

# MEETING OF THE BOARD OF SCIENTIFIC COUNSELORS, OFFICE OF INFECTIOUS DISEASES

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Centers for Disease Control and Prevention  
Tom Harkin Global Communications Center  
Atlanta, Georgia

December 9-10, 2015

A one-and-a-half day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on December 9-10, 2015, at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. In addition to Board members and CDC staff, the meeting was attended by representatives of several public health partner organizations (Appendix).

Focused discussions were held on *Legionella* infections and on climate change. The meeting also included reports from the Board's two active working groups—the Food Safety Modernization Act (FSMA) Surveillance Workgroup (FSMA SWG) and the Infectious Disease Laboratory Workgroup (IDLWG); as part of the IDLWG session, an update on CDC's advanced molecular detection (AMD) initiative was given. Additional updates and discussion topics were provided from the Center for Global Health (CGH), the National Center for Immunization and Respiratory Diseases (NCIRD), the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP).<sup>1</sup> The meeting also included a brief conversation with CDC Director Dr. Tom Frieden.

During the discussion that followed the FSMA update, the BSC approved a motion to send the annual FSMA report to the HHS Secretary.

## Opening Remarks

BSC Chair Dr. Ruth Berkelman, Rollins Professor, Emory University, called the meeting to order and was joined in welcoming participants and facilitating introductions by Dr. Rima Khabbaz, CDC Deputy Director for Infectious Diseases, and Robin Moseley, the BSC/OID Designated Federal Official.

## Update from the Center for Global Health (CGH)

Rebecca Martin, CGH Acting Director, provided the following updates:

### The Ebola Outbreak

- Liberia was declared Ebola-free on September 3, 2015.<sup>2</sup> However, a cluster of three new cases was confirmed in November
- Sierra Leone was declared Ebola-free on November 7, 2015
- The last known patient in Guinea tested negative for Ebola on November 16, 2015

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<sup>1</sup>Selected program materials from NCHHSTP, NCEZID, and NCIRD were provided to the BSC members in advance of the meeting. In addition to program updates, the Centers' meeting presentations included selected topics on which BSC guidance was requested.

<sup>2</sup> A national Ebola outbreak is considered to be over 42 days after the last patient in isolation tests negative for the virus (i.e., double the 21-day incubation period of Ebola virus).

To date, these three countries have reported 24,797 cases of Ebola (suspected, probable, and confirmed), 11,864 laboratory-confirmed cases, and 8,764 deaths. In addition to maintaining Ebola surveillance and addressing the needs of Ebola survivors, the next phase of the response will focus on strengthening health systems by building public health infrastructure to improve infection control, malaria control, and childhood immunization programs.

Activities to address the needs of Ebola survivors in the affected countries include the following:

- *Liberia*: Partnering with the Liberian Ministry of Health and WHO to create the Liberian Men’s Health Screening Program, which maintains a registry of approximately 1,500 Ebola survivors
- *Sierra Leone*: Supporting sexual risk-reduction counseling and reviewing proposals to provide additional screening and medical services to survivors
- *Guinea*: Translating risk-reduction counseling materials and engaging local partners in delivery of medical services to recent survivors

## **Global Health Security Agenda (GHS): Prevent Whenever Possible, Detect Rapidly, and Respond Effectively**

- GHS activities address three risks—emerging infections, antimicrobial drug resistance, and intentional acts of bioterrorism—by improving public health frameworks, using new laboratory and surveillance tools, and implementing outbreak control measures. Each of the more than 50 GHS countries is conducting an assessment of its abilities to prevent, detect, and respond to global health threats ([CDC and the Global Health Security Agenda](#))
- The U.S. supports GHS activities in 30 countries, with CDC focusing on 4 of the 11 GHS “[Action Packages](#).” Laboratory, Surveillance, Emergency Operations, and Workforce Development
- CDC’s flagship GHS projects include the *National Stop Transmission of Polio (N-STOP)* Malaria Collaboration in Nigeria and a program to increase the number of fully immunized children in Ghana. Additional CDC GHS activities include
  - Working with WHO African Member States to establish the Africa Centers for Disease Control (Africa-CDC) as a continent-wide public health agency that facilitates responses to public health emergencies
  - Creating a CDC Global Rapid Response Team (GRRT) that supports faster response to global emergencies. GRRT has three “tiers:” 1) newly hired, dedicated staff; 2) a roster of staff already doing global emergency work or with specific expertise; and 3) a CDC-wide surge roster.

## **PEPFAR Pivot**

PEPFAR is prioritizing support for HIV treatment and prevention in high-burden populations and geographic areas, based on sub-national data on HIV cases, services, and costs. PEPFAR targets for 2017 include 12.9 million women, men, and children on antiretroviral therapy (ART); a 40% reduction in new HIV infections in young women in 10 countries; and 13 million voluntary medical male circumcisions. CDC is helping to implement the “HIV Test & Start” approach to HIV treatment, in accordance with WHO Interim Guidelines that recommend provision of ART to all HIV-infected persons, regardless of CD4 count.

## CHAMPS: Rebuilding Health Systems in Ebola-Affected Countries

The Child Health and Mortality Prevention Surveillance Network (CHAMPS) is a network of laboratory-based disease surveillance sites whose goal is to prevent childhood mortality in sub-Saharan Africa and South Asia ([see Bill & Melinda Gates Foundation press release on CHAMPS](#)). CHAMPS began with an initial \$75 million commitment from the Bill & Melinda Gates Foundation to develop six surveillance sites in 3 years. The Emory Global Health Institute, which houses the International Association of National Public Health Institutes (IANPHI), is the lead partner, under the direction of former CDC Director Jeffrey Koplan. The projected timeframe is 20 to 25 years.

## Disease Eradication in Our Lifetime

- **Eradicating Malaria.** CDC is supporting collaborative efforts to strengthen public health services to prevent, treat, and control malaria; monitor antimalarial drug and insecticide resistance; and ensure the availability of high-quality prevention products, including insecticide-treated bednets (ITNs). Campaigns to distribute ITNs in the three Ebola-affected countries have resumed.
- **Ending Polio Forever.** Poliovirus eradication efforts focus on interruption of transmission in Afghanistan and Pakistan; maintenance of a polio-free Africa; expansion of environmental surveillance; and ensuring rapid responses to outbreaks caused by wild-type polio virus (WPV) and vaccine-derived poliovirus (VDPV). Moving forward, these efforts will include introduction of inactivated polio vaccine (IPV); replacement of trivalent oral polio vaccine (OPV) with bivalent OPV; and phase-out of OPV.

CDC is advancing use of polio assets and capabilities to enhance other global health initiatives. Optimal use of these resources requires integration of public health platforms established by PEPFAR, GHSA, the President's Malaria Initiative (PMI), the CDC Global Disease Detect (GDD) Centers, and CDC's Global Immunization Division.

Dr. Martin concluded the presentation by posing three questions:

- How can we best address unique challenges of Ebola, with respect to 1) Ebola survivors and long-term healthcare system issues and 2) coordination with partners and donors?
- What are the best opportunities for CDC to ensure synthesis and sustainability of our work in the 50+ countries with CDC presence?
- What trends are you seeing that CDC might consider in developing innovations to advance our global health work—i.e., technologies, emerging health areas, new partnerships?

## DISCUSSION

### The Ebola Outbreak

- The three affected countries continue to maintain disease surveillance, and each case or cluster of Ebola is rapidly investigated. None of the cases traced to survivors has spread beyond one generation of transmission. CDC is “stepping-down,” as countries are declared Ebola-free, but continuing to help with survivor issues.
- Cases of malaria and other febrile diseases have been detected in persons who travel to the U.S. from West Africa, and in some cases malaria treatment has been delayed while hospital workers tested these persons for Ebola. CDC is working through these issues to ensure that travelers receive prompt diagnosis and treatment of febrile diseases other than Ebola.

## Sustainability and Capacity-Building

- The sustainability of CDC's efforts to transfer public health knowledge to other countries requires
  - Commitment by local governments to provide ongoing resources so that the sustainability of public health improvements is not dependent on individuals.
  - Trust and cooperation
  - Awareness of local capacities. For example, CDC should provide training in AMD techniques rather than traditional diagnostic methods in countries that lack laboratory capacity to culture micro-organisms.
  - Application of insights from behavioral science to support community engagement, which was essential to the Ebola response. CDC should intensify efforts to work with university partners to advance implementation science and turn research findings into policy.
- Carole Heilman, Director, NIAID Division of Microbiology and Infectious Diseases, reported on feedback from country leaders on how to sustain in-country research programs that receive NIH funding. The leaders said that the programs would benefit from more emphasis on research areas identified by their scientists as most important to their countries, as well as sufficient (and sustained) funding to retain scientists in their countries. Concern was also expressed about receiving different "pots" of U.S. research money with different rules.
- CDC staff are often deployed for only a few weeks during global outbreak responses, which can affect their ability to fully engage and understand the issues.

## Global Trends and Innovations

- The following global trends/issues were discussed:
  - More emphasis is needed on identifying linkages between chronic diseases (including cancers) and infectious diseases.
  - New interventions have the potential for big impact. Examples include pre-exposure prophylaxis (PrEP) for HIV prevention, new treatments for hepatitis C virus (HCV), and new diagnostics to improve treatment of drug-resistant TB.
  - HIV is regarded in many countries as a chronic disease, which has implications for HIV prevention and treatment.
- CDC's global tuberculosis program has joined CGH. As part of its activities, this program supports implementation of the *Global Plan to End TB*, which emphasizes the need for R&D to develop innovative tools.
- CGH is participating in agency-wide efforts to advance HPV vaccination by bringing together groups involved in cancer prevention and immunization.

## Partnerships and Collaborations

- The success of global health efforts depends on partnerships among universities, private sector groups, and U.S. agencies. University partners are increasingly interested not only in laboratory research but also in field work and efforts to create sustainable improvements.
- CGH collaborates with a consortium of universities (including some Fogarty Center grantees) concerned with global health research and research training. The College of Medicine and Allied Health Sciences (COMAHS) is a major partner in the Ebola vaccine trial in Sierra Leone (see page 6).

- GHSA (like PEPFAR) is a collaboration among HHS, the Department of Defense (DoD), USAID, the Department of Homeland Security (DHS), and the Department of State. Coordination meetings are hosted by U.S. embassies on a regular basis. As part of GHSA, CGH is reaching out to private-sector partners who have a stake in improving the health of their country's workforce.
- One-Health partnerships are increasingly important for disease surveillance and diagnostics. GHSA includes a Zoonosis Action Package, and NCEZID priority projects on rabies and leptospirosis depend on animal-health partners. NCEZID also has assignees at the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE).
- Beth Lautner, Director of the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), National Veterinary Services Laboratories, noted that the USDA CDC liaison (Tom Gomez) continues to initiate USDA-CDC partnerships on One-Health issues.

### **Africa-CDC**

- WHO/AFRO is coordinating governance issues related to Africa-CDC, which is scheduled for launch at the end of January 2016. At that time, a search will begin for the Africa-CDC director.
- Africa-CDC plans to establish five regional collaborating centers. CDC will help with emergency response training and with data-sharing across countries.
- Examples of recommended activities for Africa-CDC include
  - Engaging public health officials at both local and national levels
  - Sharing goals and visions with partners and working together to implement them.

