

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

2013

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FSMA Surveillance Working Group 2013 Report to HHS Secretary

SUMMARY

In 2011, the Food Safety Modernization Act (FSMA) 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. This second annual report summarizes the FSMA Surveillance Working Group's (FSMA SWG) activities and recommendations during fiscal year (FY) 2013.

The FSMA SWG held two, 2-day meetings at CDC in FY 2013, convening in December 2012 and again in May 2013 to review and provide feedback on surveillance projects and guidance on 1) responding effectively to the public health challenges resulting from the increasing use of culture-independent diagnostic tests (CIDTs); 2) utilizing meaningful performance measures for foodborne illness surveillance; and 3) advancing several CDC FSMA-related projects to enhance foodborne disease surveillance.

The issue of CIDTs was identified as a critically important area that will soon require national attention. Although the increasing use of non-culture, rapid diagnostic tests in the clinical setting offers many advantages, this shift also presents significant challenges to current laboratory-based public health surveillance systems that rely on culture. As the use of CIDTs becomes widespread, there will be a dramatic reduction in the number of isolates (i.e., live bacterial samples) available for pulsed-field gel electrophoresis (PFGE)—the DNA fingerprinting technique used by PulseNet and other large foodborne disease surveillance systems to detect foodborne outbreaks resulting from widely distributed contaminated foods. The effect of this decrease in isolates extends beyond foodborne disease surveillance and will require broad changes to many large, culture-based disease-monitoring systems in the near future. The Working Group strongly recommends that, under CDC leadership, a comprehensive strategy be developed for designing and implementing a culture-independent typing system that meets public health needs while preserving the current capabilities in the interim. This strategy should include the short-term maintenance of culture-based testing and current PulseNet capacity until longer-term solutions to meet public health needs using next-generation molecular diagnostic technologies and associated bioinformatics capacity are identified, standardized, and implemented. Implementation of such a comprehensive strategy will require adequate resources.

The FSMA SWG strongly endorsed the use of meaningful foodborne illness surveillance performance measures at the local, state, and federal levels to show progress in reducing foodborne illness, to identify the best evidence-based public health practices, and to encourage programmatic accountability. In addition, the Working Group emphasized the importance of metrics to quantify the impact of foodborne surveillance programs, policies, and regulatory changes and to track progress and improvements in food safety. However, consensus is needed to determine the most effective performance measures to utilize as well as the methods for evaluating them, since there are more measures than most state and local jurisdictions have the capacity to implement.

In the course of its work, the Working Group repeatedly noted the importance of national and state/local surveillance for foodborne illness and emphasized that the data gathered from this surveillance are critical to detect outbreaks and identify new vehicles for foodborne illness; to monitor the safety of the food supply; and to direct risk-based food safety efforts by CDC, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). Further, the Working Group noted the recent loss of capacity at state and local levels due to broad budget cuts and underscored the need for additional resources to build on and better integrate existing surveillance systems and fill existing and emerging data gaps. Finally, the Working Group repeatedly noted that foodborne illness surveillance and outbreak investigations to determine root causes 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.

FSMA Surveillance Working Group 2013 Report to HHS Secretary

INTRODUCTION

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

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 at the 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. For example, CDC's 2011 Estimates of Foodborne Illness^{1,2} (<http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>) serve as a foundation (or springboard) 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 policy, providing assessments of public health risk, and developing prevention messages for food safety improvements. These data are relied upon by other government regulatory agencies and analyzed by media, public health, and consumer organizations that provide food safety advice to consumers and policy makers. 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 (<http://www.cdc.gov/foodborneburden/attribution-1998-2008.html>).³ Building on the 2011 estimates, which showed that about 48 million people (1 in 6) get sick each year from food, these new estimates 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 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 are providing the necessary data to assist government agencies, industry, and other food safety stakeholders in their risk-management activities (http://www.cspinet.org/foodsafety/outbreak_report.html, <http://cspinet.org/foodsafety/riskymeat.html>).

CDC and the Food Safety Modernization Act (FSMA)

The Food and Drug Administration's (FDA's) Food Safety Modernization Act (FSMA) provided 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.

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 Surveillance Working Group (FSMA-SWG) of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), CDC, was created, with BSC/OID member Dr. James Hadler of Yale University's School of Public Health serving as Chair. FSMA-SWG membership comprises 21 experts representing local, state, and federal governments, academia, industry, and consumer groups (**Appendix 1**).

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, which FSMA requires, highlights the FSMA-SWG's activities and recommendations for FY 2013 and summarizes priority areas for focus in the coming year.

WORKING GROUP ACTIVITIES – FY 2013

In FY 2013, the FSMA SWG met twice at CDC to consider several recent and ongoing developments in foodborne illness surveillance that will be key to maintaining and improving surveillance systems. For FY 2013, the Working Group reviewed the topics of culture independent diagnostic tests (CIDTs) and utilization of performance measures, and provided guidance in each of these areas. The Working Group also reviewed, discussed, and provided guidance on several other CDC FSMA-related projects to enhance foodborne surveillance. For reference, a summary of selected CDC activities conducted in FY 2013 to address FSMA is included in **Appendix 2**.

Culture-independent diagnostic tests (CIDTs)

Introduction

Public health surveillance of foodborne infectious diseases is a critical component of a risk-based, prevention-focused public health system. Information gathered through surveillance (including both epidemiologic and laboratory components) is used to detect outbreaks; quantify the impact of foodborne disease; develop attribution models; inform risk assessments; set public health priorities; monitor trends in foodborne illnesses, outbreaks, and antibiotic resistance of foodborne pathogens; evaluate the effectiveness of prevention strategies; and identify rare and emerging issues that may have otherwise gone unnoticed.

Significant advances in foodborne disease surveillance in the last 20 years—most notable, the establishment of standardized, integrated molecular surveillance efforts via the laboratory-based system PulseNet—have transformed public health and made foodborne outbreaks both detectable and visible. In particular, molecular surveillance of foodborne disease-causing bacteria has allowed us to “connect the dots” and to identify linked outbreaks as well as new food vehicles and to follow the evolution of virulence factors and antimicrobial susceptibility. Despite these achievements, the full potential of molecular surveillance remains untapped. Untrained health providers, a fragmented food safety system, and inadequate funding and staff, particularly at the state and local levels, have led to incomplete participation in surveillance systems, persistent backlogs of data, and lack of data sharing. Increasing the number of laboratory-confirmed cases of foodborne disease would increase the impact of epidemiologic studies and the likelihood of finding the source of foodborne outbreaks.⁴

Recent advances in rapid clinical diagnostics for enteric pathogens are expected to increase the proportion of foodborne disease cases diagnosed and reported to public health officials and also reduce time lags.⁵ Traditionally, laboratories have relied on testing isolates from cultures of foodborne pathogens. However, new laboratory tests that are culture-independent are increasingly being used. These tests can be performed in large batches, are potentially less expensive and can more quickly provide results for patient management. However, their use also affects the capacity of public health surveillance systems that rely on isolates from culture. Because fewer isolates are available for public health use, the ability of current molecular laboratory surveillance platforms to link foodborne disease cases from different localities will be reduced. To maintain this capacity and address future challenges, public health must develop new technologies for tracking foodborne pathogens, undertake strategic planning projects to develop next-generation diagnostic platforms that meet public health needs, and make investments in public health surveillance infrastructure. The benefits and challenges identified and discussed by the Working Group regarding CIDTs are presented below.

Benefits and Challenges

Currently, most national and multistate outbreaks of foodborne disease are detected by PulseNet, whose member laboratories use pulsed-field gel electrophoresis (PFGE) to subtype isolates obtained through culture by clinical laboratories. PFGE requires bacterial isolates, and, at present, so does bacterial gene sequencing, a more precise means to test similarities/differences in bacterial pathogens.

The development and increasing use of CIDTs for bacterial enteric pathogens directly impacts the public health surveillance system (Table 1). CIDTs provide the benefit of being faster and potentially less expensive which should enable more cases of foodborne illness to be diagnosed and reported. A further benefit is many of these rapid tests are designed to look for multiple pathogens that are currently missed with culture-based technology. The central challenge for these new tests is they do not produce the cultures and pure isolates currently needed by public health surveillance systems to detect outbreaks and monitor trends in disease and antibiotic resistance.

Table 1. Benefits and Challenges of Increased Use of CIDTs

Perspective	Benefits	Challenges
Patient	<ul style="list-style-type: none"> • Rapid diagnosis • Improved sensitivity for some pathogens • Multiple agents tested for at once • Improved clinical decision making • Fewer undiagnosed cases • Fewer patients treated unnecessarily • Lower costs 	<ul style="list-style-type: none"> • Less specificity and, possibly, sensitivity • May not be clear which pathogen is causing disease • False positives may result in incorrect diagnosis and unnecessary treatment • Potential short-term loss of antimicrobial susceptibility testing
Population	<ul style="list-style-type: none"> • Rapid detection of cases • Increased case ascertainment due to increased testing • Increased sensitivity for some pathogens • Increased ability to distinguish strains of each pathogen and to detect more outbreaks 	<ul style="list-style-type: none"> • Loss of subtyping ability; antimicrobial susceptibility testing • False positives may lead to unnecessary case follow-up and investigation of pseudo-outbreaks • Potential short-term decreased ability to detect widespread, dispersed outbreaks • Disrupted/decreased ability to monitor trends; estimate illnesses • Need to develop new case definitions accounting for a variety of rapid methods

Adapted from Cronquist et al,⁵ and Atkinson et al.⁷

As clinical laboratories switch to CIDTs, public health laboratories will likely be forced to assume the task of culturing specimens and obtaining pure isolates.⁶ However, the public health laboratory system is not designed for large numbers of primary cultures and lacks the resources to absorb the increased workload.⁷ As a result, fewer microbial DNA fingerprints will be uploaded to PulseNet and the time from initial diagnostic test to an isolate being available for PFGE will be lengthened.

Until PulseNet incorporates newer technology, the reduced availability of isolates will cause a decrease in the capacity of public health to detect and solve large and important outbreaks, track trends in the incidence of foodborne illness, and monitor antibiotic resistance. In addition, industry and regulators will not have the information they need to identify gaps in food safety, which will likely lead to an increase in cases of foodborne illness. The decrease in (or loss of) culture-based testing will also have a negative impact on food safety systems beyond PulseNet, affecting several components of the national foodborne illness monitoring platforms, including the Foodborne Diseases Centers for Outbreak Response enhancement (FoodCORE), OutbreakNet, the National Antimicrobial Resistance Monitoring System (NARMS), the FDA Coordinated Outbreak Response & Evaluation (CORE) Network, and the Predictive Analytics component of the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Public Health Information System (PHIS). Unfortunately, although the promise of new technology is great, there is currently no technology that can replace culture for the detection of clusters of foodborne illness based on the characteristics of the pathogen.

Examples of Potential Action

The Working Group reviewed work done by other groups examining the CIDT challenge and identified several potential solutions that could address the immediate threat to culture-based surveillance systems resulting from widespread adoption of CIDTs. These solutions could maintain or even enhance the current capacity of these systems to detect and investigate outbreaks until newer technologies are developed and incorporated (Table 2).

Table 2. Potential Actions for Improving Public Health Surveillance of Foodborne Diseases*

Area	Potential Actions
Develop Molecular Methods	<ul style="list-style-type: none"> ▪ In collaboration with key stakeholders, conduct timely, real world validation studies of new testing methods to define performance characteristics ▪ Develop subtyping methods that will function independently of pathogen isolation ▪ Develop genomic and metagenomic molecular methods for disease surveillance
Improve Clinical and Laboratory Practice	<ul style="list-style-type: none"> ▪ Develop best practice documents and clinical guidelines for laboratories to follow and disseminate widely ▪ Conduct provider/health system surveys to determine populations for which CIDTs are being used ▪ Conduct routine surveys of clinical laboratories to monitor uptake of new test methods
Preserve Isolates	<ul style="list-style-type: none"> ▪ Recommend reflex culture of positive specimens at clinical laboratories. ▪ Request forwarding of clinical material to state public health laboratories for culture ▪ Assess need to change specimen submission requirements and determine specifics for submitting clinical material to state public health laboratories for culture ▪ Establish sentinel site surveillance to ensure isolate submission for characterization of specific attributes of pathogens.
Adapt Surveillance	<ul style="list-style-type: none"> ▪ Modify case definitions used by public health to include cases identified by CIDTs and consider pilot implementation in geographically limited systems (e.g., FoodNet) ▪ Collect data on cases not meeting confirmed case definitions and modify data systems to capture more detailed laboratory data for cases ▪ Enhance the quality and quantity of exposure information by improving exposure assessments and reporting tools (e.g., as soon as a diagnosis is made, patients should be systematically interviewed to identify potential sources of exposure) ▪ Improve information flow and data sharing between databases.
Provide Resources	<ul style="list-style-type: none"> ▪ Provide resources to public health laboratories to confirm CIDT findings and generate isolates for PulseNet, NARMS, etc. ▪ Expand state and local capacity for foodborne illness response by increasing extramural food safety funding provided through CDC's Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC) ▪ Invest in infrastructure and research ▪ Advocate for adequate public health funding for surveillance

*Adapted from the Association of Public Health Laboratories (APHL; www.aphl.org/) white paper;⁸ the Center for Foodborne Illness Research & Prevention (CFI; <http://www.foodborneillness.org/>) white paper;⁹ and Cronquist et al.⁵

Each of these approaches has advantages and disadvantages, but none are potential long-term solutions. Cost and practicality are major issues for each potential solution. However, the benefits of implementing these stop-gap measures will clearly outweigh the costs. Loss of capacity in systems such as PulseNet would affect our ability to continually and consistently detect and investigate foodborne illness. Information gained from these investigations significantly benefits public health by improving our understanding of the epidemiology of foodborne disease as well as our ability to detect and control outbreaks and monitor antimicrobial resistance. This information directly impacts the public by ensuring that contaminated food is removed from further sale before

additional people become sick and also drives improvements in food safety in both the regulatory and industry arenas. Several federal projects have identified critical needs and priorities for improving foodborne disease surveillance. For example, CDC has identified food safety as an Agency *Winnable Battle* (<http://www.cdc.gov/winnablebattles/>) and cited two areas in which action would have a significant impact on public health: 1) improving knowledge of the incidence, trends, burden, and causes of foodborne disease outbreaks; and 2) improving capacity to detect and respond quickly to foodborne disease outbreaks. Similarly, CDC's *Infectious Disease Framework* (<http://www.cdc.gov/oid/framework.html>)¹⁰ identifies critical elements, priorities, and key activities to guide public health actions to improve public health infrastructure around foodborne disease, including addressing the potential impact of CIDTs on disease surveillance. Under FSMA, CDC is mandated to coordinate and integrate federal, state, and local foodborne disease surveillance systems; increase participation in national surveillance networks; facilitate timely sharing of information; develop improved epidemiologic and laboratory tools; and improve attribution of illnesses to specific foods. Addressing these challenges and ensuring the long-term viability of the nation's foodborne illness surveillance system will require strategic planning and new investments in our surveillance infrastructure.

Based on their review and discussions, the Working Group strongly recommends that, under CDC leadership, **a comprehensive strategy be developed for designing and implementing a culture-independent typing system that meets public health needs while preserving the current capabilities in the interim.** This strategy should include the following short- and long-term actions. Implementation of a comprehensive strategy will require adequate resources.

Short-term Action:

- Preserve isolates. Maintaining the capacity to obtain isolates from persons with foodborne illness should be a public health priority. Because of the increasing use of CIDTs, ensuring these cultures will be the responsibility of state public health laboratories, which are already under-resourced. Clinical laboratories could be required to culture specimens that are positive by CIDT (reflex-culturing) or to transport specimens to public health laboratories for culturing. In either case, additional resources are required for public health laboratories to work with the clinical laboratories to preserve the ability to obtain viable specimens for culture.
- Adapt surveillance mechanisms to incorporate new laboratory diagnostic methods and technologies.¹¹ Surveillance case definitions often require a positive culture for a case to be considered confirmed. These definitions will need to be modified so that cases identified by culture-independent methods are included in case counts and not lost to national surveillance data. However, before case definition changes are made, these tests will each need to be carefully validated. Otherwise, national counts could be inflated by false-positive reports or underestimated from false-negative findings.
- Enhance surveillance by improving exposure assessment. The ability to constantly detect and investigate cases of foodborne illness has enabled great improvements in food safety and public health. Enhancing the quality and quantity of information obtained regarding exposure to contaminated foods by improving exposure assessments and reporting tools will have positive impacts and may offset some of the challenges of CIDTs. However, obtaining exposure information is labor-intensive.¹² Most state and local public health agencies lack full workforce capacity and rely heavily on extramural funding provided through CDC's Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC) to support their surveillance activities. Increased extramural food safety funding for ELC grants, the development of new exposure assessment and reporting tools, and public health training programs are needed.

These actions cannot be accomplished without adequate resources for state and local public health agency laboratories.

Long-term Action: Invest in infrastructure and research.

- Develop new molecular methods for disease surveillance (PulseNet-NextGen). Next-generation diagnostic technologies offer many opportunities for improved tracking of foodborne pathogens, but the science is not yet fully developed, and, as mentioned above, bacterial gene sequencing still relies on the availability of a culture. Genomics and metagenomics, in particular, may serve as useful tools for detecting and characterizing foodborne pathogens. However, development of these methods will require a concerted research effort and re-tooling of the national and international subtype-based surveillance infrastructure.
- Modernize foodborne illness surveillance systems by incorporating new molecular methods for pathogen identification and characterization. Shifting to a new system will require strategic planning. Many of the next-generation molecular methods require pathogen reference libraries that do not yet exist. Further, it will be necessary to build consensus on shared standards and consistency. Finally, public health agencies at the federal, state, and local levels will need increased bioinformatics capacity to handle the volumes of molecular data that will be generated. Significant investments in strategic planning and infrastructure are critically needed. These capacity development efforts should be coordinated with those of federal food regulatory agencies to ensure alignment of various federal activities as we move toward a better integrated food safety system.

Performance Measures to Enhance Federal, State, and Local Foodborne Illness Surveillance.

The Food Safety Modernization Act directs CDC and its partners to enhance surveillance of foodborne illness. Performance measures are tools that can be used to evaluate the timeliness and effectiveness of foodborne disease surveillance. To improve U.S. capacity to prevent and control foodborne disease, performance measures can allow integration of data at state, regional, or national levels which, in turn, can

- Promote common understanding of key elements of foodborne disease surveillance;
- Facilitate training of food program staff;
- Evaluate program effectiveness and build the public health knowledge base to identify best practices.

The FSMA SWG was asked to provide CDC guidance on how to best use performance measures to enhance foodborne illness surveillance at the federal, state, and local levels. For the purposes of that discussion, the following definitions were used:

- **Performance measure:** *a quantifiable description of program accomplishments, particularly progress towards pre-established goals*
- **Indicator:** *a process or step that helps accomplish a specific objective*
- **Metric:** *a measurement of how well the process or step is being conducted*
- **Target:** *a threshold or range of values for how well the process or step should be conducted*

As background information, the Working Group was briefed on ways in which CDC has been working with its state and local partners and the Council to Improve Outbreak Surveillance and Response (CIFOR) to develop improved surveillance measures for foodborne illness outbreak investigations.¹² Examples of these performance measures include the following:

- *Foodborne illness outbreak rate*: Rate of outbreaks reported per 1 million population (http://www.cspinet.org/foodsafety/outbreak_report.html); and http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a1.htm?s_cid=mm6203a1_w.
- *Isolate submissions to public health laboratory*. Number and percent of isolates from confirmed cases submitted to a public health lab
- *Public Health Emergency Preparedness (PHEP) E. coli O157 and Listeria subtyping interval*: Percent of PFGE subtyping results for *E. coli* O157:H7 and *Listeria* submitted to the PulseNet national database within 4 working days of receiving the isolate at the PFGE lab
- *Outbreak etiology, vehicle for transmission, and contributing factor reporting to the National Outbreak Reporting System (NORS)*:
 - Number and percent of outbreaks for which an etiology was identified and reported to NORS
 - Number and percent of outbreaks for which a vehicle for transmission was identified and reported to NORS
 - Number and percent of outbreaks for which contributing factors were identified and reported to NORS

CDC has also been using CIFOR-adopted performance measures similar to those described above to help enhance surveillance in the food safety programs it helps support (e.g., the Foodborne Disease Active Surveillance Network (FoodNet), the Foodborne Disease Outbreak Surveillance System, PulseNet, NARMS, the National Electronic Norovirus Outbreak Network (CaliciNet), the Environmental Health Specialists Network (EHS-Net), FoodCORE, and the Integrated Food Safety Centers of Excellence). In addition, CDC's Public Health Emergency Preparedness Program's performance measures and the Office of State, Territorial, Local and Tribal Support's *Prevention Status Report* (<http://www.cdc.gov/stltpublichealth/psr/>) will include foodborne illness metrics to measure state's progress in reaching desired goals.

With this information as background, the Working Group considered and provided guidance on the following questions:

- What is the value of performance measures for foodborne illness surveillance?

The Working Group believes that standardized performance measures could promote a common understanding of key elements of foodborne disease surveillance and response. They could improve performance by identifying performance gaps within and between states, examine reasons for those gaps, and stimulate effective actions to address them. Performance measures could help states justify ongoing and future investments and inform priority setting.

- How should performance measures be selected?

The Working Group suggested that measures be chosen in collaboration with state and local health departments, based on the importance of these measures in achieving food safety goals related to disease prevention, disease surveillance, and outbreak response. Performance measures should be prioritized based on the burden and severity of specific diseases and data necessary for attributing foodborne diseases to particular food sources. For example, gaps in attribution result in part from incomplete outbreak investigations and food exposure assessments. Where applicable, performance measures should be linked to CIFOR guidelines (<http://www.cifor.us/>).¹³

- What are the barriers to implementing performance measures?

The Working Group believes that implementation barriers include disagreement on which measures are most important and difficulties in gathering performance data (e.g., technical issues involved in sharing or gaining access to data). These obstacles result in a difficult and complicated reporting process that functions differently across various state structures for gathering disease surveillance (e.g., centralized vs. decentralized). In general, state and local agencies lack human and financial resources to modify data reporting systems to gather and report performance data. These agencies also have concerns for political ramifications if measures are misinterpreted or suggest poor performance. To date, there have been insufficient incentives and lack of “champions” to move reporting systems forward.

- What are the key factors to implementing performance measures?

The Working Group agreed that key factors in developing performance measures include a shared vision of their importance; state and local health department involvement in the development and implementation of performance measures; recognition that external evaluations are being conducted without health department participation; and the opportunity to ensure mutual accountability among federal, state, and local partners; Meaningful performance measures should be maintained through an iterative process with regular review, discussion, and modification. To be sustainable, the measures should be easy to record and report and health departments should be prepared to invest dedicated staff time and resources for their implementation.

- What additional factors could support performance measure implementation in low-resource states?

The Working Group emphasized that implementation of performance measures in low-resource states could be facilitated by providing incentives such as partnering them with high performance states (e.g., Integrated Food Safety Centers of Excellence) as used with the Rapid Response team mentoring program

(<http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/ucm297407.htm>), linking the use of the metrics to accreditation, and exploring the use of incentives that are conditional on performance measure improvement.

The Working Group strongly endorsed the use of meaningful foodborne illness surveillance performance measures at the local, state, and federal levels to encourage programmatic accountability, build the public health knowledge base to identify best practices, and show progress in reducing foodborne illness. They noted that the use of these metrics at the state and local levels will help national efforts to quantify the impact of foodborne surveillance programs, policies, and regulatory changes and to track progress on improvements in the food safety system.

RESOURCES

The FSMA SWG acknowledged that additional resources are required 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 (reduction of >50,000 personnel from 2008-2012 according to estimates from the National Association of County and City Health Officials and the Association of State and Territorial Health Officials), including hiring experienced foodborne epidemiology, laboratory, and environmental personnel. This 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 continues to be concerned about the lack of attention to adequate funding for programmatic efforts uniquely directed by CDC and implemented by state and local health departments. Specifically, none of the surveillance requirements authorized by FSMA have received corresponding additional appropriations to allow for adequate implementation.

NEXT STEPS

- To provide additional guidance on these and other emerging priority areas, the Working Group will devote time at future meetings to explore a major priority area in more depth and provide associated advice for future actions. These reviews will include expert presentations on current status and progress of each priority followed by a discussion on what enhancements could be made to improve foodborne illness surveillance in that area. Two priority areas to be reviewed in more depth during FY 2014 are
 - How to enhance surveillance for norovirus infections, which are the leading cause of foodborne illness in the United States
 - How to improve surveillance, analysis, and utilization of antimicrobial resistance data for foodborne disease pathogens

In conclusion, the Working Group believes that important progress has been made in the implementation of FSMA but that significant gaps remain that impact the quality of foodborne illness surveillance data. Ensuring states have the staff and resources to fully investigate outbreaks by identifying both the food and pathogen responsible and reporting of these data to the NORS along with improvements in the integration and sharing of data are prerequisites to the formulation, implementation, and evaluation of science-based disease prevention and control policies and to an improved overall integrated food safety system.

Appendix 1: Surveillance Working Group

Working Group Members

Meetings in December 2012 and May 2013

BSC Representative Members:

- Chair: James Hadler, MD, MPH – Associate Professor, Yale University
- Harry Chen, MD – Commissioner, Vermont Department of Health

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:

- 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
- Mary Currier Mallette, MD, MPH – Association of State and Territorial Health Officials
- Joseph Russell, MPH, RS – National Association of County and City Health Officials
- John Tilden, Jr., MS, DVM, MPH – National Association of State Departments of Agriculture

Consumer Partner Members:

- Caroline Smith DeWaal, JD – Center for Science in the Public Interest
- Sandra Eskin, JD – The Pew Charitable Trust
- Barbara Kowalczyk, PhD – Center for Foodborne Illness Research and Prevention

Industry Partner Members:

- Catherine Adams Hutt, PhD, RD – National Restaurant Association
- Russell S. Flowers, Jr., PhD – Mérieux NutriSciences Corporation
- Joan Menke-Schaenzer – ConAgra Foods, Inc

Academia Partner Members:

- Craig Hedberg, MS, PhD – Professor, University of Minnesota
- Leeann Jaykus, PhD – Professor, North Carolina State University
- John Glenn Morris, Jr., MD, MPH&TM – Professor, University of Florida

Appendix 2: 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. Relying on CDC's expertise in this area, FSMA directs the agency to improve governmental coordination and integration, evaluate and improve foodborne illness surveillance systems, and enhance external stakeholder collaboration. All are critical components of surveillance.

CDC is supporting the implementation of FSMA through many activities. Despite reduced resources at the local, state, and federal levels and no appropriation to support CDC FSMA activities, in FY 2013 CDC met ongoing requirements and supported existing infrastructure for laboratory, surveillance, and response activities and allocated \$1M to continue activities of the five Integrated Food Safety Centers of Excellence. Below is a summary of selected CDC accomplishments in support of FSMA. Most of these activities build upon existing infrastructure and labor capacity, but some are new and exclusively address CDC surveillance responsibilities under FSMA.

I. Improving Governmental Coordination and Integration

Food safety is a shared enterprise among local, state, and federal public health partners. FSMA recognizes that strong coordination among partners is essential to rapidly detect food safety problems, determine where those problems are occurring, and identify and use effective strategies to prevent foodborne illness. To that end, CDC is working to strengthen coordination and data sharing across government agencies and with external partners. Selected examples of these efforts are described below.

Coordinate federal, state, and local foodborne illness surveillance systems.

- ***Multistate foodborne illness outbreak investigations***

CDC supported federal, state, and local health agencies through monitoring 15-40 clusters of potential foodborne illness per week, resulting in approximately 10 major multistate outbreak investigations in FY 2013 (**Appendix 3**). Additionally, CDC is enhancing foodborne illness and outbreak metrics in the Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC) sites and is working with the Council to Improve Foodborne Outbreak Response (CIFOR) to develop performance measures and associated targets for their guidelines for states to use in their outbreak investigations. The council serves many professional organizations focused on state and local health department activities.

- ***CDC support of FDA Implementation of FSMA***

CDC is working closely with FDA to support its FSMA implementation efforts by providing expert guidance to a number of FDA work groups, including those focusing on produce, food defense, and state and local capacity. For example,

- CDC representatives participated in the National Agriculture and Food Defense Strategy Interagency Workgroup, which has drafted a National Agriculture and Food Defense Strategy that includes an implementation plan and a coordinated research agenda. (FSMA Section 108).
 - FSMA Section 108, directs the development of a National Agriculture and Food Defense Strategy under which FDA, USDA, the Department of Homeland Security (DHS), the Environmental Protection Agency (EPA), CDC, and state, local and tribal health authorities can work together to protect the food supply from hazards that might be intentionally added to food in the United States.

- CDC representatives have served on the Advisory Committee to the FDA Rapid Response Team (RRT) Network. The RRT network, currently comprising 18 states, in collaboration with FDA, has been developed over the past 3 years, in response to several FSMA directives aimed at FDA (FSMA Sections 202, 205c, and 209).
- CDC has contributed to the FDA-led report on the Food Emergency Response Network (FSMA 202 [b]).
 - Sections 202: FDA is directed to, in coordination with other agencies, report on progress in implementing a national Food Emergency Response Network that coordinates the capacity of state and local laboratories to be integrated with federal laboratories to respond to food-related emergencies.
 - Section 205 (C): Directs FDA to leverage and enhance food safety and defense capacities of the states to improve outbreak response and investigation, build state inspection capacity and coordination with FDA, and better share information among federal and state agencies.
 - Section 209: Directs FDA to administer programs to improve the training of state and local food safety officials.
- CDC representatives participated in the FSMA 110(g) Food Safety Research Report Interagency WorkGroup, which is drafting the development of a joint food safety and food defense research plan and report (FSMA 110[g]).
 - FSMA Section 110g directs the Secretary of HHS, the Secretary of Agriculture, and the Secretary of Homeland Security to submit to Congress, on a biennial basis, a joint food safety and food defense research plan which may include studying the long-term health effects of foodborne illness.
- CDC has partnered with FDA and USDA/FSIS on each biennial issue of the Food Code, a model ordinance developed through the Conference for Food Protection.
- CDC enteric disease surveillance and food safety experts participated in several FSMA working groups, serving as subject matter experts and advisors on proposed regulations (e.g., the Produce Rule), cost analyses, and analyses related to establishing FSMA performance standards (Section 104) and food tracing (Section 204).

***Toxoplasma gondii* serosurveillance:** At CDC, collaboration between the Division of Parasitic Diseases and Malaria in the Center for Global Health and the Division of Health and Nutrition Examination Surveys in the National Center for Health Statistics resulted in testing of 7,072 surplus serum samples from the National Health and Nutrition Examination Survey (NHANES) for 2009-2010. ***Trichinellosis* surveillance:** In collaboration with state colleagues and the Council of State and Territorial Epidemiologists (CSTE), the sensitivity and specificity of national trichinellosis surveillance was enhanced by creating probable and suspected case definitions. Previously, asymptomatic persons were counted as “confirmed” in an outbreak setting based on a positive laboratory result, which may not have reflected recent exposure. Also, persons with signs and symptoms compatible with trichinellosis who ate a food product found to contain *Trichinella* parasites but for whom no biologic specimens were available for testing could not be classified as cases.

Interagency Collaboration to Pilot the Application of Whole Genome Sequencing for Enhanced, Integrated Surveillance of the Foodborne Pathogen Listeria monocytogenes in the U.S.:

Detecting contamination of foods, quickly and accurately identifying the causative foodborne pathogen, and controlling foodborne illness outbreaks are national priorities. *Listeria monocytogenes* is estimated to cause nearly 1,600 illnesses each year in the United States, with more than 1,400 related hospitalizations and 250 related deaths. Beginning in 2013, FDA, the National Institutes of Health (NIH), and CDC partnered to pilot an integrated surveillance system for *L. monocytogenes* based on the application of whole genome sequencing to identify specific strains of *Listeria* in contaminated food and environmental isolates (FDA) and in isolates from persons with foodborne illness (CDC). Knowing the exact order of molecules in a foodborne pathogen's genome allows scientists to more quickly and accurately identify specific strains of bacteria in foods, find cases linked to foodborne disease outbreaks under investigation, identify where the original contamination of food(s) likely occurred, and quickly identify which food products need to be recalled. This groundbreaking collaboration has built upon several projects, including

- 1) the FDA supported Genome-Trakr initiative, launched in 2008, in which whole genome sequencing is used to identify specific strains of *Listeria* spp. in isolates obtained from contaminated food and food-processing environments by FDA and collaborating states (<http://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/>)
- 2) the CDC supported *Listeria Project*, launched in 2005, in which contributing states and PulseNet laboratories submit *Listeria* isolates from persons with foodborne illness to CDC for both PFGE testing (http://www.cdc.gov/listeria/pdf/ListerialInitiativeOverview_508.pdf) and, with this pilot, whole genome sequencing, and
- 3) bioinformatics expertise and big data storage and analysis infrastructure provided by NIH (<http://www.ncbi.nlm.nih.gov/guide/>). The genome sequences from food, environmental, and clinical isolates are being archived in a NIH/National Center for Biotechnology Information (NCBI)--supported genomic reference database. During the pilot, contaminated food, environmental, and clinical isolates are sequenced and uploaded into the NCBI data base, along with basic demographic, clinical, and laboratory metadata. The sequences and accompanying metadata are accessible to public health officials at all three agencies. Sequences and corresponding metadata from food and environmental isolates uploaded by FDA are being made publicly accessible in real time. For the clinical isolates, CDC is working with contributing states and PulseNet laboratories to determine at what stage, in relation to current ongoing outbreaks, the accompanying metadata can be made publicly accessible in a way that will advance the timeliness and effectiveness of outbreak detection, investigation, and control, while protecting patient confidentiality and ensuring compliance with CDC and state data sharing agreements.

FoodNet Surveillance: Continued collaboration among CDC, FDA, USDA/FSIS, and 10 state health departments participating in FoodNet resulted in major publications on the

- Incidence of *Salmonella* and *Salmonella* serotype Enteritidis to monitor progress toward High Priority Health Objectives.
- Incidence and trends of infection with pathogens transmitted commonly through food.^{3,14}

Hepatitis A surveillance: Continued to work with CDC's Division of Global Migration and Quarantine (DGMQ) and the Mexican national government to implement the Border Infectious Disease Surveillance System (BIDS), a surveillance system for monitoring diseases such as viral hepatitis along both sides of the U.S.-Mexico Border.

- Initiated a new cooperative agreement with 7 sites—Massachusetts, Philadelphia, San Francisco, New York, Florida, Washington, and Michigan—to monitor trends in incidence and risk factors for viral hepatitis A.

Increase participation of public health and food regulatory agencies and laboratories in national networks

Local and state health departments are the foundation of food safety efforts because they investigate outbreaks, conduct disease surveillance, and implement local control measures. FSMA recognizes the critical role of local, territorial, tribal, and state agencies in a national food safety system with provisions to coordinate, integrate, and enhance surveillance and outbreak response activities at all levels. Therefore, CDC is using existing resources to enhance and integrate these critical national surveillance, outbreak detection, and response networks by providing funding, tools and training, and strategic leadership. These enhancements are expected to improve the quality of data obtained. Strong data are needed to quickly identify the source of outbreaks and inform prevention efforts, and these enhancements will help ensure that data are analyzed and shared quickly to help in rapid response to food safety gaps. Specifically, CDC provided approximately \$15 million in FY 2013 funding to local and state public health departments through the ELC and the Emerging Infections Programs (EIP) to support critical foodborne illness surveillance efforts. This funding was essential to maintain core infectious disease capacity to track, detect, investigate, and respond to emerging foodborne disease threats. Other activities to support national networks included:

Supporting enteric disease labs:

- Coordinated the national proficiency testing program for the identification and subtyping of *Salmonella*, *Escherichia coli*, *Shigella*, and *Campylobacter*; 64 laboratories participated in the 2013 cycle.
- Offered a *Salmonella* workshop to train state partners on isolation, identification, and serotyping of *Salmonella* and expanded the number of states trained to use a new *Salmonella* serotyping assay to 40.
- Trained more than 30 partners from state and local public health laboratories, USDA, and FDA, and more than 10 partners from foreign countries in PulseNet methods during the past year.
- Contributed to a joint CDC/FDA/USDA/State public health laboratory project to publicly release whole genome sequence-based surveillance data for *L. monocytogenes* via NCBI/Genbank.

Preparations for the launch of CryptoNet to selected FoodNet/FoodCORE/OutbreakNet states: To improve the surveillance and outbreak investigation of cryptosporidiosis, CDC's Waterborne Disease Prevention Branch developed CryptoNet, a molecular subtyping system (similar to PulseNet) that targets *Cryptosporidium* infections. This system was tested internally during the 2009-2013 outbreak seasons and was shown to be very useful in identifying outbreaks, tracking infections and contamination sources, and investigating sporadic cases. In FY 2013, several collaborative state public health laboratories, including New York, New Hampshire, Vermont, Michigan, Minnesota, Maine, North Carolina, Colorado, Tennessee, Wisconsin, Oregon, and Idaho, submitted outbreak and/or sporadic case samples for molecular analysis and inclusion in Cryptonet.

Establishment of the Norovirus Sentinel Testing and Tracking (NoroSTAT) Network: Beginning in August 2012, a network of five sentinel states was established to improve the timeliness of norovirus outbreak reporting through NORS and CaliciNet, allowing near real-time assessment of norovirus activity. These five states (Minnesota, Ohio, Oregon, Tennessee, and Wisconsin) include ≈33 million residents or 11% of the total U.S. population spread across several regions of the country. In addition, these states historically had the highest per capita reporting rates for norovirus outbreaks and therefore were least likely to be affected by underreporting biases. State health departments that participate in NoroSTAT report suspected norovirus outbreaks through NORS and CaliciNet within 7 business days of notification of the outbreak to the state health department. NoroSTAT reporting 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.

CaliciNet enhancements: In FY 2013, CaliciNet (the national norovirus outbreak reporting network) increased the number of participating certified states from 25 to 28. Specimens from norovirus outbreaks from the remaining 22 states were typed by 5 regional CaliciNet support centers. Norovirus typing information was submitted for 1,333 norovirus outbreaks, 14.1% of which had been epidemiologically identified as foodborne.

Share surveillance information on a timelier basis among federal, state, and local agencies.

The National Antimicrobial Resistance Monitoring System (NARMS):

- Launched the NARMS web-based communication tool in October 2012 with the 54 state and local participating public health departments. By August 2013, 94% of participants had successfully uploaded information on the bacterial isolates tested by NARMS. Progress was made on development of functions that will enable communication of test result data back to the submitter using the same secure web-based tool.
- Produced interactive graphs of NARMS human isolate antimicrobial resistance data for all bacteria tested using dashboard software. These web-ready graphs have been posted on the NARMS public-facing webpage (<http://www.cdc.gov/narms/interactive-data-displays.html>).
- Tested over 550 bacteria from outbreaks or for enhanced surveillance for emerging resistance, including representatives of *Campylobacter*, *Escherichia coli*, *Salmonella*, and *Shigella*. Findings for outbreaks were reported back to submitting sites and key CDC stakeholders as soon as results were approved. NARMS developed a standard operating procedure that outlines the process for requesting state health department submission of isolates from outbreaks for antimicrobial susceptibility testing.

The Foodborne Disease Outbreak Surveillance System (FDOSS):

- Conducted four foodborne disease outbreak webinars to enhance sharing of surveillance data with and to provide training to state and local health departments on foodborne disease outbreak reporting. Nearly all states participated.
- Decreased the time to provide online access to outbreak line listing from >5 years to <2 years.
- Updated the online *Food Tool* (<http://www.cdc.gov/outbreaknet/FOOD-faq.html>) to improve public access to past foodborne outbreak data

Identify and propose solutions to eliminate key barriers at federal, state, and local levels to improve foodborne illness surveillance.

Environmental Health Specialist Network (EHS-Net) Enhancements: The National Voluntary Environmental Assessment Information System (NVEAIS) received OMB clearance on August 23, 2013, and is scheduled to be available to food safety programs in the near future. This new system will allow for local and state health departments to report contributing factors and environmental antecedents from foodborne outbreak environmental assessments associated with retail food service to CDC. The system is being made available at the same time as the e-learning training on *How to Conduct a Foodborne Illness Outbreak Environmental Assessment*. The e-Learning training is internet based and free to users world-wide. It is designed to improve domestic foodborne outbreak environmental assessments and the quality of the data reported to NVEAIS and other surveillance systems.

II. Evaluating and Improving Surveillance Systems

Develop improved epidemiological tools and microbiological methods for obtaining quality exposure data and identifying/classifying cases.

Improved data collection via FoodNet

- Developed a plan for implementation of foodborne disease exposure questions for *Salmonella* serotype Enteritidis cases
- Continued development of a set of attribution questions on exposures of interest to be added to routine surveillance

Improved multistate foodborne outbreak tracking system: CDC partnered with Palantir Technologies to develop Palantir SEDRIC (the System for Enteric Disease Response, Investigation, and Coordination), a web-based platform that can be used to facilitate collaborative multistate foodborne outbreak investigations. During the year, SEDRIC has been made available to 314 users in 48 states, CDC, FDA, and USDA/FSIS.

Identification of new food vehicles causing foodborne illness: CDC and its partners also identified new food vehicles during foodborne outbreak investigations. Information on risks from these foods, which have never before been tied to outbreaks or illnesses, provide a feedback loop to industry and regulators to allow development of better safety standards. For example, since 2006, CDC has identified at least 15 new foods that have become contaminated and made people sick—including Turkish tahini sesame paste that made 16 people from nine states sick with *Salmonella* Montevideo and *Salmonella* Mbandaka infection in 2012 (Appendix 3).

Development of better methods to detect, investigate, respond to, and control multistate foodborne outbreaks: CDC has also continued support of the FoodCORE program, a group of seven centers that are enhancing foodborne disease outbreak response. Using targeted resources, the centers develop innovative and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. Leveraging laboratory, epidemiology, and environmental health capacity, FoodCORE centers successfully developed and applied model practices to build capacity for routine and surge capacity needs, making faster, more complete investigations possible. FoodCORE centers improved timeliness and completeness of their foodborne disease outbreak response programs and used performance metrics to document progress. The first annual summary for FoodCORE activities was completed; the report is available on the FoodCORE website (<http://www.cdc.gov/foodcore/>), along with program highlights and additional information for FoodCORE performance metrics and model practices.

Examples of activities undertaken by CDC's Enteric Diseases Laboratory Branch to enhance lab methods:

- Began the effort to assess the use of whole genome sequencing as part of the PulseNet armamentarium for characterization of outbreak-related foodborne pathogens and began exploring the utility of the method for molecular serotyping and characterization of associated virulence, antimicrobial resistance, and house-keeping genes of foodborne pathogens.
- Deployed *Salmonella* molecular serotyping assay to state health departments and facilitated making the assay available at reduced pricing through a commercial partner.
- Completed the validation of mass spectroscopy (Endo-PEP MS) for the detection of botulinum neurotoxin in clinical and non-clinical specimens and began plans to implement the method routinely in the surveillance of botulism in the United States. This project will remove the need for using the reference method for botulinum neurotoxin testing (the mouse bioassay) outside CDC.

- Initiated a 1-year proof-of-concept study of the use of whole genome sequencing for enhanced surveillance of listeriosis in collaboration with CDC, FDA, USDA, NIH, and public health and agricultural partners locally, nationally, and internationally.

Examples of efforts undertaken by CDC's parasitic diseases laboratory to improve cyclosporiasis and trichinella diagnoses:

- Designed, optimized, and utilized a TaqMan assay designed for identification of *Cyclospora cayetanensis* (identification to the species level), as a confirmatory diagnostic technique on 75 specimens during the recent multistate cyclosporiasis outbreak investigation.
- Developed a new DNA extraction method to improve molecular diagnosis of cyclosporiasis.
- Identified and evaluated a new EIA kit for serologic diagnosis of *Trichinella* infection. Laboratory staff optimized the test and improved its specificity, resulting in a new assay that is more reliable and consistent than the previous assay, directly affecting the completeness and accuracy of surveillance and outbreak data.

Tracking and analysis of culture-independent test use in laboratories: FoodNet continued to actively track and analyze the use of culture-independent tests in the laboratories serving the surveillance area. Abstracts presented during IDWeek 2012 included "Diagnostic practices for detection of enteric infections in clinical laboratories – FoodNet, 2012"¹⁵ and "Changes in diagnostic methods used by clinical laboratories to detect Shiga toxin-producing *Escherichia coli* (STEC) infections – FoodNet, 2007-2012."¹⁶

Improved attribution of foodborne illness outbreaks to specific foods.

Since its creation in 2011 the CDC/FDA/FSIS Interagency Food Safety Analytics Collaboration (IFSAC) has focused analytic efforts on developing methods to estimate foodborne illness source attribution for priority pathogens. In 2013, IFSAC project teams, composed of members of each agency and coordinated by a steering committee, completed the following:

- Provided estimates of the proportion of *Salmonella* serotype Enteritidis (SE) illnesses attributable to shell eggs and other major commodities as part of a Health and Human Services Priority Goal to reduce SE illnesses transmitted by shell eggs (http://goals.performance.gov/goal_detail/HHS/372).
- Worked to develop a shared method to estimate the proportion of foodborne illnesses caused by *Salmonella*, *Campylobacter*, *Escherichia coli* O157:H7, and *Listeria* attributable to 24 different food categories.
- Provided consultations to member agencies and participated in a series of information exchanges with the Interagency Risk Assessment Consortium; these consultations have established precedents for improved communication and collaboration on top food safety priorities.
- Agreed on a shared communication plan to inform the public and stakeholders about IFSAC activities and projects. As part of communication efforts, IFSAC held a webinar in June 2013 to update nearly 200 participants from food industry, consumer advocacy groups, academia, and public health on recent changes to food categories used for foodborne illness source attribution ([Webinar](#)), held a symposium at the annual meeting of the International Association of Food Protection (IAFP), and is developing related webpages scheduled to go live in early FY 2014.

Other CDC-supported activities to enhance attribution include the following:

- USDA/FSIS and the University of Florida utilized NHANES *Toxoplasma gondii* data to help determine the annual cost and quality-adjusted life-year losses attributed to foodborne toxoplasmosis in the United States. In this evaluation, *Toxoplasma gondii* was a leading source of costs and loss of quality-adjusted life years.¹⁷
- The Foodborne Disease Outbreak Surveillance System developed 1) a new food commodity scheme for classifying foods implicated in outbreaks and 2) new methodology to examine outbreak details to more accurately attribute outbreaks to foods.

III. Enhanced External Stakeholder Collaboration and Sharing of Information

Share surveillance information on a timelier basis with the food industry, academia, consumers, and the public

Media and public interest has been higher for foodborne illness and outbreaks than for almost any other CDC program.

In 2012, CDC received more than 1,600 media requests for information on food safety issues –ranging from complex data releases to outbreak updates.

Stakeholders—from farmers to regulators to consumers—rely on CDC for information to help keep the food supply safe, including practical information the public can use.

CDC manages strategic partnerships by **promoting, exchanging, and disseminating** information through oral and written briefings, websites, blogs and social media, partner updates, and media interviews.

Since the inception of FSMA, CDC has worked diligently to improve sharing of timely information through integrating communication, science, and policy expertise. This team approach better meets today's

need for fast and accurate information, often in the form of social media, and reaches a broader audience base. Partners prefer that CDC share relevant information on new and complex data directly, in lieu of, or in addition to, scientific publications.

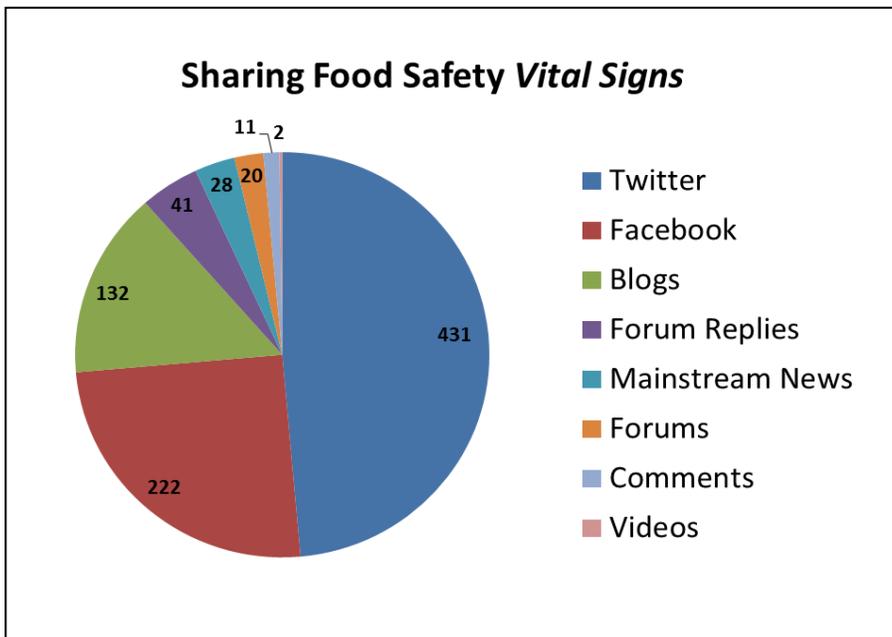
Historically, food safety communications included annual surveillance summaries with data from the surveillance networks, scientific publications and presentations, and outbreak alerts. Today, the public demands more information—more frequently and through multiple platforms.

Science & Communications—Targeting Food Safety

One way that CDC blends science and communications is through its **Vital Signs** program (<http://www.cdc.gov/vitalsigns/>), a campaign using the latest available surveillance data to produce a call-to-action about an important public health topic. CDC's first *Vital Signs* devoted to food safety (<http://www.cdc.gov/VitalSigns/Foodsafety/index.html>) focused on one of the most common germs found in food—**Salmonella**. This year's *Vital Signs* food safety report (<http://www.cdc.gov/VitalSigns/Listeria/index.html>) examined one of the most deadly germs spread by contaminated food—*Listeria monocytogenes* (**Listeria**), and described high-risk populations and actions that can be taken to protect those who are most at risk. It also highlighted the importance of safety measures to prevent contamination of cheese and raw produce, such as those included in the 2011 FSMA. The 2013 report also provided a national snapshot of illnesses, infection rates, and foods associated with *Listeria* outbreaks reported to the CDC during 2009-2011. Three monitoring systems were used to collect data: the **Listeria Initiative**, a national system for rapid response and reporting of *Listeria* cases; **FoodNet**, an active surveillance network for tracking trends in nine foodborne infections; and **Foodborne Diseases Outbreak Surveillance**, a unique system that captures outbreak data on agents, foods and settings.

Metrics:

- In one month, there were **746 news articles** on the *Vital Signs* information in the form of 483 online broadcasts, 67 news web sites, 122 television station shows, 24 online print version stories, 16 daily newspapers, and 16 blogs and other media. For comparison, the two previous *Vital Signs* releases garnered 318 and 444 news articles respectively.
- Potential reach of more than 420 million people.
 - Defined as the number of people who could have potentially seen one of these articles, by virtue of average copies sold per day (circulation), or broadcast or cable TV (Nielsen), or online (counting unique site visitors per month).



Twitter was the #1 way *Vital Signs* was shared

Selected 2013 Partnership Highlights:

In 2013, CDC made it a priority to consistently engage partners prior to major data releases, to update and develop new websites with interactive tools and graphics, to engage the media, and to send regular partner notifications.

2013 highlights included:

- Provided over 10 briefings to 300 partners for key data releases
- Doubled web page views on CDC's websites for food safety
- Created new or updated major websites for Integrated Food Safety Centers of Excellence, (<http://www.cdc.gov/foodsafety/centers/index.html>), PulseNet (<http://www.cdc.gov/pulsenet/>), NARMS (<http://www.cdc.gov/narms/>), Foodborne Outbreak Tracking and Reporting (<http://www.cdc.gov/foodsafety/fdoss/index.html>), and others
- Hosted 30 executives and communicators from 17 major food companies for a day-long meeting
- Co-authored CDC's Antibiotic Resistance Threats Report (<http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>), with world-wide distribution. Geared to policy and public audiences, the report, for the first time, consolidated CDC data to show the alarming and major problem of antimicrobial resistance for the United States
- Sent monthly updates to food safety partners through CDC's GovDelivery distribution channel reaching 30,000 subscribers--a 7,000 jump in monthly subscribers since January. (<http://www.cdc.gov/foodsafety/announcements.html>.)

Epi Ready Team Training: CDC's Food Safety Office/Division of Foodborne, Waterborne, and Environmental Diseases funded the National Environmental Health Association to conduct three Epi-Ready Team Training courses during the spring and summer of 2013 in Racine, Wisconsin; Plainview (Lubbock), Texas; and Contra Costa County, California. More than 140 local and state officials participated in the 2-day classroom courses which covered topics such as outbreak team formation, planning, detection, and investigation by teams of epidemiologists, laboratorians, environmental health specialists, public health nurses, communication experts, and others.

Food Allergy and Anaphylaxis Management: FSMA §112(b)(1) required the Establishment of Voluntary Food Allergy and Anaphylaxis Management Guidelines for use in schools and early childhood education programs. To help address this requirement, CDC convened an expert panel to inform guidance priorities and content, and summarized scientific and school health-related data and papers related to managing food allergies in schools. Subsequently, an advisory working group of federal agencies and relevant organizations was formed to inform school food allergy guidance. Federal agency partners included the Department of Education, USDA, and several other HHS agencies (FDA, NIH/National Heart, Lung, and Blood Institute). Experts in the fields of food allergy included the Food Allergy and Anaphylaxis Network; the Food Allergy Institute; American Academy of Allergy, Asthma, and Immunology; and the American College of Allergy, Asthma, and Immunology. Educational and school-health agency representatives included those from the National School Boards Association, National Education Association, National Association of School Administrators, National Association of School Nurses, and the American School Health Association. Proposed guidelines were drafted and cleared by the HHS Secretary, and the new guidelines (http://www.cdc.gov/healthyyouth/foodallergies/pdf/13_243135_A_Food_Allergy_Web_508.pdf) were released on October 30, 2013. The National Association of School Nurses, The American Academy of Pediatrics, and Food Allergy Research and Education are supporting the release with communication materials and trainings.

Integrated Food Safety Centers of Excellence: The five Integrated Food Safety Centers of Excellence (CoEs) (Colorado, Florida, Minnesota, Oregon, Tennessee), which are housed in state health departments and partnered with universities, had a productive year. Accomplishments include training needs assessments completed by Florida (covered Alabama, Florida, Georgia, and Puerto Rico) and Colorado (state, city, and county staff in Colorado). The findings of these needs assessments will be used to develop various types of

training material related to foodborne disease outbreak detection, investigation, and control for local and state officials. Colorado developed a catalog of current outbreak training courses across the United States to ensure that no duplication will occur in the development of the CoE training material. Florida conducted assessments of outbreak plans and procedures in every county in the state. The results will help guide development of the training course content. The Minnesota CoE led the development of the initial set of performance indicators and metrics for the CoEs and is developing a set of model practices based on years of experience in successfully detecting and investigating foodborne disease outbreaks. The Tennessee CoE led the development of the CoE design element (logo) and recommended content for CoE websites. Additionally, Tennessee is developing a web-based training course on outbreak detection and response that will be publicly available. The Oregon CoE has conducted on-site assistance to the Alaska Department of Health regarding outbreak detection and investigation techniques and processes. Additionally, Oregon has developed several software applications that have the potential to substantially improve tracking foodborne illness and investigating outbreaks. CDC conducted site visits to two CoEs, and an annual CoE Vision meeting was held in Atlanta to examine progress and establish future priorities and discuss possible projects.

Appendix 3: Selected Multistate Foodborne Illness Outbreaks, United States, FY 2013

Pathogen	Distribution	Vehicle
<i>Salmonella</i> Typhimurium and Newport	261 illnesses reported from 24 states	Cantaloupe
<i>Salmonella</i> Braenderup	127 illnesses reported from 15 states	Mangoes
<i>Salmonella</i> Bredeney	42 illnesses reported from 20 states	Peanut butter
<i>Salmonella</i> Typhimurium	22 illnesses reported from 6 states	Ground beef
<i>Salmonella</i> Heidelberg	134 illnesses reported from 13 states	Chicken
<i>Salmonella</i> Saintpaul	84 illnesses reported from 18 states	Cucumbers
<i>Salmonella</i> Montevideo and Mbandaka	16 illnesses reported from 9 states	Tahini sesame paste
Multidrug-resistant <i>Salmonella</i> Heidelberg	362 illnesses reported from 21 states and Puerto Rico*	Chicken
<i>Cyclosporiasis</i>	631 illnesses reported from 25 states	Salad mix, cilantro
Hepatitis A	162 illnesses reported from 10 states	Pomegranate seeds

*as of 10/29/2013

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