluation: Strategies to Facilitate Agencies' Use of Evaluation in Program Management and Policy Making*, GAO-13-570 (Washington, D.C.: June 26, 2013); *Performance Measurement and Evaluation: Definitions and Relationships,* GAO-11-646SP (Washington, D.C.: May 2011); and *Managing For Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.: Sept. 9, 2005).

Background

How Foodborne Illness Occurs and How It Is Detected

Foodborne Pathogens: *Listeria monocytogenes*

Listeria monocytogenes can cause a serious infection in humans – listeriosis. The disease primarily affects pregnant women, newborns, older adults, and people with weakened immune systems.

CDC estimates *Listeria* causes about 1,600 infections and 260 deaths in the United States every year. *Listeria* can cause a variety of symptoms, depending on the person and the part of the body affected, including fever and diarrhea, similar to other foodborne pathogens; miscarriage, premature delivery, or life-threatening infections in a newborn; or confusion, loss of balance, and convulsions.

In 2019, *Listeria* in mushrooms, hard-boiled eggs, deli-sliced meats and cheeses, and other foods was linked to multistate foodborne illness outbreaks.

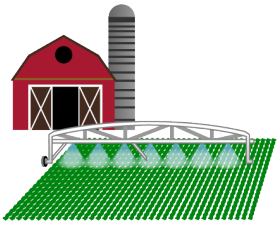
Source: GAO analysis of CDC information (text); CDC (image). I GAO-21-23

Many different foodborne pathogens can contaminate foods.[12] According to CDC's website, *Listeria monocytogenes*, *Salmonella*, and Shiga toxin-producing *E. coli* are among the pathogens that most commonly cause multistate foodborne illness outbreaks. Some foods—such as certain fruits, vegetables, and raw foods of animal origin—are more often associated with foodborne illness than others. However, according to

[12]We use the terms "foodborne pathogens" and "foodborne illnesses" throughout this report to mean pathogens or illnesses that are commonly spread through food. These pathogens can also spread through nonfoodborne routes, such as contact with an animal, another sick person, or contaminated water. An epidemiological investigation is necessary to determine if the source of a single case, or an outbreak of cases, was foodborne.

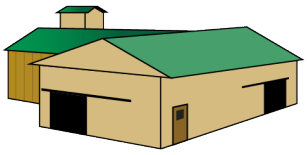
CDC, any food can become contaminated during the various stages in the food production chain, as shown in figure 1.

Figure 1: Food Production Chain and Examples of Sources of Contamination
Food—including produce, meat, poultry, and processed products—may become contaminated at various stages in the production chain.



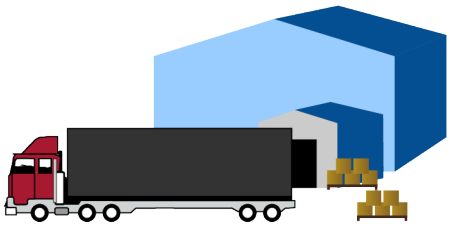
Production

If the fields are irrigated with contaminated water, fruits and vegetables can be contaminated before harvest.



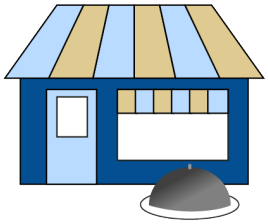
Processing

During the slaughter process, pathogens from an animal's hide or intestines can contaminate the meat.



Distribution

If refrigerated foods are left on a loading dock for extended periods in warm weather, they could reach temperatures that allow foodborne pathogens to grow.



Restaurant preparation

Improper handwashing by food workers, particularly any that remain on the job while ill, can contaminate food.

Home preparation

If a cook uses a cutting board or knife to cut raw chicken and then uses the same knife or cutting board without washing it to slice tomatoes for a salad, the tomatoes can be contaminated by foodborne pathogens from the chicken.

Source: GAO analysis of Centers for Disease Control and Prevention information. | GAO-21-23

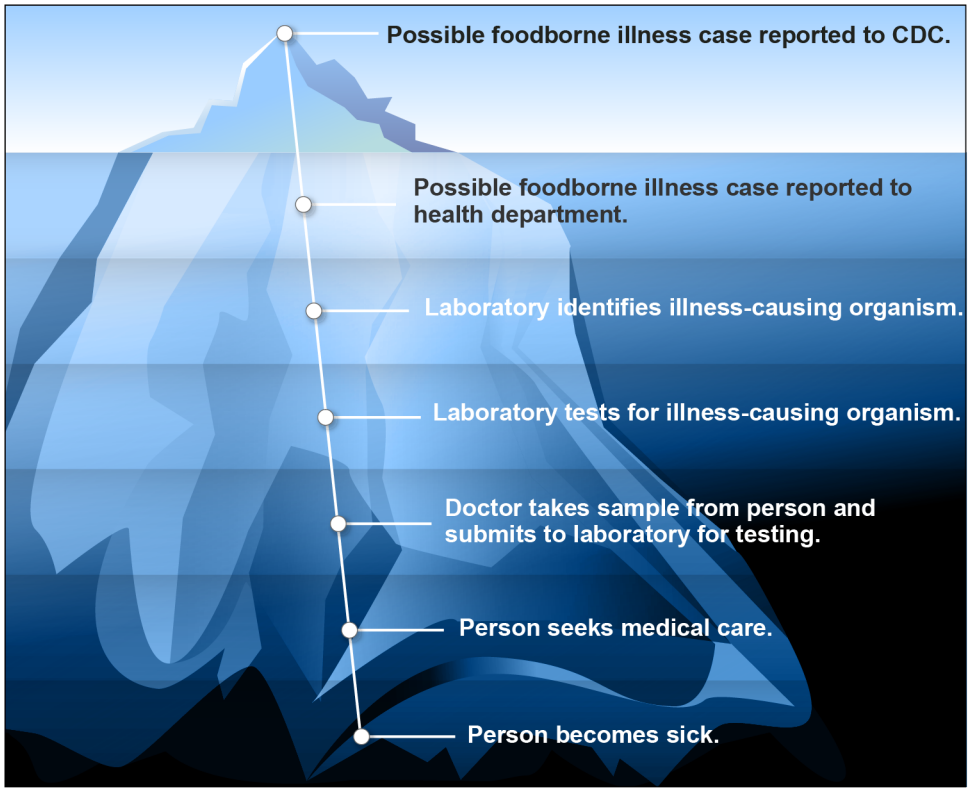
CDC uses several surveillance systems to track and monitor reports of foodborne diseases in the United States, such as PulseNet and the Foodborne Diseases Active Surveillance Network (FoodNet) (discussed later in this report). Most information in these systems comes from state and local health agencies. CDC uses data from its surveillance systems to identify outbreaks, monitor trends, and measure how well prevention programs are working. However, according to a 2011 CDC report, only a small proportion of foodborne illnesses are diagnosed and reported to public health agencies.[13] Underdiagnosis occurs if a sick person does not seek medical care or does not have a specimen taken for laboratory

[13]Scallan, et al., "Major Pathogens."

testing. Underreporting occurs because not all laboratory confirmed illnesses are reported to CDC. According to CDC, many steps must occur for an illness in the population to be registered in CDC's foodborne illness surveillance systems, as shown in figure 2.

Figure 2: Steps That Must Occur for a Possible Case of Foodborne Illness in the Population to Become Visible to the Centers for Disease Control and Prevention (CDC)

Because of the many steps that must occur for a possible case of foodborne illness to be diagnosed and reported, only a small proportion of illnesses—the tip of the iceberg—is visible to CDC.



Source: GAO analysis of Centers for Disease Control and Prevention information. | GAO-21-23

Note: A case of illness does not become a case of foodborne illness until an investigation links it to a food source.

Key Tools to Identify and Monitor Foodborne Illnesses

PulseNet

Foodborne Pathogens: *Salmonella*

Salmonella bacteria can cause illness, known as salmonellosis, in humans. There are thousands of kinds of *Salmonella*.

CDC estimates *Salmonella* causes about 1.35 million infections, 26,500 hospitalizations, and 420 deaths in the United States every year. Most people infected with *Salmonella* develop diarrhea, fever, and abdominal cramps, and most recover without treatment. However, *Salmonella* can sometimes infect blood, bones, joints, or the nervous system (spinal fluid and brain) and cause severe disease.

In 2019, *Salmonella* in cut fruit, ground beef, whole papayas, raw tuna, and other foods was linked to multistate foodborne illness outbreaks.

Sources: GAO analysis of CDC information (text); CDC (image). I GAO-21-23

CDC's primary method for identifying possible multistate foodborne illness outbreaks is through PulseNet, a national laboratory network established in 1996. PulseNet databases enable CDC to connect individual foodborne illness cases to identify clusters of illness. The network analyzes DNA fingerprints, or specific patterns created by the genetic makeup, of the pathogens making people sick, along with the pathogens found in food and the environment. (Microbiologists generate these fingerprints using laboratory techniques that we discuss below.) The PulseNet databases contain over half a million DNA fingerprints generated from samples collected from people, food, and the environment. CDC estimates that

each year PulseNet helps public health officials identify about 1,500 clusters of foodborne disease at the local or state levels, 250 clusters that span multiple states, and 30 multistate outbreaks that are linked to a food source. Every state has at least one public health laboratory that can match up foodborne pathogens from sick people across different locations using PulseNet's databases.

DNA Fingerprinting

CDC and state laboratories have historically used one of two tools to determine how closely related pathogens are to one another and how likely it is that they are part of the same outbreak. These methods are described below.

Foodborne Pathogens: *Escherichia coli* (*E. coli*)

E. coli are a large and diverse group of bacteria found in the environment, foods, and intestines of people and animals. Although most strains of *E. coli* are harmless, others can cause illness or disease in people.

CDC estimates Shiga toxin-producing *E. coli* cause more than 265,000 illnesses each year in the United States, with more than 3,600 hospitalizations, and 30 deaths. Some kinds of *E. coli* can cause diarrhea, while others cause urinary tract infections, respiratory illness and pneumonia, and other illnesses. For example, Shiga toxin-producing *E. coli*, can cause severe stomach cramps; diarrhea; vomiting; and a life-threatening complication called hemolytic uremic syndrome, which can compromise kidney functioning.

In 2019, *E. coli* in salad kits, romaine lettuce, flour, ground beef, and other foods were linked to multistate foodborne illness outbreaks.

Sources: GAO analysis of CDC information (text); CDC (image). I GAO-21-23

- **Pulsed-field gel electrophoresis** is a technique used to characterize bacteria isolated from patients or contaminated food sources to produce a DNA fingerprint with a specific pattern, made

up of DNA fragments, or bands. According to CDC, pulsed-field gel electrophoresis can compare pathogen genomes using 15 to 30 bands in a pattern. In the past, laboratories would upload this pattern to PulseNet, and database managers would investigate the pattern to see if it may be causing an outbreak or is part of an ongoing outbreak.

- **Whole genome sequencing** is a more modern laboratory technique that analyzes samples of foodborne pathogens to identify their unique DNA fingerprint.[14] This technique provides a nearly complete reading of the millions of units that make up the pathogen's DNA. Therefore, whole genome sequencing provides more detailed and precise data for identifying possible outbreaks than pulsed-field gel electrophoresis.

CDC Plays a Central Role in Identifying and Responding to Multistate Foodborne Illness Outbreaks and Helps Build the Capacity of State and Local Agencies

CDC's roles and responsibilities during a multistate foodborne illness outbreak include analyzing federal foodborne illness surveillance networks to identify possible outbreaks; leading investigations to determine the food causing the outbreak; and communicating with the public, in coordination with federal, state, territorial, and local regulatory and public health agencies. Outside the context of an ongoing outbreak, CDC supports a variety of programs to build the capacity of federal, state, territorial, and local governments to identify and respond to foodborne illness outbreaks.

CDC Identifies Multistate Foodborne Illness Outbreaks, Investigates Likely Sources, and Communicates with the Public

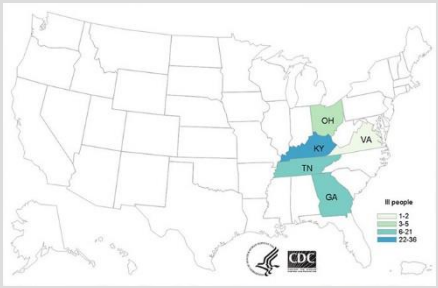
CDC is responsible for three key functions during a multistate foodborne illness outbreak: (1) identifying possible outbreaks using a number of

[14]The genome, or genetic material, of an organism is made up of DNA. Each organism has a unique DNA sequence composed of bases (A, T, C, and G). The sequence of the bases in an organism identify its unique DNA fingerprint, or pattern. Determining the order of bases is called "sequencing."

pathways; (2) coordinating investigations with public health officials in affected states and territories, as well as federal regulatory partners, to determine likely food sources of outbreaks; and (3) communicating with the public about the likely food source of the outbreak and what steps can be taken to prevent further infections. While the steps for identifying, investigating, and controlling multistate foodborne illness outbreaks are described below in a linear fashion, these steps are frequently iterative, and CDC's response to an outbreak can shift back to earlier steps depending on what data are collected and what is learned during the course of the response.