## **Update from the National Center for Immunization and Respiratory Diseases (NCIRD)**

Dr. Khabbaz, who is also serving as NCIRD Acting Director, provided the following updates:

### **NCIRD Leadership Changes**

- Amanda Cohn is Senior Advisor for Vaccine Policy and Executive Secretariat of the Advisory Committee on Immunization Practices (ACIP)
- Tim Barrett is Associate Director for Laboratory Science
- Dave Daigle is Associate Director for Health Communication Science
- James Kile is Senior Advisor for Global Health Security
- The Influenza Coordination Unit (ICU) has moved to NCIRD OD (from OI OD); Lisa Koonin continues to serve as Acting ICU Director
- Starting December 13, Sam Posner will be Associate Director for Science
- Laurie Markowitz and the HPV Team will be moving to DVD from DSTDP/NCHHSTP

### **Outbreak Responses**

Recent examples include measles, Legionnaires' disease, enterovirus D68 (EV-D68), and drifted H3N2 influenza viruses in the United States; MERS in Saudi Arabia and South Korea; Ebola in West Africa; meningitis in sub-Saharan Africa; and H7N9 in China.

## Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE)

- The target population of STRIVE, which has seven study sites, includes healthcare workers and other Ebola front-line responders. All participants are randomized for immediate or deferred vaccination (deferred for 18-24 weeks). Following vaccination with the Merck/NewLink VSV-ZEBOV vaccine, each participant is monitored for Ebola virus disease and vaccine-related adverse events. A subset of participants are also enrolled in sub-studies on vaccine safety and immunogenicity.
- STRIVE partners include the Sierra Leone Ministry of Health and Sanitation (MoHS) and COMAHS. U.S. partners include NIH and the Biomedical Advanced Research and Development Authority (BARDA).
- 8,680 people were enrolled between April and August 21, 2015, with more than 7,500 participants vaccinated to date in the immediate and deferred groups. Deferred vaccination is scheduled for completion in mid-December 2015, with vaccine-safety follow-up continuing for all participants.

## MenAfriNet

- MenAfriNet is a regional meningitis surveillance network established to evaluate the impact of the meningococcal A conjugate vaccine (MACV) vaccine, which came into use in 2010 ([see CDC update on goal of eliminating epidemic meningitis as a public health concern in Africa](#)). Meningitis is hyper-endemic in 26 sub-Saharan countries (the “Meningitis Belt”), with 90% of annual epidemics due to serogroup A. Thus far, 217 million people in 15 countries have been immunized with MACV, with no vaccine failures.
- Data from MenAfriNet have documented MACV effectiveness in high-risk countries,<sup>3</sup> and WHO is planning to integrate MACV into the WHO Expanded Program on Immunization (EPI).
- Epidemics of non-A meningitis continue to threaten the region, including a 2015 epidemic of a new serogroup C strain in Niger that caused 8,537 cases of illness.

## Middle East Respiratory Syndrome (MERS)

- MERS-CoV was exported to the Republic of Korea by an infected traveler in May 2015, causing an outbreak of 186 cases. The index patient was a 68-year-old man with a history of travel to Bahrain, the United Arab Emirates (UAE), the Kingdom of Saudi Arabia (KSA), and Qatar. The virus was linked to cases in KSA. As in past outbreaks, disease spread was amplified by healthcare-facility transmission.
- A [study conducted in UAE](#) suggests that MERS-CoV infections in humans are linked to infected camels.
- A [study conducted in KSA](#) identified physical contact with dromedary camels 2 weeks before illness onset as a risk factor for primary MERS-CoV illness. Diabetes mellitus, heart disease, or smoking were each independently associated with illness.

## Poliovirus

- India was certified polio-free in 2014, and July 24, 2015, marked 1 year since the most recent case of wild polio virus in Nigeria. Wild poliovirus type 2 (WPV2) was declared eradicated on September 20, 2015.

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<sup>3</sup> See: The Meningitis Vaccine Project: The Development, Licensure, Introduction, and Impact of a New Group A Meningococcal Conjugate Vaccine for Africa. Clin Infect Dis. 2015 Nov 15;61(suppl 5).

- A major aim of the [Polio Eradication and Endgame Strategic Plan, 2013-2018](#), is to minimize facility-associated risk. As part of this effort, CDC is helping to implement the WHO Global Action Plan (GAPIII), which aims to secure poliovirus specimens held in laboratories. Phase I of GAPIII involves a survey and inventory to support containment of WPV2 specimens by the end of 2015. Phase II involves containment of OPV2-containing materials within 3 months of global withdrawal of OPV2.
- Karen DeSalvo, Assistant Secretary for Health (Acting), has appointed Olen Kew, NCIRD/DVD, as National Poliovirus Containment Coordinator for the United States. A National Polio Certification Commission is being established, with members identified by the [Taskforce for Global Health](#).

## Influenza

### Domestic Issues

- FluView data indicate that the 2015-16 influenza season is off to a slow start. National Influenza Week is in progress (December 6-12). CDC is planning to release a report on early season influenza vaccination coverage, using data from the National Immunization Survey and Internet panel surveys that include data from pregnant women and healthcare workers. CDC provided [testimony about the benefits of flu vaccination](#) to the House Energy and Commerce Committee on November 19.
- No human infections with highly pathogenic avian influenza A H5 have been reported among more than 100 exposed persons ([“Infection Risk for Persons Exposed to Highly Pathogenic Avian Influenza A H5 Virus–Infected Birds, United States, December 2014–March 2015”](#)).

### International Issues

- Current international goals include
  - Creating global capacity for effective monitoring and creating the evidence base for influenza prevention and control
  - Decreasing the global impact of seasonal, pandemic, and avian influenza through support for prevention and control policies

### Enhancing Immunization Infrastructure

- An orientation for new immunization program managers was held in Atlanta, November 4-6, by the Association of Immunization Managers and NCIRD’s Immunization Services Division. The agenda covered the Vaccines for Children (VFC) program, CDC’s Vaccine Tracking System (VTrckS) and vaccine ordering; adolescent and adult vaccinations; immunization information systems; immunization laws and policies; and data quality and use. The program managers also participated in a pandemic influenza outbreak exercise.
- Examples of recent and ongoing global and domestic vaccine campaigns include:
  - [Every Breath Counts. Stop Pneumonia Now](#)
  - [You Can Start Protecting Your Baby from Whooping Cough Before Birth](#)
  - [Prevent Cervical Cancer with the Right Test at the Right Time](#). Activities scheduled for Cervical Health Awareness Month (January) include a webinar mini-series about the benefits of the HPV vaccine.

## DISCUSSION

### HPV Vaccination and Vaccine Hesitancy

- HPV immunization rates in the United States are relatively low, although teen surveys indicate some improvement. Focus groups indicate that pediatricians (who are unlikely to see patients with cervical cancer) may not strongly recommend the vaccine to parents or may suggest waiting until children/teens are older. CDC is helping to educate pediatricians and bring together groups concerned with immunization and cancer. The 2015 U.S. measles epidemic increased public understanding of the importance and value of immunization.
- Although national data indicate that only 1% of U.S. children receive no vaccines, a few communities have high rates of non-vaccination. CDC is working with state health departments to identify these communities and determine the reasons for vaccine hesitancy, which differ among sites. The HHS National Vaccine Policy Office (NVPO) is also addressing this issue.
- WHO has highlighted [vaccine hesitancy](#) as a major challenge for global health.
- It was suggested that CDC consider targeting cervical carcinoma for world-wide eradication. The three necessary factors for disease eradication are present: an effective intervention, reliable diagnostics, and a virus that infects only humans.

### Platforms for Vaccination of Adults and Teens

- Low rates of adult and teen vaccination continue to be a challenge. Improved adult vaccination will require better adult vaccines and better ways to deliver them.
- CDC's current approach to delivery of teen vaccines is to build a platform for joint delivery of three vaccines: Tdap vaccine, meningococcal vaccine, and HPV vaccine.
- Around the world, public health authorities are taking varied approaches to promoting HPV vaccination; some countries that lack established platforms for teen vaccination have higher rates of HPV vaccination than the United States.
- Assuming that its effects are found to persist, it was suggested that HPV vaccine might be administered in the U.S. as a component of universal infant immunization, like the vaccine against hepatitis B virus (HBV). However, CDC's teen-platform approach may prove more and more valuable as time goes on.

### Ebola Vaccine

- STRIVE in Sierra Leone and the ring-vaccination trial in Liberia tested the same Ebola vaccine, and the STRIVE Scientific Steering Committee has approved the use of the ring protocol in Sierra Leone if new cases or clusters are detected. Luciana Borio, Acting Deputy Chief Scientist, FDA, reported that vaccine-safety data generated by STRIVE were used in making the decision to extend ring-vaccination to Sierra Leone.
- Although the Ebola vaccine trials have not produced efficacy data—because the outbreak is largely over—they have generated data on safety and immunogenicity. Since the ring-vaccination trial provided limited safety data, the STRIVE safety data may be important for vaccine licensure.

## Meningitis Vaccines

- At the time MACV was developed, the risk assessment suggested that the incidence of serogroup A was far greater than the incidence of other serogroups.
- *Rana Hajjeh*, Director, NCEZID Division of Bacterial Diseases, noted that MenAfriNet data were used to detect the 2015 type C outbreak in Niger and to support the outbreak response. The ongoing goal is to identify major circulating non-A serotypes and develop a multi-valent vaccine by 2020.

## MERS Vaccines

- It would be valuable to learn more about progress towards development of a vaccine against MERS-CoV.

## Focused Discussion: *Legionella* Infections

Cynthia Whitney, Chief, NCIRD Respiratory Diseases Branch, requested BSC advice on addressing rising rates of Legionnaire's disease (LD). Last summer CDC sent a team to New York City to help investigate the largest LD outbreak since the disease was identified in 1976.

### Overview of Legionellosis in the United States: *Laura Cooley*, NCIRD Medical Epidemiologist

- LD infections have high case-fatality rates (5%–20% for community-acquired LD and 14%–40% for healthcare-associated LD) and account for up to 30% of community-acquired pneumonias that require ICU admission. LD causes 8,000–18,000 hospitalizations in the United States each year,<sup>4</sup> with hospitalization costs estimated at more than >\$433 million per year.<sup>5</sup>
- The national incidence of LD rose 286% between 2000 and 2014, based on data from the National Notifiable Diseases Surveillance System (NNDSS).<sup>6</sup> Among LD cases, 96% were sporadic and 4% were associated with outbreaks.<sup>7</sup> LD rates exhibited seasonal variation, peaking in the summer months.
- LD outbreaks comprise two-thirds of all reported non-drinking-water outbreaks.<sup>8</sup> LD outbreaks are caused by events and conditions that amplify *Legionella* in the water supply (e.g., warmer temperatures, stagnant water, presence of biofilms); that aerosolize *Legionella* in water droplets (e.g., via showerheads and cooling towers); and that transmit *Legionella* to susceptible persons (e.g., spewing of water from a contaminated whirlpool spa).

