Board of Scientific Counselors, Deputy Director for Infectious Diseases

Food Safety Modernization Act Surveillance Working Group

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

2019

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BSC/DDID FSMA Surveillance Working Group 2019 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 (BSC), Office of Infectious Diseases (now Deputy Director for Infectious Diseases, DDID), a federal advisory committee. FSMA also required this working group to provide an annual report to the Secretary of Health and Human Services with advice and recommendations regarding the improvement of foodborne illness surveillance. This eighth annual report summarizes the FSMA SWG's activities during FY 2019 and the BSC/DDID's recommendations based on the findings of the FSMA SWG.

The FSMA SWG held two 2-day meetings in FY 2019, convening in December 2018 and again in May 2019 at CDC in Atlanta, to review and respond to specific questions 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 2018 Working Group meeting focused on responding to specific questions on CDC foodborne illness surveillance data systems and strategies, the Interagency Food Safety Analytics Collaboration (IFSAC) activities and analytic approaches, and recent significant produce outbreaks.

The May 2019 meeting focused on a review and discussion of two major topic areas: the challenges and opportunities of whole genome sequencing (WGS) for illness detection and response, and water as a food safety program.

The Working Group applauded recent increases in funding for food safety infrastructure, but the issues identified in this report emphasize the need for continued resources for these activities.

BSC/DDID FSMA Surveillance Working Group 2019 Report to HHS Secretary

INTRODUCTION

This report describes the fiscal year (FY) 2019 activities of the Food Safety Modernization Act Surveillance Working Group (FSMA SWG) of the Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC/DDID), 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 20 experts representing local, state, and federal governments; academia; industry; and consumer groups (Appendix).

During FY 2019, the Working Group reviewed activities and responded to specific questions on CDC foodborne illness surveillance data systems and strategies, the Interagency Food Safety Analytics Collaboration (IFSAC) activities and analytic approaches, and recent significant produce outbreaks. The Working Group also reviewed and discussed the challenges and opportunities of whole genome sequencing (WGS) for illness detection and response, and water as a food safety program.

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 future 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 the Foodborne Diseases Active Surveillance Network (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 in foodborne illness surveillance systems so they can 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, this FSMA SWG was created.

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 responses in FY 2019 and summarizes priority areas for focus in the coming year.

WORKING GROUP ACTIVITIES—FY 2019

During its eighth year, the FSMA SWG met twice, in December 2018 and May 2019 at CDC in Atlanta, to consider several recent and ongoing developments in foodborne illness surveillance that are key to maintaining and improving surveillance systems. The December 2018 Working Group meeting focused on responding to specific questions on CDC foodborne illness surveillance data systems and strategies, IFSAC activities and analytic approaches, and recent significant produce outbreaks. The May 2019 meeting focused on a review and discussion of two major topic areas: the challenges and opportunities of WGS for illness detection and response, and water as a food safety program. FSMA SWG leadership reported the working group's activities and findings to the BSC/DDID at its meetings, also in December 2018 and May 2019, for discussion, for approval of the annual report, and to make recommendations to CDC and to the HHS Secretary. These topics and Working Group discussions are summarized below. Previous annual reports are posted on the BSC/DDID FSMA SWG website.

I. CDC Foodborne Illness Surveillance Data Systems and Strategies

Overview of DFWED Foodborne Illness Surveillance in Its Current State

The mission of CDC's Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) is to improve public health nationally and internationally through the prevention and control of disease, disability, and death caused by foodborne, waterborne, and environmentally transmitted infections. DFWED supports states' capacity to conduct surveillance through the Epidemiology and Laboratory Capacity (ELC) for Infectious Diseases Cooperative Agreement and the Emerging Infections Program (EIP). The ELC is CDC's national funding strategy that supports state, local, and territorial health departments in combatting domestic infectious disease threats. The EIP is a network of 10 state health departments that act as a national resource for surveillance, prevention, and the control of emerging infectious diseases by providing the highest quality scientific information to monitor emerging problems, evaluate public health interventions, and inform policy.