CDC Identifies Multistate Foodborne Illness Outbreaks through a Number of Pathways

Detection of Shiga toxin-producing *E. Coli* outbreak in beef in 2019



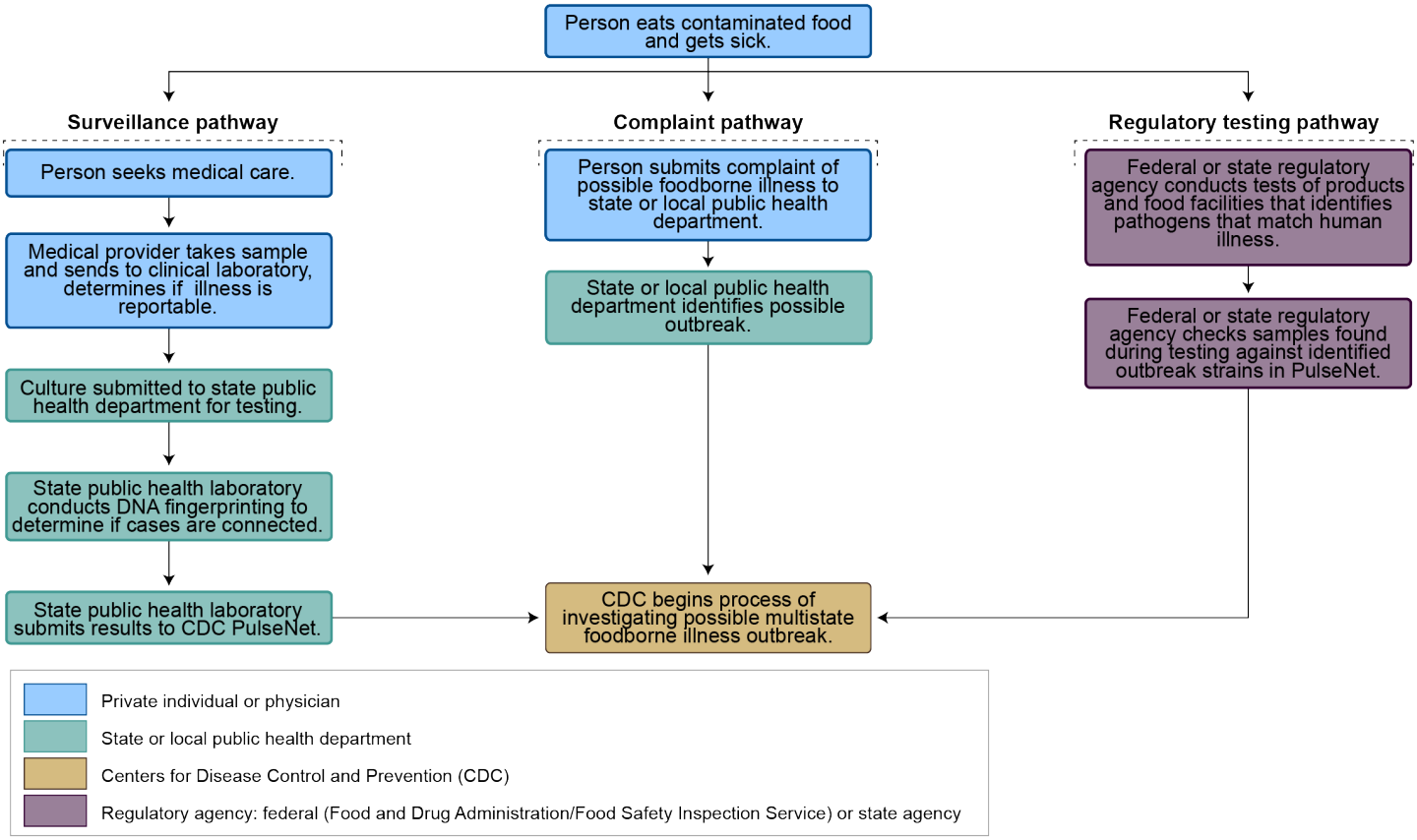
On March 28, 2019, the states of Kentucky and Georgia reported to PulseNet increased levels of *E. coli* O103 infections in their states. *E.coli* O103 is one of several strains of the bacteria known to produce the Shiga toxin, which can cause severe and potentially life-threatening illness in people. Pulsed-field gel electrophoresis analysis suggested that this was a new strain of *E. coli*, though whole genome sequencing analysis had not yet been completed.

CDC decided, based on the PulseNet reports from these two states, to open a multistate investigation to identify the outbreak sources. By April 1, clusters had appeared in two additional states, and whole genome sequencing analysis confirmed that illnesses in Kentucky and Ohio were part of the same outbreak.

Sources: GAO analysis of CDC information (text); CDC (image). I GAO-21-23

During a multistate foodborne illness outbreak, CDC serves as lead coordinator for FSIS; FDA; and state, territorial, and local health departments in identifying the possible outbreak, and in defining its size and extent. As shown in figure 3, a multistate foodborne illness outbreak is typically identified through one of three pathways. In the first pathway—surveillance—a state public health laboratory submits to PulseNet the results of DNA fingerprinting from testing of multiple samples from different patients. CDC analyzes these fingerprints to determine if the individual foodborne illness cases are connected. According to CDC officials, approximately 80 percent of multistate outbreak investigations are identified through PulseNet.

Figure 3: Three Pathways for Identifying a Multistate Foodborne Illness Outbreak
CDC officials said that most multistate outbreaks are identified through the surveillance pathway.



Source: GAO analysis of CDC and Council to Improve Foodborne Outbreak Response documents. | GAO-21-23

In the second pathway—complaints—sick people may submit complaints to a state or local public health department about potential exposure to a foodborne illness from a product purchased at, for example, a restaurant or grocery store.[15] These officials may conduct their own investigation and may report the outbreak to CDC.

The third pathway is routine regulatory testing of food products or environmental sampling by agencies such as FDA or FSIS. During the course of testing done as part of their routine inspections, these regulatory agencies may find pathogens related to previously identified illnesses, which may point to a possible outbreak. According to CDC

[15]Sick people may also submit complaints to federal regulatory agencies, such as the FSIS Consumer Complaint Monitoring System.

officials, CDC has a standing weekly call with federal regulatory agencies to discuss their sampling results. CDC may decide to initiate an investigation if outbreaks reported through any of these pathways are determined to be multistate.

CDC Investigates Likely Food Sources in Coordination with Its Federal, State, and Local Partners

Once CDC determines that several cases across multiple states may be connected, the agency coordinates with public health officials in affected states to investigate whether a common food is causing the infections.[16] According to CDC officials, CDC generally actively investigates a possible outbreak when illnesses are not limited to a single geographic area; when the number of reported illnesses is increasing; when the illnesses are severe; or when the possible outbreak is unusual in some way, such as the demographics of the people who are sick. In smaller or more localized possible outbreaks, CDC officials typically monitor clusters to determine if CDC needs to become involved. According to CDC officials, CDC typically does not become involved if (1) the outbreak appears to be associated with international travel, (2) illnesses are not recent, or (3) DNA fingerprints of pathogens collected from ill people's samples show a wide diversity.[17]

Once officials determine that cases are likely to be connected, state or local public health investigators begin collecting information to determine the food source of the outbreak. This information can take several forms, including the following:

- **Epidemiological information**, such as patterns in when and where people got sick; clusters of sick people who ate at the same restaurant, shopped at the same grocery store, or attended the same event; or interviews with sick people to look for common foods eaten by the group. State and local public health

[16]CDC typically does not become involved if a cluster is located in a single state. However, CDC may provide state public health agencies with resources and assistance for single-state outbreaks upon request.

[17]According to CDC officials, outbreaks associated with international travel are generally caused by food exposures that occur outside the United States, which limits the actions that CDC can recommend to the public. CDC leaves investigation of these outbreaks to the country where the exposure occurred. A wide diversity in DNA fingerprinting among people's illnesses suggests that cases may not be related to one another and are thus not a connected outbreak.

investigators interview sick people with CDC-developed questionnaires, such as the National Hypothesis Generating Questionnaire, to determine what foods the people ate and whether more than the expected number ate a particular type of food. These investigators may also use state or locally developed questionnaires to interview sick people. In cases where investigators are not able to identify a potential food source using the questionnaire, they may conduct in-depth, open-ended interviews. CDC compares the information collected on foods eaten by sick people against several data sources—such as population survey data on food consumption among healthy adults and food history data collected from sick people in unrelated past outbreaks—to determine the likely source of the outbreak.

- **Traceback information**, which comes from state and federal regulatory agencies identifying a common point of contamination in the food production chain by reviewing records collected from restaurants or stores where sick people ate or shopped. This information is used to identify food production facilities, farms, or restaurants for investigators to inspect for food safety risks.
- **Laboratory and environmental testing information**, such as results of product testing of suspected contaminated food items found in a sick person's home or in a retail location to determine if they contain the pathogen causing the outbreak or of environmental testing of areas where the suspected food item was grown, processed, or otherwise handled. CDC uses DNA fingerprints from foodborne pathogens collected in this testing to confirm if the same fingerprint can be found in the sick people.[18]

According to CDC officials, epidemiological information alone can be used to establish a suspected food source for a possible outbreak, while traceback or laboratory and environmental testing is used to corroborate and confirm the suspected food source.

Once this evidence is collected and investigators have strong evidence for what food has caused the outbreak, federal and state regulatory agencies take the lead in attempting to control the outbreak. During this part of the investigation, FDA or FSIS may call firms whose products are suspected in the outbreak. CDC plays a supporting role in these calls, during which CDC may provide the firm with the epidemiological evidence

[18]According to CDC, DNA fingerprints from food and environmental testing are uploaded to PulseNet by numerous federal, state, and local agencies but are most commonly obtained by FDA, FSIS, and state departments of agriculture.

used to support the regulatory agency's conclusions about the involvement of particular foods. CDC considers an outbreak over once new reported illnesses connected to the outbreak appear to have stopped, although CDC and public health officials generally continue surveillance for several weeks to ensure that reported illnesses do not rise again.[19]

CDC Communicates with the Public about Foodborne Illness Outbreaks

CDC publicly communicates about the source of foodborne illness outbreaks, provides actionable advice for consumers and retailers, and disseminates recall information in conjunction with the federal regulatory agency involved. Depending on the circumstances of each multistate foodborne illness outbreak that CDC identifies, the agency may post announcements on its website to tell people what they can do to protect their health. Such announcements typically include information on the affected product (either a general type of food or a specific food), the number and location of cases associated with the outbreak, the progression of the outbreak over time, steps people can take to protect themselves (such as avoiding certain foods), and how people can report symptoms to their local public health department. CDC's advice may be updated as more specific information becomes available.

Federal regulatory agencies, states, and others may also communicate about outbreaks. For example, the state of Maryland issued the first public communication about a *Salmonella* outbreak that appeared to be caused by papayas on July 19, 2017, warning customers in the state not to eat Caribeña's yellow Maradol papayas, based on reports of illnesses in people eating papayas purchased from one grocery store. On July 21, 2017, CDC issued a nationwide recommendation "that consumers not eat, restaurants not serve, and retailers not sell yellow Maradol papayas," after receiving reports of additional cases of the same pathogen across the country. On July 22, 2017, FDA issued a similar but narrower warning: "Consumers should not eat Caribeña brand Maradol papayas from Mexico and should throw away any such products they have in their home." On July 26, 2017, FDA announced the first voluntary recall related to this investigation. As a result of FDA's traceback activities, CDC changed its advice to more closely align with FDA's advice, stating that

[19]CDC defines this as the number of new cases dropping back to expected levels, since there may be some number of sporadic cases of a given illness not connected to an outbreak at any given time.

"CDC recommends that consumers not eat, restaurants not serve, and retailers not sell Maradol papayas from Mexico until we learn more." As the investigation progressed during August and September 2017, CDC narrowed its advice to include papayas from specific farms and distributors. (For further information about this outbreak and others that we used as case studies, see app. II.)

CDC Works to Build and Maintain Federal, State, and Local Capacity to Respond to Foodborne Illness Outbreaks

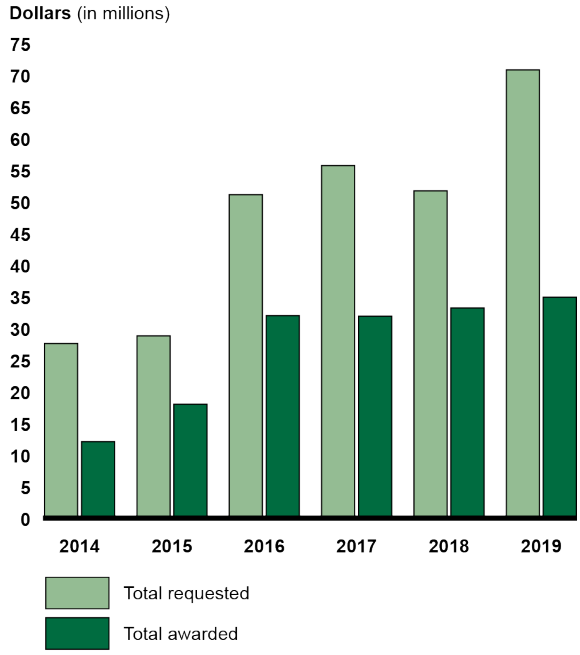
Outside the context of active multistate foodborne illness outbreak investigations, CDC works to support and increase state, territorial, and local health departments' capacity to identify and respond to foodborne illness outbreaks. CDC's principal method for helping to build this public health capacity is the Epidemiological and Laboratory Capacity (ELC) Cooperative Agreement program, which provides funding to 64 participating jurisdictions, including all 50 states, three freely associated states, five territories, and six local governments.[20] This funding supports the staff, supplies, training, and equipment needed for public health departments to participate in nationwide surveillance networks. For example, officials from one state public health agency we interviewed said that CDC grant programs directed funding to the majority of their foodborne illness outbreak work, including staff and laboratory work. Each year, participating jurisdictions make requests for any of the allowable project areas under the ELC program, including foodborne disease programs.[21] As shown in figure 4 below, CDC has increased awards of funding for foodborne disease programs under ELC from roughly $12 million in fiscal year 2014 to roughly $35 million in fiscal year 2019. Requests for this funding from participating jurisdictions also increased over this period.

[20]In addition to the 50 states, three freely associated states (Micronesia, Palau, and the Marshall Islands), five territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands), and six local governments (Chicago, IL; Houston, TX; Los Angeles County, CA; Philadelphia, PA; New York City, NY; and Washington, D.C.) received ELC funding. The section of ELC that funds foodborne programs also funds capacity for waterborne, enteric (intestinal), and environmentally transmitted diseases.

[21]ELC awards funding to several other project areas, including healthcare associated infections, antibiotic resistance, and diseases borne by vectors (such as mosquitos, fleas, and ticks). ELC also awards funding to cross-cutting epidemiological and laboratory capacity and several disease-specific programs, such as surveillance for fungal diseases.

Figure 4: CDC Epidemiological and Laboratory Capacity Cooperative Agreement Funding for Foodborne Disease Programs Compared with Amounts Requested, Fiscal Years 2014-2019

The Centers for Disease Control and Prevention (CDC) provides tens of millions of dollars per year in awards to fund state and local foodborne disease programs but does not fund all requests.



Source: GAO analysis of CDC data. | GAO-21-23

Whole genome sequencing helped CDC determine that an apparent 2016 *Salmonella* Saintpaul outbreak was two different outbreaks

Starting in September 2016, CDC received *Salmonella* Saintpaul pulsed-field gel electrophoresis patterns from eight states that appeared to be related to one another. Initial interviews with sick people completed in November 2016 showed that many of them had eaten chicken, though not at higher rates than expected when compared with CDC's population surveys. Whole genome sequencing completed in November 2016 showed that cases from Massachusetts and Maryland appeared to be closely related. Patient interviews indicated most had eaten chicken but from several different brands purchased from multiple grocery store chains. Further whole genome sequencing conducted in December showed that bacteria from ill people were actually genetically distinct, even though the pulsed-field gel electrophoresis pattern was the same. This and other information led CDC to suspect that this investigation contained cases that were actually part of two different, unrelated outbreaks that happened to share a similar pulsed-field gel electrophoresis pattern. In the end, while CDC suspected that the food source of one of these outbreaks may have been chicken, officials were unable to confirm the source of either outbreak.

Source: GAO analysis of CDC information. I GAO-21-23

According to CDC, one of the key efforts funded through the ELC program in recent years has been to help public health laboratories in state health departments transition from pulsed-field gel electrophoresis to whole genome sequencing as the gold standard method for identifying related clusters of pathogens that may be outbreaks.

According to CDC officials, CDC and public health laboratories used pulsed-field gel electrophoresis for over 20 years. However, this technology was phased out as of July 2019, and CDC and its federal, state, territorial, and local partner laboratories in all 50 states now exclusively use whole genome sequencing methods to identify, investigate, and control outbreaks caused by foodborne pathogens, according to CDC officials.

The additional detail obtained from whole genome sequencing allows CDC to link DNA fingerprints from different cases to each other that might not have been linked using pulsed-field gel electrophoresis, helping to

solve some outbreaks sooner. For example, CDC officials told us that after CDC began using whole genome sequencing for *Listeria* in an initial pilot phase, the number of listeriosis outbreaks the agency was able to identify tripled, and CDC was able to solve more listeriosis outbreaks while they were still small. Furthermore, CDC officials noted that part of their difficulty in solving a 2016 *Salmonella* Saintpaul outbreak, suspected to have been caused by chicken, was that it was actually two unrelated outbreaks happening at the same time. However, the pulsed-field gel electrophoresis methods used at the time could not detect the differences between the two outbreak pathogens.

CDC has also used the ELC program to award funding to a number of other initiatives for helping state and local health departments improve their capacity to track, investigate, and respond to foodborne illness outbreaks, including the following:

- **Integrated Food Safety Centers of Excellence** help build capacity in the health departments in five regions of states and territories by developing and providing online and in-person resources, training, and technical assistance for foodborne disease surveillance and outbreak investigations.[22] All of the centers of excellence are tied to a university partner, which can facilitate discussion of additional ideas for training, technical assistance, and peer-to-peer information-sharing.
- **FoodCORE** works with 10 centers covering nine states and New York City to develop new and better methods to identify, investigate, respond to, and control multistate outbreaks of foodborne diseases. FoodCORE centers work to enhance public health laboratory surveillance, epidemiologic interviews and investigations, and environmental health assessments to develop model practices for outbreak response.
- **OutbreakNet Enhanced** works with 29 sites in 26 states and three cities to help them share their experiences and insights to improve their response to foodborne illness outbreaks and to improve the completeness and timeliness of epidemiologic investigation activities.

[22]These centers of excellence are located in Colorado, Minnesota, New York, Tennessee, and Washington State.

CDC uses several surveillance networks, such as PulseNet (described earlier in this report) and FoodNet. FoodNet is an active surveillance network in 10 states that monitors the burden of eight different foodborne illnesses in the United States.[23] FoodNet focuses on surveillance for sporadic illnesses, but through linkages with other systems it can provide information on illnesses related to recognized outbreaks. According to CDC officials, FoodNet allows CDC to collect and analyze extensive data on long-term trends in foodborne illnesses over time, enabling CDC and its partners to evaluate progress toward the prevention of enteric (intestinal) illnesses and to attribute the illnesses it tracks to specific foods and settings. Among other things, FoodNet periodically conducts a population survey that CDC uses to systematically collect data on food consumption, food behaviors, and health care utilization for foodborne illnesses. These data allow investigators to compare baseline food consumption and behaviors that would be expected in the population with those observed among outbreak cases, such as responses gathered from the National Hypothesis Generating Questionnaire during outbreak investigations, to rapidly focus in on suspected sources of foodborne illness outbreaks. According to CDC documents, these data can be used to improve public health practice and develop interventions that may reduce the burden of foodborne illness.[24]

CDC also provides a web-based platform, known as the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), that allows federal, state, and local investigators to access information from several CDC systems and share data with one another during an outbreak investigation. SEDRIC can also allow investigators to create data visualizations that help manage clusters under investigation, see potential trends in time and space, and clarify relationships among cases.

[23]FoodNet sites are located in Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee, as well as certain counties in California, Colorado, and New York. According to CDC, FoodNet's surveillance area covers approximately 48 million people, or 15 percent of the U.S. population. FoodNet monitors the following pathogens: *Campylobacter, Cyclospora, Listeria, Salmonella*, Shiga toxin-producing *E. coli, Shigella, Vibrio*, and *Yersinia.*

[24]Other, more specialized surveillance systems that CDC uses to track and monitor reports of foodborne and waterborne diseases include the Foodborne Disease Outbreak Surveillance System, the National Antimicrobial Resistance Monitoring System for Enteric Bacteria, and the National Surveillance of Bacterial Foodborne Illnesses.

CDC Has Taken Some Steps to Address Challenges Related to Clinical Methods and Communication, but Additional Actions Could Strengthen Its Efforts

In identifying and responding to multistate foodborne illness outbreaks, CDC faces challenges related to clinical methods and communication, and it has taken some steps to respond to these challenges. More specifically, such challenges include (1) adapting to increased use by clinical laboratories of a new method of diagnosing foodborne illnesses that may reduce CDC's ability to identify outbreaks; and (2) balancing the competing needs for timeliness and accuracy in its outbreak communications, while also maintaining public trust. CDC has taken some steps to address these challenges but has not developed a plan to address the impact of the new diagnostic method or made its communication decision-making framework publicly available.

Increasing Use of a New Method to Test for Foodborne Illness May Reduce CDC's Ability to Identify Outbreaks, but CDC Has Not Developed a Plan to Address This Challenge

A change in how foodborne illnesses are diagnosed may lead to CDC receiving less of the detailed information about foodborne pathogens that the agency needs to identify multistate foodborne illness outbreaks, according to CDC officials. Under the traditional method of diagnosing foodborne illnesses, clinical laboratories use stool samples collected from patients to culture (grow) an isolate of the foodborne pathogen. This process, which typically takes multiple days, allows public health laboratories to identify specific characteristics about the foodborne pathogen, such as its DNA fingerprint. However, according to CDC, many clinical laboratories are primarily using culture-independent diagnostic tests (CIDTs), a new clinical testing method that can detect foodborne pathogens with greater speed and less expense than the traditional method. Specifically, CIDTs allow clinical laboratories to identify the general type of foodborne pathogen—such as *Salmonella* or *E. coli*—in a stool sample within hours, allowing physicians to more quickly diagnose and treat patients. CIDTs also have the advantage of testing for a wider variety of pathogens than traditional methods. However, as their name

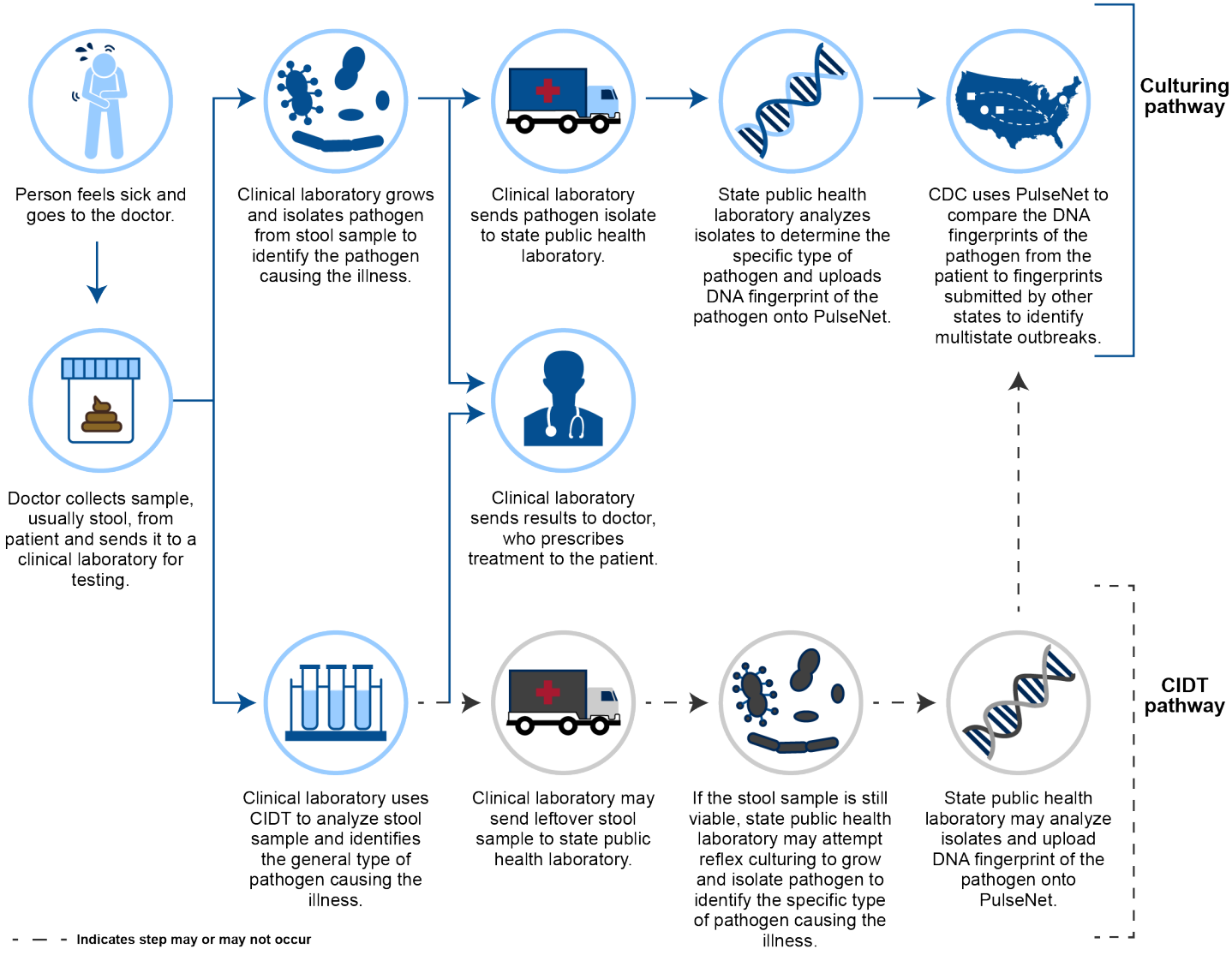
implies, CIDTs do not include culturing of the sample, so specific information about the foodborne pathogen, such as its DNA fingerprint, is not identified.

As discussed earlier, CDC uses a pathogen's DNA fingerprint in PulseNet to connect individual foodborne illness cases and identify clusters of illness and outbreaks. According to CDC, because CIDTs do not generate the specific data about pathogens that are needed for CDC's public health surveillance systems, CDC's ability to identify outbreaks could be reduced. CDC began monitoring the use of CIDTs in clinical laboratories in 2010, and it reported in 2019 that clinical laboratories are increasingly using CIDTs to diagnose foodborne illness. For example, CDC reported that for six of the seven bacterial pathogens monitored by FoodNet, infections diagnosed solely by CIDT increased by 114 percent overall in 2016 compared with 2013-2015.[25] CDC officials told us that CIDTs have led to a decrease in the availability of detailed information that public health scientists need to identify and link foodborne illness cases in PulseNet. In addition, CDC reported that no isolates were collected for 25 percent of bacterial infections reported as laboratory confirmed in 2017.[26] Figure 5 illustrates how CIDTs can affect CDC's ability to identify foodborne illness outbreaks.

[25]Ellyn P. Marder, et al., "Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2013–2016," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report*, vol. 66, no. 15 (Apr. 21, 2017).

[26]Ellyn P. Marder, et al., "Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report*, vol. 67, no. 11 (Mar. 23, 2018).

Figure 5: How Culture-Independent Diagnostic Tests (CIDTs) Can Affect CDC's Ability to Identify Foodborne Illness Outbreaks



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) information. | GAO-21-23

CDC and the public health system at large are responding to the loss of isolates in several ways. The Association of Public Health Laboratories—which represents state and local governmental health laboratories in the United States—has recommended that clinical laboratories using CIDTs should still culture samples from patients with positive tests, known as reflex culturing. However, it has acknowledged that doing so will add unreimbursed expense for laboratories—a cost that many healthcare systems may not want to bear. In the short term, some state public health

departments are performing reflex cultures to try to preserve the ability to identify foodborne illness outbreaks using DNA fingerprinting. However, CDC officials told us that this approach creates an additional burden on state public health departments, which may have limited resources and competing priorities, such as responding to the COVID-19 pandemic.

Furthermore, reflex cultures do not always yield pathogen information from a sample that has already undergone culture-independent testing, because CIDTs do not require pathogen viability to function. According to a 2018 CDC report, false positives, low numbers of pathogens, storage or transport problems, or insensitive culture techniques can also compromise reflex culture results.[27] According to CDC officials, CDC is pursuing potential solutions to these issues, such as piloting more efficient methods that health departments could use when performing reflex cultures and developing advanced testing methods that may not require isolates to provide the information needed for foodborne illness surveillance. However, officials said these innovations are in the early stages of development and could be years away from implementation.

Under federal standards for internal control, management should identify, analyze, and respond to risks related to achieving defined objectives, which for CDC include identifying and responding to outbreaks.[28] CDC, along with its partners, has recognized the need for strategic planning to address the challenge posed by CIDTs, but the agency has not yet developed such plans. For example, CDC reported in 2017 that strategies were needed to preserve access to bacterial isolates for further characterization and to determine the effect of changing trends in testing practices on surveillance.[29] In addition, in May 2018, the Food Safety Modernization Act Surveillance Working Group—a working group established by CDC, consisting of CDC experts; regulators; academics; and public health, consumer, and industry stakeholders—met at CDC's request to identify CIDT knowledge gaps and generate potential solutions. The working group recommended that CDC develop an action

[27]Marder, et al., "Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017."

[28]GAO-14-704G.

[29]Marder, et al., "Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2013–2016."

plan that CDC and stakeholders can use to guide efforts and ensure continued foodborne illness surveillance into the future.

According to CDC officials, CDC has entered into a cooperative agreement with the Association of Public Health Laboratories beginning in June 2020 to develop a white paper intended to eventually inform such an action plan. While developing a white paper is an important step and should provide valuable information, until CDC develops a plan to address the increasing use of CIDTs, it will face a growing risk that it will not have the information it needs to effectively and efficiently identify and respond to foodborne illness outbreaks.

CDC Faces Competing Needs for Timeliness and Accuracy in Its Outbreak Communication While Maintaining Public Trust

According to CDC officials, deciding when to release information to the public can be one of the most challenging parts of responding to an ongoing foodborne illness outbreak—CDC must balance the need to communicate quickly to prevent additional illnesses against the need to provide accurate and specific information, while also maintaining the public's trust in its credibility. In 2011, in coordination with FDA and USDA, CDC developed an internal public communication framework, which describes six common communication scenarios to aid in decision-making about when, what, and how to communicate during a foodborne illness outbreak. According to CDC officials, CDC updated its framework in 2018 to respond to an increasing desire for transparency about CDC's communication decision-making process from consumer groups and industry representatives.

Under the framework, when making communication decisions, CDC officials primarily consider (1) the level of public health concern, such as the severity of the illnesses or the vulnerability of the groups affected; and (2) the specificity of the public health concern, such as whether a specific food item has been identified as the likely source.[30] Depending on these factors, CDC may prepare

[30]CDC also considers other factors, such as the strength of the available evidence, what information is pending, and whether media coverage may result in the spread of misinformation.

- a **"reactive" media statement**, or internal talking points to be used to respond to any inquiries from the media or others;
- an **Investigation Notice** to provide information about an outbreak not yet linked to a specific food source, or an outbreak linked to a general type or category of food rather than to a specific food; or
- a **Food Safety Alert** to provide specific advice to consumers, restaurants, and retailers about foods to avoid eating or selling. This advice may include information about a recall or other warnings.

Table 1 shows the approaches CDC would consider based on the combined level of a public health concern and the specificity of the concern.

Table 1: CDC's Primary Considerations and Scenarios for Multistate Foodborne Outbreak Public Communication

Scenario	Level of public health concern	Specificity of public health concern	Approaches to consider
1	low	low	Reactive media statement
2	low	medium	Reactive media statement or Investigation Notice
3	low	high	Food Safety Alert
4	high	low	Reactive media statement or Investigation Notice
5	high	medium	Investigation Notice or Food Safety Alert
6	high	high	Food Safety Alert

Legend:

○ Low

◒ Medium

● High

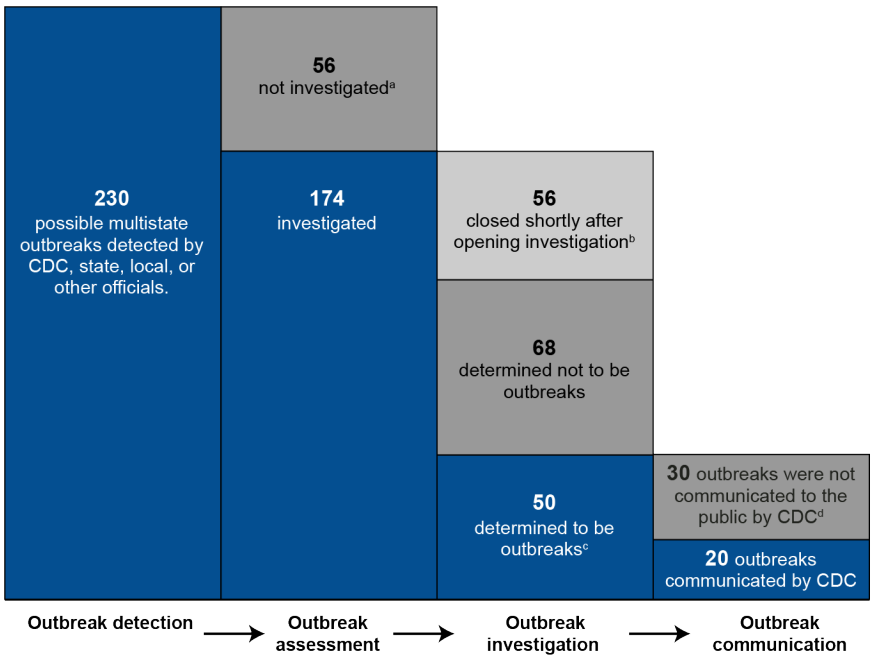
Source: GAO analysis of information provided by the Centers for Disease Control and Prevention (CDC) | GAO-21-23

According to CDC officials, however, most of CDC's outbreak investigations do not include communication to the public. CDC did not communicate about 30 of the 50 outbreaks it determined to be actual multistate outbreaks in 2016, the most recent year for which comprehensive data on CDC's investigation and communication outcomes were available at the time of our analysis (see fig. 6). In our review of CDC's communication framework, selected case studies,[31] and

[31]See app. II for further information about our case studies.

interviews with CDC officials, we found that CDC may decide not to communicate to the public during outbreaks if the agency cannot provide actionable steps for consumers to take. For example, CDC may not communicate to the public about an outbreak if CDC cannot identify a food source or if it identifies the food source well after the product's shelf life has passed. According to CDC officials, nonspecific warnings can have negative consequences, such as unnecessary food waste, and can be difficult for consumers, restaurants, or retailers to know how to translate into specific actions.

Figure 6: Summary of CDC's Multistate Foodborne Illness Outbreak Investigations, Outcomes, and Related Communications for Calendar Year 2016



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) information. | GAO-21-23

Note: Data for 2016 were the most recent comprehensive data available at the time of GAO's analysis.

[a]According to CDC, reasons for not investigating a possible outbreak include that illnesses are (1) occurring at the normally expected rate, (2) occurring too far in the past for CDC to obtain quality data, (3) taking place in only one state, and (4) being associated with international travel.

[b]Investigations were closed when they showed that cases of illness were outside CDC's purview because they were within a single state, associated with international travel, or not part of outbreaks.

[c]Of these 50 investigations, 28 revealed a confirmed source, 11 had a suspected source, and 11 had an unknown source.

[d]CDC may decide not to communicate to the public about confirmed outbreaks if the agency cannot provide actionable steps for consumers to take—for example, if CDC identifies the food source well after the product's shelf life has passed.

According to CDC officials and agency documents, it is vital for CDC to be a credible and trustworthy source of information to the public during an ongoing foodborne illness outbreak. However, in the absence of public information about how CDC decides when, what, and how to communicate about an outbreak, three independent groups focused on preventing or reducing foodborne illness questioned CDC's criteria for its communication decisions. For example, representatives of two of these groups, one of which represents hundreds of consumer advocacy stakeholders, told us they believe CDC considers the interests of the food industry when deciding to communicate and, as a result, is not communicating about outbreaks and thus endangering public health.[32] These representatives said that it was unclear to them how CDC determines that outbreaks are of sufficient concern to notify and warn the public. One group told us that, while there is information on CDC's website about the criteria that CDC considers when communicating with the public, it is not clear how CDC weighs these criteria to make communication decisions. Representatives of one group also questioned whether CDC waits for FDA and FSIS to issue recalls before communicating important information to the public. According to these independent groups, CDC could address some of these concerns by being more transparent about how the agency decides when and what to communicate.

Further, the accuracy of information that CDC provides about outbreaks can be a concern for industry stakeholders. In particular, one industry group we interviewed, consisting of dozens of representatives from the produce industry, cited a past instance in which CDC prematurely and incorrectly named a product as the source of an outbreak, causing damage to the industry.[33] A representative of this group also told us that CDC has been overly cautious in the past about when to declare an outbreak is over, which has harmed produce growers.

CDC officials told us they recognize an increased desire for transparency from the public about what CDC knows at various stages in an

[32]According to CDC officials, financial impacts to the food industry are neither an explicit nor an implicit consideration when CDC is deciding whether and when to post an Investigation Notice or Food Safety Alert.

[33]CDC officials reported that they are unaware of any recent investigations in which the incorrect food item was implicated as the cause of a multistate foodborne outbreak. CDC officials noted a 2008 *Salmonella* Saintpaul outbreak in which the early investigation identified an epidemiologic association with raw tomatoes, but subsequent epidemiologic and microbiologic evidence implicated jalapeño and serrano peppers.

investigation and how it decides what information to communicate publicly. Officials said they are also aware of industry criticism about CDC's communications advice being too broad and of suggestions that CDC could more narrowly tailor its advice to reduce harm to firms that were not the source of the outbreak. According to these officials, the agency has tried to educate food safety stakeholders about its communication decision-making process during presentations at conferences. The officials also noted that nothing in CDC's communication framework considers economic damage to industry; they emphasized that CDC's primary concern is to provide actionable information to the public in a way that is not confusing or overly broad.

CDC officials said they are planning to submit a version of the agency's communication framework for publication in a peer-reviewed risk communication journal. Officials said this effort would increase CDC's credibility with the public and provide guidance to other professionals in the risk communication field. CDC officials said that they plan to share related information with the public on CDC's website. However, they said that competing priorities—such as responding to ongoing foodborne illness outbreaks and the COVID-19 pandemic—have delayed these efforts.

According to CDC's Crisis, Emergency, and Risk Communication principles, being honest, timely, and accurate encourages the public to trust CDC's information and follow its guidance; people are more likely to follow the public health advice of organizations they trust. As we have found in our prior work, improving risk communication may increase public confidence in the federal management of foodborne illness outbreaks and the safety of the U.S. food supply.[34] Further, under federal standards for internal control, agency management should externally communicate the necessary quality information to achieve the entity's objectives[35]—in this case, maintaining public trust. By making publicly available CDC's decision-making process for communicating about multistate foodborne illness outbreaks, including the scenarios it considers to aid in decision-making, CDC could better foster public trust in its information and guidance during multistate outbreaks of foodborne

[34]GAO, *Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight*, GAO-17-74 (Washington, D.C.: Jan. 13, 2017).

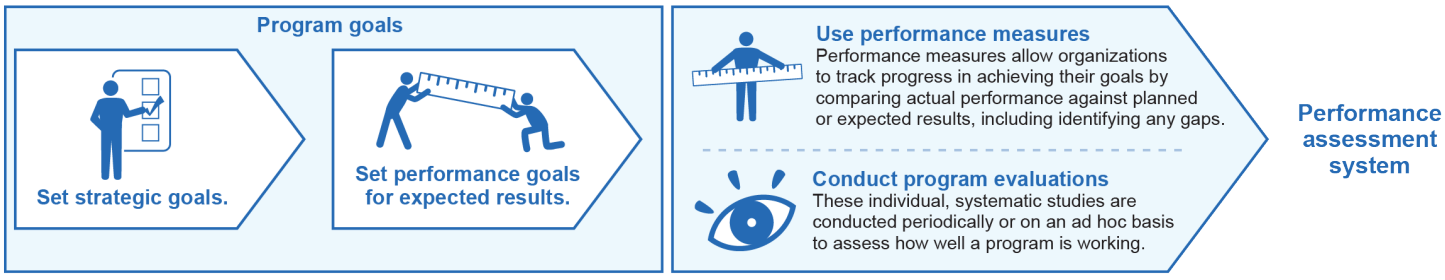
[35]GAO-14-704G.

illness, potentially increasing the effectiveness of its outbreak communication efforts.

CDC Has Taken Some but Not All Necessary Steps to Evaluate Its Performance in Responding to Multistate Foodborne Illness Outbreaks

CDC has recently begun to take steps to evaluate its performance in identifying and responding to multistate outbreaks of foodborne illness, but it does not yet have all the elements of a program performance assessment system—which is an important component of effective program management. As we have previously reported, a program performance assessment system consists of three key elements: program goals (both strategic goals and performance goals), performance measures, and program evaluations.[36] (See fig. 7.) CDC has set some strategic goals for its foodborne illness investigation efforts, but it has not set performance goals, developed performance measures, or evaluated its multistate foodborne illness outbreak investigation program.

Figure 7: Key Elements of Program Performance Assessment Systems



Source: GAO. | GAO-21-23

[36]GAO, *Juvenile Justice Grants: DOJ Should Take Additional Actions to Strengthen Performance and Fraud Risk Management,* GAO-20-202 (Washington, D.C.: Dec. 18, 2019); and *Veterans Outreach Justice Program: VA Could Improve Management by Establishing Performance Measures and Fully Assessing Risks*, GAO-16-393 (Washington, D.C.: Apr. 28, 2016).

CDC Has Set Some Strategic Goals but Not Performance Goals

Strategic goals are long-term goals that set a general direction for a program's efforts, while performance goals define the specific results an agency expects its program to achieve in the near term.[37] In its strategic plan, CDC's National Center for Emerging and Zoonotic Infectious Diseases, whose responsibilities include identifying and responding to multistate foodborne illness outbreaks, outlines a roadmap for achieving the center's vision "to prevent infections, protect people, and save lives." For example, the center's strategic plan states that the center will "identify opportunities for prevention and intervention by expanding scientific information on the incidence, trends, burden, source attribution, and characteristics of foodborne and waterborne pathogens and infections." In addition, the plan states that one of the center's activities is to "continue to enhance CDC surveillance to inform prevention and treatment of disease and provide data that can be used by CDC as well as public health, academic, and clinical partners to prevent, control, and manage infectious diseases."

However, the plan does not include performance goals related to identifying and responding to multistate foodborne illness outbreaks that would help define the specific results the center wants to achieve. CDC officials responsible for foodborne illness investigations told us that the center's strategic plan covers the years 2018-2023 and was finalized in 2017. Since then, CDC officials have begun to consider the goals to be included in the next iteration of the plan. Without setting performance goals for identifying and responding to multistate foodborne illness outbreaks as the first step of a program performance assessment system, CDC may not be able to define the results it expects to achieve through its efforts to protect the public from these outbreaks, which cause a disproportionate number of hospitalizations and deaths compared with single-state outbreaks.

CDC Is Taking Initial Steps to Set Performance Measures for Multistate Foodborne Illness Outbreak Investigations

[37]GAO-16-393.

but Has Not Aligned These Measures to Performance Goals

Performance measures are concrete, objective, observable conditions that permit the assessment of progress made toward achieving the agency's goals.[38] As we have previously reported, establishing linkages between an organization's goals and performance measures creates a "line of sight," so that everyone understands how program activities contribute to the organization's goals.[39] CDC's Framework for Program Evaluation emphasizes the importance of measuring and monitoring performance with appropriate performance measures.[40] However, as noted above, CDC has not yet developed performance goals for its response to multistate foodborne illness outbreaks that would allow it to make these linkages.

In an effort to develop a baseline set of performance measures for multistate foodborne illness investigations, CDC officials began a pilot project in 2018 to collect and analyze data from multistate outbreak investigations that occurred in 2016—the latest year for which CDC had complete data when the effort started. CDC officials told us the data they are analyzing will help them measure how quickly a food was identified as the source of an outbreak; the length of time from opening an investigation to publishing a notification to the public; and the proportion of outbreaks solved (i.e., with a confirmed or suspected vehicle identified), among other things.

CDC officials shared a preliminary list of multistate outbreak process and performance metrics with FDA and FSIS and received feedback from both agencies in June 2020. As of July 2020, CDC officials were using that feedback to finalize the list of metrics. CDC officials planned to publish a summary of their 2016 data by the end of 2020. Once the 2016

[38]GAO-20-202.

[39]GAO: *Illegal Marijuana: Opportunities Exist to Improve Oversight of State and Local Eradication Efforts,* GAO-19-9 (Washington, D.C.: Nov. 14, 2018).

[40]According to a publication listed on CDC's Office of Program Performance and Evaluation's website, the framework ensures that CDC staff members view evaluation as integral to a cycle of continuous program improvement. As used at CDC, this cycle consists of program planning, implementation, measuring and monitoring of performance, and evaluation, all operating in concert to iteratively implement, test, and refine program approaches for maximum effectiveness and continues to serve as the backbone of the CDC evaluation process. https://www.cdc.gov/eval/framework/index.htm, accessed on May 20, 2020.

baseline effort is completed, CDC intends to analyze outbreak investigations data for subsequent years. According to CDC officials, this approach will allow the agency to evaluate whether the data from the pilot project are useful, determine what data may be missing, and incorporate stakeholder suggestions. It will also help them determine what performance measures may be appropriate and to establish a baseline against which they can compare performance in subsequent years. In July 2020, CDC officials told us they intend to publish additional reports showing data from 2017 through 2019 by the end of 2020 but stated that this time line may be delayed because of staff being deployed to respond to the COVID-19 pandemic.

As discussed above, CDC has not yet defined performance goals for its response to multistate foodborne illness outbreaks. While setting performance measures is an important part of developing a program performance assessment system, such measures must be aligned with performance goals if they are to measure progress toward meeting those goals. CDC officials acknowledged the need to develop performance measures that align with goals in a strategic plan; however, they said that the baselining effort is not directly connected to the center's strategic plan and, therefore, there are no linkages between the performance measures they are developing and any performance goals. By CDC developing measures to assess its performance that are aligned with performance goals, such as the proportion of outbreaks solved, as the second step of a program performance assessment system, the agency could more fully and accurately assess progress toward achieving its foodborne illness surveillance and identification goals and identify areas for improvement in multistate outbreak investigations.

CDC Has Not Conducted Program Evaluations of Its Foodborne Illness Outbreak Investigation Efforts

According to best practices in performance management, program evaluations are individual systematic studies using performance measures and other information to answer specific questions about how well a program is meeting its objectives.[41] Agencies can incorporate that knowledge into agency decision-making.[42] In addition, we have found that

[41]GAO, *Grade-Crossing Safety: DOT Should Evaluate Whether Program Provides States Flexibility to Address Ongoing Challenges*, GAO-19-80 (Washington, D.C.: Nov. 8, 2018).

[42]GAO-19-9.

managers can use performance information to continuously improve organizational processes, identify performance gaps, and improve their performance.[43]

CDC officials have not yet conducted program evaluations of their efforts to identify and respond to multistate foodborne illness outbreaks. According to CDC officials, their effort to develop a baseline set of performance measures is a first step in evaluating their multistate outbreak investigation efforts. CDC officials told us that, after completing their analyses of baseline data for 2016 compared with subsequent years, they plan to use the performance data to inform their management decisions. However, CDC officials did not indicate whether they planned to conduct formal program evaluations in the future. By conducting program evaluations, as part of the third step of a program performance assessment system, CDC should be able to determine how well the agency is meeting its objectives, identify potentially underperforming areas, and use that information to improve its performance to better support its mission and balance competing priorities.

Conclusions

As the lead federal agency for addressing public health, CDC has a key role in responding to multistate foodborne illness outbreaks—a common and costly public health problem. CDC has developed a wide array of tools to identify multistate foodborne illness outbreaks, determine what pathogen has caused an outbreak, investigate what food caused the outbreak, and to communicate with the public about potentially contaminated products. Yet CDC faces a challenge from the increasing use of CIDTs by clinical laboratories to diagnose foodborne illnesses, which may reduce CDC's future ability to identify outbreaks using existing surveillance systems. CDC has taken some steps to address this challenge, but CDC has not developed a plan to address it. By developing such a plan, CDC will have greater assurance that it will continue to have the information it needs to effectively and efficiently identify and respond to foodborne illness outbreaks.

CDC also faces a challenge in balancing the need to communicate quickly about foodborne illness outbreaks to prevent additional illnesses against the need to provide accurate and specific information, while also

[43]GAO, *Managing For Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.: Sept. 9, 2005).

maintaining the public's trust in its credibility. By making publicly available CDC's decision-making process for communicating about multistate foodborne illness outbreaks, including the scenarios it considers to aid in decision-making, CDC could provide the public with greater assurance that CDC is managing foodborne illness outbreaks effectively.

In addition, CDC has not taken all of the steps necessary to develop a system for assessing its performance in reducing the burden of foodborne illnesses in the United States. In particular

- CDC has taken some steps to establish a roadmap for the foodborne illness program's mission, but the steps in this roadmap do not include performance goals to determine if CDC's mission is being achieved. By setting performance goals for identifying and responding to multistate foodborne illness outbreaks as the first step of a program performance assessment system, CDC could define the results it expects to achieve through its efforts to protect the public from these outbreaks, which cause a disproportionate number of hospitalizations and deaths compared with single-state outbreaks;
- CDC has taken some steps to establish a performance baseline for its multistate foodborne illness outbreak investigations, which could help CDC determine what performance measures are appropriate and compare performance in these investigations over subsequent years, such as the proportion of outbreaks CDC is able to solve. However, these measures are not aligned with CDC's goals in its strategic plan and, as noted above, CDC has not yet developed specific performance goals for its response to multistate foodborne illness outbreaks. By developing measures to assess its performance that are aligned with performance goals, as the second step of a program performance assessment system, the agency could more fully and accurately assess progress toward achieving its foodborne illness surveillance and identification goals and identify areas for improvement in multistate outbreak investigations; and
- finally, CDC has not conducted program evaluations of its foodborne illness outbreak investigation efforts. By conducting program evaluations, as part of the third step of a program performance assessment system, CDC could determine how well the agency is meeting its objectives, identify potentially underperforming areas, and use that information to improve its

performance to better support its mission and balance competing priorities.

Recommendations for Executive Action

We are making the following three recommendations to CDC:

The Director of the Centers for Disease Control and Prevention should develop a plan for addressing risks that the increasing use of culture-independent diagnostic tests poses to CDC's continued ability to identify foodborne illness outbreaks. (Recommendation 1)

The Director of the Centers for Disease Control and Prevention should make publicly available CDC's decision-making process for communicating about multistate foodborne illness outbreaks, including the scenarios it considers to aid in decision-making. (Recommendation 2)

The Director of the Centers for Disease Control and Prevention should implement a program performance assessment system for its multistate foodborne illness outbreak investigations, including setting performance goals, assessing progress toward achieving those goals with performance measures, and conducting program evaluations. (Recommendation 3)

Agency Comments

We provided a draft of our report to HHS and USDA for review and comment. HHS concurred with all three of our recommendations, and indicated that it plans to take actions that appear to be responsive to our recommendations. HHS also noted that the agency's response to multistate foodborne disease outbreaks, as well as staff deployments to support the current COVID-19 response, may delay nonemergency projects, including their response to our recommendations. HHS provided technical comments on the draft, which we incorporated as appropriate. USDA told us that the agency did not have comments on the draft.

As agreed with your office, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Agriculture, and other interested parties. In addition, the

report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions regarding this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who contributed to this report are listed in appendix IV.

Sincerely yours,

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report (1) describes the Centers for Disease Control and Prevention's (CDC) roles and responsibilities in identifying and responding to multistate foodborne illness outbreaks, including collaboration with federal, state, territorial, and local partners; (2) examines challenges CDC faces in identifying and responding to multistate foodborne illness outbreaks and the steps CDC has taken to address these challenges; and (3) examines the extent to which CDC evaluates its performance in identifying and responding to multistate foodborne illness outbreaks.

To conduct this review, we obtained documents on planning, funding, reporting, and strategic planning from CDC officials in the National Center for Emerging and Zoonotic Infectious Diseases, Division of Foodborne, Waterborne, and Environmental Disease. Within that CDC center, we interviewed officials responsible for identifying and responding to multistate foodborne illness outbreaks. We also interviewed officials in other agencies involved in investigating multistate foodborne illness outbreaks, including the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS). We also reviewed funding data from the Epidemiological and Laboratory Capacity (ELC) Cooperative Agreement program, including requests for grant funding from state, territorial, and local health departments to build epidemiological and public health lab capacity from 2014 through 2019. To assess the reliability of this funding award information, we reviewed relevant documentation and interviewed knowledgeable CDC officials about how they assess the reliability of the data. We found the ELC data to be sufficiently reliable for describing annual funding requests and amounts funded by CDC.

To identify CDC's roles and responsibilities in identifying and responding to multistate foodborne illness outbreaks, we reviewed and analyzed relevant federal laws as well as guidance and standard operating procedures and other relevant documentation, such as memorandums of understanding between CDC and federal, state, territorial, and local partners. To help illustrate CDC's roles and responsibilities in active investigations and to illustrate the challenges CDC faces in identifying

and responding to multistate foodborne illness outbreaks, the team selected four nongeneralizable case studies involving multistate foodborne illness outbreaks from 2014 through 2019. (See app. II.) These case studies include (1) outbreaks where CDC coordinated with different federal agencies (two with FDA and two with FSIS); (2) one outbreak where a food source was suspected but not confirmed; and (3) one outbreak where the food source was imported from outside the United States. In selecting among outbreaks to include, we used several criteria. We selected outbreaks of *Salmonella*, Shiga toxin-producing *E. coli*, and *Listeria* that affected more than three states, lasted over 60 days, and affected the greatest number of people.[1] We also selected outbreaks from different years, including one from a year recent enough that whole genome sequencing was used to identify the outbreak. To aid our selection, we requested that CDC provide us with certain descriptive information about all multistate foodborne illness outbreaks over the 5-year period from 2014 through 2018 from the National Outbreak Reporting System, which is CDC's principal web-based platform for local, state, and territorial health departments in the United States to report data on all waterborne and foodborne disease outbreaks.[2] To assess the reliability of this descriptive information, we reviewed relevant documentation and interviewed knowledgeable CDC officials about how they assess the reliability of the data. We found the data to be sufficiently reliable for providing information about multistate foodborne illness outbreaks to support the selection of case studies.[3]

For each of the four case studies we selected, we interviewed the relevant agency officials at CDC and the federal regulatory agencies who worked on the outbreak investigation. We focused on the time line of the

[1]We selected these pathogens because they are the pathogens tracked by FoodNet that are most likely to have caused multistate foodborne illness outbreaks. Our threshold for identifying the greatest number of people depended on the pathogen involved in the outbreak. Of the outbreaks in our sample, *Listeria* outbreaks had an average of 11 cases, Shiga toxin-producing *E. coli* outbreaks had an average of 26 cases, and *Salmonella* outbreaks had an average of 61 cases.

[2]This information included, among other things, what federal agency CDC coordinated with (FDA or FSIS), total number of cases reported, total number of hospitalizations, total number of deaths, dates of initial and final cases reported, type of pathogen and strain, product type that was contaminated, and states involved.

[3]At the time of our case study selection, National Outbreak Reporting System data for 2018 had not yet been finalized through the CDC cleaning and verification process. However, we judged that this would not affect our ability to select cases. As of March 2020, National Outbreak Reporting System data for 2018 had been finalized.

outbreak, communication and coordination among the various agencies involved in the investigation, and officials' perspectives on the challenges involved in the investigation. We also interviewed public health officials in Arizona about their response to the 2014 outbreak of *Listeria monocytogenes* in caramel apples, but we were not able to interview officials in three other states about the other outbreaks because of the demands on state health agencies from the Coronavirus Disease 2019 (COVID-19) pandemic.[4] While this is a limitation, we believe the evidence collected is sufficient for the purposes of illustrating the challenges CDC faces and describing CDC's roles and responsibilities in identifying and responding to multistate foodborne illness outbreaks.

To identify and understand other federal roles and responsibilities, we also conducted site visits to FDA's Southeast Food and Feed Laboratory, FSIS's Eastern Laboratory, and CDC laboratory facilities to observe how these laboratories analyze samples, among other things. We also interviewed officials from the National Center for Emerging and Zoonotic Infectious Diseases, as well as key officials from FDA and FSIS with responsibilities for foodborne illness outbreaks. We also interviewed associations representing state, territorial, and local public health officials, including the Council of State and Territorial Epidemiologists, the National Association of State Departments of Agriculture, and the Association of Food and Drug Officials.

To help identify challenges CDC faces in identifying and responding to multistate foodborne illness outbreaks, we conducted a review of literature from the last 10 years in 18 databases.[5] Our initial search identified over 130 items based on the search criteria. From this list, the team analyzed summary-level information about each item to select those that were relevant for our review. In total, we identified 30 studies related to the identification of and response to multistate foodborne illness outbreaks that we reviewed. Using those studies, we identified challenges that CDC faces in identifying and responding to multistate foodborne

[4]We reached out to the state of New York on the 2017 outbreak of *Salmonella* in papayas, the state of Kentucky on the 2019 outbreak of Shiga toxin-producing *E. coli* in ground beef, and the state of Massachusetts on the 2016 outbreak of *Salmonella* suspected to have been in chicken.

[5]The challenges we discuss in this report are not intended to represent all of the challenges CDC faces. Databases searched included but were not limited to: Scopus, ABI/INFORM, BIOSIS, EconLit, Foodline, Food Safety and Technology Abstracts, and ProQuest. The search terms included, but were not limited to, foodborne illness, *Salmonella*, Shiga toxin-producing *E. coli*, *Campylobacter*, *Listeria*, detect, address, respond, manage, challenge, detection, identification, and outbreak.

illness outbreaks. These challenges included the use of data management systems such as PulseNet and FoodNet, the use of whole genome sequencing and pulsed-field gel electrophoresis to trace foodborne illness outbreaks to their source, and other challenges we identified in prior interviews.

To obtain an in-depth understanding of the challenges CDC faces in identifying and responding to multistate foodborne illness outbreaks and how CDC is responding to these challenges, we interviewed cognizant officials from CDC, FDA, and USDA. Where applicable, we drew on our four case studies of outbreak investigations to provide illustrative examples. We also interviewed officials from state health agencies; associations representing state, territorial, and local public health officials; and other nongovernmental food safety, consumer, and industry stakeholder groups to get their views on the challenges CDC faces in identifying and responding to these outbreaks. We identified stakeholders to interview through consultation with agency officials and nonfederal stakeholders and through our review of literature. We conducted interviews with representatives or researchers from

- three state public health agencies;
- three industry stakeholder groups;
- two associations representing state, territorial, and local public health officials;
- two associations representing state, territorial, and local food safety officials;
- three groups focused on preventing or reducing foodborne illness; and
- one university.

Because this is a nongeneralizable sample, the results of these interviews do not represent the views of all stakeholders involved in or with an interest in the CDC's response to multistate foodborne illness outbreaks. However, they illustrate the range of perspectives on these topics. We assessed the agency's actions against CDC criteria, including its best practices for risk communications and recommendations from a CDC-led working group on culture-independent diagnostic tests. In addition, we determined that the control activities component and the information and communication component of federal standards for internal control were significant to this objective, along with the underlying principles that management should (1) identify, analyze, and respond to risks related to

achieving defined objectives; and (2) externally communicate the necessary quality information to achieve the entity's objectives.[6] We assessed whether CDC had implemented these principles in responding to the challenges we identified.

To examine the extent to which CDC evaluates its own performance in identifying and responding to multistate foodborne illness outbreaks, we interviewed officials from the Division of Foodborne, Waterborne, and Environmental Disease about their performance management practices, including the division's efforts to assess progress. We also reviewed the strategic plan for the National Center for Emerging and Zoonotic Infectious Diseases, which is the center primarily responsible for carrying out CDC's foodborne illness investigations. To determine how CDC is assessing its progress toward meeting goals for these activities, we collected and analyzed information on performance measures and reviewed leading practices in performance management, such as the GPRA Modernization Act of 2010,[7] as well as leading practices for performance management and evaluation.[8] We then compared CDC strategic documents with these criteria to determine if all elements of a performance assessment system were included in CDC's planning documents.

We conducted this performance audit from March 2019 to October 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

[6]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014).

[7]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRA stands for the Government Performance and Results Act of 1993; Pub. L. No. 103-62, 107 Stat. 285 (1993). Although these requirements apply to departments (e.g., HHS), we have previously reported that they can serve as leading practices at other organizational levels, such as component agencies (e.g., CDC) for performance management. See, for example, GAO, *Coast Guard: Actions Needed to Enhance Performance Information Transparency and Monitoring*, GAO-18-13 (Washington, D.C.: Oct. 27, 2017); and *Motor Carriers: Better Information Needed to Assess Effectiveness and Efficiency of Safety Interventions*, GAO-17-49 (Washington, D.C.: Oct. 27, 2016).

[8]See, for example GAO, *Program Evaluation: Strategies to Facilitate Agencies' Use of Evaluation in Program Management and Policy Making*, GAO-13-570 (Washington, D.C.: June 26, 2013); *Performance Measurement and Evaluation: Definitions and Relationships,* GAO-11-646SP (Washington, D.C.: May 2011); and *Managing For Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.: Sept. 9, 2005).

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Description of Case Studies Used in This Report

Listed below are partial time lines and brief descriptions of the four outbreak investigations we selected as case studies to illustrate various aspects of the Centers for Disease Control and Prevention's (CDC) roles and responsibilities in foodborne illness outbreaks, as well as various challenges CDC faced in investigating these outbreaks.[1] For each of the four case studies we selected, we interviewed the relevant agency officials at CDC and the federal regulatory agencies who worked on the outbreak investigation. We also interviewed public health officials in Arizona about their response to the 2014 outbreak of *Listeria monocytogenes* in caramel apples, but we were not able to interview officials in three other states about the other outbreaks because of the demands on state health agencies from the Coronavirus Disease 2019 (COVID-19) pandemic.[2]

Listeria monocytogenes in Caramel Apples: November 2014 to March 2015

Beginning in late 2014, CDC investigated an outbreak of *Listeria monocytogenes* that was ultimately linked to caramel apples. In total, this outbreak had 35 confirmed cases in 12 states, resulting in 34 hospitalizations and seven deaths. Below is a time line of key events in this investigation.

- **November 14, 2014:** CDC first detected a possible multistate outbreak after state epidemiologists from Arizona and New Mexico

[1]Two of our case study outbreak investigations—the 2016 investigation of *Salmonella* Saintpaul in chicken and the 2017 investigation of *Salmonella* in papayas—involved multiple outbreaks that overlapped.

[2]We reached out to the state of New York on the 2017 outbreak of *Salmonella* in papayas, the state of Kentucky on the 2019 outbreak of Shiga toxin-producing *E. coli* in ground beef, and the state of Massachusetts on the 2016 outbreak of *Salmonella* suspected to have been in chicken.

reported four cases of listeriosis from the previous month, two of which were found in children who were otherwise healthy. Analysis of pulsed-field gel electrophoresis patterns in PulseNet indicated that these cases might be connected to a cluster of five cases from Missouri and Minnesota.[3]

- **November 2014–December 2014:** As additional cases came in, CDC conducted whole genome sequencing and found these cases to be highly correlated.[4]
- **December 5, 2014:** State investigators began interviewing affected patients, using the standard National Hypothesis Generating Questionnaire. Initially, these questionnaires seemed to indicate that strawberries were a potential source for this outbreak.
- **December 12, 2014:** With 27 cases associated with this outbreak, reports of strawberry consumption by patients were decreasing, so CDC requested that states begin to use open-ended questionnaires in interviews with patients.
- **December 15, 2014:** Interviewers from the state of Texas found that one patient remembered eating caramel apples. Subsequent reinterviews with other affected patients found five other instances where the individual had eaten caramel apples.[5]
- **December 17, 2014:** CDC officials found 11 of 13 patients they interviewed had reported eating caramel apples, and they found another 15 patients that reported eating caramel apples from different stores and brands the following day.
- **December 18, 2014:** The Minnesota Department of Health posted a press release telling people in the state that they should not eat

[3]Pulsed-field gel electrophoresis uses foodborne pathogen samples collected from patients or contaminated food sources to produce a DNA fingerprint with a specific pattern, made up of DNA fragments, or bands. According to CDC, pulsed-field gel electrophoresis can compare pathogen genomes using 15 to 30 bands in a pattern.

[4]Whole genome sequencing is a more modern laboratory technique that analyzes samples of foodborne pathogens to identify their unique DNA fingerprint. This technique provides a nearly complete reading of the millions of units that make up the pathogen's DNA.

[5]At the time, caramel apples were considered an unlikely source of *Listeria monocytogenes* infections, given the high level of acidity in apples, the high temperature of the melted caramel, and the lack of previously documented outbreaks linked to this food. Subsequent investigations showed that *Listeria monocytogenes* could be introduced into apples when they were punctured by the wooden sticks used to hold the apples.

caramel apples. The Food and Drug Administration (FDA) began conducting traceback investigations on the caramel apples. FDA ultimately identified four firms associated with the outbreak: one apple supplier and three caramel apple producers.

- **December 19, 2014:** CDC issued a national recommendation that "U.S. consumers not eat any commercially produced, prepackaged caramel apples, including plain caramel apples as well as those containing nuts, sprinkles, chocolate, or other toppings, until more specific guidance can be provided."
- **December 22, 2014:** CDC issued its second update on the progress of the investigation. The apple supplier issued its first recall.
- **December 24, 2014, to January 6, 2015:** The apple supplier expanded its recall. The three firms that FDA identified as producers associated with the outbreak announced voluntary recalls of commercially produced prepackaged caramel apples.
- **December 31, 2014:** CDC updated its public announcement with new case counts, investigation and recall updates, and to include cases in Canada that were also connected to the outbreak.
- **January 8, 2015:** CDC updated its public announcement with information on the recalls.
- **February 12, 2015:** CDC issued its final public communication on the outbreak, summarizing the investigation and associated recalls.
- **March 4, 2015:** CDC officially closed the outbreak investigation.

Salmonella Saintpaul in chicken (suspected): September 2016 to March 2017

Beginning in September 2016, CDC investigated an outbreak of salmonellosis from *Salmonella* Saintpaul suspected to have been in chicken.[6] Initial examinations using pulsed-field gel electrophoresis led CDC officials to believe that this was one outbreak, but CDC later determined, using whole genome sequencing, that this was two unrelated outbreaks. According to CDC officials, the eastern outbreak associated

[6]According to CDC, there are more than 2,500 serotypes of *Salmonella,* though fewer than 100 serotypes account for most human infections. CDC tracks the 30 most common serotypes that cause infections in humans, which include Anatum, Infantis, Newport, Saintpaul, and Thompson.

with this investigation affected 70 people from 11 states, 14 of whom were hospitalized, while the western outbreak affected 21 people in four states, two of whom were hospitalized. CDC did not issue any public communications about this outbreak because CDC could not determine the source before the product was off store shelves. Below is a time line of key events in this investigation.

- **September 22, 2016:** CDC first detected a possible multistate outbreak when PulseNet identified a cluster of 21 patients in eight states that had the same pulsed-field gel electrophoresis pattern for *Salmonella*.
- **September 27, 2016:** CDC began investigating this outbreak.
- **September 30, 2016:** CDC requested that states begin interviewing patients, using the National Hypothesis Generating Questionnaire.
- **October 3, 2016:** Interviews conducted using the questionnaire found that three of the four patients in California had shopped at the same warehouse store chain, so CDC requested that states collect shopper card information from these patients to help determine if there were any common items in their purchase histories.
- **October 11, 2016:** PulseNet identified 11 new cases from two new states—Massachusetts and Maryland—that appeared to be connected to this outbreak.
- **October 14, 2016:** CDC held its first multistate call with health departments from the affected states. At this point, CDC did not have a clear signal for any particular food item, but chicken and leafy greens were the most commonly reported items.
- **November 7, 2016:** By this point, CDC had completed whole genome sequencing on five cases from Maryland and Massachusetts, which indicated that these cases were likely from a common source.
- **December 5, 2016:** PulseNet identified, using pulsed-field gel electrophoresis, two U.S. Department of Agriculture chicken isolates matching the outbreak strain.[7] Results from additional completed questionnaires indicated chicken as a commonly

[7]A strain is a genetic variant or subtype of a bacteria.

reported food item but not at higher-than-expected levels compared with the FoodNet's Population Survey of food exposures.[8] Taken together, this led CDC to believe that chicken was the likeliest cause of this outbreak. CDC followed up with USDA to get additional information about the chicken isolates, particularly to determine if any of the chicken had been sold under store brand names.

- **December 12, 2016:** More cases with the outbreak strain were reported. However, only one patient in those cases reported eating chicken from the brands that USDA identified.
- **December 14, 2016:** CDC completed whole genome sequencing analysis on 16 isolates from patients in eastern states, which showed some level of genetic relatedness but less than was typical in previous *Salmonella* Saintpaul outbreaks. At this point, CDC believed that the chicken hypothesis might not explain all illnesses in the cluster and that the investigation might contain cases from two different outbreaks that had the same pulsed-field gel electrophoresis pattern. CDC decided to conduct open-ended interviews with patients to explore other potential routes for exposure and to conduct whole genome sequencing on isolates from the West Coast to see if they were related to the East Coast cases.
- **December 27, 2016:** California identified a new subcluster of patients associated with this outbreak who had eaten at the same Mexican restaurant. CDC collaborated with California to develop a questionnaire focusing on foods associated with Mexican-style restaurants and other exposures of interest from interviews. CDC requested that other states use this focused questionnaire to interview any patients who resided in or had traveled to western states.
- **December 29, 2016:** Whole genome sequencing data came back comparing the East Coast and West Coast isolates. These data seemed to confirm that there were two simultaneous, overlapping *Salmonella* outbreaks.
- **January 4, 2017:** CDC officially separated the investigations of the two outbreaks into two separate clusters, although CDC continued to request that states interview with the focused

[8]According to CDC, the FoodNet Population Survey is used to estimate how often people eat certain foods. These data can help investigators assess exposures that might be risk factors for foodborne illness, such as consumption of risky foods.

questionnaire new patients who resided in or reported travel to western states.

- **January 17, 2017:** CDC determined that the East Coast cluster of the outbreak was over and closed the investigation, with chicken as the suspected food source. However, CDC continued to monitor for new cases with the outbreak pulsed-field gel electrophoresis pattern. CDC found 10 additional cases associated with the East Coast cluster in the last 2 weeks of January.
- **February 3, 2017:** CDC closed the investigation into the West Coast cluster, since no new cases associated with it had been reported since December. CDC also reopened the investigation into the East Coast cluster of the outbreak.
- **February-March 2017:** CDC continued to monitor for new cases associated with the East Coast cluster but found very few new cases. These cases produced very limited food exposure information, and there was limited product information on chicken consumed.
- **March 9, 2017:** CDC permanently closed the investigation into the East Coast cluster.

Salmonella (multiple serotypes) in imported papayas: June 2017 to November 2017

Beginning in June 2017, CDC investigated four salmonellosis outbreaks involving papayas imported from Mexico. The *Salmonella* serotypes for these outbreaks included (1) primarily *Salmonella* Kiambu and *Salmonella* Thompson, (2) *Salmonella* Newport and *Salmonella* Infantis, (3) *Salmonella* Anatum, and (4) *Salmonella* Urbana. In total, these outbreaks sickened 251 people, of which 220 were sickened by the Kiambu and Thompson outbreak.[9] That outbreak also resulted in 68 hospitalizations and one death. The other outbreaks were associated with 11 hospitalizations and one death, collectively. Below is a time line of key events in this investigation.

[9]Of the 220 people sickened in the primarily Kiambu and Thompson outbreak, 144 people were infected by *Salmonella* Thompson, 54 by *Salmonella* Kiambu, 12 by *Salmonella* Agona, seven by *Salmonella* Gaminara, and three by *Salmonella* Senftenberg.

- **June 2017:** CDC first detected a possible multistate outbreak when PulseNet identified 13 cases of *Salmonella* Kiambu with the same rare pulsed-field gel electrophoresis pattern.
- **Early July 2017:** State public health officials interviewed patients, using the National Hypothesis Generating Questionnaire. Initial interviews found that the affected population reported that they were of Asian or Hispanic ethnicity and consumed higher-than-average amounts of papayas, mangos, and sprouts.
- **July 17, 2017:** The Maryland Department of Health identified a cluster of patients who all reported eating papayas from the same grocery store. Initial testing that the Maryland Department of Health conducted also reported *Salmonella* on papayas from this store. These tests were later linked to the outbreak strain of *Salmonella* Kiambu, as well as two other strains. These papayas were all labeled as Caribeña Maradol papayas from Mexico.
- **July 19, 2017:** The Maryland Department of Health issued a warning that people in the state of Maryland should "avoid eating Caribeña's yellow, Maradol papayas because of potential contamination with *Salmonella* bacteria."
- **July 21, 2017:** Additional cases of the outbreak strain of *Salmonella* Kiambu were detected in 11 other states, and whole genome sequencing indicated that these cases were closely related genetically. CDC issued a nationwide warning, recommending "that consumers not eat, restaurants not serve, and retailers not sell yellow Maradol papayas until we learn more."
- **July 22, 2017:** FDA issued a similar but narrower warning that "consumers should not eat Caribeña brand Maradol papayas from Mexico and should throw away any such products they have in their home."
- **July 26, 2017:** A distributor who sold Mexican papayas to the Maryland grocery store issued the first voluntary recall associated with this outbreak. CDC changed its advice to more closely align with the FDA advice, saying, "CDC recommends that consumers not eat, restaurants not serve, and retailers not sell Maradol papayas from Mexico until we learn more." At this point, the investigation expanded, as CDC found illnesses related to *Salmonella* Thompson that had been isolated from the Maryland papayas.
- **August 4, 2017:** CDC updated the public on the number of cases associated with this outbreak, while maintaining its prior advice.

- **August 7, 2017:** Two additional distributors who had sold Mexican papayas issued voluntary recalls. FDA placed a farm in Mexico that had sold papayas to the distributor under recall on an import alert.[10] FDA testing of other papayas from this farm found five different serotypes of *Salmonella* present, including Kiambu and Thompson.
- **August 11, 2017:** CDC updated the public on the number of cases associated with this outbreak and modified its advice, recommending that consumers not eat, restaurants not serve, and retailers not sell Maradol papayas from the farm in Mexico on FDA import alert.
- **August 2017:** CDC found additional people infected by the other *Salmonella* strains found on papayas from the farm under import alert. FDA increased testing of all papayas from Mexico to see if other imported papayas were contaminated with *Salmonella*. This testing uncovered two new outbreaks of *Salmonella* Newport, Infantis, and Urbana from papayas.[11] These outbreaks were associated with farms on the opposite side of Mexico from the first farm.
- **September 1, 2017:** CDC revised its advice to the public, telling consumers not to eat papayas from any of the three farms.
- **September 14, 2017:** CDC determined that a *Salmonella* Anatum outbreak from earlier in the year was associated with imported papayas from Mexico. While this outbreak investigation had been closed in the spring, FDA determined that some products associated with this outbreak might still be on store shelves.
- **October 2017:** Illnesses from the primary *Salmonella* Kiambu and Thompson outbreaks continued to be reported.
- **November 3, 2017:** CDC closed all four investigations, since few new cases had been reported, and contaminated product was likely to be off shelves.

[10]If FDA finds that imported products from particular firms or countries appear to violate the Federal Food, Drug, and Cosmetic Act, FDA may place the products, firms, or countries on an import alert. An import alert informs FDA field staff and the public that the agency has enough evidence to detain products at U.S. ports of entry without physically examining them (known as detention without physical examination). See GAO, *Imported Seafood Safety: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions,* GAO-20-62 (Washington, D.C.: November 2019).

[11]FDA found the *Salmonella* Newport and Infantis infections on the same farm and thus investigated these infections as one outbreak.

Shiga toxin-producing *E. coli* O103 in beef: March 2019 to June 2019

Beginning in March 2019, CDC investigated an outbreak of Shiga toxin-producing *E. coli* O103 involving ground beef. In total, this outbreak sickened 209 people in 10 states, resulting in 29 hospitalizations. Below is a time line of key events in this investigation.

- **March 28, 2019:** CDC first detected a possible mutlistate outbreak when the states of Kentucky and Georgia both reported increased levels of *E. coli* O103 infections. Kentucky identified its cluster using pulsed-field gel electrophoresis. Georgia had stopped doing pulsed-field gel electrophoresis and was waiting for whole genome sequencing to confirm it had a cluster. Based on the pulsed-field gel electrophoresis patterns from Kentucky, CDC identified additional cases in Ohio and Tennessee.
- **March 29, 2019:** CDC formally began its investigation.
- **April 1, 2019:** CDC held its first coordinating call with the four states. At this point, whole genome sequencing had determined that the isolates from Kentucky and Ohio had the same DNA fingerprint. CDC asked states to conduct interviews with patients, using the National Hypothesis Generating Questionnaire, focusing on exposures from fast food, ground beef, American-style cheese, and processed chicken.
- **April 4, 2019:** CDC found that 31 of 34 people interviewed with the questionnaire reported having eaten ground beef, although some had eaten it at restaurants, and others had eaten it at home. Kentucky identified a subcluster associated with a prison.
- **April 5, 2019:** CDC posted its first investigation notice, stating that “a specific food item, grocery store, or restaurant chain has not been identified as the source of infections.”
- **April 8, 2019:** CDC found that 55 of 61 patients interviewed using the National Hypothesis Generating Questionnaire reported having eaten ground beef. Tennessee identified a second subcluster associated with a restaurant location.
- **April 9, 2019:** CDC issued a second investigation notice, updating the case count.
- **April 12, 2019:** CDC updated the investigation notice, informing the public that “preliminary information suggests that ground beef

is the source of this outbreak" and provided additional information about how to safely handle and cook ground beef. The Tennessee Department of Health collected an unopened box of raw beef for testing from a restaurant associated with a cluster of patients. USDA's Food Safety Inspection Service (FSIS) collected ground beef samples from the Kentucky prison for testing.

- **April 18, 2019:** CDC found that 81 of 101 people interviewed with the National Hypothesis Generating Questionnaire reported having eaten ground beef. However, the samples collected from the Kentucky prison came back negative for the outbreak strain.
- **April 22, 2019:** Samples from the Tennessee restaurant came back positive for *E. coli*, though neither pulsed-field gel electrophoresis nor whole genome sequencing had yet been completed to confirm that it was the outbreak strain.
- **April 23, 2019:** A firm that had used the same source material that was tested at the Tennessee restaurant recalled approximately 113,000 pounds of raw ground beef products. CDC updated its Investigation Notice, stating, "USDA-FSIS and state regulatory officials are continuing their traceback investigations to determine the source of raw ground beef supplied to grocery stores and restaurants where ill people reported eating. At this time, no common supplier, distributor, or brand of ground beef has been identified. Consumers should follow steps to handle ground beef safely and cook it thoroughly."
- **April 24, 2019:** FSIS found that the ground beef sample collected from the Tennessee restaurant yielded the outbreak strain. FSIS also retested samples collected from the Kentucky prison and found *E. coli* O103. However, whole genome sequencing showed this strain was not closely related to the outbreak strain. A second firm, which had been identified as the source of the ground beef that FSIS collected from the prison subcluster in Kentucky, recalled 53,200 pounds of raw ground beef.
- **April 25, 2019:** The Georgia Department of Public Health identified another subcluster associated with a restaurant and began to collect records for traceback. The Georgia Department of Public Health also collected ground beef samples from a retail store, but all of these samples turned out negative for *E. coli* O103.
- **April 26, 2019:** CDC changed its investigation notice to a Food Safety Alert and updated the information to include the new case count and information about the recalls. FSIS conducted

traceback investigations into beef eaten by patients but was never able to determine a common source for the outbreak.

- **June 19, 2019:** CDC closed the investigation and posted the final Food Safety Alert.

Appendix III: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

September 28, 2020

Steve Morris
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Food Safety: CDC Could Further Strengthen Its Efforts to Identify and Respond to Foodborne Illnesses"* (Job code 103329/GAO-21-23).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes -S
Digitally signed by Sarah C. Arbes -S
Date: 2020.09.30 11:25:00 -04'00'

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED —"FOOD SAFETY: CDC COULD FURTHER STRENGTHEN ITS EFFORTS TO IDENTIFY AND RESPOND TO FOODBORNE ILLNESSES" (GAO-21-23)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1
The Director of the National Center for Emerging and Zoonotic Infectious Diseases should develop a plan for addressing risks that increasing use of culture-independent diagnostic test poses to CDC's continued ability to identify foodborne illness outbreaks.

HHS Response

HHS concurs with GAO's recommendation.

The increasing use of culture-independent diagnostic tests (CIDTs) presents a unique challenge. The nature of CIDTs limit options for obtaining the genetic data needed to identify foodborne illness outbreaks, in the absence of innovative new solutions. CDC is developing an action plan to address the challenges CIDTs pose on foodborne disease surveillance and outbreak detection. The action plan will likely address three main topics regarding CIDTs: public health decision making; preserving isolate-based surveillance; and moving towards culture-independent molecular surveillance. It is expected to be finalized in 2021, after which it will be communicated with federal, state, and local public health and industry partners.

Since the development of the action plan relies on feedback from CDC subject matter experts, timelines may be impacted by staff COVID-19 response activities.

Recommendation 2
The Director of the National Center for Emergency and Zoonotic Infectious Diseases should make publicly available CDC's decision-making process for communicating about multistate foodborne illness outbreaks, including the scenarios it considers to aid in decision-making.

HHS Response

HHS concurs with GAO's recommendation.

Through the Interagency Foodborne Outbreak Response Collaboration (IFORC), CDC developed an initial public communications framework for multistate outbreaks in 2011. CDC continually seeks feedback on how communications decisions are made from a variety of stakeholders, including consumer groups, the food industry, public health partners, and regulatory partners. Feedback from these stakeholders were incorporated into a 2018 update to the multistate outbreak communications framework. CDC's *Public Communication during Foodborne Outbreaks* web page describes the principles behind multistate outbreak communications decisions. In addition, CDC plans to publish the updated public communications framework in a peer-reviewed risk

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communication journal, along with the background and rationale for the framework, and will provide a link to the publication on the webpage[1] once it is published.

Response to multistate foodborne disease outbreaks as well as staff deployments to support the current COVID-19 response may delay non-emergency projects, including drafting manuscripts, developing other documents and procedures, and conducting analyses.

Recommendation 3

The Director of the National Center for Emergency and Zoonotic Infectious Diseases should implement a program performance assessment system for its multistate foodborne illness outbreak investigations, including setting performance goals, assessing progress toward those goals with performance measures, and conducting program evaluations.

HHS Response

HHS concurs with GAO's recommendation.

In 2018, CDC began a pilot project to analyze data on multistate foodborne and zoonotic outbreaks of *Salmonella*, Shiga toxin-producing *E. coli*, and *Listeria monocytogenes* infections investigated by CDC. The goal of this pilot project was to develop the methods and measures for two related products, one of which is the "Performance and Process Measures Summary". This performance and process summary was developed with input from federal partners and is intended for use by governmental agencies to evaluate performance in responding to multistate foodborne and zoonotic outbreaks. The indicators included in this summary correspond to different phases of the outbreak investigation and include performance measures, such as the proportion of outbreaks solved and the proportion of outbreak investigations leading to a product recall, and process measures that help provide additional context to interpret the performance measures.

During Fall 2020, CDC will work to align the proposed list of indicators for the Performance and Process Measures Summary with the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Strategic Plan: 2018 –2023[2] and to operationalize routine generation of the indicators. In 2021, CDC will develop specific targets for the performance measures that allow for objective assessment of progress, in support of the goals in the NCEZID Strategic Plan.

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[1] https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/communication/index.html
[2] https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf)

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contact

Steve D. Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Nico Sloss (Assistant Director), Perry Lusk, Jr. (Analyst-in-Charge), Tara Congdon, Caitlin Dardenne, Cynthia Norris, Bruna Oliveira, Josie Ostrander, Sara Sullivan, Andrew Titmus, and Ginny Vanderlinde made key contributions to this report. Kevin Bray, Colleen Candrl, Lorraine Ettaro, Benjamin Licht, Donna Morgan, Sushil Sharma, and Sarah Veale also contributed to this report.

Appendix V: Accessible Data

Data Tables

Accessible Data for Figure 1: Food Production Chain and Examples of Sources of Contamination

Step	Example
Production	If the fields are irrigated with contaminated water, fruits and vegetables can be contaminated before harvest
Processing	During the slaughter process, pathogens from an animal's hide or intestines can contaminate the meat.
Distribution	If refrigerated foods are left on a loading dock for extended periods in warm weather, they could reach temperatures that allow foodborne pathogens to grow
Restaurant preparation	Improper handwashing by food workers, particularly any that remain on the job while ill, can contaminate food.
Home preparation	If a cook uses a cutting board or knife to cut raw chicken and then uses the same knife or cutting board without washing it to slice tomatoes for a salad, the tomatoes can be contaminated by foodborne pathogens from the chicken

Accessible Data for Figure 2: Steps That Must Occur for a Possible Case of Foodborne Illness in the Population to Become Visible to the Centers for Disease Control and Prevention (CDC)

Step	Text
1	Possible foodborne illness case reported to CDC
2	Possible foodborne illness case reported to health department
3	Laboratory identifies illness-causing organism
3	Laboratory tests for illness-causing organism
4	Doctor takes sample from person and submits to laboratory for testing
5	Person seeks medical care
6	Person becomes sick

Accessible Data for Figure 4: CDC Epidemiological and Laboratory Capacity Cooperative Agreement Funding for Foodborne Disease Programs Compared with Amounts Requested, Fiscal Years 2014-2019

Year	Total Requested (in millions)	Total Awarded (in millions)
2014	$27.6	$12.1
2015	$28.8	$18
2016	$51.1	$32
2017	$55.7	$31.9
2018	$51.7	$33.2
2019	$70. 8	$34.9

Accessible Data for Figure 5: How Culture-Independent Diagnostic Tests (CIDTs) Can Affect CDC's Ability to Identify Foodborne Illness Outbreaks

Step	Text
1	Person feels sick and goes to the doctor.
2	Doctor collects sample, usually stool, from patient and sends it to a clinical laboratory for testing.
3A	Clinical laboratory grows and isolates pathogen from stool sample to identify pathogen causing the illness.
4A	Clinical laboratory sends pathogen isolate to state public health laboratory.
5A	State public health laboratory analyzes isolates to determine the specific type of pathogen and uploads DNA fingerprint of the pathogen onto PulseNet.
6A	CDC uses PulseNet to compare the DNA fingerprints of the pathogen from the patient to fingerprints submitted by other states to identify multistate outbreaks.
3B	Clinical laboratory uses CIDT to analyze stool sample and identifies the general type of pathogen causing the illness.
4B	Clinical laboratory may send left-over stool sample to state public health laboratory.
4C	Clinical laboratory sends results to doctor, who prescribes treatment to the patient.
6C	If the stool sample is still viable, state public health laboratory may attempt reflex culturing to grow and isolate pathogen to identify the specific type of pathogen causing the illness.
7C	State public health laboratory may analyze isolates and upload DNA fingerprint of the pathogen onto PulseNet.

Accessible Data for Figure 6: Summary of CDC's Multistate Foodborne Illness Outbreak Investigations, Outcomes, and Related Communications for Calendar Year 2016

Step	Example
Outbreak Detection	• 230 possible multistate outbreaks detected by CDC, state, local, or other officials
Outbreak Assessment	• 56 not investigated [a] • 174 investigated
Outbreak Investigation	• 56 closed shortly after opening investigation [b] • 68 determined not to be outbreaks • 50 determined to be outbreaks[c]
Outbreak Communication	• 30 outbreaks were not communicated to the public by CDC [d] • 20 outbreaks communicated by CDC

Agency Comment Letter

Accessible Text for Appendix III Comments from the Department of Health and Human Services

Page 1

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