CDC activities to address LD include

- **Disease Surveillance**
  - Passive surveillance activities include state-level reporting of LD cases and outbreaks via NNDSS and detection of travel-associated clusters.

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<sup>4</sup> Marston BJ et al. *Arch Intern Med*. 1997;157(15):1709–18.

<sup>5</sup> Collier SA et al. *Epidemiol Infect*. 2012;140: 2003–13.

<sup>6</sup> Dooling K et al. *MMWR*. 2015; 64(42):1190-3.

<sup>7</sup> Hampton L et al. *MMWR*. 2011;60(32):1083-6.

<sup>8</sup> Beer KD et al. *MMWR*. 2015;64(31):842-848.

- Ongoing surveillance activities include data collection by 1) the Active Bacterial Core surveillance (ABCs) program, which monitored LD between 2011 and 2014 and found the same rate of disease as NNDSS, and 2) the [Etiology of Pneumonia in the Community \(EPIC\) study](#), which detected *Legionella* in 1.4% of specimens from patients with undiagnosed pneumonia.
- **Outbreak Support.** Each year, CDC participates in an average of three field investigations and up to 200 consultations on LD outbreak responses. Technical assistance is provided for epidemiologic investigation, surge capacity, specialized laboratory testing, and risk communications.
- **Laboratory Activities.** During outbreaks, CDC provides laboratory support for isolation of *Legionella* from unusual clinical specimens (e.g., lung tissue), for environmental sampling and culture, and for matching clinical and environmental isolates. CDC is also working to develop diagnostic and typing methods for *Legionella*, including AMD methods and serotype-specific urinary antigen testing. CDC also conducts proficiency testing and accreditation for laboratories that culture *Legionella* from environmental samples.
- **Disease Prevention.** NCEZID, the National Institute of Occupational Safety and Health (NIOSH), and the National Center for Environmental Health (NCEH) provided input to the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) for development of the following documents:
  - ASHRAE Guideline 12-2000, which provides environmental and operational guidelines for building water systems.
  - American National Standards Institute (ANSI)/ASHRAE Standard 188-2015, which updates industry standards for maintenance of centralized building water systems, including cooling towers. Standard 188-2015—which is written for engineers—outlines steps for creating water management plans and presents a facility-level approach to *Legionella* prevention.

## The Role of Environmental Health Services in LD Prevention and Control: Jasen Kunz, NCEH Environmental Health Scientist

Environmental factors allow *Legionella* to survive and reach susceptible hosts. Since 2012, the NCEH Environmental Health Services Branch (EHSB) has partnered with NCIRD to

- Develop evidence-based environmental prevention practices that reduce the burden of disease
- Provide environmental health guidance to support Epi-Aids and outbreak investigations and fulfill requests for technical assistance from state and local health departments
- Revise *Legionella* [Environmental Assessment Tools](#) and develop training videos to improve responses to LD outbreaks

At an earlier meeting, the NCEH/NCIRD partnership posed the following questions to NCEH's Board of Scientific Counselors:

1. Based on identified gaps, how should EHSB prioritize developing targeted environmental health-related *Legionella* training and guidance specific to state and local environmental health (EH)? What can EHSB do to maximize the likelihood that such training will be effective and sustainable in the long-term?
2. Based on critical needs, what does the Board see as EHSB's unique role in supporting CDC's overall *Legionella* response and prevention activities? How can NCEH maximize the likelihood that its contributions to *Legionella* prevention will be impactful and enduring?

In response, the NCEH BSC stated that it

- Supports the shift from a response-based to a prevention-based approach that recognizes the importance of environmental health investigations
- Supports capacity-building of state and local EH staff, as well as of building owners and managers, through the development of prevention-based and response-based EH education and training programs
- Wants to ensure that reporting systems for outbreaks and cases are robust and include environmental information
- Would consider focusing resources initially on prevention strategies aimed at high-risk settings
- Would consider facilitating the adoption of evidence-based prevention practices (e.g., ASHRAE 188) into nationwide building codes
- Agrees that EH-focused resources are needed to reduce the incidence of legionellosis

### **Legionella Program Review: Matt Moore, NCIRD Medical Epidemiologist**

Earlier this year, an internal *Legionella* Program Review was held that included panelists from CDC/OD, NCEZID, NCEH, NIOSH, and NCIRD. Areas of focus included

- Secondary prevention activities for LD (i.e., activities designed to prevent additional morbidity and mortality after an outbreak has been detected), as well as primary prevention activities (i.e., activities designed to prevent sporadic disease and outbreaks from occurring in the first place).
- Potential future prevention activities for CDC's *Legionella* program and prioritization of 3-year program objectives for primary and secondary prevention.

The panelists identified five key challenges:

#### **1. Now that ASHRAE 188 is available, how should CDC balance primary prevention and outbreak response?**

##### **Key input from the panelists:**

- Primary prevention should be a major focus of CDC's *Legionella* program
- ASHRAE 188 is a strong document, with opportunities for strong roll-out and implementation
- Outbreak response capacity must be maintained and, ideally, strengthened

##### **Key outcome:** CDC must prioritize primary prevention. CDC should

- Translate ASHRAE 188 for public health and building owner/manager audiences
- Consider a "checklist" format that can be used by building and cooling tower owners/operators
- Communicate clearly and frequently about common environmental deficiencies which, if addressed, could prevent disease

#### **2. Time to identify the environmental source of an outbreak is too long**

##### **Key input from the panelists:**

- Use of clinical and environmental culture isolates frequently pushes confirmation of source to  $\geq 14$  days
- In 2015, reliance on availability of culture isolates (both clinical and environmental) to determine "same-different" should not be necessary

**Key outcomes:**

- CDC should advance efforts to reduce the time to identification of the source to <7 days using novel specimen-typing techniques
- In the next 3-5 years, AMD technology may help to identify markers that will enhance environmental control efforts
- The “three-legged stool” of *Legionella* prevention consists of epidemiologic, laboratory, and environmental data

**3. CDC lacks dedicated environmental expertise needed to adequately advance prevention**

**Key input from the panelists:**

- Despite NCIRD’s engagement with NCEH, NCEZID, and NIOSH during outbreaks, there are no environmental or engineering resources dedicated to the *Legionella* program
- During outbreaks, CDC encourages state and local health departments (or affected buildings) to hire environmental consultants. These consultants vary in their experience and qualifications.
- CDC is often asked to comment on potential environmental deficiencies with which we are unfamiliar

**Key outcomes:**

- CDC should build internal capacity regarding environmental and engineering expertise relevant to *Legionella* prevention
- CDC should leverage partnerships with environmental health and engineering organizations

**4. Clarifying the role of routine environmental testing for *Legionella***

**Key input from the panelists:**

- The evidence base is inadequate to promote routine environmental testing as a sole prevention strategy
- Measurement of other parameters, especially temperature and chlorine, are more important than testing for *Legionella*
- There are opportunities for CDC, in partnership with others, to strengthen the evidence base

**Key outcomes:**

- CDC should work with partners to
  - Promote maintenance of potable water systems and cooling towers as a primary prevention strategy (consistent with ASHRAE 188)
  - Articulate how routine environmental testing for *Legionella* fits into implementation of ASHRAE 188

**5. Disinfection is key to primary prevention, but CDC is not positioned to evaluate specific strategies**

**Key input from the panelists:**

- CDC can serve as a clearing house for published information, but there are limitations associated with CDC serving as “evaluator” of private-sector products such as disinfectants for potable water

- CDC should not take on this role; this area may fall more naturally to the Environmental Protection Agency (EPA) or others

**Key outcomes:**

- CDC should leverage external partners to evaluate disinfection technologies to build the evidence base
- In the interim, chlorine is an excellent disinfectant, and CDC should promote its use for primary (and secondary) prevention

## **Proposed Agenda for Prevention of Legionellosis: Brian Raphael, NCIRD Research Microbiologist**

An agenda for prevention of legionellosis, developed in response to the five key challenges, is outlined below. Some activities would be best be accomplished by partners and some by CDC.

### **1. Balance primary prevention and outbreak response**

- Enhance and communicate primary prevention policy
  - Develop tools for prevention based on ASHRAE 188, including best practices, checklists, and guidance on changing building codes (*Timeline: 1-3 years*)
  - Collaboratively, evaluate new prevention strategies, including such initiatives as the New York City plan to register cooling towers (*Timeline: 1-3 years*)
  - With partners, support development of an all-hazards standard for building water systems (*Timeline: 5+ years*)
- Use outbreak investigations to strengthen primary prevention (*Timeline 1-2 years*)
  - Identify environmental factors that increase risk of *Legionella* transmission
    - Compare factors in facilities with outbreaks to those without
    - A similar approach used successfully with foodborne outbreaks associated with restaurants
- Release urgent communications for common environmental deficiencies, via a *Legionella* Health Alert Network

### **2. Identify sources of outbreaks faster**

- Improve epidemiological methods for detection and response (*Timeline: 1-2 years*)
  - Evaluate and incorporate advanced epidemiological methods for cluster identification (e.g., SaTScan, GIS mapping, and use of cooling tower registries to investigate clusters)
  - Improve guidance for response to healthcare-associated LD (e.g., provide guidance on the response to a single case and on the role of environmental health specialists)
- Develop nonculture-based detection methods (*Timeline 3-5 years*)
  - Develop and implement metagenomic detection methods
    - Reduce the time to confirm outbreak environmental sources
    - Utilize metagenomic approaches to identify potential risk
    - Collaborate with experts on microbial ecology

### 3. Increase environmental expertise for primary prevention (*Timeline: 1-2 years*)

- Build engineering/environmental expertise
  - Enhance environmental assessment activities and identification of deficiencies
  - Provide guidance on environmental prevention measures, including post-outbreak
  - Develop partnerships with other groups working in this area
- Work with partners to determine how water quality measures correlate with the presence of *Legionella*
  - *Legionella* is only one of many water quality measures
  - Clear consensus that temperature and biocides can/should be measured more frequently than *Legionella*

### 4. Clarify role of routine environmental testing/evaluate outcomes where testing is performed

- Evaluate culture and culture-independent methods
  - Work with partners to evaluate PCR on water samples (*Timeline: 1-2 years*)
  - Identify appropriate action levels/targets (*Timeline: 1-2 years*)
  - Develop assays to detect highly pathogenic strains in water systems (*Timeline: 5-10 years*)
- Leverage collaborations with external partners to contribute to the evidence base for routine environmental testing

### 5. Evaluate disinfection strategies for primary prevention and encourage stakeholders to develop an evidence base

- Work with partners (e.g., industry, academia) to develop an evidence base for primary disinfection
  - Existing biocides
  - Novel disinfectants/biocides
  - Role of biofilm

## DISCUSSION

In conclusion, Dr. Whitney asked the BSC to consider the broad areas proposed for CDC focus vs. external focus; the prioritization proposed among CDC-led projects; the inclusion of short-term (lower risk) and long-term (potentially game-changing) activities among priority activities; and the role CDC should play in advancing activities with an external focus.

### Why are rates of LD increasing in the U.S.?

- The causes of increases in LD are unclear. More awareness, diagnosis, and better reporting of LD are unlikely to account for all of the increase, although some geographic disparities may be due to disparities in testing.
- Warmer summers may have led to more outbreaks linked to cooling towers; re-modeling projects that disrupt old pipes with *Legionella* in their biofilms may also contribute.

- Increasing rates of LD might be associated with 1) aging infrastructure, 2) aging populations (with weakened immune systems) who use this infrastructure; and 3) changes in precipitation or temperature. Thus far, studies suggest that rising LD rates correlate with increased rates of precipitation but not necessarily with temperature.

### LD Priorities

- The first two items in the proposed agenda (on primary prevention and sources of outbreaks) are the highest priorities for CDC. The last two (environmental testing and disinfection) are the primary concern of CDC partners.
- Examples of actions recommended for CDC by BSC members include the following:
  - Help translate the ANSI/ASHRAE standards into language appropriate for facility managers and public health workers and consider developing an LD prevention checklist for hospitals and other high-risk facilities. CDC should also communicate to industry partners the benefits of implementing the ANSI/ASHRAE standards.
  - Evaluate the impact of the New York State plan to register cooling towers
  - Advance development of metagenomic and AMD techniques to characterize LD strains and study their geographic distribution. This effort would also detect any emergence of drug-resistance in *Legionella*.
  - Partner with FDA to provide technical assistance to diagnostic companies to help them include *Legionella* sequences in multi-panel tests for pathogens of the lower respiratory tract
  - Develop partnerships with associations of structural and industrial engineers and consider increasing in-house engineering expertise that could be leveraged across CDC
  - Determine what thresholds of *Legionella* should be used in different situations to trigger emergency response vs. steps aimed at decreasing *Legionella* in a water supply system or maintaining low levels.
  - Determine in which situations environmental testing for LD would be most useful. Examples include conducting LD testing in high-risk environments, such as cooling towers and hospitals. CDC might reach out to the Society for Healthcare Epidemiology of America (SHEA) on efforts to conduct environmental testing in hospitals.

### Sporadic LD Cases

- Although the vast majority of cases are sporadic, the environmental factors that favor them are unknown. In essence, prevention efforts are based on reviewing evidence only on recognized outbreaks that comprise 4% of cases and may not be representative of cases considered to be sporadic.
- The water-system deficiencies that cause recognized outbreaks (e.g., inadequate disinfection) may or may not be the same as those that cause sporadic cases
- CDC stated that previous attempts to link sporadic cases to risk factors in the home were not successful, with the studies complicated by many potential exposures outside the home.
- In terms of research, LD is a neglected disease. CDC should partner with NIH, EPA, the Occupational Safety and Health Administration, the Department of Veterans Affairs, and academic and industrial partners to advance our understanding of *Legionella*. Interdisciplinary research (epidemiologic and environmental) on sporadic LD cases might focus on

- Assessing reasons for regional disparities in LD rates (e.g., differences in precipitation or temperature)
- Identifying risk factors for sporadic cases by comparing facilities where sporadic cases occur with facilities where sporadic cases have not been reported
- Using AMD to assess the genetic diversity and environmental sources of LD strains that cause sporadic cases in different geographic areas. AMD testing might indicate that some apparently sporadic cases are actually part of undetected outbreaks
- Determining whether contaminated cooling towers in cities like New York lead to further contamination, causing sporadic LD cases
- Conducting serologic surveys that shed light on LD transmission routes
- Collection of data to determine the impact of environmental monitoring for *Legionella* as a prevention tool for premises with large plumbing systems

### Additional Comments on LD Prevention

- For primary prevention, it may be more important to pay attention to stagnation (lack of flow) than to disinfection
- A better understanding of how weather changes contribute to LD outbreaks could advance prevention efforts
- It is important to raise awareness of LD among building inspectors, maintenance workers, and owners and operators of pools and spas. Building owners generally do not consider LD infection as a high priority; for hospitals and other high-risk environments, the practical benefit of prevention activities is more evident.
- Resources for LD prevention are lacking at the global level. CDC has reached out to colleagues in London and in Australia who have considered these issues. Their main message to building owners is that water systems run better and lose less energy if they are well maintained.
- Models for LD prevention include efforts by Ontario and New York City to register, maintain, and environmentally monitor cooling towers and fulfill ANSI/ASHRAE standards and public health recommendations.
- Carole Heilman stated that for *Legionella*, NIAID currently supports five basic research grants and no applied research grants.

## Update from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

NCEZID Director Beth Bell highlighted several recent NCEZID accomplishments:

- [\*Vital Signs – Safer Food Saves Lives\*](#) (November 2015)
- [\*Vital Signs – Making Health Care Safer – Stop Spread of Antibiotic Resistance\*](#) (August 2015)
- ***Listeria* Whole-Genome Sequencing (WGS) Project**, which uses real-time WGS to analyze clinical specimens from all *Listeria* cases identified in the U.S., as well as some environmental samples. Its aims are to detect disease clusters that might represent an outbreak; solve outbreaks faster; and identify the food sources of *Listeria* cases.

- The project began in 2013 as a collaboration among CDC, FDA, USDA, the National Center for Biotechnology Information (NCBI), and state and local health departments to develop next-generation sequencing (NGS) methods for PulseNet. Ten pilot states will conduct WGS-based surveillance for *Campylobacter* and STEC (by the end of 2015) and for *Salmonella* (during 2016).
- **Listeria WGS Metrics.** Following the transition to WGS, the number of *Listeria* clusters detected has increased, the number of outbreaks solved has increased (e.g., with a food source identified), and the median number of cases per cluster has decreased due to faster cluster detection and prevention of further cases. The number of *Listeria* cases linked to a food source also increased.
- **Antimicrobial Resistance (AR) Isolate Bank**, which was launched by CDC and FDA in June 2015 to support research and development of new diagnostic tests and antibiotic drugs. To date, the AR Bank contains over 220 isolates of carbapenem-resistant enterobacteriaceae (CRE) and other multi-drug-resistant gram-negative rods. In its first 3 months, CDC used the bank to fill 35 orders from diagnostic test manufacturers, pharmaceutical companies, and academic researchers.
- **[Get Smart About Antibiotics Week: November 16-22.](#)** This year's components included a Presidential proclamation, a 24-hour global Twitter chat, and extensive international activities.
- **E-Pathology**, a new electronic platform that allows physicians and scientists to submit images and slides to CDC pathologists for evaluation. It combines diagnostic assistance, real-time tele-pathology imaging, and reference and training services. This technology may be particularly useful for doctors in remote and resource-poor settings.
- **Response to the Dengue Outbreak in Hawaii**, which includes the first cluster of locally acquired dengue reported in Hawaii since 2011. As of December 2, 2015, there have been 122 confirmed cases (106 residents and 16 visitors), with 143 additional cases under investigation. The outbreak included 2 confirmed and 5 suspected cases among participants of the Kona Ironman triathlon competition, which occurred in October.

## DISCUSSION

- CDC and partners are investigating possible connections between Zika infections in Brazil and the birth of babies with microencephaly and between chikungunya infection in Reunion Island and cases of encephalitis in babies and the elderly. Surveillance for encephalitis has been heightened in Puerto Rico, which experienced a large chikungunya outbreak last year.
- Guillermo Ruiz-Palacios, National Institutes of Health and Tertiary Referral Hospitals, Mexico City, commented that chikungunya and Zika have spread rapidly through Mexico, Latin America, and coastal areas. He noted that local factors—such as urbanization, warmer temperatures, and large storms that provide favorable conditions for mosquitoes—may have favored disease transmission. At the present time, all three diseases—dengue, chikungunya, and Zika—are occurring simultaneously in Latin America and might spread to the southern United States. Public health workers from Mexico and the U.S. are working together at the border to evaluate cases of disease and monitor local transmission.
- Visitors to Hawaii learned about the dengue outbreak from news coverage, websites, and healthcare providers, as well as CDC's travel website.
- Multiplex assays may be a useful tool for tracking these three mosquito-borne diseases. For now, the public health sector is the major or only source of serologic and AMD assays for chikungunya and Zika.

- It is important to explain to the public what AMD techniques can and cannot do; technology cannot solve all problems. However, in this case, AMD has the potential to improve diagnosis of these three mosquito-borne diseases, as well as tickborne diseases that are difficult to distinguish and diagnose.

## Update from the Office of Advanced Molecular Detection and Report back from the Infectious Disease Laboratory Working Group

### AMD Update

Greg Armstrong, Director, Office of Advanced Molecular Detection (OAMD), provided an overview of CDC's AMD Initiative—a 5-year laboratory-modernization program that focuses on NGS, bioinformatics, and related technologies. AMD priorities include

#### Foodborne Disease

- **WGS to Genotype PulseNet Specimens.** AMD's 5-year objective for foodborne diseases is to transition PulseNet from pulsed-field gel electrophoresis (PFGE) to WGS, working in collaboration with FDA, USDA, and NCBI. Using WGS to characterize PulseNet specimens represents the largest public health application of AMD technology to date; it is also the first use of this technology by most PulseNet laboratories. The plan is to transition a series of PulseNet pathogens to WGS over the next 3 years, including *Listeria* (October 2015), *Campylobacter* and STEC (by March 2016), *Salmonella* (by March 2017), and *Vibrio* and *Yersinia* (by March 2018). (Metrics for the *Listeria* WGS Project are provided on page 17.)
- **Culture-Independent Diagnostic Tests (CIDTs) of Enteric Bacterial Pathogens.** Obtaining isolates of enteric bacterial pathogens will become increasingly challenging as CIDTs replace culture-based tests in clinical laboratories. Short-term solutions include requiring clinical laboratories to conduct culture-based tests when initial CIDTs are positive (reflex culture) or to submit specimens to public health departments. Long-term solutions include development of amplicon (PCR) sequencing and conducting WGS directly from stool samples (expected by 2019, although it may take longer).

#### Tuberculosis

- ***Mycobacterium tuberculosis* (MTB) Genotyping.** AMD's 5-year objective for MTB is to transition from Mycobacterial Interspersed Repetitive Units/Variable Number Tandem Repeat (MIRU/VNTR) genotyping to WGS. A pilot program, which began in Michigan and California in mid-2015, will be expanded to four additional states in early 2016. Steps include exploring the feasibility of sequencing MTB simultaneously with bacterial PulseNet pathogens (by mid-2016); finalizing a model for a national MTB WGS Network (by January 2017); and operationalizing the Network (by December 2017).
- **Tuberculosis CIDTs.** WGS of MTB directly from sputum samples will allow both genotyping and inference of drug susceptibility. The plan is to develop WGS methods (using spiked samples) by the end of 2016 and to validate these methods in real specimens by the end of 2017. This project is ahead of its proposed timeline.

## Influenza Virus WGS

AMD's 5-year objective for influenza is to transition characterization of flu viruses from a process requiring isolation, serial culture, and sequencing to a one-step process involving WGS of viral sequences directly from clinical specimens. The plan includes establishing WGS standards by mid-2015; conducting WGS on the majority of specimens by January 2016; establishing the first reference laboratory (in Wisconsin) by June 2015 and the second and third by March 2016; and moving to a cloud-based data management system by September 2016. In the future, all AMD activities are likely to use cloud resources, for both storage and computing.

## Healthcare-Associated Infections (HAIs) and Antimicrobial Resistance

The 5-year AMD objectives are to transition HAI typing from PFGE to WGS; develop tools that facilitate use of WGS to detect AR genes; and develop and apply a "microbiome disruption index" to promote judicious use of antibiotics to treat HAIs. Priorities include WGS typing of *Clostridium difficile*, CRE, and MRSA; tracking transmissible elements that carry AR genes; developing a "connectivity index" to assess transmission of multidrug-resistant organisms between healthcare facilities; and using the [SSTAR tool for WGS-based detection of AR determinants](#).

In conclusion, Dr. Armstrong described cross-cutting priorities to improve AMD infrastructure (e.g., expanding capacities for data storage and high-performance computing, enhancing the Research Grade Network, and advancing workforce development). Other AMD priorities include

- Application of WGS to HCV, malaria, mosquito-borne viruses (dengue, Zika, and chikungunya; see page 17), and additional bacterial pathogens of public health importance (i.e., gonococcus, *Legionella*, streptococcus, meningococcus, and *Bacillus anthracis*)
- Development of diagnostics for use during outbreaks of unexplained respiratory diseases and viral vaccine-preventable diseases
- Development of methods and procedures to ensure integration of genomic and epidemiologic data

## Report back from the Infectious Disease Laboratory Working Group (IDLWG)

Jill Taylor, IDLWG co-chair, provided the following feedback from the IDLWG's meeting on October 26:

- **Articulate a Vision and a Strategy.** As AMD enters its third year of funding, CDC should identify specific and measurable outcomes that document its success (including cost savings). As part of this effort, CDC should provide a comprehensive picture of the impact of AMD on public health microbiology and clinical practice and describe the laboratories of the future. CDC should also develop a sustainability plan for AMD.
- **Collaboration and Partnerships.** AMD must maintain strong collaborations and coordinate closely with other federal agencies. CDC should focus on its core mission (i.e., improving disease surveillance and public health infrastructure); leverage efforts by FDA and NIH; provide researchers with infectious disease datasets, including as much metadata as feasible; and take the lead in resolving issues about minimal necessary metadata, data ownership, and privacy.
- **Urgent Priority Project: CIDTs for Enteric Bacteria.** CDC should work with public health and clinical laboratories to identify interim solutions for maintaining disease surveillance as bacterial isolates become more difficult to obtain. One solution might involve a challenge grant to industry partners to accelerate use of WGS with stool samples.

- **Training.** Workforce development requires focused and purposeful training for state and local public health partners, including both laboratorians and epidemiologists. Over the long-term, CDC should also facilitate training for physicians on how to use AMD data.
- **Moving forward.** CDC should focus on integration of genomic data with data from multiple diverse streams (epidemiologic, laboratory, environmental, and behavioral), with precision medicine as a long-term goal. CDC should also review the benefits of intensified use of other diagnostic technologies (e.g., rapid phenotypic and genotypic tools for detecting drug resistance). The IDLWG also supports CDC’s suggestion about holding an external “Blue Ribbon” review panel to provide guidance on future needs.

## DISCUSSION

### Which questions can next-generation sequencing answer that have not been answered before?

- The value of NGS data for public health purposes—and whether short sequences are meaningful for a given use, such as linking an outbreak to a food source—will become clear over time and will likely differ for different organisms. In all cases, it will be necessary to communicate WGS findings in a consistent way.
- Dr. Armstrong noted that the AMD program requires participating CDC laboratorians to define the expected public health outcomes of their activities
- Although WGS is not necessary for every pathogen or situation, in some cases—e.g., assessing the genetic diversity and environmental sources of *Legionella* (see page 10)—the application of WGS and other new technologies may be very valuable.
- More experience is needed to understand the uses of WGS. Examples of proven uses include
  - Identifying foodborne disease outbreaks involving cases that are geographically dispersed
  - Inferring TB drug susceptibilities to improve treatment
  - Understanding TB transmission patterns to inform intervention and control
  - Identifying pathogens that are not easy to culture
  - Evaluating vaccine antigens when pathogens are not easy to culture

### External Input to Guide AMD

- Because technologies are rapidly changing, CDC might consider establishing an external group to provide ongoing advice on technical issues. Dr. Armstrong said that CDC will continue to hold ad hoc meetings with the IDLWG and might hold a second AMD-related blue ribbon panel. The first panel (in 2010) was on bioinformatics; the next one might focus on the role of NGS in public health. Objectives would include obtaining input on new technologies and on biases and sources of error in sequencing equipment.
- Dr. Heilman reported that NIH efforts in this area include
  - *Data integration.* Over the past 10 years NIAID has focused on integration of data on host and pathogen relationships, including redundancies and indirect relationships. More recently, NIAID has used this knowledge base to conduct metadata analyses for predictive modeling.
  - *Direct sequencing of primary isolates.* Techniques for WGS of respiratory pathogens in sputum samples are already available.

- *Culturing the “unculturable.”* At the same time that culture-based diagnostic testing is becoming obsolete, microbiome research is sparking renewed interest in culture-based approaches for studying multiple species of bacteria that live in the gut and other organs.

### **Drug-Resistant Gonorrhea**

- CDC monitors drug-resistant gonorrhea strains in the population through the 26-site Gonorrhea Isolate Surveillance Project (GISP). AMD performs WGS on GISP isolates and is working with the Sanger Institute, the Broad Institute, and NCBI to make these data more widely available.
- WGS is not currently used in clinical settings to identify the best treatment options for drug-resistant gonorrhea. Instead, STD clinics tend to rely on empiric therapy. A point-of-care test for drug-resistant gonorrhea therefore might be very valuable.

### **Bioinformatics Capacity**

- Technical training is needed at the state and local levels to increase bioinformatics capacity.
- While WGS will eventually be conducted at all state laboratories, bioinformatics analysis of WGS data might be performed at fewer sites—perhaps in regional centers.
- Dr. Armstrong said that OAMD supports this approach and is working through the Epidemiology and Laboratory Capacity (ELC) program to encourage development of regional networks for bioinformatics.

### **Data Standardization**

- Standardization of WGS data is essential to enable communication and collaboration among partners who use different sequencing platforms and information systems
- Dr. Armstrong said that NGS is a “very convergent technology” because DNA data are inherently digital and easier to standardize than data from disease-specific culture-based tests
- PulseNet laboratories share the same software, which evolved along with the PulseNet network
- In the future, CDC may be able to accept data from laboratories that use different software systems by providing a single port of data entry to CDC

### **Other Comments**

- As AMD enters its third year, it is important to explain why continued support will be needed to sustain CDC’s modernized laboratory work
- Collaboration and synergy with NIH and other partners is essential in addressing HAIs
- Educating epidemiologists on how to interpret and make use of AMD data should be a priority
- Beth Lautner, USDA Food Safety and Inspection Service (FSIS), reported that molecular data were used during a recent outbreak of avian influenza to pinpoint viral spread from wild birds to poultry and follow transmission between and among farms. The data from the outbreak investigation may be used in court.

# Report of the Food Safety Modernization Act Surveillance Working Group

The Food Safety Modernization Act Surveillance Working Group (FSMA SWG), established in 2011, is charged with providing advice and recommendations to CDC and FDA (and through them to HHS) on criteria for the designation of Integrated Food Safety Centers of Excellence (submitted in 2012) and improvement of foodborne illness surveillance. The Working Group includes 21 members representing the BSC, CDC, USDA, FDA, academia, consumer groups, industry, and state and local health organizations.

Harry Chen, Chair of the FSMA SWG, reported on the group's December 7-8 meeting and presented highlights from the FY 2015 Annual Report to the HHS Secretary.

## FSMA SWG December 7-8 Meeting

In addition to finalizing the FY 2015 Annual Report, the FSMA SWG focused on three areas:

### 1. Engaging industry in foodborne illness surveillance

- When PulseNet detects a foodborne outbreak, consultations with industry partners often help public health responders generate hypotheses about the outbreak's source, trace-back contaminated products, and take action to stop the outbreak
- Use of industry data to guide outbreak responses and develop public policy on food safety is facilitated by data-sharing platforms such as VoluntaryNet, a collaboration between PulseNet and the University of Georgia Center for Food Safety that allows food industry partners to share data anonymously. Industry partners also participate in the CDC-Food Industry Safe Foods Forum.
- Public health use of data generated by store loyalty (or "shopper") cards was highlighted in a recent *Vital Signs* ([\*Safer Food Saves Lives: Stopping multistate foodborne outbreaks\*](#)).
- Challenges to use of industry data during investigations of multistate outbreaks include insufficient data on product distribution; varying levels of consumer support for shopper-card programs; difficulties with trace-back activities (especially when outbreaks are associated with produce); and lack of subtyping conducted by industry.

### ***Food Safety and Inspection Service (USDA/FSIS) perspective on engaging the food industry***

- FSIS conducts approximately 190,000 analyses every year and uses these data to advance outbreak investigations, monitor current and emerging threats, prepare risk assessments and attribution models, inform food safety policies, and evaluate trends
- Industry partners collect 100 times as much data, providing a rich source of information that can help identify key drivers of foodborne illness related to food production and processing and enhance the safety of U.S.-produced meat and poultry products

### ***FDA perspective on engaging the food industry***

- Communication is critical to build trust and share information to drive response and prevention initiatives. FDA and CDC utilize information from clusters, outbreaks, environmental assessments, surveillance assignments, and analysis of multiple outbreaks to help industry understand risk and learn from past events. FSMA is helping to build industry food-safety cultures with a prevention focus.

- FDA supports an open, participatory approach to policy setting, discussion of food safety issues, and outbreak prevention and control. Activities include outreach to companies regarding disease clusters and outbreaks; dialogue with CDC to address questions about implicated food products or ingredients; and participation in professional and association meetings to identify opportunities to enhance food safety. FDA also provides food-safety guidance to industry through the [FSMA Technical Assistance Network](#) (TAN).

***Feedback: How can we better engage industry in enhancing foodborne illness surveillance?***

FSMA SWG recommends that CDC and public health partners

- Maintain consistent and ongoing engagement with industry partners, keeping in mind CDC’s mission and the priorities of each partner
- Establish criteria for data quality by standardizing and validating diagnostic tests. A third-party convener might help coordinate this process.
- Identify “champion companies” with strong food-safety corporate culture, supply-chain leverage, and resources and reach to make an impact
- Encourage companies to
  - Share data (e.g., sales and consumption data, trace-back data, and food/environmental data)
  - Provide assistance during outbreak investigations (e.g., by providing loyalty card data and product distribution data)
  - Advance corporate policies that promote food safety (e.g., using suppliers who use food-safety best practices)
  - Provide assistance with consumer alerts (e.g., by making robo-calls) and mitigation (e.g., by supporting vaccination programs to control and prevent outbreaks of hepatitis A)
- Be aware of industry needs (e.g., to maintain profitability, avoid recalls and outbreaks, avoid liability due to outbreaks, and resolve outbreaks quickly). During outbreaks, industry partners may require assistance to interpret WGS data and communicate WGS results to the public

Challenges to engagement with industry partners include

- Consumer demand for fresh and natural foods may lead industry to limit traditional food safety strategies
- A hostile corporate “takeover” climate may limit company resources for food-safety culture and capacity
- Passage of FSMA and establishment of the [Global Food Safety Initiative](#) (GFSI) have raised the bar for company action, and companies may be concerned about liability
- Industry partners are diverse, including small and large companies, processors, retailers, producers, manufacturers, and food services

**2. Plans proposed by the Interagency Food Safety Analytics Collaboration (IFSAC)**

- IFSAC coordinates efforts by FDA, USDA/FSIS, and CDC to generate estimates of foodborne illness source attribution and inform food-safety policy

- IFSAC has achieved its short-term (2012-13) strategic goals and is advancing its longer term (2014-16) strategic goals ([see the IFSAC Strategic Plan](#))
- IFSAC has developed a new food categorization scheme to increase the accuracy and utility of the food categories used to describe foods implicated in outbreaks and to generate foodborne illness source attribution estimates

#### Feedback:

- ***Should IFSAC seek external technical input on individual projects?*** The FSMA SWG recommends that IFSAC engage with academic institutions, non-academic research partners, and Integrated Food Safety Centers of Excellence. IFSAC should also consider developing a peer review group or advisory committee.
- ***Are there analytical needs that IFSAC should consider as part of a new strategic plan?*** The FSMA SWG recommends that IFSAC
  - Include more granularity in its categorization scheme, to help determine where to focus food safety efforts
  - Analyze the impact of (1) recalls and (2) greater speed in outbreak investigations
  - Compare sources of O157 STEC and non-O157 STEC
  - Identify levels in the food chain where contamination occurs
  - Improve access to food-testing data, particularly for produce, to track the effects of interventions
- ***Future Directions of IFSAC.*** The FSMA SWG can continue to serve as a strategic advisory group to IFSAC. The FSMA SWG also recommends that IFSAC share data with [Interagency Risk Assessment Consortium](#) (IRAC).

### 3. Updates on shigellosis and surveillance tools for foodborne illness

- Shigellosis causes half a million illnesses in the U.S. each year, making it the third most common bacterial enteric illness in the U.S. (after *Salmonella* and *Campylobacter*). Among U.S. shigellosis cases, 31% are foodborne (see "[Foodborne Illness Acquired in the United States—Major Pathogens](#)"). A travel-related case or a foodborne outbreak may seed additional outbreaks of Shigellosis, involving transmission by food or water or person-to-person within a childcare facility or another community setting.
- Updates were also provided on
  - The National Antimicrobial Resistance Monitoring System (NARMS), which is a collaboration among CDC, USDA, and FDA that analyzes isolates of drug-resistant enteric bacteria isolated from humans, farm animals, and retail meat. A new NARMS project—[NARMS Now: Human Data](#)—allows members of the public to download antibiotic resistance data in an easy-to-use format.
  - The [National Outbreak Reporting System](#) (NORS), which facilitates reporting of enteric and waterborne disease outbreaks by state, local, and territorial public health agencies).
  - The [Foodborne Outbreak Online Database \(FOOD Tool\)](#), which facilitates outbreaks tracking and reporting.

## DISCUSSION

- Government and private sector partners should speak with one voice when outbreaks occur
- Waterborne contamination as a cause of foodborne outbreaks (e.g., due to flooding) might be a future topic for discussion by FSMA SWG. Obtaining clean water sources is an increasing challenge for many farmers in many areas. Another topic might be how to improve surveillance for diseases associated with imported food.
- Sporadic cases of illness are common with *Shigella*, as with *Legionella* and norovirus. However, attribution models are largely based on outbreak data, for both enteric and non-enteric foodborne pathogens. It is important to understand the underlying level of infection that occurs outside of outbreaks. (See also: discussion of sporadic LD cases on page 15).

### FSMA SWG Annual Report to the HHS Secretary

The FY2015 Annual Report received a unanimous endorsement from the BSC members. It addresses two key topics:

- 1. Improving governmental coordination, integration, and collaboration.** The Annual Report includes recommendations regarding
  - The Interagency Food Safety Analytics Collaboration (IFSAC)
  - The Interagency Foodborne Outbreak Response Collaboration (IFORC)
  - Multi-agency collaborations to use WGS in foodborne illness surveillance
  - Collaborations with state and local partners to enhance foodborne illness surveillance
  - Development of surveillance tools to improve
    - Nationwide monitoring of cyclosporiasis
    - Investigations of multistate outbreaks of enteric diseases (e.g., making use of the System for Enteric Disease Response, Investigation, and Coordination [SEDRIC]).
- 2. Environmental surveillance for foodborne illness.** The Annual Report includes recommendations for
  - Enhancing environmental surveillance for foodborne diseases, making use of the [National Environmental Assessment Reporting System](#) (NEARS) and the [e-Learning system](#)
  - Improving dissemination of data from the [Environmental Health Specialists Network](#) (EHS-Net) to public health and industry partners
  - Integrating and improving environmental foodborne surveillance data
  - Improving surveillance for foodborne *Vibrio* illness

## Update from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

NCHHSTP Director Jonathan Mermin provided the following updates:

### NCHHSTP Staffing Changes

- Eva Margolies, Associate Director for Planning and Policy Coordination, is retiring

- Rich Wolitski, Associate Director for Performance Improvement, is on detail to HHS as Director of the Office of HIV/AIDS and Infectious Disease Policy
- Michele Owen is the new NCHHSTP Associate Director for Laboratory Science

## Outbreak of HIV Infection in Indiana Associated with Injection Drug Use

The epidemic curve indicates that the outbreak began in November 2014, peaked in April 2015, and then ebbed rapidly as infected persons were identified and treated. Re-testing of high-risk persons by the Indiana State Department of Health and CDC identified 3 additional people who tested positive for HIV, bringing the total to 184.<sup>9</sup>

## NCHHSTP Atlas

[The Atlas](#) has been updated to include 2013 data for HIV, STDs, and TB; county-level data and origin-of-birth data for TB; and an advanced query option for exploring the data at deeper levels. The *Atlas* can generate customized tables with data for multiple states or counties, years, and subpopulations.

## NCHHSTP Division Updates

### Division of HIV/AIDS Prevention

- The 2015 National HIV Prevention Conference was held in Atlanta, December 6-9
- The High-Impact Prevention program aims to double the number of jurisdictions with integrated HIV prevention and care planning, to implement priority interventions, and to focus on persons living with HIV/AIDS and MSM. Indicators of recent success include
  - A 9% decrease in annual new HIV diagnoses between 2010 and 2014. The decrease was 6% in men and 21% in women, with a 32% decrease in infections attributed to injection drug use and a 2% decrease in young black MSM (following a 114% increase during the prior 5 years). The proportion of persons with HIV who are aware of their status increased, indicating that the decrease in new diagnoses is not due to decreases in testing.
  - A 9% decrease in mortality among persons diagnosed with HIV in all racial and ethnic groups (between 2010 and 2013), and a 28% decrease in mortality among African-Americans diagnosed with HIV (between 2008 and 2012). Nevertheless, HIV disparities persist. HIV prevalence varies with population density, poverty, education, employment, homelessness, and region of residence.
- The [State HIV Progress Report](#) indicates that all 2015 HIV targets have been met by one or more states. In five states, at least 90% of people living with HIV know their status—which also fulfills the updated *National HIV/AIDS Strategy* goal for 2020.
- Recent web postings include
  - [Vital Signs: Daily Pill Can Prevent HIV: Reaching people who could benefit from PrEP](#)
  - A user-friendly, on-line [HIV Risk Reduction Tool](#) that provides HIV risk estimates and prevention messages
  - An online toolkit and app entitled “[Every Dose Every Day](#)” that helps improve adherence to HIV medication regimens

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<sup>9</sup>Adams, J. HIV outbreak in Indiana. *N Engl J Med* 2015;373:1379-81.

## Division of Adolescent and School Health

- CDC Public Health Grand Rounds on [Adolescence: Preparing for Lifelong Health and Wellness](#)
- A mobile-friendly version of the [Healthy Youth Website](#)
- A fact sheet entitled “[Bullying and Absenteeism: Information for State and Local Education Agencies](#)”
- [School Health Policies and Practices Study \(SHPPS\), 2014](#), which reports that sex education messages can counter false information
- A [study on substance abuse as a risk for HIV, hepatitis, and STDs among teens](#), which found that rates of injection drug use are rising among some sexual minorities, even though teenagers overall have very low rates of injecting drugs.

## Division of Viral Hepatitis

- CDC and the HHS Office of Minority Health have asked the Institute of Medicine to assess the feasibility of eliminating HBV and HCV in the United States. IOM will examine scientific and policy issues related to the prevention, detection, control, and management of HBV and HCV.
- The [Cherokee Nation Health Services HCV Elimination Project](#) was launched in October
- The Viral Hepatitis Action Coalition hosted a meeting on “[Stopping the Hepatitis C Virus Epidemic Among Young Persons Who Inject Drugs](#),” in Atlanta on July 20, 2015.
- CDC estimates of HCV mortality trends and of the number of people living with viral hepatitis in the U.S. have been updated.

## Division of STD Prevention (DSTPD)

- [Sexually Transmitted Diseases Treatment Guidelines, 2015](#). The *Guidelines* include new diagnostic, treatment, and prevention recommendations, including alternative treatment regimens for gonorrhea. An updated Pocket Guide, Wall Chart, and Apple version of the *STD Treatment Guide app* are also available.
- [2014 STD Surveillance Report](#), which found that rates of chlamydia, gonorrhea, and syphilis increased in 2014 for the first time since 2006. Rates of chlamydia increased by 3% since 2013; rates of primary and secondary syphilis by 15%; and rates of gonorrhea by 5%—with young people between the ages of 15 and 24 accounting for the highest rates of chlamydia and gonorrhea.
- [Clinical Advisory on Ocular Syphilis](#), which says that more than 150 cases of ocular syphilis have been reported over past 2 years from 20 states. Rates of congenital syphilis have also increased.
- A [webinar on the Disease Intervention Specialists \(DIS\) Certification Project](#), hosted by the Public Health Accreditation Board, the National Association of City and County Health Officials (NACCHO), the National Coalition of STD Directors, and CDC.

## Division of Tuberculosis Elimination

- [Reported Tuberculosis in the United States, 2014](#). 9,421 cases of TB cases were reported in 2014, which is a 1.5% decline from 2013 and the smallest decrease in more than a decade. The percentage of persons with TB who were HIV-positive was 6%, which represents a 7% decrease since 2011 and a 48% decline since 1993. Up to 13 million people in U.S. have latent TB.
- [Interactive Core Curriculum on Tuberculosis: What the Clinician Should Know](#)

## DISCUSSION

### Why are STD rates increasing?

- Although data through 2014 show rates of hepatitis, TB, and HIV to be decreasing, rates of other STDs (chlamydia, gonorrhea, and syphilis) are increasing rapidly. The reasons for these increases are under investigation; one possibility is that they are due in part to changes in reporting related to the expansion of Medicaid under the Affordable Care Act. Increases in syphilis are occurring primarily among MSM, many of whom are HIV-infected. Several state health officials at the meeting expressed concern about rising syphilis rates.
- Several BSC members wondered whether HIV funding could be used to combat STDs since doing so would be related directly to HIV prevention (i.e., both STDs and HIV rates are increasing most significantly in the same population: MSM).
- The availability of PrEP might lead to decreased use of condoms, and therefore to higher rates of STDs. However, Dr. Mermin noted that PrEP was not yet in use when the increases occurred.
- Another possibility is that the increased concentration of gay and bisexual men in social situations—aided by online dating apps—is leading to faster disease transmission in those groups.

### STD Clinics and Holistic Health Centers

- Many states have closed their STD clinics, which were far more likely than other healthcare facilities to test for and diagnose STDs. The erosion in local resources for STD control has led to gaps in public health services, including a lack of screening during pregnancy to prevent congenital syphilis.
- Gail Bolan, DSTPD Director, said that CDC is considering new ways to rebuild public health infrastructure to address STDs, perhaps by creating a new type of holistic health center to advance sexual health, especially for teens.

### Other Comments

- Syphilis reduction is a public health success that is now being reversed. CDC will hold a consultation on syphilis in late January.
- Congenital cases of HIV and syphilis are regarded as sentinel events, indicating that current prevention efforts are insufficient. Clusters of syphilis in teens might be also be regarded as sentinel events.
- HIV and STDs represent four of the six most commonly reported infectious diseases. It is important to emphasize that chlamydia and gonorrheal infections can lead to infertility and ectopic pregnancies.
- Because adherence to HIV prevention or treatment regimens is difficult to maintain, efforts to develop long-acting agents, as well as vaccines, are continuing.

## Focused Discussion: Climate Change and Health

Ben Beard, Associate Director for Climate Change and Chief, Bacterial Diseases Branch, Division of Vector-Borne Diseases, NCEZID, along with George Luber, Chief, Climate and Health Program, Division of Environmental Hazards and Health Effects, NCEH, provided an overview of climate and health activities at CDC.

## Background

- The third [National Climate Assessment](#), published in 2014, summarizes the impact of climate change on Public Health, Energy, Water, Transportation, and Agriculture, and other U.S. sectors. The first of four key messages in the chapter on human health states that climate change threatens human health and well-being in many ways—causing extreme weather events, wildfires, decreased air quality, and illnesses transmitted by food, water, and insect vectors.
- One of the best ways to understand linkages between climate change and health is through the One Health paradigm, which views disease emergence as occurring at the interface of humans, animals, and the environment
- Climatic variables such as temperature and rainfall have a significant impact on disease transmission, affecting populations of insect vectors and host animals, as well as the replication rate of disease agents. Severe storms and El Niño Southern Oscillation events have been shown to mediate disease outbreaks.
- Climate-sensitive diseases include zoonotic, vectorborne, waterborne, and foodborne diseases, as well as diseases associated with soil and dust. Examples of vectorborne and zoonotic diseases include West Nile virus (WNV) infection, Lyme disease, rabies, dengue, Rift Valley fever (RVF), and Chagas disease. Other environmentally associated diseases include *Escherichia coli* O157H7 infection, cholera, leptospirosis, vibriosis, valley fever, and primary amoebic meningoencephalitis.

## Examples of Climate-Sensitive Diseases

### Rift Valley Fever

- Rift Valley fever is a mosquito-borne zoonotic disease caused by a *Phlebovirus* (family Bunyaviridae). It is found in parts of east and southern Africa, most commonly affecting livestock. An epizootic in Kenya in 1950-1951 caused an estimated 100,000 deaths in sheep; an outbreak in Egypt in 1977 among both animals and humans caused more than 600 human deaths.
- Major RVF outbreaks in east Africa coincided with strong El Niño events in 1997-1998 and 2006-2007. The direct cause may have been flooding of mosquito habitats, which can cause explosive outbreaks among animals and humans.
- The National Oceanic and Atmospheric Administration's (NOAA's) Climate Prediction Center indicates that the current El Niño likely will peak during the Northern Hemisphere winter (2015-16) and abate during late spring or early summer. It is expected to rank among the top three strongest El Niño episodes since 1950. The National Science and Technology Council (NSTC) Pandemic Prediction and Forecasting S&T Working Group plans to issue an Emerging Health Risk Notification stating that the risk of El Niño-driven RVF outbreaks is high in east Africa and that intensified efforts are needed to mitigate the threat. Countries at risk will likely require assistance with animal vaccination and mosquito control.

### West Nile Virus Disease

- WNV disease is a mosquito-borne zoonotic disease caused by a *Flavivirus* whose major reservoir hosts are birds. Humans and other mammals are considered “dead end” hosts because they do not contribute to maintenance of the virus in nature. In most people, WNV infection is asymptomatic; however, about 25% of cases experience fever with headache and other symptoms. Less than 1% of cases experience serious, life-threatening neuroinvasive disease.

- Weather patterns likely played a role in the 2012 WNV outbreak, which was the largest outbreak since 2003, with over 5,600 cases, including 2,873 cases of neuroinvasive disease and 286 deaths. The outbreak took place after a mild winter followed by an early spring and warm summer. The long growing season together with hot summer temperatures apparently led to larger mosquito populations and higher infection rates in both birds and mosquitoes, which ultimately led to greater transmission to humans.
- Precipitation may also influence the risk of infection with WNV, through its effect on mosquito populations. Because different vector species predominate in different parts of the country, the impact of precipitation on mosquito populations can vary regionally. Consequently, there is less certainty regarding the impact of precipitation on outbreaks of WNV.

## Lyme Disease

- Lyme disease is a tickborne disease caused by the spirochete bacteria, *Borrelia burgdorferi*. The bacteria is harbored in small rodents and sometimes in birds. Hosts for the ticks include small mammals and birds (for immature tick stages), as well as large mammals, particularly deer (for adult ticks).
- Disease in humans can range from flu-like illness with fever, fatigue, and rash to potentially fatal carditis, facial palsy, neurologic symptoms, and arthritis in later stages of illness. U.S. Lyme disease cases are under-reported by a factor of approximately 10-fold, with the estimated number of actual cases close to 300,000 cases per year.<sup>10</sup>
- Between 2001 and 2014, the distribution of cases of Lyme disease expanded in a northwestward direction—up and across the northeastern U.S., through Massachusetts, Pennsylvania, and New York, and upward through New Hampshire, Vermont, and Maine. During the same period, cases also expanded in all directions in the upper Midwest, as well as southward in the eastern U.S., through Maryland, Delaware, and Virginia. These data suggest that although climate change is likely driving northward disease expansion, other factors—such as reforestation, deer population expansion, and the growth of suburbs—are also influencing the spread of animal hosts and insect vectors.<sup>11</sup>
- A meteorological-based empirical model for Lyme disease onset, which uses simulations from five global climate models and four scenarios, suggests that
  - The national average annual onset of Lyme disease will arrive 0.4-0.5 weeks earlier for the years 2025-2040 ( $p < 0.05$ ), and 0.7-1.9 weeks earlier for the years 2065-2080 ( $p < 0.01$ )
  - Climate warming may have co-driven Lyme disease emergence in northeastern North America and in the future may drive substantial disease spread into new geographic regions and increase tick-borne disease risk where the climate is currently suitable.

## Reasons for Disease Emergence

Diseases emerge at the human/animal/environmental interface because of changes in

- *Environmental systems*, including higher temperatures, changes in precipitation, natural disasters, and periodic climate systems

<sup>10</sup>Hinckley AF, Connally NP, Meek JI, Johnson BJ, Kemperman MM, Feldman KA, White JL, Mead PS. Lyme disease testing by large commercial laboratories in the United States. *Clin Infect Dis*. 2014 Sep 1;59(5):676-81.

<sup>11</sup>Monaghan AJ, Moore SM, Sampson KM, Beard CB, Eisen RJ. Climate change influences on the annual onset of Lyme disease in the United States. *Ticks Tick Borne Dis*. 2015 Jul;6(5):615-22.

- *Land use*, including human encroachment into wilderness areas, extractive industries, deforestation, habitat fragmentation, biodiversity loss, urbanization, and changes in urban planning.
- *Food and agricultural systems*, including intensifying or expanding farming systems, greater livestock density, trade networks and globalization, unregulated/irregular use of drugs and vaccines, and livestock mixing patterns.
- *Human behaviors*, including hunting and consumption practices, cultural patterns and processes, travel capabilities, breakdown of governance, and antimicrobial usage patterns.

## CDC's Climate and Health Program

- The goal of CDC's Climate and Health Program (CHP), established by NCEH in 2009, is to help states and cities address health challenges associated with climate change, by providing scientific guidance, developing decision-support tools, and ensuring that public health concerns are considered in climate change adaptation and mitigation strategies.
- CHP provides support to 16 states and two cities, through the [Climate Ready States and Cities Initiative](#), to implement the Building Resilience against Climate Effects (BRACE) framework, which helps health departments to identify (and plan for) likely climate impacts in their communities, potential health effects associated with those impacts, and ways to assist populations that are most at risk.
- CHP activities conducted in collaboration with NCEZID include
  - Coordination of TickNET, ArboNET, and activities to advance implementation of BRACE
  - Participation in the [interagency group on Climate Change and Human Health](#) (CCHHG) of the U.S. [Global Change](#) Research Program (USGCRP). CCHHG, which is co-chaired by George Luber, CDC/NCEH, and Juli Trtanj, NOAA, drafted the [USGCRP Climate and Health Assessment](#)
  - Administration of CDC-NCAR<sup>12</sup> training courses, workshops, and the CDC-NCAR Joint Resident Postdoctoral Fellowship Training Program in Public Health and Climate Science
  - Development of a NOAA/CDC Memorandum of Understanding that provides a cooperative framework for strengthening science and services related to understanding, communicating, and reducing climate change impacts on the environment, public health, and public safety
  - Participation in the International Circumpolar Health Surveillance Climate Change Working Group, hosted by the NCEZID Arctic Investigations Program

In conclusion, Dr. Beard noted that an integrated understanding of climate, ecology, and epidemiology is critical for predicting and averting epidemics of infectious diseases. Prevention and mitigation of emerging infectious disease threats related to climate change requires

- Continued investment in disease surveillance to track disease trends
- Maintenance of a strong national public health system that can quickly detect, report, and respond to diseases that emerge in new areas
- Development of decision-support tools and adaptation strategies
- Investment in environmental data collection and disease/climate modeling efforts applicable to future climate scenarios

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<sup>12</sup> The [National Center for Atmospheric Research](#) (NCAR) is a federally funded research and development center devoted to service, research, and education in the atmospheric and related sciences.

## DISCUSSION

### The Impact of Climate Change on Health

- The impact of climate change on health is described in the recent [U.S. National Climate Assessment](#). Direct effects include increases in vectorborne, foodborne, and waterborne diseases; indirect effects include impacts on food and water security.
- Malnutrition is likely to be a major health issue related to climate change, because of crop failures caused by unpredictable rainfall. Higher concentration of carbon dioxide in the air can also affect concentrations of micronutrients in crops.
- Climate change will also impact the availability of potable, clean water—compounding food production issues in many countries. Water security and water quality is also a domestic issue.
- Global health issues, including global efforts to address Lyme disease (e.g., by the [Global Lyme Alliance](#)), should be integrated into the larger effort to address climate change
- The CDC Climate Change and Health program aims to demonstrate the value of addressing climate change issues in the context of public health by
  - Helping disease-specific programs at CDC implement projects to mitigate the health impacts of climate change
  - Assisting health authorities in other countries to assess climate change impacts on health, using the BRACE framework

### Education on Climate Change and Health

- The public health community can help raise awareness about dangers to health caused by infectious diseases, environmental degradation, ground water withdrawal, rises in sea levels, and drought
- The NCEH Climate and Health program hosted a special session at the 2015 Epidemic Intelligence Service (EIS) meeting and issued a Public Health Grand Rounds on [Climate Change and Health – From Science to Practice](#) in December 2014
- It is typical for EIS officers assigned to the CDC Division of Vector-Borne Diseases to focus on One Health issues, because One Health issues are (and have always been) intrinsic to addressing zoonotic diseases
- University partners might develop a Green Paper on health diplomacy to raise global awareness of public health issues affected by climate change
- Does CDC have a role to play in mitigating climate change as well as mitigating its impact?

### Vectorborne Diseases

- Mosquito and tickborne diseases require renewed attention, both in the U.S. and globally. The rapid spread of Lyme disease vectors in the U.S. is the result of a number of factors and likely influenced by climate change. (See also: discussion of dengue, Zika, and chikungunya viruses on pages 17 and 18).
- Dr. Luber described a crowd-sourcing tool that allows individuals to send pictures of ticks to the [TickEncounter Resource Center, University of Rhode Island](#), for identification and mapping. Another [crowd-sourcing tool](#) tracks blooms of blue-green algae.

- In regard to research,
  - Intensified efforts are needed to develop and validate Lyme disease diagnostics, vaccines, and other control measures (e.g., next-generation pesticides)
  - The HHS Working Group on Lyme and Other Tickborne Diseases has posted a webinar on [Vaccines for Lyme Disease—Past, Present, and Future](#)
  - CDC is working with NIH to identify biosignatures for early-stage Lyme disease
  - The AMD Initiative includes a project to develop metagenomic methods for diagnosis of tickborne illnesses
  - USDA and CDC can work together to track and model the spread of vectorborne diseases and disease vectors among animals and humans

## Topics for Future BSC Meetings

Robin Moseley invited the BSC to propose topics for BSC meetings in 2016, which are tentatively scheduled for May 4-5 and December 7-8. Suggestions included

- Transitioning to culture-independent diagnostic testing for enteric pathogens
- Developing a U.S. strategic plan for emergency development of vaccines when new threats emerge
  - Addressing surveillance and prevention and control for Lyme disease and other tickborne diseases
  - Mosquito-borne diseases such as Zika, and chikungunya
  - MERS-CoV
- Providing follow-up reports on
  - Antimicrobial resistance and HAIs
  - Impacts of climate change on public health, domestically and globally
  - Addressing increased rates of STDs

## BSC Conversation with the CDC Director

CDC Director Thomas Frieden thanked the BSC members for their help and advice. He reported that about 100 CDC staff members remain in Ebola-affected countries in West Africa, transitioning from an emergency to a completion operation. Lessons learned from the Ebola response, as detailed in after-action reports, include

- ***Each country must be ready to detect and stop outbreaks.*** This idea is basic to the GHSA and the 2005 International Health Regulations.
- ***Better global capacity and organization can improve outbreak responses.*** Advances in technical expertise (and new emergency procedures) at WHO and the establishment of GRRTs at CDC (see page 2), to facilitate rapid response to global public health emergencies.
- ***Improved infection control at healthcare facilities in developing countries is essential.*** Without good infection control, healthcare facilities can become foci for amplification of outbreaks.

Dr. Frieden also briefly mentioned the following topics:

- **Antimicrobial Resistance.** AR is the number-one domestic budget priority for CDC.
- **Legionnaires' Disease.** Recent outbreaks in New York City revealed gaps in our knowledge of how this disease emerges and spreads. (See also page 9.)
- **HIV Prevention.** The public health community has progressed from a debate about what should be done, to a consensus on what should be done, to today's emphasis on getting it done. The National HIV Prevention Conference held December 6-9 focused on opportunities to do more at home and abroad.
- **Laboratory Safety.** CDC laboratories serve as reference laboratories for the world and are critical to CDC's success.

## DISCUSSION

- **Environmental Issues.** Increased emphasis on linkages between infectious diseases, food safety, climate change, and the environment will impact public health in a positive way.
- **Global Health Capacity Building.** It is important to build global health infrastructure that can address whatever disease may emerge and not be limited by funding restricted for specific diseases. Dr. Frieden noted that CDC continues to work with PEPFAR partners to advance capacity-building efforts and is using polio programs to strengthen global infrastructure for outbreak response (see also page 3). CDC is also working with DoD to increase the effectiveness and cost-effectiveness of joint programs on global health.
- **Mexico-U.S. Trans-border Collaboration on Infectious Diseases.** Guillermo Ruiz-Palacios, National Institutes of Health and Tertiary Referral Hospitals, Mexico City, commended CDC's collaboration with the Mexican Ministry of Health in responding to vectorborne diseases. Dr. Frieden said that the cross-border public health collaboration between Mexico and the U.S. is a much-valued partnership.
- **STDs and HIV/AIDS**
  - It is important to address rising rates of STDs and to ensure that HIV/AIDS does not resurge in the United States, including in rural communities where injection drug use has increased.
  - The BSC might play a role in helping re-energize CDC's effort to combat STDs and stem rising rates of congenital syphilis. Dr. Frieden agreed that the resurgence of STDs is a major challenge, with multiple drivers, including behavioral changes due to social media and closures of STD clinics. Advice from the BSC would be welcome.

## BSC Follow-up on STDs

- Following the conversation with Dr. Frieden, the BSC members discussed ways to raise awareness about the dangers of rising rates of syphilis, gonorrhea, and chlamydia.
- The BSC decided to consult with colleagues in the NCHHSTP Division of STD Prevention—which is developing a strategic plan to address STDs—on how to help move things forward.

*Note:* Three BSC members participated in a consultation on syphilis held by NCHHSTP on January 26-28, 2016.

## Update on CDC Laboratory Safety

Steve Monroe, Associate Director for Laboratory Science and Safety, reviewed CDC's ongoing effort to improve laboratory safety. Since the July 2014 moratorium on transfers of biological material out of BSL-3 and BSL-4 laboratories, CDC has completed a "Clean Sweep" inventory of biological select agents and toxins; assessed issues that led to the moratorium by addressing lab-specific safety issues; standardized disinfection practices across laboratories; enhanced custodianship of laboratory specimens; implemented an electronic specimen inventory management system; and updated the CDC Select Agent Incident Response Plan.

CDC continues to make progress in fulfilling a series of [recommendations made by the External Laboratory Workgroup of the Advisory Committee to the CDC Director](#). Those recommendations and examples of CDC efforts to address them include the following:

### Leadership

- **Create a biomedical scientist position in the Director's office to lead laboratory safety efforts.** Dr. Monroe was appointed to the new position of Associate Director for Laboratory Science and Safety (ADLSS) in September 2015.
- **Establish and communicate a "CDC Way" regarding responsible, safe science.** Laboratory safety is a major priority for the CDC Director and leadership. CDC has improved and updated procedures for reporting laboratory incidents, maintaining transparency, and sharing lessons learned about laboratory safety within the CDC laboratory community.
- **Consider laboratory safety programs and training as a fundamental mission for CDC.** Dedicated funding for the Laboratory Science and Safety Program was secured in FY2015, and additional funding has been requested for FY2016.

### Governance

- **Establish a central entity for accountability and oversight authority for laboratory safety and compliance boards.** The Office of the Associate Director for Laboratory Science and Safety (OADLSS)
  - Supports three agency review boards—the Institutional Biosecurity Board, the Institutional Biosafety Committee, and the new Laboratory Safety Review Board (LSRB)—and held a retreat to provide them with unified structure and guidance.
  - Is establishing a Laboratory Quality Council to provide high-level oversight and coordination of laboratory quality initiatives.

### Risk Assessments

- **Establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.** The LSRB meets monthly to conduct reviews of laboratory protocols for inactivation and transfer of biological materials from BSL-3 and BSL-4 laboratories to those of lower containment.
- **Risk assessments should be performed and documented before experimental work is done.**
  - OADLSS is establishing an agency-level policy that requires the use of risk assessments for experimental work (currently under review).

- A new Biological Risk Assessment Course is offered on a monthly basis to provide instruction on identifying risks associated with laboratory procedures involving biological agents.

## Laboratory Safety Training

- **Establish a standardized lab safety training curriculum with methods for competency skills mapping and refresher training.** OADLSS has
  - Developed a core safety training curriculum and rolled out its first four courses
  - Conducted an external review of the curriculum development process (in November 2015)
- **Establish a fellowship program to train scientists to serve as laboratory safety professionals.**
  - OADLSS established the Laboratory Leadership Service (LLS) as a new laboratory fellowship. The first class of seven fellows began on July 1, 2015, and selection of LLS fellows and host laboratories for 2016 is in progress.
- **Responsibilities and facilities for lab safety training should be in-house.** OADLSS has
  - Established a new Laboratory Safety Training Board to review laboratory safety training materials and serve as the decision-making body for CDC's laboratory safety training curriculum.
  - Developed a proposal for a new laboratory training center

## Culture of Safety and Incident Notification

- **Establish a culture of responsible science and accountability.** OADLSS has
  - Implemented enhanced procedures for prompt laboratory incident reporting, including the option of reporting issues anonymously.
  - Held a laboratory incident reporting forum and will post FAQs on the OADLSS intranet site.
  - Will develop a near-miss form and guidance to capture and analyze non-incident events.
- **Report and analyze incidents and corrective actions; share lessons learned with the community.** OADLSS will
  - Continue to provide internal and external updates on CDC laboratory safety improvements
  - Communicate information within the CDC laboratory community via the lab ListServe
  - Collaborate with FDA, NIH, and other HHS agencies concerning laboratory safety efforts
- **Ensure scientists operating safe laboratories are recognized for their work.** OADLSS will continue to
  - Recognize CDC Laboratory Safety Champions and highlight laboratory teams that promote the highest standards of laboratory science and safety
  - Identify innovative laboratory safety solutions through the Laboratory Safety Innovation Championship

## Progress Reporting and Laboratory Accreditation

- **Track and report progress in establishing programmatic elements and recommended processes.** OADLSS
  - Provided updates to the CDC Advisory Committee to the Director on April 13, July 17, and October 29, 2015

- