Board of Scientific Counselors, Office of Infectious Diseases

Food Safety Modernization Act Surveillance Working Group

Annual Report to the Secretary, Department of Health and Human Services

2017

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BSC/OID FSMA Surveillance Working Group 2017 Report to HHS Secretary

SUMMARY

The Food Safety Modernization Act of 2010 (FSMA), signed into law on January 4, 2011, authorized the Centers for Disease Control and Prevention (CDC) to create a diverse working group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States. Accordingly, in fiscal year (FY) 2012, CDC established a FSMA Surveillance Working Group (FSMA-SWG) under the Board of Scientific Counselors, Office of Infectious Diseases (BSC/OID), a federal advisory committee. This sixth annual report summarizes the FSMA-SWG's activities and recommendations during FY 2017.

The FSMA-SWG held two 2-day meetings at CDC in FY 2017, convening in December 2016 and again in May 2017 to review, respond to specific questions, and provide guidance on foodborne illness and outbreak surveillance projects in the following areas:

- Improving governmental coordination, integration, and collaboration
- Evaluating and improving surveillance systems
- Enhancing external stakeholder collaboration and communication

The December 2016 Working Group meeting focused on a review and discussion of the potential effects of culture-independent diagnostic tests (CIDTs) and genomic testing on outbreak surveillance and response. Specific guidance was provided on how to enhance foodborne illness/outbreak surveillance through these diagnostic tools and through activities of the Interagency Food Safety Analytics Collaboration (IFSAC).

The May 2017 meeting focused on a review and discussion of how foodborne illness surveillance and reporting activities could be further improved. Specific guidance was provided on how to improve foodborne illness/outbreak surveillance via

- The Foodborne Diseases Active Surveillance Network (FoodNet) program, with focus on recent trends in rates of enteric illnesses
- Case-case analyses using existing surveillance data
- The National Outbreak Reporting System (NORS), with focus on an overview and trends

In the course of its work, the Working Group continued to note the importance of national and state/local surveillance for foodborne illness. It emphasized that the data gathered from this surveillance are critical for detecting outbreaks and identifying new vehicles for foodborne illness; monitoring the safety of the food supply; and directing risk-based food safety efforts conducted by CDC, the U.S. Food and Drug Administration , and the U.S. Department of Agriculture. Further, the Working Group noted the loss of capacity at state and local levels and underscored the need for additional resources to build on and better integrate existing surveillance systems and fill existing and emerging data gaps. The Working Group is pleased that initial funding was appropriated in FY 2014–2017 to help move forward the important tasks authorized by FSMA, and hopes that the programmatic efforts uniquely directed by CDC and implemented by state and local health departments to meet FSMA's enhanced surveillance requirements can continue. Finally, the Working Group also stressed that conducting foodborne illness surveillance and outbreak investigations to determine root causes can lead to better hazard analysis and more targeted food safety controls at food production, processing, and distribution levels. The absence of this information undermines the effectiveness of preventive control programs mandated by FSMA for the food industry.

BSC/OID FSMA Surveillance Working Group 2017 Report to HHS Secretary

INTRODUCTION

This report describes the fiscal year (FY) 2017 activities of the Food Safety Modernization Act Surveillance Working Group (FSMA-SWG) of the Board of Scientific Counselors, Office of Infectious Diseases (BSC/OID), a federal advisory committee at the Centers for Disease Control and Prevention (CDC). This Working Group was established in FY 2012 under authorization by the Food Safety Modernization Act of 2010 (FSMA). Membership comprises 21 experts representing local, state, and federal governments; academia; industry; and consumer groups (Appendix 1).

During FY 2017, the Working Group reviewed activities, responded to specific questions, and provided guidance on how foodborne illness surveillance could be improved by enhancements in culture-independent diagnostic tests (CIDTs), genomic testing, and improvements in surveillance and reporting systems such as the Foodborne Diseases Active Surveillance Network (FoodNet) and the National Outbreak Reporting System (NORS). The Working Group also reviewed, discussed, and provided guidance on several other CDC FSMA-related projects to enhance foodborne surveillance. For reference, previous topics covered by the Working Group are summarized in Appendix 2 and a summary of selected CDC activities conducted in FY 2017 to address FSMA is included in Appendix 3.

BACKGROUND

Each year, an estimated 48 million people in the United States (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from (largely) preventable foodborne diseases.[1,2]

Foodborne illness is costly. According to a 2015 study,[3] 15 pathogens alone are estimated to cost $15.5 billion in the United States per year. This includes medical costs (doctor visits and hospitalizations), and productivity loss due to illness and time lost from work as well as premature death. Globally the World Health Organization (WHO) estimated that each year as many as 600 million, or almost 1 in 10 people in the world, fall ill after consuming contaminated food. Of these, an estimated 420,000 people die, including 125,000 children under the age of 5 years.[4]

Public health surveillance is necessary for improving food safety. Timely detection and control of foodborne disease cases and outbreaks can directly reduce their public health impact; identify new food safety hazards; and enable investigators, regulators, and the food industry to learn more about ways to prevent these diseases.

Foodborne illnesses and outbreaks are reported and investigated at the local and state levels. These investigations help identify and prevent foodborne illness in local/state jurisdictions and provide essential information for national public health and food safety systems. CDC compiles information from local and state agencies and works with them to identify and link outbreak-associated illnesses, leading to identification of contaminated foods and management and control of outbreaks. Outbreak data are collected, analyzed, and shared with many stakeholders. Data from these outbreaks serve as a foundation for action by CDC, regulatory agencies, the food-producing industry, and others interested in improving food safety.

Foodborne disease and outbreak surveillance data aggregated by CDC are essential for many functions, including informing evidence-based policies, effectively assessing public health risk, and developing prevention messages for food safety improvements. These data are relied upon by other government regulatory agencies and analyzed by the media, public health, and consumer organizations that provide food safety advice to consumers and policymakers. In January 2013, CDC released the first comprehensive set of estimates of the food categories

responsible for foodborne illnesses acquired in the United States from 1998–2008.[5] Building on the 2011 estimates, which showed that about 48 million people (1 in 6) get sick each year from food, these newer estimates along with annual foodborne illness trend data from FoodNet help regulators and industry identify the groups of foods most responsible for foodborne illness. These data also provide a historical baseline of estimates that can be further refined over time as more data and improved analytic methods become available.

Over the years, differences in data collection and reporting among states, along with issues regarding integration among various government agencies, have led to calls for improvements to ensure that foodborne illness surveillance systems provide the necessary data to assist government agencies, industry, and other food safety stakeholders in their risk-management activities.

CDC and FSMA

The Food Safety Modernization Act of 2010 provided the U.S. Food and Drug Administration (FDA) with new enforcement authority designed to achieve higher rates of compliance with prevention and risk-based food safety standards to better prevent contamination events as well as respond to and contain problems when they occur. Additionally, the law directed FDA to build an integrated national food safety system in partnership with state and local authorities. Recognizing the critical role of foodborne illness surveillance data in informing prevention efforts and CDC's expertise in this area, FSMA also directed CDC to improve governmental coordination and integration, evaluate and improve foodborne illness surveillance systems, and enhance external stakeholder collaboration.

Signed into law on January 4, 2011, FSMA authorized CDC to create a diverse working group of experts and stakeholders to provide routine and ongoing guidance to improve foodborne illness surveillance systems in the United States and to provide advice on the criteria for the designation of five Integrated Food Safety Centers of Excellence (CoEs). In response, the FSMA-SWG of CDC's BSC/OID was created, with BSC/OID member Dr. James Hadler of Yale University's School of Public Health serving as Chair from November 2011 through December 2013 and BSC/OID member Dr. Harry Chen, Commissioner, Vermont Department of Health, serving as Chair from January 2014 to November 2017.

According to FSMA legislation regarding improvement of foodborne illness surveillance systems, areas for working group discussion and provision of guidance are

> "(A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;
>
> (B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;
>
> (C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;
>
> (D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the Working Group's recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs."

This annual report to the Secretary, Department of Health and Human Services (required by FSMA) highlights the FSMA-SWG's activities and recommendations in FY 2017 and summarizes priority areas for focus in the coming year.

WORKING GROUP ACTIVITIES—FY 2017

During its sixth year, the FSMA-SWG met twice at CDC to consider several recent and ongoing developments in foodborne illness surveillance that are key to maintaining and improving surveillance systems. The December 2016 meeting focused on 1) assessing the influence of CIDTs, 2) the Interagency Food Safety Analytics Collaboration (IFSAC) activities update, and 3) assessing the effects of genomic testing on foodborne outbreak surveillance and response. The May 2017 meeting focused on 1) reviewing enteric illness trends in FoodNet, 2) assessing case-case analyses using existing surveillance data, and 3) reviewing trends in the National Outbreak Reporting System. These topics and Working Group discussions are summarized as follows. Previous annual reports and topics reviewed are listed in Appendix 2 and posted on the BSC/OID FSMA-SWG website.

I. Culture-Independent Diagnostic Tests and Their Potential Influence on Foodborne Illness Detection and Outbreak Surveillance and Response *(Discussed at the December 2016 FSMA-SWG Meeting)*

CIDT Overview

CIDTs are diagnostic tests that can detect a specific antigen or genetic sequence of an organism and do not require isolation of a living organism. CIDTs are cheaper and easier to use than culture-based tests, and their adoption by clinical and public health laboratories continues to accelerate. The first PCR-based CIDTs that test for an array of foodborne bacteria in stool—called "syndromic CIDT panels for enteric diseases"—have come on the market, and many more are in development. The transition from culture-based tests to CIDTs, despite their advantages, poses a special challenge to public health. Reduced use of culture-based tests is leading to reduced availability of bacterial foodborne isolates needed for

- Serologic subtyping and subtyping by pulsed-field gel electrophoresis (PFGE)
- Molecular subtyping by whole-genome sequencing (WGS) and multiple locus variable-number tandem repeat analysis (MLVA)
- Detection of antimicrobial resistance (AR) genes by WGS
- Culture-based tests to assess antimicrobial susceptibility
    - Until new detection methods come into widespread use, the loss of these techniques could have a significant impact on the ability to detect foodborne outbreaks and identify new patterns of foodborne drug resistance. The transition to CIDTs could also affect estimates of disease incidence and disease trends.

CDC has a three-step plan to meet this challenge:

- *Step 1: Preserve cultures.* The short-term solution is to preserve a sufficient number of cultures to allow continued use of culture-based methods for surveillance of foodborne diseases. This may be accomplished by developing streamlined pathogen-specific isolate recovery protocols; by working with the Association of Public Health Laboratories (APHL); by building infrastructure for reflex testing through pilot programs with regional PulseNet and other state health laboratories; through collaborations with the Advanced Medical Technology Association; and by working with public and private sector partners to explore potential regulatory approaches to encourage reflex testing.
- *Step 2: Build a sequence-based infrastructure for detection and subtyping of foodborne pathogens.* PulseNet—the national network of foodborne disease laboratories—is transitioning from PFGE subtyping to genomic sequencing. As of November 2016, 30 PulseNet laboratories in 27 states have the capacity to generate and analyze WGS data.
- *Step 3: Develop culture-independent methods for detection and subtyping of foodborne pathogens.* CDC's Culture-Independent and Metagenomic Subtyping applied research group is exploring ways to develop culture-independent, direct-from-specimen diagnostics that allow direct, rapid, and low-cost characterization of pathogens within clinical specimens.

FoodNet Data: Use of CIDTs to Test for *Campylobacter* Infection

FoodNet works with more than 650 clinical laboratories at 10 sites (covering 15% of the U.S. population) to conduct active surveillance for foodborne diseases, providing estimates of incidence rates and disease trends. In 2009, FoodNet began receiving increased reports of *Campylobacter* infections, including increased numbers of cases diagnosed by CIDTs. Analysis of additional data from FoodNet sites, plus data from a survey of clinical laboratories, indicated that

- The number of *Campylobacter* cases diagnosed by CIDTs doubled between 2010 and 2015.
- The number of CIDTs on the market—including PCR-based syndromic CIDT panels for enteric pathogens—is increasing. In addition, some clinical laboratories and private laboratory networks have begun using their own PCR-based laboratory-developed tests (LDTs) for detection of *Campylobacter* infection.
- Only 19–35% of clinical laboratories currently perform reflex testing for *Campylobacter*, and the number of clinical laboratories that continue to submit stool samples or isolates of *Campylobacter* to public health laboratories is decreasing.
- Greater use of CIDTs is having an impact on FoodNet estimates of disease incidence and disease trends.
    - *Incidence of* Campylobacter. When CIDT-positive results are included, estimates of *Campylobacter* incidence increased by 2% for 2010 and by 18% for 2015.
    - *Trends.* When CIDT-positive results are *not* included, there is a statistically significant decrease of 13% in disease incidence for 2016, as compared with 2013–2015. However, when both CIDT-positive results and culture-confirmed cases are included, there is no statistically significant change for 2016 as compared with 2013–2015.
- Implications
    - The apparent rise in *Campylobacter* incidence could be real or due to use of the new tests (e.g., due to false positives or higher testing rates due to greater ease of using CIDTs).

- FoodNet is gathering additional data to determine (1) whether use of CIDTs leads to increased testing and detection of more illnesses and (2) whether test sensitivity and specificity vary among CIDTs and/or differ from sensitivity and specificity of culture-based tests. It is also critical to figure out how to compensate for the loss of data on *Campylobacter* serotypes, which affects *Campylobacter* surveillance and outbreak detection.
- These issues are relevant to all foodborne pathogens, with *Campylobacter* serving as a public health "canary in the coal mine."

State CIDT Experience

CSTE perspective

- CIDTs are here to stay; the era of culture-based tests is at an end. While sentinel surveillance projects may continue (e.g., the Gonococcal Isolate Surveillance Project), efforts to preserve isolates for disease surveillance and antibiotic testing do not represent a long-term solution.
- In the long run, it will not be feasible for the public health surveillance system to make test-specific adjustments in accepting cases reports. If a specimen tests positive by an FDA-approved CIDT, the specimen will be treated as positive, with health departments continuing to conduct investigations based on disease reporting, regardless of test type. However, conclusions about food contamination (by the states or by federal agencies) is never based only on laboratory tests.
- The use of advanced molecular detection (AMD) techniques has re-invigorated the work of public health laboratories. As the transition to AMD techniques accelerates, it will be necessary to articulate how epidemiologists can use the expected "avalanche" of new WGS data for public heath action. A similar adjustment occurred 20 years ago when initial use of PFGE led to detection of increased numbers of foodborne outbreaks.
- In terms of patient care, use of syndromic CIDT panels may reveal that co-infections of bacterial and viral diseases are common.

APHL perspective

- In terms of public health, the transition to CIDTs may be regarded as a high-stakes "gamble" to improve disease surveillance and outbreak detection while lowering laboratory costs.
- Each step in the progression from culture-dependent tests to antigen-based CIDTs to PCR-based CIDTs to genomic testing has had advantages and disadvantages.
- Increased use of PCR-based syndromic CIDT panels has raised questions about test validation and variability and the need to develop a new "gold standard" for diagnosis of enteric diseases. It has also raised concerns about confirmation, interpretation, and treatment of dual positives.
- A major public health advantage of CIDTs is an enhanced ability to detect foodborne infections that often go undiagnosed, including infections caused by strains of norovirus, sapovirus, and *Shigella*.
- As of yet, many potential benefits of CIDTs—in terms of improved disease surveillance and lowered costs—remain unrealized. Ongoing activities should include the following: monitoring CIDT uptake by clinical laboratories, resolving validation issues related to use of syndromic panels and LDTs, addressing reimbursement issues for reflex testing, and finding ways to preserve isolates for disease surveillance.

Discussion/Guidance

Discussion

- *Vision for the Future.* Rapid, direct-from-sample metagenomic tests will provide clinicians and public health officials with point-of-care data on subtyping, drug resistance, and virulence. Fulfillment of this vision will require not only technical innovations in diagnostics, bioinformatics, and information technology systems but also advances in epidemiology that facilitate use of new data and new discoveries—including findings about co-infections that may alter our understanding of the one-germ/one-disease theory.
- In the meantime, it is essential to monitor the public health consequences of the transition from culture-based tests to CIDTs and to compensate for short- and medium-term disruptions caused by loss of traditional microbiological methods. The discussion about the use of CIDTs for enteric diseases is part of a broader discussion about the use of CIDTs for all types of infectious diseases.

Guidance

- **How can monitoring of CIDT use be improved?** The Working Group recommends that CDC continue to monitor the adoption of CIDTs by clinical and public health laboratories and measure the percentage of positive results that are due to CIDTs. This could be accomplished by the following: conducting a national FoodNet laboratory survey; adding a variable about testing methods to case reports of foodborne illnesses; and/or requiring Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement grant recipients to submit data on the use of CIDTs, including syndromic CIDT panels for enteric diseases. This requirement would provide CDC with CIDT data from all states and some large cities, in addition to data collected at the 10 FoodNet sites. The Working Group also recommended that CDC and FoodNet
    - Collect data on cases of foodborne disease that are identified by CIDTs alone and cases that are epidemiologically linked to other cases or sources of transmission
    - Be transparent about uncertainties in the data on CIDT sensitivity and specificity and about adjustments made in calculating disease incidence and trends based on these findings
    - Establish criteria for diagnostic data quality by standardizing and validating diagnostic tests, working with governmental and non-governmental partners. A third-party convener could help coordinate this process.
    - Help move toward development of a new consensus on a “gold standard” for enteric disease testing, taking into account
        - Data on use, variability, and validation of CIDTs
        - Data on genetic variation among pathogens
        - Costs and cost savings due to CIDTs and increased use of electronic disease reporting
- **How can cultures be maintained until metagenomics makes them unnecessary?** The Working Group noted that culture-based testing, applied in a targeted and strategic manner, would always be needed to monitor the emergence of new and emerging threats and to detect new AR genes and patterns of resistance. To preserve cultures and identify new hazards, the Working Group recommended supporting efforts by local health departments to
    - Collect patient samples during investigations of cases of foodborne disease detected by CIDTs

- Work with CDC to fill gaps in surveillance for specific pathogens in specific regions of the country

CDC and partners should also try to prioritize identification of enteric pathogens by

- Encouraging and facilitating reflex testing by clinical laboratories
- Developing sentinel surveillance networks that use culture-based testing to monitor foodborne pathogens of local or regional public health concern

Prioritization decisions should be informed by data from FoodNet, IFSAC, and the Antibiotic Resistance Laboratory Network, and efforts to develop sentinel surveillance systems should keep in mind the need to maintain a strong PulseNet laboratory in each state.

- **How should disease surveillance and outbreak surveillance be modified to compensate for changes created by culture-independent diagnostic testing?** To better understand the impact of CIDTs on foodborne disease estimates and trends, the Working Group recommended that CDC and partners collect data to
  - Assess CIDT performance characteristics and determine whether false negatives and/or false positives are a significant issue
  - Confirm clinical correlations between test results and illnesses, especially when more than one pathogen tests positive
  - Determine whether physicians' ordering practices are changing and whether larger numbers of sporadic cases of disease are detected as CIDTs replace culture-based tests
  - Determine whether, how, and why use of CIDTs is changing among certain population subgroups and within certain states or geographic regions

II. Interagency Food Safety Analytics Collaboration Update *(Discussed at the December 2016 FSMA-SWG Meeting)*

IFSAC, established in 2011, coordinates efforts by FDA, the U.S. Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS), and CDC to generate estimates of foodborne illness source attribution and inform food safety policy. IFSAC focuses on four priority pathogens—*Salmonella* spp., *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter*.

Draft IFSAC Strategic Plan for 2017–2021

The objectives of IFSAC's first Strategic Plan (2012–2016) were to generate timely estimates of foodborne illness source attribution, identify data needs and sources, improve and validate methods and modeling approaches, identify high-level resource commitments, and develop an IFSAC communication plan. Outcomes included

- Inclusion of IFSAC estimates of foodborne illness source attribution in the USDA Strategic Plan FY 2014–2018
- Creation of an IFSAC food hierarchy categorization scheme (see below) that is used in CDC's outbreak surveillance database and may be adopted by FDA and USDA/FSIS databases on foodborne illness, as appropriate

- Use of IFSAC data and analytics to prioritize additional foodborne pathogens and inform research and planning efforts at FDA

The draft IFSAC Strategic Plan for 2017–2021 builds on the accomplishments of the first plan, retaining its focus on improving foodborne illness source attribution and the understanding of how it changes over time. The new plan has a greater emphasis on complex foods as a vehicle for foodborne disease and seeks to apply new data streams and enhance existing ones. It is formatted in a more traditional way, providing high-level goals, objectives, and strategies, with implementation projects to be included in an IFSAC action plan. Its goals include the following: (1) improve the use and quality of new and existing data sources to conduct analyses and develop estimates, (2) improve analytic methods and models, and (3) enhance the use of and communication about IFSAC products.

IFSAC Projects

Once the Strategic Plan is finalized, the IFSAC Steering Committee will review, approve, and prioritize projects to advance the plan's goals and objectives. Recently completed IFSAC projects include

- A comparison of the demographic, clinical, temporal, and geographic characteristics of sporadic and outbreak-associated foodborne illness in the United States
- Creation of the IFSAC food hierarchy, a categorization scheme for foods implicated in foodborne disease outbreaks
- Development of attribution percentages by food category for the four priority pathogens

Ongoing IFSAC projects include

- Creating a template for an annual IFSAC report, with updated attribution percentages by food category for the four priority pathogens. The goal is to release the first annual report in 2017.
- Evaluating the potential use of foodborne disease datasets in identifying food contamination points and developing a predictive model to anticipate where contamination is most likely to occur
- Improving attribution of *Campylobacter* transmitted by different routes (i.e., via contaminated food or water or by person-to-person or animal contact)
- Developing methods for estimating attribution of disease to complex (multi-ingredient) foods, using three independent classification schemes
- Updating estimates of the proportion of *Salmonella* Enteritidis illnesses attributable to eggs, chicken, and other foods
- Evaluating temporal trends in food categories implicated in outbreaks involving the four priority pathogens

Discussion/Guidance

Guidance

- **Do you agree with the focus and goals of the proposed Strategic Plan?** The Working Group approved the overall focus, flow, and goals of the draft Strategic Plan, and commended the inclusion of a stand-alone goal on communications (Goal 3).

- *Additions.* The Working Group recommended that IFSAC incorporate additional information about
  - The role of industry partners and the need to develop a stronger relationship and deeper conversation with industry scientists who can help plan (and provide data for) IFSAC projects. It is especially important to provide industry partners with
    - Updated findings on attribution of foodborne illness to particular ingredients in complex foods
    - Information on access to publicly available WGS databases on foodborne illness
- The Strategic Plan should also include
  - An explicit statement of the plan's priorities, in terms of pathogens. *Salmonella* would likely be the first priority.
  - A needs-assessment strategy or project (perhaps under Strategy 1.2.2) to identify data gaps; clarify data flows; and consider data sources, access issues, and harmonization issues. In identifying data gaps, the assessment could describe situations where data are insufficient to make public health decisions. Once the assessment is complete, IFSAC should develop a plan to address data gaps, working in partnership with governmental and non-governmental organizations.
- *Presentation.* The Strategic Plan could include
  - A diagram indicating how attribution estimates that pertain to different points in food production and processing can inform the food safety policies of FDA, USDA/FSIS, and CDC. The aim would be to provide a "global picture" of how IFSAC activities fit together and what they accomplish.
  - A table laying out the plan's goals, objectives, and strategies
- *Implementation and resources.* The IFSAC agencies should consider
  - Assigning dedicated staff to IFSAC
  - Building the U.S. food safety research workforce by
    - Establishing a consortium of external IFSAC partners to advance IFSCAC goals and strategies
    - Supporting food safety research at universities, perhaps in partnership with the National Institutes of Health or National Science Foundation. As noted below, graduate students could collaborate on IFSAC projects.
  - Working with existing risk-assessment groups (e.g., at FDA and USDA) to advance prioritization and use of IFSAC data for decision-making
- *Leveraging opportunities.* IFSAC should
  - Use IFSAC attribution studies as opportunities to identify optimal ways to combine epidemiologic data with WGS data to address public health questions
  - Align IFSAC research activities on foodborne AR with related research activities conducted in fulfillment of the *National Action Plan for Combating Antibiotic-Resistant Bacteria* (CARB). Improved understanding of the risks of transmission of foodborne AR would be valuable to many CARB stakeholders.

- **Do you have suggestions or comments about IFSAC projects?**
  - ***General comments***
    - When an IFSAC action plan is drafted, the description of IFSAC projects should explain which objectives are addressed by each project.
    - Tools developed to advance IFSAC projects may later be applied to address new questions. The CoEs could help disseminate these tools to public health departments and other partners.
    - While advancing IFSAC projects, the IFSAC partners could play a role in
      - Harmonizing terminology by encouraging the use of common terms that distinguish between points of contamination related to
        - Food processing and food production
        - Food-related and environmental contamination
      - Encouraging a culture of constant updating, as methods improve and results are refined
    - Some IFSAC projects would be ideal collaborative projects for graduate students. IFSAC could encourage establishment of a fellowship program that provides students with hands-on research training in food safety science and that encourages the development of innovative tools and approaches.
    - The data generated by IFSAC projects should be visualized graphically, whenever possible.
  - ***Comments on specific IFSAC projects.*** Regarding IFSAC projects on
    - *Evaluating points of contamination,* IFSAC should try to separate out restaurant-associated food contamination and contamination associated with food processing, although these issues are ultimately related (e.g., because food that arrives in a restaurant may already be contaminated).
    - *Developing a predictive model for identifying points of contamination,* IFSAC should collaborate with the risk assessment group at the FDA Center for Food Safety and Applied Nutrition (CFSAN).
    - *Improving attribution of* Campylobacter*,* produce may prove to be a more important source of *Campylobacter* than has been recognized.
    - *Comparing the characteristics of sporadic and outbreak-related illnesses,* findings may differ when comparing spread of illness by sporadic and outbreak-related cases via different pathways.

III. Genomic Testing (e.g., WGS) and Its Potential Effects on Foodborne Outbreak Investigations and Response *(Discussed at the December 2016 FSMA-SWG Meeting)*

Next-Generation Sequencing as a Tool for Laboratory Surveillance of Foodborne Illness

PulseNet—the national network for surveillance of foodborne illness—includes more than 85 public health and regulatory-agency laboratories that use molecular subtyping (or "fingerprinting") of bacteria to identify clusters of disease that represent unrecognized outbreaks. Rapid control of outbreaks identified by PulseNet prevents 270,000 illnesses each year, saving $507 million in medical costs and lost productivity.

PulseNet is transitioning from its current subtyping method, PFGE, to WGS. The application of WGS to foodborne disease surveillance began in 2013 with the *Listeria* Whole Genome Sequencing Project, a collaboration among CDC, FDA, USDA, the National Center for Biotechnology Information (NCBI), and state and local health departments. Use of WGS to monitor *Listeria* led to faster and better detection of disease clusters and more successful outbreak investigations, including many in which *Listeria* cases were linked to a specific food source.

Since 2014, PulseNet member laboratories in 30 states have acquired the capacity to perform WGS, and 13 more are planning to purchase sequencing machines with assistance from the CDC ELC program. The PulseNet goal for 2017 is for 50 laboratories to sequence and analyze the genomes of 26,500 isolates. The transition from PFGE to WGS is proceeding in accordance with PulseNet's original guiding principles, which include the following:

- **It is easier and faster to exchange data than to exchange strains.** This principle applies to both global and domestic exchanges, because a foodborne infection on one continent may have its source on another continent. PulseNet International—which includes laboratories in 88 countries in seven regions of the world—is a major partner in efforts to harmonize the new PulseNet subtyping methods with methods used in other nations.
- **The same standardized, automated methods for data generation *and* analysis are used in all laboratories.** Use of the same methods in all laboratories will save time and resources. For individual laboratories, the transition to WGS represents a cost-efficient consolidation of multiple workflows that identify and subtype bacteria, conduct virulence profiling, and characterize antimicrobial resistance. In the future, analysis of WGS data will provide a "one-shot" characterization of each isolate, including genus/species, serotype, virulence profile, and AR genes.
- ***All relevant data* should be placed and analyzed *in one database* or in databases that may be linked**. The use of one database will help investigators avoid errors and save time when they interpret sequence data and associated metadata (e.g., patient demographics, geographic locations, and exposures). For example, an investigator will be able to place isolates on a phylogenetic tree, compare their genetic relatedness, and analyze their associations with potential sources of contamination or environmental exposure.

Use of WGS Data in Investigating a Multistate Outbreak of Shiga Toxin-producing *E. coli* (STEC) O121 and O26 Infections Associated with Flour

Outbreak detection and investigation

- Shiga toxin-producing *E. coli* cause diarrheal illness that can be severe in children and older adults. In February 2016, PulseNet identified a cluster of STEC O121 infections that shared an uncommon PFGE pattern. By the end of the month, the cluster included 25 laboratory-confirmed cases in 16 states.
- An initial hypothesis—that the infections were due to consumption of leafy greens—did not hold up on further investigation. In mid-March, a CDC investigator conducted 10 open-ended interviews to generate new hypotheses. All 10 interviewees reported that they or a household member had baked some type of food. Of the 10 interviewees, 5 recalled baking during the week before illness onset, and 3 others reported that they might have baked during that period. Of the 5 who reported baking the week before the illness began, 4 out of 5 ate or tasted the raw dough or batter, and 3 out of 4 used Gold Medal brand flour, while the 4th used either Gold Medal or another brand.

- To test the "flour hypothesis," CDC conducted a case-control study involving interviews with outbreak case-patients and a control group of persons with non-STEC enteric infections (matched by age group, gender, and state of residence). The study indicated that the outbreak illness was significantly associated with someone in the household baking something homemade with flour, using Gold Medal flour, and eating or tasting raw dough.
    - The outbreak investigators determined that three packages of leftover Gold Medal flour provided by case-patients had been produced at a single General Mills facility in Kansas City, Missouri, during the same week in November 2015. This was the first time flour had been confirmed as the vehicle of an outbreak of STEC.

Use of WGS: Product testing, traceback investigation, and product recalls

- In early May 2016, 3 additional cases of illness were identified in young children who had handled or eaten raw dough at restaurants that belonged to the same restaurant chain. WGS testing indicated that the strains of *E. coli* O121 isolated from the children were closely genetically related to each other and to the outbreak strain. On May 31, 2016, General Mills recalled batches of flour products implicated in the outbreak, including varieties of Gold Medal flour, Gold Medal Wondra flour, and Signature Kitchens flour.
- In June, FDA isolated STEC O121 from leftover flour products from Arizona, Colorado, and Oklahoma and found (via WGS testing) that the flour isolates were closely related genetically to clinical isolates. However, the Oklahoma sample was from a flour product that had not been included in the initial recall.
- In July, FDA tested an O26 strain isolated by General Mills that proved to be closely related to an O26 isolate from an ill person who was subsequently included in the investigation. Like the flour product from Oklahoma, the flour product from which the strain was isolated had not been part of the initial recall.
- Because of the WGS findings, General Mills expanded the recalls to include additional lots of flour products. Moreover, other companies that had used the recalled General Mills products to make baking mixes, frozen entrees, or snacks also issued recalls. Taken together, these recalls covered more than 200 products sold under 30 brands.

FDA and USDA/FSIS Perspectives on WGS

FDA update on WGS

GenomeTrakr is a rapidly growing network of laboratories that use WGS for pathogen identification and tracking. It was developed by FDA as a distributed (rather than centralized) network that focuses on collaborative efforts to compile and disseminate sequence data and minimal metadata in a public database, accessible to partners in government, industry, academia, medicine, and public health. Members include laboratories at CDC, FSIS, state health departments, and dozens of collaborating institutions around the world.

- GenomeTrakr facilitates
    - *Acquisition of WGS data.* The GenomeTrakr database includes more than 100,000 genomic sequences of foodborne pathogens such as *Salmonella*, *Listeria*, and STEC.
    - *Assembly, analysis, and storage of WGS data.* Open-access data curation and data storage for GenomeTrakr are provided by NCBI. The data are also disseminated by the International

Nucleotide Sequence Database Collection (INSDC), the European Molecular Biology Laboratory (EMBL) database, and the DNA Data Bank of Japan.

- *Public health application and interpretation of WGS data.* GenomeTrakr data are used to identify disease clusters, conduct traceback investigations, and develop diagnostics and analytic software.

- GenomeTrakr helps obtain maximum benefit from WGS data by combining information from clinical samples, food samples, and environmental samples. In 2012, GenomeTrakr participated in the *Listeria* Whole Genome Sequencing Project, which used WGS data to study clinical and environmental isolates of *Listeria monocytogenes*.

Benefits and current uses of WGS

- WGS is better able to distinguish among isolates than PFGE, and provides greater certainty when matching clinical, environmental, and product-associated isolates. It allows investigators to use fewer isolates in identifying linkages between illnesses and potential sources of contamination.
- Genome sequences are portable and instantly cross-compatible. Faster identification of foods involved in outbreaks can help reduce the number of foodborne illnesses and deaths in the United States and abroad.
- WGS can provide information on serotype, drug resistance, virulence, and other critical factors in a single assay, with the same technical approach used for all pathogens.
- FDA is currently using WGS data on a routine basis to inform traceback investigations and provide information for regulatory purposes. WGS testing is also used in many other activities, including supply chain management, quality assurance, and process evaluation.

Future directions

- Significant cost savings are anticipated as WGS supplants microbiological methods. However, it is likely that many more illnesses previously classified as "sporadic infections" will be linked to specific foods or environmental sources, leading to a larger number of outbreak investigations.
- The GenomeTrakr database will be used as FDA's primary reference database for the transition to culture-independent food testing and surveillance. In the future, FDA/CFSAN may also use WGS data to improve or enhance market basket surveys, compliance sampling assignments, and baseline testing programs.
- Looking ahead, optimal use of WGS data will require continued capacity building, in terms of hardware, software, and training in sequencing, bioinformatics, and data analysis.

USDA/FSIS update on WGS

The Food Safety and Inspection Service

- Continues to build capacity to sequence the genomes of isolates obtained from FSIS sampling programs, with the goal of sequencing all FSIS isolates (about 10,000 per year)
- Uses WGS data—along with PFGE data, epidemiologic data, and microbiological information—to better understand relationships between clinical and foodborne isolates
- Works with the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) to investigate AR genes and their introduction into pathogens of interest (see below)

- Participates in efforts by the Interagency Collaboration on Genomics and Food Safety (Gen-FS)—along with CDC, FDA, and NCBI—to harmonize standards and metrics for using WGS to improve food safety
    - Thus far, more than 4,600 FSIS isolates of foodborne pathogens—including *Listeria*, STEC, *Salmonella*, and *Campylobacter*—have been sequenced and uploaded to the NCBI database, along with minimal metadata that include the following: product and source; the year when the sample was collected; the state where the sample was collected; and subtyping information, when available.
    - FSIS is using WGS data to advance investigations of
        - *Infectious disease outbreaks,* in coordination with CDC, FDA, and state health departments
        - *Bacterial harborage.* FSIS is exploring the use of WGS as a tool to understand potential harborage or reoccurrence of bacterial contamination, working in collaboration with FDA in dual-jurisdiction establishments that produce FDA- and FSIS-regulated products.
        - *AR genes*
            - In 2015, FDA isolated *Salmonella* with extended spectrum beta-lactamase (ESBL) resistance from a NARMS retail poultry product purchased in December 2014. The isolate contained the bla CTX-M-65 plasmid-based resistance gene, which had never before been reported in strains isolated from food items in the United States. FSIS identified bla CTX-M-65 ESBL resistance in other isolates, investigated their sources and possible links to human cases, and notified corporations with ESBL matches. No human illnesses were found linked to FSIS-regulated products.

FSIS and the USDA Agricultural Research Service investigated an animal isolate of *Salmonella* that contains the *mcr-1* gene—which confers resistance to colistin, the last-resort antibiotic used to treat patients with carbapenem-resistant Enterobacteriaceae (CRE).

- FSIS is also working with FDA and public health partners to revise case definitions to incorporate WGS criteria; to apply those definitions in making regulatory decisions during outbreaks; and to evaluate factors that might affect analysis of WGS data from evolving strains (e.g., genetic drift).
- FSIS is committed to using the analytic power and resolution of WGS to achieve the Healthy People 2020 Pathogen Reduction Goals, working closely with public health partners and using the best available science to understand the sources of food pathogens and their prevention and control. With this goal in mind, FSIS
    - Is rapidly developing WGS capacity to conduct real-time WGS of all FSIS isolates
    - Continues to work with CDC, FDA, and NCBI to understand the "scope and applicability" of WGS findings within FSIS's regulatory context
    - Continues to utilize WGS findings and interpretations in its investigative decision-making process, as a part of the totality of available evidence.

Discussion/Guidance

Discussion

- Improved and coordinated use of genomic testing by federal agencies and other partners—including state and local health departments and scientists in industry, agriculture, and academia—could facilitate
    - Faster and earlier detection, investigation, and control of clusters and outbreaks of foodborne disease, including diseases caused by new, re-emerging, or drug-resistant strains of bacteria
    - Better understanding of the underlying biology and dynamic transmission patterns of foodborne pathogens, which can contaminate foods during food production, transport, processing, or preparation
- The transition to WGS by PulseNet laboratories—along with increased use of CIDTs by clinical laboratories—will likely lead to detection of an increased number of local foodborne disease clusters and outbreaks. With the WGS transition underway in most states, the next step is to provide localities with additional resources for conducting investigations. The future availability of resources for this purpose is uncertain.

Guidance

- **How can coordination of genomic testing between agencies be improved?** The Working Group recommended that CDC, FDA, and FSIS
    - Identify and address obstacles to collaboration and data sharing (e.g., legal and confidentiality issues) with food safety partners
    - Disseminate information about publicly accessible databases that contain WGS data and minimal metadata on foodborne pathogens to public health departments and food safety scientists in all sectors
    - Work with academic, industry, and IFSAC partners to ensure that WGS datasets are fully utilized (e.g., to link human and animal isolates, characterize environmental isolates, compare current and historical isolates, and identify the root causes of the contamination of food products)
    - Develop a framework for engaging industry partners and facilitating collaboration with industry scientists who provide foodborne isolates and analyze WGS data. One approach is to build on VoluntaryNet, a collaboration between PulseNet and the Center for Food Safety, University of Georgia, that allows food industry partners to share data anonymously.
    - Encourage communication and collaboration between the public health and agricultural communities on food safety issues (e.g., by holding meetings, distributing information, and supporting trainings on the use of WGS to improve food safety and reduce foodborne AR)
    - Intensify efforts to engage other countries in global efforts to prevent foodborne disease, including PulseNet International and the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR). When metagenomics techniques are further advanced, CDC and partners can engage countries that join PulseNet—as well as WHO, the Food and Agriculture Organization of the United Nations (FAO), and the Global Microbial Identifier—in efforts to harmonize use of metagenomics terms and techniques.

- **What resources are needed to implement genomic testing and respond to the data it generates?** The Working Group agreed that additional epidemiologic and regulatory resources would be needed to investigate a larger number of small foodborne outbreaks. The Working Group recommended that CDC consider
    - Estimating the number of additional clusters of *Salmonella* and other priority pathogens likely to be detected by PulseNet, and evaluating the resources needed to investigate them
    - Encouraging local health departments to
        - Develop or augment investigative partnerships with local agricultural departments, FDA offices, and environmental health practitioners
        - Conduct periodic assessments of the local costs of investigative activities related to foodborne illness
    - Prioritizing investigation of clusters of foodborne disease, if needed, perhaps on the basis of causative pathogen and/or cluster size

- **How can the effects of genomic testing on foodborne illness and outbreak surveillance be monitored better?** The Working Group recommended that PulseNet progress be assessed by applying the same metrics and mechanisms used before and after the transition from PFGE to WGS, using data on illnesses and outbreaks collected by FoodNet and FoodCORE (Foodborne Diseases Centers for Outbreak Response Enhancement). Metrics for measuring the effects of genomic testing might include the following:
    - Has the number of foodborne illnesses decreased?
    - Is the number of clusters higher while the number of illnesses per cluster is smaller?
    - Has WGS allowed detection of cases or clusters that would not have been detected with PFGE?

CDC might assist industry partners in developing a metric they can use to assess the impact of WGS testing on food industry practices and disease prevention efforts.

IV. Foodborne Disease Active Surveillance Network Program and Recent Trends in Rates of Enteric Illness *(Discussed at the May 2017 FSMA-SWG Meeting)*

FoodNet Overview

FoodNet is a collaboration among CDC, 10 state health departments, USDA/FSIS, and FDA. FoodNet sites have conducted active surveillance of culture-positive isolates since 1996 and CIDT-positive specimens since 2012 for *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, STEC, *Shigella*, *Vibrio*, *Yersinia*, and pediatric hemolytic uremic syndrome (HUS). The objectives of FoodNet are to determine the burden of foodborne illness, monitor its trends, attribute illnesses to food vehicles, and disseminate findings for policy determinations and preventive actions.

Recent work of FoodNet includes making information technology enhancements to improve data and data collection; re-examining data from previous case-control studies using new analytic methods; updating Council of State and Territorial Epidemiologists (CSTE) case definitions for *Campylobacter*, *Salmonella*, *Shigella*, and *Vibrio*; and finishing the STEC non-O157 case-control study.

Future work of FoodNet includes launching the next round of the Population Survey; expanding surveillance to gather additional data on risk factors, outcomes, and exposures associated with antimicrobial-resistant bacteria for *Campylobacter*, *Salmonella*, and *Shigella*; updating foodborne illness burden estimates for 2020; refining CSTE case definitions for STEC, *Yersinia*, and *Listeria*; assessing efforts to preserve isolates for PFGE and WGS molecular testing; and evaluating daycare and food worker exclusion criteria. FoodNet sites will also conduct further analysis of CIDTs, including monitoring laboratory and physician practices and calculating the sensitivity and specificity of CIDTs. These data are needed to confidently incorporate CIDT data into incidence and trend models. Additional study is needed to interpret the significance of detecting multiple pathogens with the use of CIDTs, which will require epidemiologic analyses with multiple data sources, including chart reviews.

In 2015, FoodNet data were used in 10 publications and 16 conference abstracts, including a *Morbidity and Mortality Weekly Report* (*MMWR*) article, an annual report, and manuscripts on comparing sporadic with outbreak-associated foodborne illness and on health impacts of seven foodborne pathogens in the United States using disability-adjusted life years (DALYs). In conjunction with the release of the April 21, 2017, *MMWR*, FoodNet made updates to its website, including some new links to CIDT resources. In November 2016, FoodNet launched a web-based public data access tool, called FoodNet Fast, which allows for customizable queries for case counts and incidence rates for all pathogens. In April 2017, FoodNet updated the data to include 2016 preliminary data and CIDT data. In the future, FoodNet hopes to build the capability to include laboratory survey data, FoodNet population survey data, HUS surveillance data, and the ability to model trends over time. FoodNet has been on the forefront of recent changes in foodborne illness surveillance (e.g., increased use of CIDTs and WGS) and will continue to monitor future changes (e.g., metagenomics).

Recent Trends in Foodborne Illnesses

Culture-independent diagnostic testing has a growing impact on surveillance. Burden estimates complicated by CIDTs may make comparability to previous years difficult. There is a need to determine the amount of change in incidence that can be attributed to increased use of CIDTs.

CIDTs are important to include in incidence measures because they make up a large and increasing portion of the infections reported. Moreover, they complicate trend interpretation because of changing healthcare provider behaviors or laboratory testing practices. Healthcare providers may be more likely to order CIDTs because the results are obtained more quickly, which may be increasing the number of infections identified. Some laboratories may now use CIDTs instead of culture-based tests, which may be decreasing the number of confirmed cases reported. Syndrome panel tests may increase testing for pathogens that are not typically included in routine stool cultures, such as *Vibrio*, *Yersinia*, and STEC non-O157, and therefore have been underdiagnosed in the past. Additionally, because of potentially increased sensitivity, CIDTs may identify infections that would have been culture-negative. Some CIDT-positive results may be subsequently cultured, which may be increasing the number of culture-confirmed cases. Without reflex culture, a decrease in culture-confirmed cases will occur.

All of these complexities necessitate the ability to account for CIDTs in incidence and trends. To understand these changes better, FoodNet plans to collect data on changing testing practices to help guide future incidence estimates and comparisons.

Discussion/Guidance

Guidance

The Working Group concluded that FoodNet should

- Continue its unique evaluation of changes in foodborne illness surveillance resulting from the increased use of CIDTs and WGS testing
- Address the effects of CIDTs by continuing to assess
    - Physician/laboratory testing practices
    - Specificity/sensitivity of various tests
    - Significance of detection of multiple pathogens
- Update incidence rates, accounting for the effects of CIDT use, to determine appropriate goals for Healthy People 2030
- Continually evaluate FoodNet Fast to enhance the user experience
- Determine the specific niche of FoodNet compared with other food programs (e.g., FoodCORE and CoEs), especially in states funded by multiple programs
    - Establishing a common goal of all food programs that fund a particular state can increase cooperation and sharing of resources.
- Expand some aspects of FoodNet sites' surveillance (e.g., HL7 mapping) to all health departments
- Address gaps in foodborne illness surveillance by using public-private partnerships
    - FoodNet is currently looking at hospital discharge data.

V. Beyond the Traditional Case-Control Study: Case-Case Analyses Using Existing Surveillance Data *(Discussed at the May 2017 FSMA-SWG Meeting)*

Case-control studies have been used for many years, especially in FoodNet, for targeted study of potential risk factors for infection, but they do have limitations. Case-control studies are expensive to conduct, are difficult to conduct with multiple pathogens, are hard to replicate, and have significant time requirements. Case-case comparisons of food exposures may provide an alternative solution. A case-case comparison is a modified case-control study where cases of the disease of interest are compared with cases of another disease. Compared with traditional case-control studies, the advantage of this approach is that case data may often be readily available through routine surveillance interviews. Additionally, recall and selection bias are likely more similar among the comparison groups. However, case-case comparisons can only identify differential risk, meaning the difference in risk between the cases and surrogate controls. The surrogate controls may not represent healthy controls since they were also ill. These limitations can make the results challenging to interpret, and require thorough consideration in determining the best comparison group to use.

FoodNet has shown that case-case comparisons are a valid analytic approach for national surveillance data by documenting that they produce findings consistent with previous case-control studies. Case-case analysis can thus be used to

- Better understand disease epidemiology
- More efficiently identify risk factors
- Guide development of prevention and control measures

CoE Project Mercury—Aggregating Case Surveillance Data

Oregon is an Integrated Food Safety Center of Excellence and leads Project Mercury,* which conducts case-case comparisons using existing data from hypothesis generating questionnaires for binomial calculations. Binomial probability calculations (Bernoulli trials) have been used since the 1990s to compare a rate of exposure in a group of interest (i.e., outbreak cases) with a background exposure rate. Background exposure rates can be gathered from the FoodNet Population Survey, nutrition surveys, market share data, restaurant sales data, or aggregated case exposure data from hypothesis generating questionnaires from previous sporadic cases. Despite limitations, these later case-case studies have proven useful to quickly generate hypotheses and background exposure rates. In addition, states can harness data they are already collecting for surveillance, so additional resources and infrastructure are not needed.

Population Survey

The FoodNet Population Survey, a population-based survey conducted at FoodNet sites, collects data on food and other environmental exposures, recent gastrointestinal illness, healthcare-seeking behaviors, and various other special topics. The two primary objectives of the survey are to provide data for estimating the burden of acute gastroenteritis in the United States and for hypothesis generation during foodborne cluster and outbreak investigations.

Five cycles have been completed to date. In the most recent cycle, 2006–2007, interviews were conducted using landline phones and random digit dialing (RDD) to sample households in the FoodNet catchment areas. Within the household, FoodNet used the "next-birthday" method to select a single participant. About 18,000 respondents were interviewed over a 12-month period, with subsection questions focused on food exposures, animal contact, prion disease, drinking and recreational water, travel, health, and demographics. Each FoodNet site also had the opportunity to add site-specific questions of local interest.

As the last Population Survey was done 10 years ago, the data are out of date, especially for the food exposure history information used in outbreak investigations. Specifically, there have been significant changes in food consumption (e.g., more fresh fruits, produce, imported foods).

The next cycle was projected to launch in late June 2017 using more modern methods. The sample size will increase to 36,000 respondents over a 24-month period. The sampling frames and administration modes will also expand. Fifty percent will be selected through RDD, including both landline and cell phones. The other 50% will be selected through an address-based sample using both web and mail surveys. Lastly, the questions are updated to align with the National Hypothesis Generating Questionnaire, FoodNet's Case Exposure Ascertainment, NARMS, and the FDA Food Safety Survey. Future FoodNet activities include adding data (old and new) to the FoodNet Fast website.

*The name "Project Mercury" was derived from the abbreviation Hg, which corresponds to the first two letters in the acronym for hypothesis generating questionnaire (HGQ) and which is the abbreviation for the element mercury.

Discussion/Guidance

Guidance

The Working Group concluded that despite limitations, case-case comparisons could be useful adjuncts in foodborne outbreak investigations to

- Find unexpected associations
- Allow for detection of associations related to produce items that typically show protective effects in traditional case-control studies
- Conduct similar analyses by serotype to determine associations that do not exist pathogen-wide
- Conduct analyses to determine the best comparison groups to increase confidence in the findings
- Compare with Population Survey data to validate whether case comparison group data are similar to data found in well populations
- Allow states to use their own historical foodborne case exposure data in foodborne outbreak investigations to
    - Determine more specific estimates based on counties or other regions that would not be aggregated in a national database
    - Use background rate estimates from geographic regions and cultural groups with unusual exposure rates rather than use national estimates

The Working Group recognized the importance of the Population Survey data and recommended the following:

- The Population Survey should be conducted continuously rather than periodically to ensure that the information is current.
    - Potential startup cost savings could allow for expansion nationwide compared with current survey data that cover only 15% of the population covered by the FoodNet sites.
- Data collected during this cycle should be evaluated throughout the process to allow for adjustments in collection methods.
- Preliminary data should be made available before the end of the 2-year cycle.
- Results of the Population Survey should be made easily accessible for health departments for use in case-case analyses.

VI. The National Outbreak Reporting System Overview and Update *(Discussed at the May 2017 FSMA-SWG Meeting)*

NORS Overview

NORS is a web-based platform used by local, state, and territorial health departments in the United States to report to CDC all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. It evolved from a nearly 100-year-old foodborne outbreak reporting system to include additional modalities in

2009. Main contributors now include foodborne, waterborne, animal-associated (e.g., backyard chickens, reptiles, frogs), and norovirus outbreak data.

Outbreak investigations are most often initiated by state, local, and territorial public health agencies and by CDC. Outbreaks are reported to CDC using NORS, which collects information such as date and location of the outbreak, the number of people who became ill and their symptoms, and the pathogen that caused the outbreak. The data from outbreak investigations are checked for accuracy and analyzed by CDC to provide information about national outbreak trends and for learning lessons for preventing future outbreaks.

NORS future directions include

- Integration of additional data sources, including the National Environmental Assessment Reporting System (NEARS) outbreak data, which include information on environmental contributing factors and antecedents
    - Surveillance system integration would support the identification of root causes of food contamination.
- Exploration of key surveillance data to integrate from laboratory, epidemiology, and environmental sources
- Development of a Foodborne Outbreak Prevention Initiative
    - The aim is to use NORS and other surveillance and outbreak data to identify and help address food safety problems that have led to outbreaks.
    - The initiative is expected to include two principal activities:
        - Identification of food safety issues and related policy gaps
        - Assessment of the effectiveness of food safety interventions and policies

Discussion/Guidance

Guidance

The Working Group recommended the following:

- Waterborne illness surveillance data should be better integrated with foodborne illness surveillance data due to similar symptoms and overlapping investigations by the same staff at state and local health departments.
- Additional waterborne disease data are needed to determine the burden and quantify the need for more resources.
- NORS surveillance data should be used in the short term for outbreak detection and in the long term for policies and interventions (e.g., handwashing and ill worker exclusion) to prevent outbreaks and illnesses.
- Integration of the environmental health reporting system with NORS can help reduce the amount of missing data.
- There should be an evaluation of the reason that reports include missing data variables so that performance can be improved to allow better data analysis.

RESOURCES

The FSMA-SWG acknowledged that additional resources are required to develop human resource capacity of state and local health departments to maintain cultures as CIDT use increases; to conduct timely exposure assessments; to enhance the value of new technologies, including whole genome sequencing; to find, investigate, and quickly stop multistate foodborne outbreaks; and to build on and better integrate existing surveillance systems and fill existing data gaps. There is also a critical need to build capacity at the state and local levels that have experienced severe losses in capacity, including hiring experienced foodborne epidemiology, laboratory, and environmental personnel. This effort includes the need to engage schools of public health to train the existing workforce and the next generation of state and local food safety public health scientists and practitioners.

The Working Group is pleased that partial funding has been appropriated in 2014–2017 to address the important tasks authorized by FSMA and hopes that the programmatic efforts uniquely directed by CDC and implemented by state and local health departments to meet the enhanced surveillance requirements continue to be funded. Recent investments in AR and AMD will also have positive impacts for advancing food safety. However, these funds are not solely focused on improving food safety surveillance. To advance food safety effectively, sustained investments in CDC's food safety efforts are needed.

NEXT STEPS

Since its formation 6 years ago in 2011, the Working Group has met 12 times and completed six annual reports for the HHS Secretary. Major topics and minor themes covered are summarized in Appendix 2. As nine members were completing their terms, there was considerable discussion of the value of the guidance provided, ways to improve the meetings, and potential future topics.

Based on the discussion, potential future topics may include

- How to use foodborne illness surveillance data to measure the impact of FSMA
- Providing ongoing reviews of programs like the Interagency Food Safety Analytics Collaboration and the Integrated Food Safety Centers of Excellence
- Promoting/enhancing integrated data systems among CDC, FDA, and USDA
- Providing periodic reviews of
    - Priority areas (e.g., CIDTs, WGS, antimicrobial resistance)
    - Interagency collaborations such as IFSAC, the Interagency Foodborne Outbreak Response Collaboration (IFORC), Gen-FS, and FoodNet
    - Priority pathogen (e.g., *Salmonella*, STEC, *Listeria*, *Campylobacter*) trends and ways to prevent infections
    - Orphan illnesses (e.g., toxoplasmosis, cryptosporidiosis, cyclosporiasis, hepatitis A)
- Assessing the status of capacity building in state and local health departments
- Improving root cause analysis
- Addressing challenges with imported foods

- Addressing food allergy and anaphylaxis
- Future leader training—including through schools of public health
- Examining “food testing” surveillance systems

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APPENDIX 1: FSMA SURVEILLANCE WORKING GROUP MEMBERS

Meetings held in December 2016 and May 2017

BSC Representative Members:

Chair, Harry Chen, MD—Commissioner, Vermont Department of Health

Member, Kristy Bradley, DVM, MPH—State Epidemiologist and State Public Health Veterinarian, Oklahoma State Department of Health

Member, Timothy Jones, MD—State Epidemiologist, Tennessee Department of Health (also CSTE representative)

Federal Partner Members:

Dale Morse, MD, MS—Centers for Disease Control and Prevention

Jeffrey Farrar, DVM, MPH, PhD—Food and Drug Administration

David Goldman, MD, MPH—United States Department of Agriculture, Food Safety and Inspection Service

Public Health Partner Agency Members:

Natalie Adan—National Association of State Departments of Agriculture

Robyn Atkinson, PhD, HCLD—Association of Public Health Laboratories

Thomas S. Dunlop, MPH, REHS—National Environmental Health Association

Timothy Jones, MD—Council of State and Territorial Epidemiologists

Heidi Kassenborg, DVM, MPH—Association of Food and Drug Officials

Nathaniel Smith, MD, MPH—Association of State and Territorial Health Officials

Joseph Russell, MPH, RS—National Association of County and City Health Officials

Consumer Partner Members:

Barbara Kowalcyk, PhD—Center for Foodborne Illness Research and Prevention

Dara Alpert Lieberman—Trust for America's Health

Karin Hoelzer, DVM, PhD—The Pew Charitable Trusts

Industry Partner Members:

Catherine Adams Hutt, PhD, RD—Food Industry Consultant

Scott K. Hood, PhD—General Mills

Joan Menke-Schaenzer—McDonald’s Corporation

Academia Partner Members:

Craig Hedberg, MS, PhD—University of Minnesota

Michael P. Doyle, PhD—University of Georgia

Elaine Scallan, PhD—University of Colorado, Denver

APPENDIX 2: FY 2012–16 FSMA SURVEILLANCE WORKING GROUP ANNUAL REPORTS AND MEETING TOPICS

FY 2012 Annual Report

Main topics:

- Selection Criteria for Integrated Food Safety Centers of Excellence
- Interagency Food Safety Analytics Collaboration
- Improving Foodborne Illness Surveillance Systems: Focus Areas for Future Discussion

Supplementary topics:

- Overview of the human illness surveillance requirements of FSMA – CDC
- Summary of Nov 3–4, 2011 Pew Food Safety Forum's surveillance workshop
- Overview of foodborne illness surveillance systems and challenges – CDC
- Overview of multistate foodborne outbreak investigations and challenges
- Economic analyses on FoodNet and PulseNet – CDC
- Website improvements to make data more accessible to the public
- Improved outbreak reporting mechanisms: PulseNet portal and Palantir – CDC

FY 2013 Annual Report

Main topics:

- Culture-independent diagnostic tests (CIDTs)
- Performance Measures to Enhance Federal, State, and Local Foodborne Illness Surveillance

Supplementary topics:

- CoE Congressional Report
- Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities
- Vital Signs and recent communication updates

FY 2014 Annual Report

Main topics:

- Foodborne illness and outbreaks caused by norovirus
- Antimicrobial resistance surveillance for foodborne illness

Supplementary topics:

- Whole genome sequencing *Listeria* surveillance project
- Cyclosporiasis

FY 2015 Annual Report

Main topics:

- Governmental Coordination, Integration, and Collaboration
- Environmental Factor Surveillance for Foodborne Illnesses

Supplementary topics:

- Cyclosporiasis surveillance
- *Vibrio* surveillance

FY 2016 Annual Report

Main topics:

- Industry role in enhancing surveillance
- Review of proposed plans of the Interagency Food Safety Analytics Collaboration
- Traceback surveillance
- Integrated Food Safety Centers of Excellence
- Plans for foodborne antimicrobial resistance funding

Supplementary topics:

- Multistate outbreak summary
- *Shigella* update
- Website updates (NARMS : Now, FOOD Tool, general)
- PulseNet cost-benefit paper

APPENDIX 3: SELECTED CDC ACCOMPLISHMENTS IN IMPLEMENTING FSMA SURVEILLANCE REQUIREMENTS

The Food Safety Modernization Act (FSMA) recognizes that robust foodborne illness surveillance data are needed to inform prevention efforts. FSMA directly links surveillance with prevention and highlights the need for stronger partnerships at the local, state, and federal levels. FSMA directs the Centers for Disease Control and Prevention (CDC) to

I. Improve governmental coordination and integration
II. Evaluate and improve foodborne illness surveillance systems
III. Enhance external stakeholder collaboration

CDC supports the implementation of FSMA in many ways. For instance, in fiscal year (FY) 2016, with the help of new antimicrobial resistance and food safety funding, CDC significantly increased support for existing infrastructure for laboratory, surveillance, and outbreak response activities and continued the activities of the Integrated Food Safety Centers of Excellence (CoEs).

The following summary discusses selected CDC accomplishments that support FSMA. While the majority build on existing infrastructure and labor capacity, some 2017 initiatives, such as expansion of the OutbreakNet Enhanced sites and the plan to convert PulseNet's pulsed-field gel electrophoresis (PFGE) to whole genome sequencing (WGS) testing, greatly expand CDC's surveillance capabilities under FSMA.

I. Improving Governmental Coordination and Integration

A. Coordinating federal, state, and local foodborne illness surveillance systems

Multistate foodborne illness outbreak investigations

In FY 2017, CDC supported federal, state, and local health agencies to monitor between 21 and 57 clusters of potential foodborne illness per week, resulting in eight major multistate outbreak investigations led by CDC (Table 3.1). Additional multistate outbreaks were managed by state health departments with CDC as a consultant (see FOOD Tool statistics).

CDC continues to improve foodborne illness and outbreak metrics through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement sites and by working with the Council to Improve Foodborne Outbreak Response (CIFOR) to use performance measures and associated targets as guidelines for states to use in their outbreak investigations.

Table 3.1 Selected Multistate Foodborne Illness Outbreaks, United States, FY 2017*†

Pathogen	Distribution	Vehicle
Salmonella Urbana	7 illnesses reported from 4 states; 3 hospitalizations, no deaths	Imported Maradol papayas
Salmonella Newport and *Salmonella* Infantis	4 illnesses reported from 4 states; 2 hospitalizations, no deaths	Imported Maradol papayas
Salmonella Anatum	14 illnesses reported from 3 states; 5 hospitalizations, 1 death	Imported Maradol papayas
Listeria monocytogenes	8 illnesses reported from 4 states; 8 hospitalizations, 2 deaths	Soft raw milk cheese made by Vulto Creamery
Escherichia coli O157	32 illnesses reported from 12 states; 12 hospitalizations, no deaths	I.M. Healthy brand soynut butter
Salmonella Oranienburg	8 illnesses reported from 3 states; 2 hospitalizations, no deaths	Good Earth Egg Company shell eggs
Escherichia coli O157	11 illnesses reported from 5 states; 7 hospitalizations, no deaths	Beef products produced by Adams Farm
Hepatitis A virus	143 illnesses reported from 9 states; 56 hospitalizations, no deaths	Imported frozen strawberries

*Pathogens listed in chronological order of outbreaks

†Data through 09/25/2017

CDC support of the U.S. Food and Drug Administration (FDA) implementation of FSMA

CDC works closely with FDA to support FSMA implementation efforts by providing expert participation in various interagency activities and workgroups. These efforts include the following:

- **Serving on the Network Advisory Committee to the FDA Rapid Response Teams (RRTs).** CDC representatives participated and presented on CDC's outbreak investigation teams, protocols, and disease surveillance programs during monthly RRT calls. (FSMA Sections 202, 205[c], and 209)
- **Inviting active participation by FDA and the U.S. Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) representatives in the Integrated Foodborne Outbreak Response and Management (InFORM) Conference.** FDA actively participated in planning for the November 2017 meeting of federal-, state-, and local-level laboratorians, epidemiologists, and environmental health/regulatory personnel involved in foodborne and enteric disease outbreak responses.
- **Serving on the FDA-led Partnership for Food Protection (PFP) Governing Council.** A CDC representative serves as a member of the council in monthly telephone conferences and at an annual face-to-face meeting.
- **Serving on PFP workgroups: Surveillance, Response, and Post-Response Workgroup and Laboratory Sciences Workgroup**. CDC representatives participated in PFP workgroups aimed at strengthening and enabling faster and more effective surveillance, response, and post-response

efforts through coordination among strategic partners, promoting consistency and facilitating information sharing through establishing and utilizing national laboratory best practices.

- **Serving on the Interagency Foodborne Outbreak Response Collaboration (IFORC**). In 2017, CDC served as chair of IFORC, whose overarching goal is to prevent illnesses and deaths associated with multistate foodborne outbreaks by stopping outbreaks rapidly, when they occur, and by preventing future foodborne outbreaks. IFORC is a tri-agency effort to improve coordination of federal foodborne outbreak response responsibilities of CDC, FDA, and USDA/FSIS. In 2017, the USDA Animal and Plant Health Inspection Service (APHIS) joined the collaboration.

Interagency Collaboration on Genomics and Food Safety (Gen-FS)

In FY 2015, CDC, FDA, the National Institutes of Health (NIH)/National Center for Biotechnology Information (NCBI), and USDA/FSIS began to formalize their ongoing collaboration on the application and use of WGS to improve food safety. They established the Interagency Collaboration on Genomics and Food Safety for timely access to foodborne epidemiologic, food and traceback, environmental, and laboratory data for the following applications:

- Clinical, food, and environmental foodborne pathogen surveillance
- Quick, accurate detection and mitigation of outbreaks
- Removal of contaminated food sources to prevent additional illnesses
- Studies that attribute foodborne illnesses to food sources
- Regulatory food safety research
    - **The strength of Gen-FS** is built on the complementary roles and responsibilities for protecting food safety of the four federal agencies, with state and other partners:
        - CDC oversees foodborne Illness surveillance.
        - FDA oversees regulatory oversight and surveillance of produce, seafood, dairy products, processed foods, nuts, and other foods.
        - USDA/FSIS has regulatory oversight and surveillance of meat, poultry, processed eggs, and catfish.
        - NIH/NCBI provides the big data infrastructure for data storage, curation, bioinformatics analytics, and other expertise necessary to use integrated data from different sources.

    CDC has been chair of Gen-FS since 2016.

During FY 2017, Gen-FS progressed in a number of areas, including the following:

- Expanding the participants in Gen-FS with inclusion of USDA's APHIS and Agricultural Research Service (ARS) and FDA's Center for Veterinary Medicine, and the scope to include antimicrobial resistance as it relates to WGS
- Sequencing isolates of foodborne pathogens from clinical, food, feed, and environmental sources; storing the information; and facilitating analysis and use of the data for disease surveillance, regulatory testing, and oversight of food safety
- Implementing policies to enable pathogens from clinical sources to be sequenced at FDA-supported laboratories, and food and environmental pathogens to be sequenced at CDC-supported laboratories to save time and shipping costs

- Developing and harmonizing laboratory procedures, protocols, and standards and executing a combined interagency proficiency testing program for WGS analysis
- Streamlining data sharing among partner agencies, and when possible, with the public
- Comparing, interpreting, and using WGS and metadata for analytic studies as well as publicly posting standard WGS datasets for direct comparison and assessment of various analytic tools
- Supporting state food safety agencies in their adoption of WGS technology and implementing harmonized and combined CDC and FDA WGS training and certification workshops
- Expanding real-time WGS surveillance for more foodborne bacterial pathogens

The* Listeria *Initiative

Since 2004, CDC has maintained the *Listeria* Initiative, a national surveillance system that collects information on laboratory-confirmed cases of listeriosis in the United States. To better detect and investigate illness clusters, the *Listeria* Initiative incorporates molecular subtyping data ("fingerprinting") from clinical, food, and environmental isolates, or samples, of *Listeria* to identify clusters of possibly related cases. Laboratories subtype isolates using PFGE (a type of DNA fingerprinting) and submit the results to PulseNet, the national molecular subtyping network for foodborne disease surveillance. In 2013, laboratories began examining *Listeria* isolates using whole genome sequencing with submission of results to a public access database housed by NCBI. In FY 2017, CDC

- Migrated historical *Listeria* Initiative data to a secure web-based platform, Enterics Direct
- Developed and validated an Enterics Direct module to allow entry and upload of *Listeria* Initiative data into the national database
- Participated in four regional OutbreakNet/PulseNet meetings to discuss and provide updates on data transmission enhancements for the *Listeria* Initiative
- Continued to work with states to identify ways to improve timely reporting of *Listeria* cases with linked epidemiologic and laboratory data to better detect and investigate illness clusters
- Led laboratory efforts to build capacity at state laboratories for WGS of *Listeria* isolates
- Continued to notify states weekly of recent uploads of *Listeria* isolates to PulseNet from their state to increase the percentage of isolates that have linked epidemiologic data
- Continued to strengthen integration of epidemiologic exposure data with WGS data to better detect and solve outbreaks
- Investigated outbreaks of *Listeria* infections, including an outbreak linked to soft raw milk cheese
- Increased the number of listeriosis cases linked to food source and the number of solved outbreaks as a direct result of the WGS project
- Continued routine, near-real-time WGS of all food, environmental, and clinical isolates in integrated farm-to-table listeriosis surveillance through collaboration with FDA, USDA/FSIS, NIH, and state partners

Toxoplasma gondii *surveillance*

In FY 2017, CDC's Division of Parasitic Diseases and Malaria (DPDM) continued to collaborate with multiple agencies to conduct toxoplasmosis surveillance, including

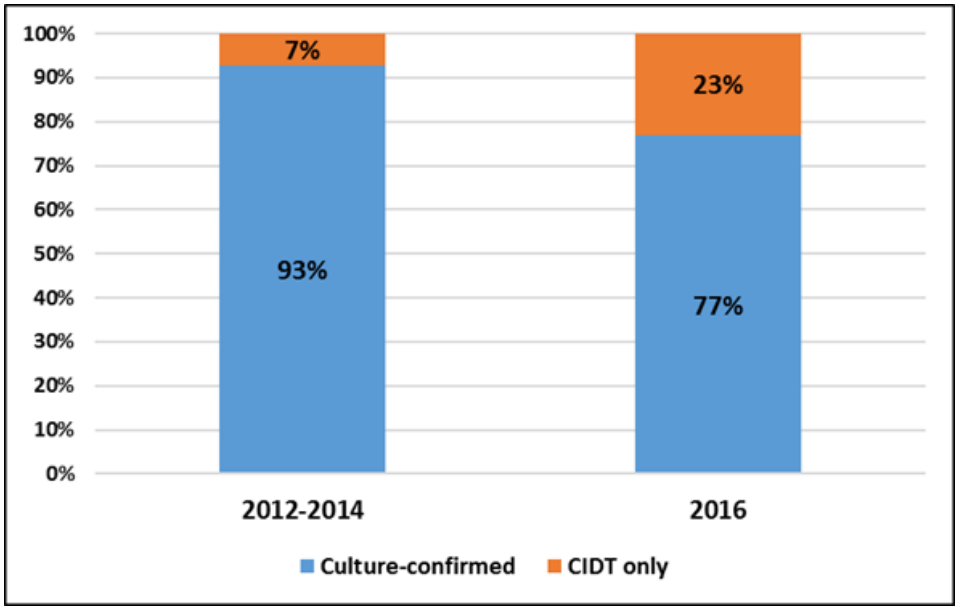
- Completion of the *Toxoplasma gondii* sero-surveillance project using serum samples from the 2013–2014 National Health and Nutrition Examination Survey. This expansion allowed completion of the periodic 6-year sample period (2009–2014) to stratify the data by race/ethnic group, gender, and region, and to fully evaluate trends. Results of the study indicate that the age-adjusted prevalence for *T. gondii* continues to decrease in the United States and that those more likely to be infected include older persons, males, non–U.S.-born persons, and those living in poverty. This survey is a collaboration at CDC among DPDM, the Center for Global Health, and the National Center for Health Statistics' Division of Health and Nutrition Examination Surveys. The manuscript has been cleared through DPDM for publication.
- Continued collaboration with USDA ARS to conduct a national survey of *T. gondii* contamination in field-raised and "organic" pork and lamb

Foodborne Diseases Active Surveillance Network (FoodNet) surveillance

CDC, FDA, USDA/FSIS, and 10 state health departments participate in the Foodborne Diseases Active Surveillance Network and collaborate to provide critical data for policymakers, the scientific community, and the public. During FY 2017, this collaboration resulted in the following:

- Published preliminary 2016 FoodNet data on the incidence and trends of infection with pathogens transmitted commonly through food in the April 21, 2017, *Morbidity and Mortality Weekly Report* (*MMWR*)
- Launched FoodNet Fast, an online interactive data query tool for FoodNet data
- Provided data updates for monitoring the Healthy People 2020 goals on the incidence of infection with *Campylobacter, Listeria, Salmonella,* Shiga toxin-producing *Escherichia coli* (STEC) O157, *Vibrio*, and *Yersinia* and on the incidence of hemolytic uremic syndrome
- Continued to provide quarterly reports on the incidence of *Salmonella* serotype Enteritidis to support the HHS High Priority Goal that aims to reduce foodborne illness in the population by decreasing the rate of *Salmonella* Enteritidis illness in the population to 1.9 cases per 100,000
- Published the 2015 FoodNet Annual Report
- FoodNet continues to monitor the use of culture-independent diagnostic tests (CIDTs) for enteric bacterial pathogens through active isolate-based surveillance and laboratory surveys conducted in all laboratories serving the FoodNet catchment area.
    - FoodNet data showed that the average annual percentage of bacterial infections under FoodNet surveillance diagnosed by CIDTs increased from 7% in 2012 to 23% in 2016 (Figure 3.1).
- FoodNet 2016 CIDT data have shown that use of CIDTs is increasing, uptake varies by pathogen, and there is growing use of multiplex PCR panels that test for multiple pathogens from one specimen.

Figure 3.1. Percentage of bacterial infections diagnosed by CIDTs, FoodNet, 2012–2014 Compared with 2016



- FoodNet has developed a statistical model to incorporate *Campylobacter* cases diagnosed by CIDTs, incorporating sensitivity and specificity of test type to estimate true cases and analyze incidence trends. Manuscripts describing this model are under journal review.
- Population survey: A total of 86 CATI (computer-assisted telephone interview), 78 web, and 132 mailed pilot surveys were completed at eight sites. Once the analysis of pilot data and questionnaire refinements are complete, we will submit the survey for IRB and OMB approvals. Full data collection began in December 2017.

B. Increasing participation of public health and food regulatory agencies and laboratories in national foodborne surveillance networks

Local and state health departments serve as the foundation of food safety efforts by investigating outbreaks, conducting disease surveillance, and implementing local control measures. FSMA recognizes the critical role of local, territorial, tribal, and state agencies in a national food safety system and incorporates provisions to coordinate, integrate, and enhance surveillance and outbreak response activities at all levels.

CDC provides resources to enhance and integrate critical national surveillance, outbreak detection, and response networks. Scientists need strong data to quickly identify the source of outbreaks and inform prevention efforts. In

CDC provides funding, tools, training, and strategic leadership. These enhancements are expected to do the following:

- Improve the quality of data obtained at the state and local levels
- Ensure that data are analyzed and shared quickly to aid in the rapid response to food safety gaps

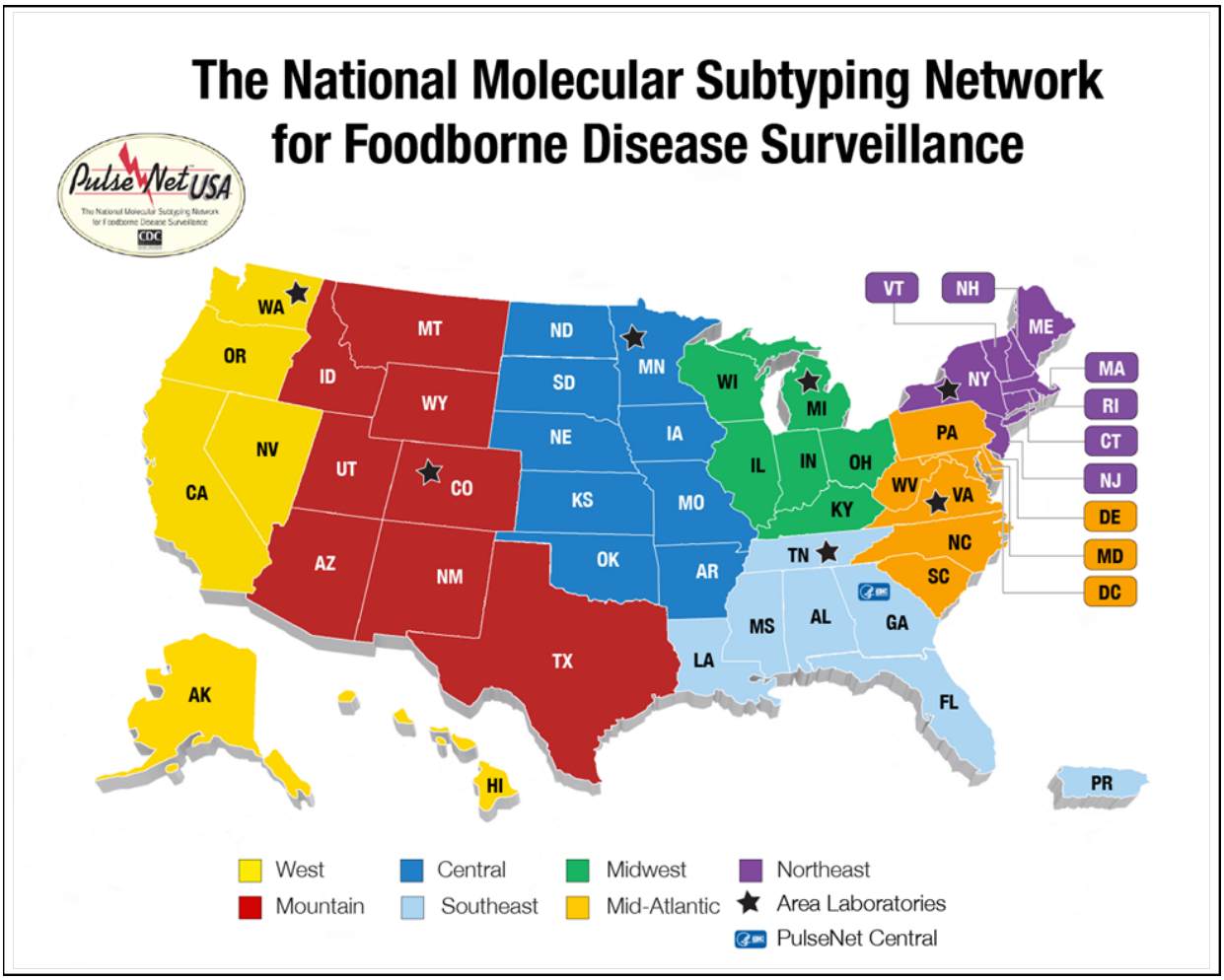
FY 2017, CDC provided approximately $36 million to local and state public health departments through the ELC Cooperative Agreement and the Emerging Infections Programs (EIP) to support critical foodborne illness surveillance efforts. This funding was essential to maintain the capacity to track, detect, investigate, and respond to emerging foodborne disease threats. Other activities to support national networks included the following:

Supporting enteric disease laboratories

PulseNet is a network of local, state, and federal public health laboratories that use PFGE and WGS—a newer method that provides the most accurate bacterial fingerprinting data possible today—to generate DNA fingerprints of foodborne bacteria. PulseNet laboratories can analyze DNA fingerprints of bacteria to quickly detect clusters and outbreaks of foodborne illness that otherwise might have gone unnoticed. Scientists study these DNA fingerprints and post their findings on the PulseNet message board so that laboratories across the country have access to and can use the findings.

PulseNet USA has 83 laboratories in seven regions of the United States (Figure 3.2). It includes public health laboratories in all 50 states (including the U.S. territory of Puerto Rico) and food regulatory laboratories within FDA and USDA.

Figure 3.2. U.S. map showing regions and locations of PulseNet laboratories



PulseNet USA headquarters are at CDC in Atlanta. PulseNet USA works with PulseNet International by supporting and participating in strategic planning meetings, training international participants at PulseNet USA headquarters, and sharing protocols and software customization.

The PulseNet Web Portal was updated in August 2017. This web-based analysis system fully integrates data sets from PulseNet and USDA/FSIS facilities for *Salmonella, Listeria,* STEC, and *Campylobacter*. Analysts, laboratory staff, and epidemiologists are able to perform real-time, integrated analyses of clinical and facility data. In this system, the user may customize reports specifically geared to state users to identify clusters, track outbreaks, and perform data mining. Additionally, WGS information is now being pulled from PulseNet into the portal, allowing users to knoew immediately if WGS has been performed on isolates.

In addition, CDC supports state and local health departments by providing laboratory testing for the confirmation of botulism outbreaks and foodborne outbreaks due to Gram-positive enteric bacteria (*Clostridium perfringens*, *Bacillus cereus*, and *Staphylococcus aureus*).

Whole genome sequencing

Implementation of WGS continued to increase in state public health laboratories in 2017. Both PFGE and WGS are used for subtyping of foodborne pathogens from stool samples and other specimens for outbreak surveillance, with PFGE beginning to be phased out in FY 2018. Progress in implementing WGS during FY 2017 included the following:

- Forty-two laboratories in 37 states have been certified and are performing WGS analysis (as close to real-time as possible), an increase of 15 laboratories since last year.
- The FY 2017 target for sequencing foodborne pathogens in PulseNet of 26,500 isolates was almost met, with sequencing 26,392 isolates (99.6% of target). The breakdown by pathogen is 4,820 STEC and *Shigella*, 19,024 *Salmonella*, 1,863 *Campylobacter*, 603 *Listeria*, 64 *Vibrio*, and 18 *Yersinia* isolates.
- WGS is used routinely for real-time surveillance of listeriosis. Pipelines for analyzing WGS data at CDC and for other federal and state participants have been developed and piloted to be implemented routinely in the states with sequencing capacity.
- WGS is used routinely for the investigation of outbreaks detected by other means caused by *Salmonella,* STEC*,* and *Campylobacter jejuni*.
- Sequences of genomes gathered as part of PulseNet surveillance are being uploaded to a public database at NCBI and made available to the food industry, academia, consumers, and the public, in addition to public health and regulatory agencies, as soon as test results are available.
- CDC is finalizing a WGS-based enteric reference identification database and organism-specific databases for *Campylobacter*, *Escherichia*, *Shigella*, and *Salmonella*. Databases for *Vibrio* and *Clostridium botulinum* are under development.
- Software developer Applied Maths and NCBI are assisting international partners such as PulseNet International in the development of analytic tools.
- CDC has received Clinical Laboratory Improvement Amendments (CLIA) approval to report patient test results derived from WGS for species-level identification of enteric pathogens, including *Listeria, Campylobacter,* and *E. coli.*

- Antimicrobial resistance gene prediction databases were evaluated, and CDC is supplementing the ResFinder tool developed by the Center for Genomic Epidemiology with in-house resistance mutation tools used routinely in the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS).

Metagenomics

Applied research has begun to detect foodborne pathogens through metagenomics approaches, including

- A project of shotgun metagenomic sequencing to identify pathogens in biological samples recovered from human cases of foodborne illness
- A project to identify targets in metagenomics samples that may be used to develop amplicon-based sequencing applications that efficiently and specifically identify and subtype foodborne pathogens, beginning with *Salmonella* and STEC

Optimizing culture methods for CIDTs

In FY 2014, a consortium of five state and local health agencies and CDC was created to develop and test best practices for isolate recovery by state and local public health laboratories that use CIDTs. The group is in the final stages of analyzing data to optimize culture methods for isolation of *Salmonella* and STEC from CIDT-positive specimens.

Establishing the Norovirus Sentinel Testing and Tracking (NoroSTAT) network

Since 2009, CDC has received epidemiologic and laboratory data on norovirus outbreaks from state health departments through the National Outbreak Reporting System (NORS) and CaliciNet (the national norovirus outbreak surveillance laboratory network), respectively. Because of reporting lags and an inability to consistently link records in NORS and CaliciNet, CDC established NoroSTAT in 2012. State health departments that participate in NoroSTAT report suspected and confirmed norovirus outbreaks through NORS and CaliciNet within 7 business days of being notified about the outbreak, thereby providing a near-real-time assessment of norovirus activity. NoroSTAT reporting also allows norovirus strain data uploaded through CaliciNet to be rapidly linked with epidemiologic characteristics of outbreaks reported through NORS by using consistent outbreak identifiers in each system.

During the first 3 years of implementation, five states participated in NoroSTAT: Minnesota, Ohio, Oregon, Tennessee, and Wisconsin. In a recently published *MMWR* article, CDC compared 3 years of data before and after implementation of NoroSTAT. States participating in NoroSTAT reduced their reporting lag to NORS from a median of 22 to 2 days and to CaliciNet from a median of 21 to 3 days. Meanwhile, non-participating states had no change in the reporting lag to NORS, with a median of 26 days both pre- and post-NoroSTAT and a more modest reduction of reporting lag to CaliciNet from a median of 21 to 11 days. CaliciNet reports that were linkable to NORS reports increased from 86% to 95% ($p < .0001$) for NoroSTAT states versus from 29% to 33% ($p = 0.016$) for other states.

NoroSTAT information can be used to

- Quickly evaluate current norovirus outbreak activity
- Compare outbreak activity with activity in previous years
- Assess strain-specific characteristics of norovirus outbreaks, including the impact of new strains on outbreak frequency and severity

Increased food safety funding enabled expansion of NoroSTAT to seven states in August 2015 with the addition of Michigan and South Carolina and further expansion to nine states in August 2016 with the

addition of Massachusetts and Virginia. The nine states currently participating in NoroSTAT include approximately 64 million residents, representing 20% of the U.S. population.

Summaries of data reported through NoroSTAT are publicly posted on the CDC NoroSTAT website and updated monthly.

NoroSTAT FY 2017 accomplishments included

- Completing 5 years of enhanced surveillance through the NoroSTAT network, including expansion from five initial sites to nine currently participating sites
- Reporting 1,234 norovirus outbreaks by NoroSTAT-participating states in the most recently completed seasonal year (August 2016 – July 2017)
- Rapidly Identifying and assessing the impacts of a recombinant GII.4 Sydney 2015 strain of norovirus through NoroSTAT surveillance
- Improving the CDC NoroSTAT website, including monthly updates of data, graphs, and text interpretations to assist with rapid dissemination of surveillance data to the public

Enhancing CaliciNet

In FY 2017, data on 768 laboratory-confirmed norovirus outbreaks were uploaded to CaliciNet. Of these, 651 (85%) outbreaks were uploaded by the 33 CaliciNet-certified laboratories in 28 states and the District of Columbia, and 117 (15%) outbreaks from the remaining 22 states were typed and uploaded by the five regional CaliciNet support centers. Of the norovirus outbreaks reported in FY 2017, 15% were epidemiologically identified as foodborne. The predominant norovirus genotype in the 2016–2017 norovirus seasonal year was a new recombinant virus, GII.P16-GII.4 Sydney, which almost completely replaced the GII.4 strain (GII.Pe-GII.4 Sydney) that had predominated in the previous 4 years. A dual typing (partial polymerase and partial capsid gene) protocol for noroviruses has been shared with all CaliciNet-certified laboratories, which are on schedule to begin this novel typing on norovirus outbreak samples in FY 2018.

Shigella *surveillance*

Shigella staff in CDC's Waterborne Disease Prevention Branch (WDPB) continued to work in collaboration with PulseNet, NARMS, and NORS to support states in investigating, facilitating antimicrobial resistance testing, and reporting outbreaks to NORS. WDPB staff provided epidemiologic consultation, reviewed interview forms, facilitated molecular and antibiotic susceptibility testing, created prevention and communication materials for the general public and specific risk groups, and began developing a shigellosis outbreak investigation toolkit for state and local partners. *Shigella* cluster detection and management processes at CDC were streamlined via improvements in internal and external communications, data collection and storage, and information sharing (e.g., using the System for Enteric Disease Response, Investigation, and Coordination [SEDRIC]). This information was used in investigations with states; in Computer-aided Ontology Development Architecture (CODA) detection algorithms; and in development of standardized operating procedures to systematize daily procedures for cluster detection, management, and closeout.

From October 2016 to September 2017, CDC led 11 multistate shigellosis outbreak and cluster investigations and assisted with 6 single-state shigellosis outbreak and cluster investigations. Outbreak case counts ranged from 5 to 277 and were detected in as many as 37 states and Puerto Rico. PulseNet assisted with identifying 13 clusters and outbreaks. Although information on specific risk behaviors was

not collected in each outbreak, at least 7 shigellosis outbreaks included case-patients who self-identified as men who have sex with men (MSM); all but one of these outbreaks were due to antibiotic-resistant strains.

NARMS testing was done for 16 outbreaks. Resistance to ampicillin and/or trimethoprim/sulfamethoxazole was seen among case-isolates from 13 outbreaks, of which 8 showed additional resistance to azithromycin and/or ciprofloxacin. Cephalosporin treatment failure was documented in one MSM-associated outbreak, and another was notable for case-isolates harboring quinolone resistance mechanisms not previously seen in the United States. In April 2017, CDC published a Health Alert Network (HAN) Health Advisory (CDCHAN-00401) to communicate the potential for reduced susceptibility to ciprofloxacin among strains harboring these resistance mechanisms and provided relevant clinical, laboratory, and public health guidance.

In FY 2017, for the first time at CDC, next-generation sequencing was used to augment PFGE and epidemiologic data from three shigellosis investigations. Sequencing led to

- Refinements in outbreak case definitions that were not possible with PFGE
- Establishing relatedness between case-isolates from case-patients for whom linkage could not be established on the basis of epidemiologic data alone
- Early insights into outbreak source and mode of transmission
- Clarifying the role of concurrent risk factors, such as self-identifying as MSM and history of international travel, in sustaining disease transmission

Additional *Shigella* program highlights included the following:

- Developing and piloting a supplemental questionnaire focused on identifying risk factors for sexual transmission, assessing clinical treatment and outcomes, and guiding public health interventions and communication efforts, with technical assistance from CDC's Division of STD Prevention
- Conducting Epi-Aid 2017-003, "Undetermined risk factors and modes of transmission for *Shigella sonnei* infection among residents of Genesee and Saginaw Counties – Michigan, 2016" in collaboration with local, state, and federal partners including PulseNet, NARMS, and the Geospatial, Research, Analysis, and Services Program at the Agency for Toxic Substances and Disease Registry (ATSDR)
- Leading a roundtable discussion at the 2017 Council of State and Territorial Epidemiologists (CSTE) Annual Conference to assess the needs of state and local health departments regarding the investigation of outbreaks associated with childcare settings and MSM
- Updating content and references for the *Shigella* and hygiene pages on the CDC website
- Starting development of a website for stakeholders involved in childcare with information on sanitation and hygiene, especially relating to prevention of enteric illness
- Continuing collaborating with CDC's Division of STD Prevention and Georgia State University to assess knowledge, attitudes, and practices of MSM regarding shigellosis, and developing and validating evidence-based communication strategies to prevent sexual transmission of shigellosis
- Supporting a New York City Department of Health and Mental Hygiene project to identify risk factors for and clinical outcomes among patients infected with azithromycin-resistant shigellosis

Developing CryptoNet

In FY 2017, CryptoNet, a molecular typing system (similar to PulseNet) that targets *Cryptosporidium* and integrates molecular typing and traditional epidemiologic data, continued to progress. CDC collaborated with state public health departments, who continued to send outbreak and sporadic case specimens for molecular analysis along with corresponding epidemiologic data to CDC. Funding was provided to states through the ELC Cooperative Agreement to develop a regional laboratory model, with some states funded to support regional typing (Minnesota, Nebraska, and Wisconsin in FY 2016; addition of Ohio in FY 2017) and other states funded to support shipping specimens to regional laboratories for typing (Alabama, Maine, New Hampshire, and Tennessee).

Key accomplishments from the program include the following:

- Improved collaboration with state partners as evidenced by an increased number of clinical specimen submissions (calendar year [CY] 2016, n=461 specimens submitted; CY 2017, n=223 specimens submitted, to date)
- Developed an access database to house epidemiologic data submitted by states
- Held monthly calls with CryptoNet states to set epidemiology and laboratory goals and track progress, including tracking of receipt of a standard CryptoNet form with specimen submissions
    - CY 2016: 284 specimens positive for *Cryptosporidium*, 226 case report forms received (80%)
    - CY 2017: 113 specimens positive for *Cryptosporidium*, 49 case report forms received (43%) as of September 2017
- Trained representatives from public health laboratories in Alabama, Nebraska, Ohio, and Tennessee (CY 2016) in how to conduct Sanger-based amplicon sequencing and subtyping

Cholera and Other Vibrio *Illness Surveillance (COVIS)*

Established in 1988, COVIS collects surveillance data on domestic foodborne and waterborne cases of cholera and vibriosis from public health departments in all 50 states and the District of Columbia. In FY 2017, CDC continued to oversee the COVIS electronic database as well as did the following:

- Continued to engage state public health agencies and laboratories in COVIS through routine surveillance and cluster and outbreak investigations
- Revised the COVIS case report form (CRF) and COVIS electronic database to capture data for cases detected by CIDTs as outlined in the updated CSTE case definition
- Continued to host a national workgroup of foodborne epidemiologists to improve communication across states to aid in outbreak and traceback investigations and to implement the use of the new COVIS CRF
- Used national surveillance to identify and close contaminated shellfish harvest areas associated with cases in multiple states
- Continued timely data sharing of case reports with FDA every week
- Expanded engagement with the Interstate Shellfish Sanitation Conference (ISSC) by developing data sharing guidelines and providing subject matter expertise at ISSC general and committee meetings

National Botulism Surveillance System

Since 1973, CDC, in partnership with CSTE, has maintained the National Botulism Surveillance System for intensive surveillance for cases of botulism in the United States. The National Botulism Surveillance System collects reports of all confirmed botulism cases in the United States and is continuously monitored for early detection of outbreaks. In FY 2017, CDC did the following:

- Continued to oversee and manage the botulism surveillance and clinical consultation systems. More than 20 epidemiologists from the Division of Foodborne, Waterborne, and Environmental Diseases consulted on more than 150 suspected botulism cases, resulting in 64 antitoxin releases.
- Provided epidemiologic assistance to the Ethiopia Ministry of Health for one outbreak in April 2017 and to the California Department of Public Health for two outbreaks in April and May 2017
- Submitted 15 manuscripts, including 6 systematic reviews, to a *Clinical Infectious Diseases* supplement dedicated to botulism. These manuscripts provide data that will inform recommendations in CDC's clinical guidelines.

Hepatitis A surveillance

As part of CDC's National Notifiable Diseases Surveillance System (NNDSS), viral hepatitis case reports are received electronically from U.S. state and territorial health departments via CDC's National Electronic Telecommunications System for Surveillance (NETSS), a computerized public health surveillance system that provides weekly updates to CDC.

Despite protection among young persons, due to universal infant vaccination since 2006, many older adults have not been vaccinated and are therefore susceptible to infection. From 2011 to 2013, an increase in the number of reported cases of hepatitis A virus (HAV) infection was observed, with the increases in 2013 due to a foodborne outbreak associated with frozen pomegranate arils (seed pods) imported from Turkey. In 2014, 1,239 cases of HAV were reported, representing a 30.4% decrease from 2013. In 2015, reported cases increased to 1,390 (a 12.2% increase from 2014), with three hepatitis A outbreaks reported. Data from 2016 are still being analyzed; however, an increase in the number of HAV cases in 2016 is expected due to the following two large foodborne outbreaks:

- In July 2016 in Hawaii, 292 people were infected by eating contaminated frozen scallops imported from the Philippines. Web postings communicated information to the public, and multiple calls with the food industry and FDA led to a recall of the product.
- During July–October 2016, 144 people from nine states were infected after eating frozen strawberries imported from Egypt. Multiple calls between CDC, FDA, and the food industry led to successful voluntary recalls of the implicated product. The public was informed with web postings by CDC and FDA and selected states.

CDC's Division of Viral Hepatitis Laboratory is working to build Global Hepatitis Outbreak and Surveillance Technology (GHOST) capacity for HAV molecular surveillance and outbreak investigation. The goal is to enable state health departments to conduct their own viral sequencing to assist in outbreak investigations. Currently, this technology is used for hepatitis C virus outbreaks. The laboratory aims to have a new GHOST module for HAV in FY 2018.

Trichinella *sp. outbreak investigation assistance*

In FY 2017, epidemiologists from CDC's Parasitic Diseases Branch (PDB) helped state and local health departments in Alaska and California investigate trichinellosis outbreaks associated with eating raw meats from multiple sources (walrus, home-raised swine, and bear). Leftover raw meat samples from the implicated meals were tested by CDC's diagnostic parasitology laboratory and positively identified as

Trichinella sp. PDB tailored prevention and control strategies for each situation based on the *Trichinella* sp. involved and the population affected.

***Technical support to Hawaii for foodborne* Angiostrongylus cantonensis**

In FY 2017, PDB epidemiologists provided technical support to the Hawaii State Department of Health for foodborne angiostrongyliasis (rat lungworm disease). Hawaii had an increased number of cases reported during FY 2017, including more cases than in 2016 from the island of Maui, which generated extensive local concerns about the disease. Technical support included developing health education materials, including creating an animated life cycle explaining how humans are exposed to rat lungworms. CDC also helped develop epidemiologic studies to explain the ecology of rat lungworm disease in Hawaii. Additionally, Hawaii received funding through the ELC grant to improve laboratory capacity to diagnose angiostrongyliasis.

***Technical support to Colorado for investigation of* Ascaris suum**

In FY 2017, PDB epidemiologists provided technical support to the Colorado Department of Public Health and Environment to investigate potential foodborne exposure to *Ascaris suum* (pig roundworms) from an organic farm that supplied produce to community-supported agriculture cooperatives, local schools, and childcare centers. Educational materials previously developed by PDB regarding *Ascaris suum* exposure for home-raised, small-scale swine farmers were pilot tested during this investigation.

C. Sharing surveillance information faster among federal, state, and local agencies

National Outbreak Reporting System

NORS receives foodborne outbreak surveillance data from public health departments in all 50 states, the District of Columbia, and each U.S. territory as well as from CDC's Outbreak Response and Prevention Branch (ORPB), which investigates multistate foodborne disease outbreaks.

- In 2016, NORS received 828 foodborne outbreak reports. These reports included information on 13,255 illnesses, 755 hospitalizations, and 15 deaths associated with foodborne illness that occurred in the United States that year.
- NORS data are key to attribution studies conducted by CDC, FDA, and USDA/FSIS. NORS staff members are working with their counterparts in the states and in ORPB to develop ways to improve data quality to strengthen these studies.
- NORS and NARMS continue to link data from the two surveillance systems to provide outbreak investigators with summary resistance data and to improve reporting by states to NARMS.
- The Foodborne Outbreak Online Database (FOOD Tool) provides public access to NORS foodborne disease outbreak data. It includes outbreak data from 1998 through 2016 and can be searched by year, state, the location of preparation, food or food ingredient, and pathogen.

NORS staff members are working with state public departments that have low outbreak reporting rates on ways to improve and reduce barriers to reporting. Part of this effort includes a redesign of the data transmission interface to make it more user-friendly to state, local, and territorial public health staff. This redesign should be launched by the end of the calendar year 2017.

NORS staff planned to incorporate the FOOD Tool in December 2017 into the newly created "NORS Dashboard." The NORS Dashboard will provide public access to foodborne, waterborne, person-to-person, animal contact, and environmental contamination outbreak data. All of the foodborne outbreak data from the FOOD Tool will be available in the NORS Dashboard.

National Antimicrobial Resistance Monitoring System for Enteric Bacteria

NARMS, established in 1996, is a collaboration between CDC, FDA's Center for Veterinary Medicine (CVM), USDA/FSIS, and state and local health departments. The NARMS program at CDC monitors antimicrobial resistance among enteric bacteria isolated from humans. Other components of NARMS include surveillance for resistance in enteric bacteria isolated from retail meats, conducted by FDA/CVM in collaboration with selected state health departments, and surveillance for resistance in enteric bacteria isolated from animals, conducted by USDA ARS and FSIS. The goals of NARMS include

- Monitoring trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals
- Disseminating timely information on antimicrobial resistance to stakeholders in the United States and abroad to promote interventions that reduce resistance among foodborne bacteria
- Conducting research to better understand the emergence, persistence, and spread of antimicrobial resistance
- Assisting FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals
- At CDC, NARMS conducts surveillance among the entire U.S. population. Public health laboratories in each state systematically select every 20th nontyphoidal *Salmonella, Shigella,* and *E. coli* O157 isolate as well as every *Salmonella* ser. Typhi, *Salmonella* ser. Paratyphi A, and *Salmonella* ser. Paratyphi C isolate received. These isolates are sent to CDC for antibiotic susceptibility testing.
- Public health laboratories in the 10 states that participate in CDC's FoodNet forward a frequency-based sample of *Campylobacter* isolates to CDC for susceptibility testing. In 2009, NARMS began susceptibility testing of all *Vibrio* isolates other than *V. cholerae*. Beginning in 2011, NARMS improved testing of isolates from enteric disease outbreaks.
- In 2012, NARMS launched a web-based surveillance database for human isolates that was adopted by more than 95% of states within 6 months. Since 2013, states have been able to view and download results for their isolates.
- In August 2015, NARMS launched NARMS Now: Human Data, an interactive, public access tool that allows users to view and download the latest resistance data on enteric bacteria from humans. Isolates received by NARMS are tested to determine the minimal inhibitory concentration for each antimicrobial agent on the NARMS panel. Each year, NARMS reports the susceptibility results for human isolates in an annual report published by CDC and in an Integrated Report published by FDA/CVM. In addition, results from NARMS surveillance and studies are published in peer-reviewed journals.

Significant accomplishments in FY 2017 included the following:

- CDC NARMS continued to work with federal NARMS partners at FDA and USDA to integrate surveillance data.
    - Developed the 2015 NARMS Integrated Report published in October 2017

- Provided human surveillance data to FDA NARMS data for incorporation into the following:
  - NARMS Now Integrated Data (publicly accessible data)
  - Improved interactive data visualization tool (released with the 2015 Integrated Report)

- NARMS worked closely with PulseNet to provide antimicrobial resistance funding to state and local health departments via the ELC grant.
  - NARMS distributed over $9 million to support WGS capacity to improve detection of and surveillance for antibiotic-resistant intestinal bacteria found in ill people.
  - Funding paid for four new whole genome sequencers and maintenance support of up to 32 sequencers funded in the previous year. Funding also went toward salaries of staff scientists who work toward conducting whole genome sequencing on bacteria, including *Salmonella, Shigella,* and *Campylobacte*r. These advancements will allow for faster identification and response to foodborne outbreaks and rapid identification of known markers of antibiotic resistance.
- NARMS worked closely with FoodNet to provide funding for the collection of exposure and outcome epidemiologic data associated with antimicrobial resistance in FoodNet sites via the ELC grant.
  - NARMS distributed over $1.2 million to support epidemiologic staff salaries and information technology systems to transmit data to CDC.
  - Data collection and transmission are to commence in January 2018 as part of enhanced case exposure ascertainment.
  - Epidemiologic data, such as international travel history, will be paired with resistance information obtained from WGS to examine associations.
- NARMS worked closely with federal and other external partners to identify enteric pathogen isolates containing *mcr* genes from U.S. residents.
  - In 2017, NARMS collaborated with state and local public health departments to investigate 12 cases of *Salmonella* and 1 case of STEC containing *mcr* genes to better understand risk factors for *mcr* acquisition, to assess the risk of transmission to others, and to provide public health recommendations.
  - In several *mcr* cases associated with international travel, NARMS has worked with international partners to share information and enable local investigation.
  - All isolates sequenced by NARMS to date have been screened for the five known *mcr* genes and their variants.
- NARMS identified the emergence of *Shigella* that have plasmid-mediated quinolone resistance genes and ciprofloxacin minimum inhibitory concentrations in the susceptible range. Because of the concern that these strains may have clinically significant reduced susceptibility to fluoroquinolone antibiotics, CDC scientists
  - Issued an official health advisory
  - Summarized and presented data to the Clinical and Laboratory Standards Institute (CLSI), which develops clinical laboratory testing standards
- NARMS developed and published estimated incidence of resistant *Salmonella* infections for the first time.
  - NARMS routinely reports the percentage resistant of a subset of isolates.
  - Incidence of resistant *Salmonella* is needed to determine burden and trends.

- To mark the 20th anniversary of NARMS, scientists from CDC, FDA, and USDA wrote an article that describes the role of NARMS in providing data that help address the problem of antimicrobial resistance and shows how such a program can have broad positive impacts on public health through surveillance, research, and outbreak activities.
- NARMS continued to make antibiotic susceptibility testing data accessible in SEDRIC.
  - The latest data are uploaded every week.
  - SEDRIC allows federal and state public health partners to view the latest resistance data for isolates that are a part of outbreaks.
  - Antibiotic susceptibility testing data can aid hypothesis generation during outbreak investigations.
- NARMS and NORS databases continued to be linked to aid attribution studies to determine
  - The food and animal sources for resistant *Salmonella* transmitted to humans
  - The difference between foods causing resistant infections versus foods causing susceptible infections
- NARMS enhanced linking to PulseNet by
  - Linking WGS identifiers of PulseNet records to NARMS isolates and importing these data into the NARMS database, so sequences housed by NCBI can be queried among NARMS isolates sequenced at the state
  - Importing PulseNet records of non-NARMS isolates into the NARMS database so isolates sequenced at the state (but not shipped to NARMS) can be analyzed for presence of resistance genes
  - Now linking daily through the Data Broker, allowing for greater efficiency
- NARMS developed an automatic resistance-detection algorithm and information technology platform to help quickly identify concerning resistant isolates and emerging resistance trends.
- NARMS made publicly accessible data more timely by releasing preliminary data to NARMS Now: Human Data.
  - Isolate data for non-closed-out years can be downloaded within 3 months of data approval.
  - NARMS is currently working on incorporating multidrug resistance patterns into the interactive displays.
- All 2015 nontyphoidal *Salmonella* were sequenced, and sequencing of all 2016 *Salmonella* and select other pathogens received by NARMS is in process.
  - Variables were refined in the database to house the identified resistance genes and variables that predict the phenotypic resistance profiles based on the genetic data.
- The CDC NARMS 2015 Human Isolates Surveillance Report was developed (to be published in fall 2017).
  - The NARMS annual report will include WGS data of bacteria from people with nontyphoidal *Salmonella* infections. Genetic data provided by this sequencing can be used to identify resistance genes and predict antimicrobial resistance.
  - These data include a list of resistance genes (and predicted resistance) identified through WGS of 2015 nontyphoidal *Salmonella* submitted to NARMS.

D. Identifying and proposing solutions to eliminate key barriers at federal, state, and local levels to improve foodborne illness surveillance

National Center for Environmental Health enhancements

CDC's National Center for Environmental Health (NCEH) is continuing to provide free, online, interactive training on conducting environmental assessments during foodborne illness outbreak investigations. Since 2014, over 5,700 users have registered to take this training. In 2017, 781 users registered for the training course. NCEH is continuing to collect outbreak environmental assessment data through the National Environmental Assessment Reporting System (NEARS). NEARS is a surveillance system that enables ongoing, systematic collection, management, analysis, interpretation, and dissemination of foodborne outbreak environmental assessment data. NEARS began data collection in April 2014.

Program participation in NEARS has increased over 100% since its 2014 launch (from 11 to 26 programs) and has increased 23% in the past year (from 21 to 26 programs).

- Sixteen state programs currently participate in NEARS: Alaska, California, Connecticut, Delaware, Iowa, Massachusetts, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, South Carolina, Tennessee, Washington, and Wisconsin.
- Ten local programs currently participate in NEARS: Chicago Department of Public Health (Illinois), Coconino County Public Health Services District (Arizona), Davis County Health Department (Utah), Fairfax County Health Department (Virginia), Harris County Public Health Department (Texas), Jefferson County Public Health Department (Colorado), Kansas City Health Department (Missouri), New York City Department of Health and Mental Hygiene (New York), Sharon Health Department (Massachusetts), and Southern Nevada Health District (Nevada).

CDC staff are working to integrate and improve coordination and linkage of foodborne outbreak data from NEARS and NORS. In 2017, activities included

- Finalizing a plan to move the NEARS data collection system to the NORS information technology platform
- Linking and conducting data analyses of 2014–2016 NORS and NEARS data. These analyses revealed that 86% of the outbreaks reported into NEARS were also in NORS.
- Releasing reports summarizing NEARS data in aggregate and for each participating NEARS site for 2014 and 2015 on the CDC website
- Working with the National Network of Public Health Institutes (NNPHI) to develop and implement a Foodborne Illness Outbreak Investigation Environmental Assessment Training and Certification Program. This program builds the capacity of state and local food safety program staff to conduct environmental assessments during outbreak investigations. Additionally, information about NEARS is included in the program and an Environmental Assessment Toolkit has been developed to enhance the program. The National Environmental Health Association will host this program and will serve as the credentialing body for certification. The program will be free and available online in 2017.
- Finalizing a plan to make NEARS data publicly accessible to federal, state, and local food safety partners, food industry, academia, consumers, and the public on the Data.CDC.Gov website. This website offers built-in visualization tools, interactive dashboards, web applications, and unique user experiences that will help disseminate foodborne outbreak environmental assessment data reported to NEARS. These data will be online by January 2018.

The Environmental Health Specialists Network (EHS-Net)

EHS-Net is a collaborative forum of environmental health specialists who work together to improve environmental health practice by developing and sustaining a network of environmental health specialists who collaborate with epidemiologists, laboratorians, and other public health professionals to conduct practice-based research to identify and prevent environmental risk factors contributing to foodborne illness.

- In 2015, two sites were added to EHS-Net, bringing the total number of sites to eight. These include California; Harris County, Texas (the third most populous U.S. county); Minnesota; New York City; New York State; Southern Nevada Health District (includes 70% of Nevada's population); Rhode Island; and Tennessee.
- EHS-Net sites are conducting activities that increase collaboration and communication between epidemiologic and environmental health programs during foodborne illness outbreak investigations, ensuring that environmental assessments are conducted during foodborne illness outbreak investigations, and reporting those environmental assessment data into NEARS. EHS-Net–funded research projects for food safety activities are under the jurisdiction of departments of health or other agencies responsible for regulatory oversight of retail food service, including restaurants, delis, cafeterias, and schools. Some of their activities include
  - Increasing the percentage of staff who take training on conducting environmental assessments during outbreaks (Rhode Island)
  - Facilitating joint training on outbreak investigation data reporting to CDC (NORS and NEARS) for environmental and epidemiology staff, and implementing a process to ensure data validation for these data (Tennessee)
  - Increasing the number of outbreaks in which environmental assessments are conducted (all sites)

Improving identification of outbreak contributing factors

Contributing factors are conditions that enable or amplify an outbreak, such as improper food preparation practices that lead to pathogen cross-contamination. Identification of contributing factors is a key component of outbreak investigations to understand and prevent foodborne illness and outbreaks. NCEH is focused on improving the rate of identifying outbreak contributing factors.

- NCEH released its first publication based on NEARS data in 2017. This publication describes outbreak investigation characteristics linked with the identification of outbreak contributing factors. These characteristics include timely and comprehensive environmental assessments. These findings highlight the need for strong environmental health and food safety programs that have the capacity to complete such environmental assessments.
- NCEH also released an infographic describing outbreak contributing factors and their importance, and how food safety programs can improve their identification of contributing factors during outbreak investigations.
- NCEH promoted these documents with its target audience.

II. Evaluating and Improving Surveillance Systems

To implement FSMA requirements to evaluate and improve surveillance systems, CDC has improved epidemiologic tools and microbiological methods for obtaining quality exposure data and identifying and classifying cases. Selected CDC activities include the following:

A. Tracking and analyzing laboratory use of CIDTs

Foodborne Diseases Active Surveillance Network

- Continued to measure effects of CIDTs on foodborne illness surveillance
- Continued to collect information on laboratory methods used to diagnose FoodNet pathogens
- Continued to collect reports of infections diagnosed using CIDTs

B. Developing better methods to detect, investigate, respond to, and control multistate foodborne outbreaks

System for Enteric Disease Response, Investigation, and Coordination

SEDRIC is a customized, commercial, web-based software from Palantir Technologies. It facilitates collaborative multistate enteric disease outbreak investigations by integrating surveillance data in real time, visualizing outbreak data rapidly, and providing a secure platform for collaboration.

Access to SEDRIC is provided free of charge to state, local, and other federal users. SEDRIC runs via a browser window and does not require the installation of additional software. The current system provides users access to outbreak dashboards, time trend maps, customizable traceback diagrams, historical human and non-human isolates in PulseNet, antimicrobial resistance information, and patient line list management capabilities. Progress in 2017 included the following:

- Successful deployment continued, with more than 600 (350 active) SEDRIC users from CDC, all 50 states (plus Puerto Rico and Guam), FDA, and USDA/FSIS.
- States have obtained cluster-specific outbreak information 24–48 hours faster using SEDRIC than through typical laboratory communications.
- Eight SEDRIC training sessions covering approximately 200 users were conducted, with 46 states having completed at least introductory training (in addition to 9 local jurisdictions) and 21 states having completed advanced training (in addition to 6 local jurisdictions).
- Routine integration of data was completed for all of the PulseNet pathogens into SEDRIC.
- The ability to use SEDRIC to rapidly collect epidemiologic data from ill persons via a web-based questionnaire tool was investigated. This includes the ability to deploy online the National Hypothesis Generating Questionnaire, which collects information on more than 300 food items and other exposures commonly seen in multistate outbreaks. The initial mapping of variables will be completed by December 2017, and future data integrations are planned for FY 2018.
- A generic line list editor was created to manage outbreaks that are in a single state or not PulseNet pathogens. The line list editor will be tested and deployed in the first quarter of FY 2018.

C. Capacity-building for enhanced epidemiologic activities

Through the ELC Cooperative Agreement, targeted funds are provided to help improve grantees' ability to detect, investigate, and control enteric disease outbreaks through the OutbreakNet Enhanced and

FoodCORE (Foodborne Diseases Centers for Outbreak Response Enhancement) programs. There are currently 36 sites funded as part of OutbreakNet Enhanced and FoodCORE, including 8 new OutbreakNet Enhanced sites that were funded for the 2017–2018 grant year.

Foodborne Diseases Centers for Outbreak Response Enhancement

The FoodCORE centers work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. Currently, 10 centers participate, covering about 18% of the U.S. population.

- FoodCORE supports enhanced laboratory, epidemiologic, and environmental health activities related to outbreak surveillance and response. Key findings from FoodCORE include the fact that from the first year of the program (October 2010) to the end of the seventh year (September 2017), the centers completed molecular subtyping for a higher proportion of *Salmonella*, STEC, and *Listeria* isolates (83% versus 95%) and reduced the average time to complete testing from a median of 11.5 to 4.5 days. The centers attempted epidemiologic interviews with more *Salmonella*, STEC, and *Listeria* case-patients (88% versus 98%), and the average time to attempt interviews was maintained at less than 2 days. During the fifth year, more than 375 environmental health assessments were conducted.
- FoodCORE findings, data, and lessons learned have been presented at various national meetings and conferences, and in partnership with other food safety programs. Updated programmatic findings, including the fifth year of data and model practices, were presented at the CSTE Annual Conference in June 2017; at the National Conference on Health Communication, Marketing, and Media in August 2016; at the American Evaluation Association (AEA) Annual Conference in October 2016; and at the American Public Health Association (APHA) conference in November 2016. Data summaries and additional model practices will be made publicly available during FY 2018. FoodCORE center staff also presented their own center-specific experiences at a variety of local, state, and national conferences, meetings, and training sessions. Data and summary information from previous grant years are publicly available on the FoodCORE website and updated annually.

OutbreakNet Enhanced initiative

OutbreakNet Enhanced is a CDC program started in August 2015 that provides support to state health departments to improve their capacity to detect, investigate, control, and respond to foodborne disease outbreaks. OutbreakNet Enhanced is coordinated by CDC's Capacity and Implementation Team and funded through the ELC Cooperative Agreement.

- Currently, 26 states participate as OutbreakNet Enhanced sites. States use funds to hire additional epidemiologists and students to interview people with foodborne illness and travel to training events and conferences to build on outbreak response skills. The intent of funded activities is to implement faster and more complete review of surveillance data, improve interviewing and data sharing, and document improvements in performance metrics. Priority areas for improvement are detection and rapid interviewing of *Salmonella*, STEC, and *Listeria* cases. The ability to detect and respond to other bacterial, viral, and parasitic foodborne disease outbreaks is also strengthened. OutbreakNet Enhanced sites collaborate with each other and with CDC to share experience and insights to improve foodborne disease outbreak response.
- During FY 2017, OutbreakNet Enhanced sites submitted the first annual metrics reports for process evaluation. Data and summary information will be publicly available on the OutbreakNet Enhanced website during FY 2018 and will be updated annually. Findings from the program were presented at the CSTE Annual Conference in June 2017 and at CDC's Evaluation Day in September 2017.

Improving cyclosporiasis surveillance and outbreak investigation resources

CDC's Parasitic Diseases Branch (PDB) coordinates national surveillance and outbreak response for cyclosporiasis.

- As of October 4, 2017, CDC had been notified of 1,065 laboratory-confirmed cases of cyclosporiasis with illness onset in 2017. Of these, 597 (56%) had illness onset on/after May 1 and became infected in the United States. These 597 persons were from the following 36 states: Arizona, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York (including New York City), North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.
- Deployment of the web-based cyclosporiasis national hypothesis-generating questionnaire was expanded from 15 states in 2016 to 35 states and New York City in 2017. This expansion allowed for quicker analysis and dissemination of extended food exposure data to state and federal partners during the summer 2017 cyclosporiasis outbreak season. Receiving extended food exposure data electronically also allowed CDC to receive and analyze the data more quickly by eliminating the scanning/faxing of paper forms from states to CDC, and the data entry step at CDC.
- CDC held weekly conference calls with FDA colleagues to provide updates on the case and cluster investigations. CDC participated in FDA's weekly CORE Response Tactics calls regarding cyclosporiasis cluster traceback activities. CDC also held a 50-state call in late July and again in mid-August to update all state and public health partners on case counts and current investigations. CDC also held multiple individual state calls with Connecticut, Michigan, North Carolina, Tennessee, and Texas, among others, to discuss cluster investigations as needed.
- A Health Alert Network Health Advisory was released in early August alerting public health partners, healthcare providers, and hospitals about an increase in cyclosporiasis cases during the 2017 season. The advisory also provided guidance on the testing and reporting of cyclosporiasis cases. The advisory was sent out through multiple communication channels, including state HAN coordinators, Epi-X (Epidemic Information Exchange), GovDelivery, and the Clinician Outreach and Communication Activity (COCA) listserv and social media page, and was posted on CDC's Emergency Preparedness and Response website—reaching an estimated 110,000 subscribers or more.
- Formal web postings for the 2017 season began in mid-August when an Epi-Aid request was received from Texas to assist in the investigation of a cyclosporiasis cluster. These web postings were updated weekly.
- In August, the Texas Department of State Health Services requested CDC assistance with the investigation of an outbreak of cyclosporiasis associated with a Mediterranean restaurant in the Houston area. Three Epidemic Intelligence Service (EIS) officers and a staff member from PDB deployed on Epi-Aid 2017-030 "Undetermined source for *Cyclospora cayetanensis* infection among residents eating at Restaurant A – Houston city, Harris County, Fort Bend County, and Brazoria County, Texas, 2017" to assist in the investigation, which included developing a restaurant-specific questionnaire and conducting a case-control study. Final numbers included 22 cases linked to the outbreak that were identified and interviewed and 61 controls that were recruited.
- There are currently no molecular methods with which to link *Cyclospora* cases to each other or to particular food vehicles or sources, which makes it extremely difficult to characterize the extent of particular outbreaks or to distinguish between multiple concurrent outbreaks. As part of a *Cyclospora* advanced molecular detection project that began in 2014, the PDB laboratory sequenced the near-complete genomes of *Cyclospora* samples obtained during recent and more distant outbreaks. Using

comparative genomic sequence analysis, variable regions that could potentially be useful for a typing tool were identified. Activities in 2017 included evaluating these regions for epidemiologic value. Pending continued funding, plans call for the continued evaluation of these regions for epidemiologic value and development and evaluation of a typing strategy for outbreak investigations.

- Eighteen states received food safety funds through the ELC funding mechanism for cyclosporiasis activities. These ELC funds are used to
  - Increase detection of cyclosporiasis by using a multiplex PCR gastrointestinal pathogen panel test to screen stool specimens from patients with symptoms indicative of cyclosporiasis
  - Retrieve positive stool specimens from primary diagnostic laboratories and forward them to CDC for confirmation
  - Assist CDC with validation of genotyping markers

  The PDB laboratory has received 51 specimens from eight states.
- A PDB surveillance epidemiologist presented on "Use of the Cyclosporiasis National Hypothesis Generating Questionnaire by U.S. Public Health Jurisdictions, 2014–2016" at the 2017 CSTE annual meeting.
- More information about *Cyclospora* can be found on CDC's *Cyclospora* pages.

Microbial quality of irrigation water

CDC's Waterborne Disease Prevention Branch completed work on a 2-year research project in collaboration with the Center for Produce Safety (CPS). The project investigated the use of a large-volume water sampling technique, dead-end ultrafiltration (DEUF), and methods for detecting pathogens (e.g., *Salmonella, Cryptosporidium*) and alternative microbial water quality indicators for irrigation water. Water samples were collected from May 2015 through April 2016 from three irrigation ponds located on southeast Georgia farms to evaluate FSMA recommendations for water quality monitoring, including the effect of collection method, seasonality, and water quality parameters on pathogen detection. Key findings and recommendations included the following:

- DEUF procedures were established for irrigation water, and recovery efficiencies for the DEUF method were determined for pathogenic bacteria, human parasites, and human-specific fecal bacteria and viruses from irrigation water.
- The DEUF method increased detection rates of pathogens (*Salmonella* and *Cryptosporidium*) and alternative indicators (bacteriophages, human-specific fecal markers) compared with 1-L grab samples.
- DEUF is recommended for advanced monitoring of irrigation water when target analytes are suspected to be present at low concentrations, as with pathogens or alternative indicators such as fecal source tracking markers.
- The human-specific fecal marker and bacteriophages were detected more frequently after rain events, suggesting a runoff-related human contamination source. *E. coli* concentrations increased after rain events.
- *Salmonella* detections were not associated with *E. coli* concentrations above FSMA water quality standard levels, indicating that these thresholds for *E. coli* were not predictive of *Salmonella* presence. However, there was an association between *E. coli* (and enterococci) concentration and *Salmonella* detection and concentration.

- Of the 131 subtyped *Salmonella* isolates collected from the irrigation ponds, approximately half matched PFGE patterns of clinical *Salmonella* isolates in the PulseNet database, and all isolates cultured from the ponds were serotypes potentially pathogenic to humans.

Using results from this irrigation water quality project, WDPB staff contributed to technical discussions with CPS, FDA, academia, and industry partners regarding water testing methods and approaches for *E. coli* under FSMA and other potential microbial water quality measures.

Recovery of* Cyclospora cayetanensis *from agricultural water samples

WDPB collaborated with FDA's Center for Food Safety and Nutrition to evaluate sample collection and recovery methods for *Cyclospora cayetanensis* from irrigation water and spent produce wash water. WDPB's large-volume sample collection method, DEUF, performed as well or better in recovering *C. cayetanensis* from irrigation water than U.S. Environmental Protection Agency Method 1623, which is recommended for recovery of the parasite *Cryptosporidium* from drinking water. A continuous flow centrifugation (CFC) method was also validated for recovery of *C. cayetanensis* from irrigation water and spent produce wash water.

WDPB participated in a multi-laboratory validation study to evaluate the performance of FDA's newly designed real-time PCR assay for detection of *C. cayetanensis* from agricultural samples. This assay will be used in conjunction with the DEUF-based method and will be added to the Bacteriological Analytical Manual (BAM) for *C. cayetanensis* recovery from agricultural samples.

D. Improving attribution of foodborne illness outbreaks to specific foods

Interagency Food Safety Analytics Collaboration (IFSAC)

Since its creation in 2011, IFSAC, a collaboration of CDC, FDA, and USDA/FSIS, has focused its analytic efforts to develop methods to estimate foodborne illness source attribution for four priority pathogens—*Salmonella, E. coli* O157, *Campylobacter*, and *Listeria*. In 2017, IFSAC project teams, composed of members of each agency and coordinated by a steering committee, did the following:

- Completed and publicly released a new 5-year Strategic Plan and accompanying Action Plan
- Continued collaborative progress on several projects of tri-agency interest with implications on foodborne illness source attribution. Of particular note,
  - A scientific manuscript on the tri-agency food categorization scheme is in press at *Foodborne Pathogens and Disease*.
  - Substantial progress was made on developing a novel approach to using outbreak data to model changes over time in the number of illnesses by pathogen-food category.
  - IFSAC finalized methods and an accompanying public report (release planned for the first quarter of FY 2018) for foodborne illness source attribution estimates for 2013 for *Salmonella, E. coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data.
- Updated the IFSAC website regularly with past, current, and future activities on foodborne attribution illness efforts to inform federal, state, and local officials and other stakeholders

III. Collaborating and Sharing Information with External Stakeholders

A. Sharing surveillance information faster with the food industry, academia, consumers, and the public

Stakeholders—food producers, regulators, and consumers—depend on CDC for practical and understandable information about keeping the food supply safe. Historically, food safety communications included annual summaries with data from surveillance networks, scientific publications and presentations, and outbreak alerts. Today, partners and the public want access to more information—more frequently, and through multiple channels.

Since the introduction of FSMA, CDC has integrated communication, science, and policy expertise to improve the exchange and dissemination of food safety information. This team-based approach supports FSMA's call to action to provide fast, accurate, and relevant information.

Selected activities that support CDC's effort to collaborate and share information

- Posting foodborne disease outbreak notices to raise awareness to protect consumers' health. CDC communicates with the public and media about outbreaks of foodborne illness through investigation notices and other means. As of September 30, 2017, CDC had posted notices for eight foodborne outbreaks. These notices include consumer advice, epidemiologic information, and details about the investigation.
- Communicating on new and emerging antibiotic-resistant infections and threats. CDC provided timely information to the public and stakeholders on outbreaks of antibiotic-resistant infections, including *Salmonella* Heidelberg. In addition, CDC did the following:
  - Posted 2015 data to the CDC NARMS Now: Human Data website and shared highlights with stakeholders. NARMS studies have contributed significantly to CDC's understanding of resistant intestinal infections and how antibiotic-resistant bacteria flow through the food chain to people.
  - NARMS scientists at CDC began making data available faster to the public through the interactive NARMS Now site. New on the site this coming year will be downloadable, preliminary surveillance data for isolates tested as recently as 3 months before the current date.
  - Helped raise awareness of antibiotic resistance in foodborne bacteria and the importance of judicious antibiotic use through a variety of activities, ranging from formative research to understand the knowledge, attitudes, and behaviors of key audiences to widespread dissemination of key messages through awareness days (One Health Day, U.S. Antibiotic Awareness Week, and more)
- Providing targeted food safety advice to consumers and food safety educators
  - CDC prepared and posted feature articles, blogs, social media messages, and infographics throughout 2017 that coincided with seasonal cooking activities and celebrations. New this fiscal year were Spanish translations of all consumer materials. CDC collaborated with external partners, including other federal agencies, industry, and non-governmental organizations, to share important food safety messages widely for winter holidays, summer celebrations, and other seasonal cooking occasions.

- For National Food Safety Education Month in September 2017, CDC focused communications on raising awareness of groups of people at higher risk for food poisoning (children under age 5, adults aged 65 and older, pregnant women, and people with weakened immune systems). Material included a commentary distributed in 250,000 copies of *USA Today* and a video, graphics, and a feature (in English and Spanish) with tips to help prevent foodborne illness. These materials were shared through CDC's website and social media channels and on FoodSafety.gov. CDC also published an *MMWR* announcement.

- Expanded the CDC Food Safety website and added consumer pages in Spanish. The food safety site includes advice on how to keep food safe, advice on how to prevent food poisoning, information on which foods are most often associated with foodborne illness, and common symptoms of food poisoning. The site also includes information for healthcare professionals, health departments, and industry.
- Expanded online information on *Campylobacter*, a common foodborne infection
- Provided food safety education materials and presentations on consumer behavior change to consumer food safety educators at the 2017 Consumer Food Safety Education Conference
- Worked with USDA and FDA through FoodSafety.gov to provide consistent safe food handling advice across the U.S. government, to consumer food safety educators, and to the public. CDC also works with non-governmental organizations such as the Partnership for Food Safety Education to share safe food handling information.
  - Presented an annual holiday food safety Twitter chat with participation from federal and state partners, the food industry, and food safety advocacy organizations. The December 2016 chat, with NBC News Health as co-host, reached an audience of 10.4 million with seasonal, targeted food safety messages. The audience increased by more than 20% from holiday chats in 2014 and 2015.
- *We Were There.* This quarterly lecture series focuses on historically important, CDC-led epidemiologic and laboratory investigations. In May 2017, the series explored the 1993 *E. coli* O157 outbreak linked to fast-food hamburgers, which killed four children and caused more than 700 illnesses, and the subsequent changes in food safety regulation. "How Deadly Burgers Made Food Safer – The Impact of the 1993 *E. coli* O157 Outbreak" was streamed live online, including through Facebook Live, and archived for later viewing.
- CDC launched FoodNet Fast, an interactive online program for getting information on cases of illness reported to FoodNet. FoodNet Fast makes it easy for users to see how rates of illness have changed over the past 20 years for nine pathogens transmitted commonly through food: *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, STEC, *Shigella*, *Vibrio*, and *Yersinia*.
- CDC published the 2016 FoodNet preliminary data, documenting trends in foodborne illness and how increasing use of rapid diagnostic tests (CIDTs) is affecting public health's ability to monitor those trends.
- In June 2017, CDC and international scientists published a paper in the journal *Eurosurveillance* that shared the vision for using whole genome sequencing for global foodborne illness surveillance.
- Created a video on antibiotic-resistant foodborne infections, explaining how they occur and how the public can take steps to protect their health

Regional PulseNet meetings

Between November 2016 and April 2017, CDC and its partners planned and conducted four PulseNet and OutbreakNet regional meetings. Laboratorians, epidemiologists, and environmental health specialists from federal, state, and local public health partner organizations attended. The participants and content of these meetings reflected the multidisciplinary nature and changing landscape of foodborne disease outbreak detection and response. Several members of CDC's Division of Foodborne, Waterborne, and Environmental Diseases attended and spoke at the regional meetings. They also exchanged expertise and discussed surveillance for, detection of, and response to enteric diseases.

Attendees benefitted from open discussion sessions, peer-to-peer exchange, and networking with other colleagues in their region. Across all regions, over 95% of participants rated the overall educational content and quality of the meeting as "excellent" or "good." Participants used the same words to describe discussions, relevance to practice, selection of topics, and quality of presenters.

The PulseNet and OutbreakNet regional meetings prepare the public health workforce to respond strategically to food safety challenges by strengthening and expanding partnerships across disciplines and agencies. The dialogue on the changing landscape of enteric disease surveillance, outbreak detection, and response will continue at the national InFORM Conference in November 2017.

Epi-Ready: team-based training approach

CDC funded the National Environmental Health Association (NEHA) to conduct 2-day Epi-Ready team training courses since 2003. These courses cover foodborne disease outbreak topics such as team formation, planning, detection, and investigation by epidemiologists, laboratorians, environmental health specialists, public health nurses, communication experts, and others. CDC also recently funded NEHA to conduct two train-the-trainer versions of the course for three-member laboratory, epidemiology, and environmental teams from the Integrated Food Safety Centers of Excellence.

Using FY 2016 funding, the CoEs successfully conducted three NEHA-managed Epi-Ready courses in non-CoE states. In addition, because of their participation in the NEHA train-the-trainer courses, several CoEs independently conducted other Epi-Ready courses using their own trainers. For example, the Tennessee CoE conducted four additional Epi-Ready courses using FY 2016 CDC funds.

Food allergy and anaphylaxis management

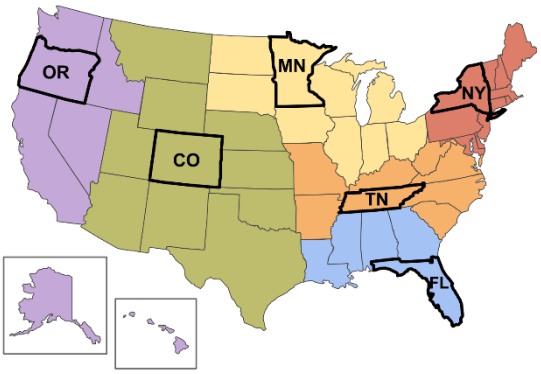
To meet FSMA requirements to establish guidelines for voluntary food allergy and anaphylaxis management for use in schools and early childhood education programs, CDC convened a panel of federal, medical, and school-affiliated experts. This panel informed guidance priorities and content, and summarized scientific and school health–related data and papers related to managing food allergies in schools. In 2013, guidelines were released, and in 2014, multiple food allergy publications for specific school audiences were created. The guidelines and publications included an allergy toolkit, tip sheets for school personnel, and downloadable PowerPoint presentations for specific school audiences.

During FY 2015, CDC launched the Food Allergies in Schools Toolkit, found on the new Healthy Schools website. From September 2016 – August 2017, the webpage had 13,089 unique visitors with 17,397 page views. The CDC food allergy guidelines were downloaded more than 2,200 times. In addition, items from the toolkit (e.g., tip sheets, PowerPoint presentations) were downloaded more than 3,200 times. In June 2016, the National Association of School Nurses was awarded a 5-year cooperative agreement for technical assistance and professional development to states, their constituents, and other stakeholders to manage chronic conditions in schools. The National Association of School Nurses will disseminate CDC resources, such as the food allergy guidelines and toolkits, and educate school

nurses and others about how to use CDC resources. Activities may include webinars, live presentations, and the establishment of a training-of-trainers network.

Integrated Food Safety Centers of Excellence

The CoEs were established by the Food Safety Modernization Act to be resources for other public health professionals who respond to foodborne illness outbreaks. The CoEs develop free online products (published on the CoE food safety tools website) and provide services including training and peer-to-peer consultation to health departments in their regions and across the country. CDC named Colorado, Florida, Minnesota, New York, Oregon, and Tennessee state health departments and their partner academic institutions as CoEs.



The CoEs focus their work on four main strategies:

- *Strategy A*—Strengthen foodborne illness surveillance and outbreak investigations outside their state by providing consultations, developing tools/resources, offering general assistance, and improving capacity of information systems
- *Strategy B*—Evaluate and analyze the timeliness and effectiveness of foodborne illness surveillance and outbreak response, and perform program evaluation, quality improvement, and other special projects
- *Strategy C*—Train and educate students and public health personnel in laboratory, epidemiologic, and environmental investigation of foodborne illness
- *Strategy D*—Disseminate information through outreach/marketing activities to local, state, and federal public health officials and other stakeholders to increase awareness of tools and resources for food safety and foodborne illness surveillance and outbreak response

Select CoE projects in FY 2017 include the following:

- Strategy A
  - The Colorado CoE developed a target audience framework to guide development of training and resources for public health professionals who investigate foodborne illness outbreaks.
  - The CoEs continued working on foodborne illness complaint systems, including Florida's development of a system to track Twitter reports for potential cases of foodborne illness.
  - The CoEs provided one-on-one consultation to health departments throughout the country, including an ongoing mentorship with OutbreakNet Enhanced sites.
  - The CoEs provided support on the CIFOR Guidelines Toolkit evaluation, including a series of webinars developed by the New York CoE.
- Strategy B
  - Colorado received supplemental funding to conduct an assessment of veterinary prescription practices, perceptions, and factors influencing the use of antimicrobial drugs.

- Florida continued work on the source attribution for enteric pathogens by pathway (foodborne, person-to-person, environmental, and animal contact) by conducting a structured review by subject matter experts.
- Oregon continued to lead Project Mercury, which empowers health departments to use their case exposure interview data to generate hypotheses to determine potential sources of foodborne outbreaks.

- Strategy C
  - Colorado released an Environmental Assessment Just-in-Time Training in collaboration with the National Association of County and City Health Officials (NACCHO) and relaunched their Environmental Assessment QuickTrain with new content.
  - CoEs conducted training needs assessments and delivered trainings based on the identified needs.
  - The CoEs released new training videos, including one on how to use the SEDRIC Object Explorer.
  - The CoEs delivered Epi-Ready trainings, including the first CoE-led train-the-trainer session.
  - The CoEs developed new case studies, including two developed by Minnesota: "*E. coli* O157:H7 – Multistate Outbreak Associated with Hazelnuts, 2010" and "*Listeria monocytogenes* – Multistate Outbreak Associated with Soft Cheese, 2013."
  - The CoEs led academic courses and offered continuing education certificates in food safety topics.
  - The CoEs delivered trainings and guidance on whole genome sequencing, including a training series led by the New York CoE; it includes four modules, and four webinars were presented by representatives from all CoEs and CDC.
  - The CoEs released web courses, including Tennessee's "Initial Foodborne Illness Investigation."
- Strategy D
  - The CoEs presented their work at meetings and conferences, including CSTE, the International Association for Food Protection, and NEHA.
  - Florida made improvements to the CoE food safety tools website to include added search capabilities.
  - The CoEs continued to produce a quarterly newsletter under the guidance of Tennessee.

Council to Improve Foodborne Outbreak Response

CIFOR is a multidisciplinary collaboration of eight national associations and three federal agencies that seek to improve methods at the local, state, and federal levels to detect, investigate, control, and prevent foodborne disease outbreaks. CIFOR includes representatives from epidemiology, environmental health, public health laboratories, and regulatory agencies involved in foodborne disease surveillance and outbreak response. The food industry is represented on the standing CIFOR Industry Workgroup.

CIFOR underwent a strategic planning process during two meetings that culminated in the creation of four Development Teams (Identify, Lead, Promote, and Evaluate):

- The Identify Development Team evaluates gaps in detection, investigation, and prevention of outbreaks that might lead to the creation of CIFOR projects. Areas under study are communication issues, after-action reports, and several critical laboratory issues, including CIDTs and WGS.
- The Lead Development Team manages the production of the third edition of the CIFOR Guidelines.

- The Promote Development Team updates the CIFOR Clearinghouse and the CIFOR website and creates many communication pieces for CIFOR member association/agency websites.
- The Evaluate Development Team updates the CIFOR metrics and assesses how to measure the impact of CIFOR products.

Cooperative agreements

The CDC Food Safety Office manages several cooperative agreements with national associations. Many, but not all, of the activities funded through these associations involve CIFOR Development Teams, workgroups, projects, and products. The goal is to improve foodborne disease surveillance and outbreak response at the local and state levels, which directly affects federal disease control efforts. Funding these associations facilitates a collaborative effort between CDC and local and state experts to develop solutions to barriers that hinder outbreak detection and response.

- ***Association of Public Health Laboratories (APHL)***

  APHL assists with many CIFOR projects, including management of the following: the new CIFOR Lead Development Team; the CIFOR Lab-Epi Integrated Reporting software (to help states and large cities more quickly identify clusters of enteric illness); C-MET (CIFOR Metrics Entry Tool), the web portal for states to upload their results for the 16 CIFOR metrics with target ranges; the CIFOR Outbreaks of Undetermined Etiology (OUE) Guidelines; and the APHL Food Safety Workgroup, which is addressing many issues, including WGS and CIDTs.

- ***Association of State and Territorial Health Officials (ASTHO)***

  ASTHO members and staff help develop all CIFOR products, such as the CIFOR Guidelines and the Guidelines Toolkit. They also attend CIFOR deliberations and meetings, develop a range of foodborne illness fact sheets and background materials for state health officials, and participate in food safety activities through the Environmental Health Policy Committee. ASTHO manages the CIFOR Identify Development Team.

- ***Council of State and Territorial Epidemiologists***

  CSTE is engaged in many CIFOR activities, including convening the in-person meetings of the CIFOR Council and Governance Committee twice a year, hiring the contractor to update the CIFOR Guidelines, leading the CIFOR strategic planning effort, and managing the CIFOR Evaluate Development Team. CSTE also managed the production of an in-depth assessment of foodborne illness complaint systems during the past year and will post the report and recommendations on the CIFOR website. Additionally, CSTE manages the CSTE Food Safety Fellowship (fellows are placed in state health departments for 2 years) and houses the content of the Epi-Ready team training course on the CSTE website (content is publicly available).

- ***National Association of County and City Health Officials***

  NACCHO maintains the CIFOR website, including the CIFOR Clearinghouse; manages the standing CIFOR Industry Workgroup; and co-manages (with NEHA) the new CIFOR Promote Development Team. NACCHO has been deeply engaged in updating the CIFOR website over the past year. NACCHO also has a very active Food Safety Workgroup, which is involved in a range of issues related to foodborne illness reporting and investigation at the local level, especially the environmental health aspect.