DFWED uses the following 14 surveillance systems to track and monitor reports of foodborne and waterborne diseases in the United States:

- COVIS: Cholera and Other *Vibrio* Illness Surveillance
- CryptoNet: Molecular-based Cryptosporidiosis Surveillance
- FDOSS: Foodborne Disease Outbreak Surveillance System
- FoodNet: Foodborne Diseases Active Surveillance Network
- LEDS: Laboratory-based Enteric Disease Surveillance (formerly PHLIS: Public Health Laboratory Information System)
- LI: *Listeria* Initiative
- NAFIS: Network for Aquatic Facility Inspection Surveillance
- NARMS: National Antimicrobial Resistance Monitoring System for Enteric Bacteria
- NNDSS: National Notifiable Diseases Surveillance System

- NORS: National Outbreak Reporting System
- NTPFS: National Typhoid and Paratyphoid Fever Surveillance
- OHHABS: One Health Harmful Algal Bloom System
- PulseNet: National Molecular Subtyping for Foodborne Diseases
- SI: STEC [Shiga toxin-producing *Escherichia coli*] Initiative

Surveillance can be passive, when healthcare providers/laboratories send reports to a health department on the basis of a known set of rules and regulations, or active, when health department staff contact healthcare providers/laboratories to solicit reports. The surveillance systems also differ in how they survey populations. Populations under surveillance can be national or sentinel, and the systems may record every single case or use a sampling scheme.

The surveillance systems record cases and outbreaks by different methods including

- Case-based surveillance - counts diagnosis of illness in a person
- Isolate-based surveillance - counts laboratory characterization of an isolate or a specimen
- Event-based surveillance - based on an event and no individual level data are reported

In addition, diseases reported in the data systems are categorized as reportable, nationally notifiable, and standardized:

- Reportable disease cases are mandatorily reported to state, local, and/or territorial jurisdictions when identified by a healthcare provider, hospital, or laboratory. State, local and territorial jurisdictions establish their lists of reportable diseases.
- Nationally notifiable disease cases are voluntarily reported to CDC by state and territorial jurisdictions, and not all nationally notifiable conditions are reportable in every state.
- Standardized surveillance captures cases meeting agreed-upon case definitions set by the Council of State and Territorial Epidemiologists (CSTE) that can be sent to CDC.

DFWED Surveillance Going Forward (2019 and Beyond)

Some CDC surveillance systems exist in silos, but improvements in connectedness are continually being made. Culture-independent diagnostics tests (CIDTs), WGS, and ongoing, agency-wide initiatives for surveillance modernization continue to transform DFWED's surveillance systems. It is important that CDC dovetail and improve systems for national surveillance and support improved reporting from states to the National Notifiable Disease Surveillance System (NNDSS).

DFWED began working on a new surveillance strategy in 2018 to modernize and improve connectivity among surveillance systems. This strategy includes (1) forming a working group of experts in epidemiology, laboratory methods, surveillance, outbreak investigation, and bioinformatics; (2) holding regular meetings to discuss coordination of major surveillance efforts; and (3) organizing a retreat focused on developing a strategic plan. These efforts have resulted in the following surveillance objectives and strategies:

- Optimize data collection and transmission
    - Hire and retain staff with informatics skills
    - Support state partners

    - Change data, processes, and systems in response to what is useful
- Link data sources in a timely manner
    - Define standards for surveillance data and systems
    - Improve compatibility between data and systems
- Drive action-oriented analyses
    - Use and develop methods to identify public health problems
    - Monitor progress towards prevention efforts
    - Identify data needed for prevention efforts
- Disseminate data and conclusions to catalyze action
    - Discuss results and plans with partners
    - Translate surveillance data to prevention actions
    - Communicate successes and challenges

Currently, DFWED is supporting improved reporting from all states to NNDSS by piloting in several states the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG) for multiple pathogens. The FDD MMG is expected to eventually be adopted by all states and will lead to streamlined data transmission between states and CDC. The FDD MMG is a guide for all jurisdictions on how to send data via an HL7 (Health Level 7) format for multiple nationally notifiable conditions and contains a subset of data elements.

Discussion/Response

Discussion

The Working Group's discussion included the following observations:

- CDC has very rich data on enteric diseases and foodborne illness, but the current surveillance data system is at times outdated, inefficient, and in need of better integration.
- While progress is being made, it is taking a significant amount of time to move away from records in paper form and provide data to multiple systems at CDC (i.e., 1991 *MMWR* Editorial Note).
- Surveillance data should be disseminated regularly and include information on whether the overall goal of reducing burden of foodborne illness is being achieved. Data interpretation may be complicated because better detection and better investigation increases reported cases and outbreaks; however, it is important to monitor progress toward achieving the desired outcome.
- Data and analyses disseminated by CDC should be actionable and provide enough detail to inform the frontline public health workforce.
- Having data electronically accessible to partners and the public (e.g., FoodNet Fast, NARMS Now) is more important than focusing on integrating data into fewer reports. Outward-facing, accessible data should be the goal.
- State and local health departments are the main users of data reported by CDC, but consumers, healthcare institutions, academic institutions, and industry also use these data and should be considered audiences.

- Delays in data release make it challenging for industry to act to prevent future outbreaks. Surveillance data should be made available to industry so they can determine factors associated with outbreaks and take preventive actions. Additionally, further discussion is needed about FDA's ability to share producer information with industry.
- In addition to improving data collection, CDC should focus on collecting the "right" data rather than more data. Utilizing information from IFSAC projects (e.g., attribution and source predictive modeling) may help investigators determine which exposures are most valuable to focus resources to collect information.
- Improvements to surveillance need to focus on what would enhance public health work. The technology that is used should be streamlined rather than trying to use all new technology that may be overwhelming and, ultimately, reduce efficiencies.
- Electronic reporting of all notifiable diseases to CDC should be required. This includes a need for more automatic/electronic data systems for organisms such as *Cyclospora* and *Cryptosporidium*, which are, currently, largely labor-intensive paper systems.
- Funding to improve state epidemiological and laboratory capacity to conduct surveillance is a key priority. States continue to face technical and information technology challenges, because modernizing their systems is expensive. Funding support for states to improve core epidemiological capacity is also needed, as it is essential that investigations occur in a timely manner.
- Outbreaks could be detected much earlier if there was better surveillance. CDC has invested millions of dollars to transition its systems to align with current technology (e.g., WGS) and provide support to states to do the same. Nevertheless, the technological landscape is ever-changing, forcing CDC to adapt to be at the forefront.

Response

Based on these discussions, the Working Group expressed interest in updates at future meetings on data integration efforts, including specific actions to advance the objectives and strategies. The Working Group highlighted the following possible responses:

- Continued infrastructure improvements are needed to enhance
    - States' ability to send electronic reports to CDC
    - CDC's ability to receive electronic data from states
    - CDC's ability to connect data systems to reduce redundancy
    - CDC's ability to adapt current systems to new technology (e.g., WGS)
    - Making data available for users (e.g., using NORS Dashboard and NARMS NOW as models)
- Better traceforward/traceback data points, as well as better exposure data, are needed.
- New electronic and standardized epidemiological tools and informatics training are essential, as CDC aims to eventually phase out paper reporting and move to 100% electronic reporting from states.
- Challenges with data sharing persist. Improved surveillance data sharing from industry to FDA and CDC and vice versa is needed. Federal agencies should work closely with industry outside of outbreaks because communication is limited due to legal issues during outbreaks.

- State and local epidemiologists should receive training on interpretation of WGS surveillance data, so they can better prioritize which clusters to investigate.
- Surveillance data should be actionable to be more helpful to regulators and decision-makers. State regulators are interested in knowing their state's illness rates, how they compare with other states regionally and nationally, and the foods causing illness, in addition to ways to eliminate sources of contamination.

II. IFSAC Activities and Analytic Approaches

IFSAC Updates and Progress on Assigning Point of Contamination

The Interagency Food Safety Analytics Collaboration, established in 2011, coordinates efforts by CDC, the U.S. Food and Drug Administration (FDA), and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA/FSIS) to identify, plan, and conduct selected food safety and foodborne illness analytic projects and improve coordination of federal food safety analytic efforts. Some of IFSAC's accomplishments in 2018 included a publication on the updated scheme for categorizing foods implicated in foodborne disease outbreaks; an annual report on foodborne illness source attribution estimates for four priority pathogens: *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter*; and informing partners of IFSAC work at national and international conferences.

One of IFSAC's current projects is the Point of Contamination (POC) project, which evaluates CDC, FDA, and FSIS datasets' utility in assessing points of contamination in foodborne disease outbreaks. The project resulted in the development of a method that utilizes multiple Foodborne Disease Outbreak Surveillance System (FDOSS) variables to classify outbreaks based on the regulatory jurisdiction under which contamination likely occurred, which may help break down and group certain points in the supply chain, such as retail versus manufacturing. The jurisdiction-based approach is now automated: 80% of outbreaks reported during a 16-year period can be auto-classified based on the regulatory jurisdiction (the remaining 20% require manual review). The next steps in the POC project include focusing on manually reviewing unassignable outbreaks and summarizing findings.

III. CDC and FDA Updates on Recent Produce Outbreaks

Cyclosporiasis Outbreaks

During the 2018 cyclosporiasis outbreak season (May–August), there were 2,299 laboratory-confirmed, domestically acquired cases reported to CDC. Many of the cases could not be linked to an outbreak and/or vehicle. Importantly, this was the first time *Cyclospora* was detected in domestically grown products. Preliminary data analyses revealed several notable produce-associated cyclosporiasis outbreaks including

- 250 cases linked to Kwik Trip/Del Monte pre-packaged vegetable trays
- 511 cases linked to McDonald's salads
- Two basil-associated clusters including 16 cases in two states
- Three cilantro-associated cases at Mexican-style restaurants: 53 cases[6]

Epidemiological Challenges

The lack of a laboratory subtyping method, such as pulsed-field gel electrophoresis (PFGE) or WGS, for *Cyclospora* significantly hampers epidemiological investigations. Large amounts of case exposure data must be reviewed line by line to find potential clusters of illness resulting in significant delays in identifying an illness cluster and more outbreaks that go unsolved. At present, a subtyping method is not feasible for multiple reasons:

- *Cyclospora* cannot be cultured.
- Most stool samples contain too few oocysts.
- Two sporocysts from the same oocyst may be genetically distinct because *Cyclospora* reproduces sexually in the gut of infected humans.

CDC is working to develop a molecular typing technique that can be used to link infections caused by genetically related *Cyclospora* organisms to each other and to a food vehicle/source; many of these efforts are in collaboration with FDA. In addition to the lack of molecular typing, other epidemiological challenges with cyclosporiasis include the impact of CIDTs on surveillance and reporting and changes in how data are collected and transmitted to CDC.

E. coli O157 Outbreak

In 2018 an outbreak of *E. coli* O157 infections linked to romaine lettuce occurred and was the largest outbreak of Shiga toxin-producing *E. coli* since the 2006 outbreak associated with spinach. It involved 210 cases (96 hospitalizations, 27 cases of hemolytic uremic syndrome, and 5 deaths) from 36 states. Infections were linked to romaine lettuce via epidemiological, traceback, and laboratory evidence:

- A high percentage of ill people reported eating romaine lettuce (87% or 145/166 interviewed).
- FDA traceback linked consumed lettuce to farms in the Yuma growing region.
- WGS results showed that the illnesses were all closely related genetically, and water isolates collected and analyzed by CDC from three locations of the irrigation canal in the region of the outbreak were closely related to the clinical isolates.

Public health authorities were successful in rapidly identifying and investigating illness sub-clusters to help confirm the outbreak vehicle, issuing public warnings within 8 days of identifying the multistate outbreak, and demonstrating the value of WGS in an investigation.

Epidemiological Challenges

- People who eat lettuce eat it often, and many have multiple exposures.
- Many people do not remember the type of lettuce they ate.
- Short shelf life limits ability to test leftover product.
- Lack of growing location on packaging complicated the consumer/retail warnings.

IV. Challenges and Opportunities of WGS for Illness Detection and Response

The implementation of WGS as the new standard subtyping method in PulseNet began in spring 2019. CDC has worked for several years to increase laboratory and epidemiological capacity for the transition from PFGE to WGS. As of April 26, 2019, 50 states including 64 labs have converted to BioNumerics 7.6, and 48 states

including 55 labs are WGS Analysis Certified for *Listeria*, *Salmonella*, *Escherichia*, and *Campylobacter*. In addition, there have been numerous trainings, webinars, and meetings to prepare for the transition to WGS including

- 50-State OutbreakNet calls
- 50-State Laboratory calls
- PulseNet Webinars
- PulseNet/OutbreakNet Regional meetings
- CSTE's Advanced Molecular Detection (AMD) Molecular Epidemiology training
- MiSeq/BioNumerics training
- Integrated Food Safety Centers of Excellence WGS training (BioNumerics and WGS interpretation) webinars
- CoE "Office hours" (live consultations for WGS facilitated by CoE staff)

Discussion/Response

Discussion

The Working Group's discussion included the following observations:

- Concerns exist regarding the future need to triage cluster investigations as states transition to WGS due to the potential increased epidemiological workload and due to reductions in federal funding awarded to states for testing.
- Efforts are underway to create a hierarchical nomenclature consisting of a sequence of five or six numbers (allele codes) that will indicate the relatedness of isolates. Outbreaks will still have outbreak codes, but allele codes will be the WGS equivalent of PFGE patterns. In addition, epidemiologists and laboratorians will still be able to use WGS trees to examine data, but allele codes will be used more often.
- WGS predicts resistance of all sequenced isolates, not only those submitted to CDC for phenotypic resistance testing. WGS will help to rapidly identify known antimicrobial resistance (AR) genes, which will enable public health response in near real time and enable isolates and resistance determinants to be compared globally. In addition, AR surveillance for multistate outbreaks will become timelier and more representative, especially for single-state outbreaks. NARMS will continue to receive 1 in 20 surveillance pathogens to detect novel resistance.
- Although *Campylobacter* is not routinely sequenced, it has been sequenced to help with AR patterns in the past. *Campylobacter* isolate sequencing will also be impacted by the increased use of CIDTs by clinical laboratories.
- Concerns were expressed regarding BioNumerics' global usability and upkeep. Efforts are underway to create a software that is open-source, as well as prepare for metagenomics.
- A concerted effort by federal partners is needed to create a single/joint pipeline for states to submit human, animal, and environmental data. Data currently go through the National Center for Biotechnology Information (NCBI) and then to the PulseNet database.

- WGS helps define "clades of concern"—groups of closely related strains that persist for years. These clades of concern have caused repeated outbreaks from similar sources, more sporadic cases over time, are often multidrug resistant, and may not appear as classic time-place-person outbreaks. Defining clades of concern can provide focus for intensive investigation, traceback, and environmental assessment and new prevention measures by industry and regulatory partners.

Response

Based on these questions, the Working Group highlighted the following possible responses:

What do you see as CDC's role in helping to prevent, or limit, the emergence of multidrug-resistant (MDR) strains in food animals and subsequent transmission to humans?

CDC could

- Address ongoing and recurring clades (strains of concern)
- Improve epidemiological tools for rapid identification of clusters with limited WGS of isolates and increase in CIDT-diagnosed patients
- Examine resistant agents in produce, not just resistance from agents in humans and animals
- Look at AR in sporadic illnesses, not just in outbreaks
- Evaluate information about environmental sources of resistance to enable CDC to identify resistance genes before human illness occurs
- Strengthen its capability to handle large, complex data sources (i.e., WGS)

How can CDC engage regulatory, animal, and agriculture partners with public health problems, where there is unclear, or lack of, regulatory oversight?

CDC could

- Use an interdisciplinary, interagency, One Health approach as was demonstrated with enteric zoonotic issues and backyard flocks
- Engage the USDA Animal and Plant Health Inspection Service on farm-related issues with a focus on the current gap in access
- Explore solutions with the new DFWED Prevention Coordination Unit

What do your organizations or agencies see as opportunities for WGS in the next year?

Opportunities

- Increased identification of clusters and outbreaks
- Help regulators/policy-makers focus on priority areas

Challenges

- Triaging to address the potential increase in cluster volume
- Increased resources (human and IT) needed
- Effectively communicating what data mean to public/stakeholders

V. Water as a Food Safety Program, "The Water We Eat"

Water quality is an essential component to food safety. Food production processes use water in many ways including irrigation, cleaning, cooling, and storing. While there are limited environmental data to support the etiological connection, water contamination has been suspected in recent foodborne disease outbreaks. Acquiring data to support the connection is challenging due to the following:

- Most contamination occurs long before field investigations are performed, which reduces the likelihood of detecting the causative agent or pathogen
- Time delays between the time of contamination and recognition that an outbreak is occurring
- Subsequent time needed to organize and plan environmental investigations
- Collecting samples in diverse and dynamic environments
- The capacity for testing is usually only available at the federal level

CDC's Waterborne Disease Prevention Branch (WDPB) is working to address these challenges. WDPB's core mission activities include providing outbreak response support for foodborne disease outbreaks in which water quality is a potential risk factor. These efforts include

- Providing guidance on how to conduct environmental investigations and assessment of water resources as part of root cause analyses
- Research on irrigation water quality, produce wash water systems, and water quality in processing facilities
- Improving field and laboratory investigation methods
- Building federal, state, and local capacity for environmental investigations
- Health promotion related to safe water, sanitation, and hygiene
- Contributing to science-based best practices and policies for agricultural water

WDPB Surveillance Activities

The U.S. burden of waterborne diseases is estimated at 7.2 million cases, which includes 600,000 emergency department visits, 120,000 hospital stays, and 7,000 deaths, and costs $3.2 billion (hospital stays and emergency department visits) annually. The top pathogens implicated in the cases are norovirus, giardiasis, and cryptosporidiosis. Ninety-four percent of the deaths and 78 percent of the costs are biofilm-associated (non-tuberculous mycobacteria infection, Legionnaire's Disease, *Pseudomonas* pneumonia, and septicemia).

WDPB currently collects data about waterborne illness through the following systems:

- Waterborne Disease and Outbreak Surveillance System (WBDOSS)
    - Collects data on waterborne disease outbreaks associated with drinking water, recreational water, environmental, and undetermined exposures to water
- National Outbreak Reporting System (NORS)
    - Detects foodborne, waterborne, and enteric outbreaks due to person-to-person, animal contact, or unknown mode of transmission

- One Health Harmful Algal Bloom System (OHHABS)
    - Collects environmental event data and clinical information from human and animal cases of harmful algal bloom exposure
- CryptoNet
    - Collects data on cryptosporidiosis using molecular-based surveillance

Food-water Nexus Partnerships and Capacity Building & Looking Forward

Capacity can be improved by recognizing the overlap and synergies between programs:

- Local environmental health programs, local health departments, and water utility emergency preparedness
- State and federal food and water programs
    - CDC ELC funding to support combined food and water programs
- Infectious disease and environmental health programs
    - CSTE Infectious Disease and Environmental Health committees now jointly discussing food and water priorities

Discussion/Response

Discussion

The Working Group's discussion included the following observations:

- Efforts are underway to determine attribution estimates of foodborne disease caused by contaminated water.
- Currently, there is little state or national capacity to conduct environmental investigations for water-related foodborne disease. No explicit field or lab training programs exist for waterborne disease; however, WDPB conducts ad hoc training in sample collection as part of outbreak responses.
- Federal collaboration (CDC, FDA, U.S. Environmental Protection Agency) is key. Quality assurance and standardization of methods should be included across agencies.

Response

Based on these questions, the Working Group highlighted the following possible responses:

What should CDC be doing to support increasing state capacity for water-related food safety investigations?

CDC could

- Provide data (burden of waterborne disease) to explain the need for increased state capacity
- Explore ways to include more environmental scientists/microbiologists on investigations
- Train states to conduct water sampling/testing and environmental studies
- Expand roles of regional labs and CoEs that have expertise in water-related food safety investigations

Should CDC obtain and synthesize more information on water contributions to foodborne disease outbreaks?

CDC could

- Prospectively and retrospectively, systematically analyze the role of water in foodborne outbreaks

Should CDC be involved in collecting and analyzing data to understand environmental root causes and conduct risk characterizations for how water is used in food production?

CDC could

- Provide technical support for regulatory investigations
- Conduct and collaborate on non-regulatory, research studies

VI. CDC Updates

Surveillance Modernizations Efforts

During the 2018 BSC FSMA SWG discussions, there was significant interest in learning more details about CDC's Division of Foodborne, Waterborne, and Environmental Diseases' next steps to modernize and better integrate CDC's surveillance systems. At the May 2019 BSC FSMA SWG meeting, CDC DFWED shared plans to

- Complete the Data and IT Modernization Strategic Plan work started in 2018
- Assess all systems in DFWED
    - Inventory by surveillance data life cycle
    - External evaluation against guiding principles and system requirements
- Develop a roadmap for system modernization including priorities, actions, assignments, and timelines

Information from FoodNet Surveillance

Nearly 36,000 surveys were completed for the Population Survey. The final data set is expected in August, and the analysis should be complete by December 2019.

May 2018 CIDT Meeting Follow-up Actions

The May 2018 BSC FSMA SWG meeting focused on identifying CIDT issues and knowledge gaps and generating potential solutions in public health practice, surveillance, and technology. Follow-up discussions at the May 2019 BSC FSMA SWG meeting revolved around the already commonplace but still increasing use of CIDTs in the clinical world and the need for CDC and regulatory agencies to determine how to best adapt to the technology. Federal and state agencies involved in foodborne illness surveillance are in a transitional and transformational stage of using WGS as a standard in PulseNet, where an isolate is necessary, yet future technology, such as the use of metagenomics, may not require an isolate. Future discussion on this topic is anticipated given the challenges faced now and in the future.

DFWED Mission Coordination Update and the Future

As a result of a strategic assessment, DFWED anticipates

- Division-level coordination of surveillance system development including connections with agency-wide efforts

- Coordinated expansion and exploration of WGS methods and other technological platforms across DFWED
- Better integration of ELC-supported activities and connections with DFWED activities
- Improved coordination of communications and strategic partnerships across DFWED
- Developing priorities for prevention in support of each branch's efforts

Globalization of the Food Supply: Implications for the United States

The number of outbreaks linked to imported foods in the United States has steadily increased. In addition, molecular testing has identified many new food vehicles as the source of multistate foodborne outbreaks in the United States; of note, 42% of these outbreaks have been associated with imported food products.

Challenges of food globalization for the United States:

- Consumer demand 24/7, 365 days
- Increasing global food supply
    - More than 20% of food is imported
    - Food is imported from more than 150 countries
    - Food is imported through more than 300 ports
    - Approximately 200,000 foreign firms are registered by the FDA

The International Food Safety Authorities Network (INFOSAN) is the voluntary network of national authorities involved in food safety from around the world (600+ participants from 188 member states managed jointly by the Food and Agriculture Organization and World Health Organization). INFOSAN aims to

- Promote the rapid exchange of information during food safety–related events
- Share information on important food safety–related issues of global interest
- Promote partnerships and collaboration between countries, and between networks
- Help countries strengthen their capacity to manage food safety emergencies

Review of 2018 U.S. foodborne disease outbreak notifications posted in WHO INFOSAN:

- All CDC multistate outbreak website postings were shared with INFOSAN.
- Those outbreaks with potential international link were posted as INFOSAN events.
- INFOSAN followed up with potential donor and receiving countries.

Challenges encountered in foodborne disease outbreaks from internationally distributed products:

- Determining whether illnesses are occurring in other countries when a U.S. outbreak is identified
- Traceability to growers/producers
- Overcoming reluctance of countries to share outbreak information including WGS results
- Ability to identify the root causes of contamination at growers/producers

RESOURCES

The Working Group applauded recent increases in funding for food safety infrastructure, but the issues addressed in this report emphasize the need for continued resources for these activities. As CIDTs and other technologies continue to rapidly evolve, public health and regulatory agencies will face substantially increased costs in responding to the transition. For example, the increasing use of CIDTs in clinical settings will shift the burden of performing reflex cultures and additional confirmatory testing to public health laboratories. Data management and translation of increasingly large amounts of new types of data into formats that are meaningful to outbreak investigators and regulators will require increased investment in laboratory and informatics infrastructure. Additional research will be needed to guide the food industry and regulatory agencies in using increasingly sensitive and detailed data to find and eliminate threats at various levels in the food chain. The number of foodborne disease outbreaks being identified by new technologies is already rising and will continue to do so.

NEXT STEPS

Since its formation 8 years ago in 2011, the FSMA SWG has met 16 times and developed eight annual reports for BSC discussion and transmittal to the HHS Secretary. There was considerable discussion of the value of the guidance provided thus far, ways to improve the FSMA SWG meetings, and potential future topics.

Based on the discussion, examples of potential future topics include

- Periodic enteric disease surveillance system reviews
- Providing updates of interagency collaborations (e.g., IFSAC, IFORC [Interagency Foodborne Outbreak Response Collaboration], Gen-FS [Interagency Collaboration on Genomics for Food and Feed Safety])
- Addressing challenges with imported foods (globalization of food)
- Improving identification of recurring outbreaks and working with regulators to identify and eliminate their root causes
- Building state capacity (e.g., CoEs and OBNE [OutbreakNet Enhanced]) and workforce development (e.g., informatics)
- Addressing Illnesses involving pathogens less frequently associated with foods or outside of CDC DFWED's focus (e.g., cryptosporidiosis, toxoplasmosis, hepatitis A)
- Industry updates related to sharing surveillance data, legal issues, and product labeling to assist traceback
- Identification of stealth sources (e.g., spices)
- Improving surveillance and outbreak data to support FDA's effort to potentially measure changes in foodborne illness due to implementation of FSMA-related regulations
- Population Survey
- Prevention

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APPENDIX: FSMA SURVEILLANCE WORKING GROUP MEMBERS

Meetings held in December 2018 and May 2019

BSC Representative Members:

Chair, Timothy F. Jones, MD—State Epidemiologist, Tennessee Department of Health

Member, Kristy K. Bradley, DVM, MPH—State Epidemiologist and State Public Health Veterinarian, Oklahoma State Department of Health (also CSTE representative, see below)

Member, Lee W. Riley, MD—Professor and Chair, Division of Infectious Diseases and Vaccinology, School of Public Health, University of California, Berkeley

Federal Partner Members:

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

Stic Harris, DVM, MPH—Food and Drug Administration

Denise R. Eblen, PhD—United States Department of Agriculture, Food Safety and Inspection Service

Public Health Partner Agency Members:

Natalie Adan—National Association of State Departments of Agriculture

Denise M. Toney, PhD, HCLD (ABB)—Association of Public Health Laboratories

Michele DiMaggio, REHS—National Environmental Health Association

Kristy K. Bradley, DVM, MPH—Council of State and Territorial Epidemiologists (see above)

Ernest M. Julian, PhD—Association of Food and Drug Officials

Lillian Shirley, BSN, MPH, MPA—Association of State and Territorial Health Officials

Mark Bergtholdt, REHS, MPH—National Association of County and City Health Officials

Consumer Partner Members:

Sarah Sorscher, JD, MPH—Center for Science in the Public Interest

Karin Hoelzer, DVM, PhD—The Pew Charitable Trusts

Industry Partner Members:

Natalie Dyenson, MPH—Dole Food Company, Inc.

Scott K. Hood, PhD—General Mills

Michael J. Roberson, MS, CFS, CP-FS—Publix Super Markets, Inc.

Academia Partner Members:

Jeffrey B. Bender, DVM, MS—University of Minnesota

Michael P. Doyle, PhD—University of Georgia

Elaine Scallan, PhD—University of Colorado, Denver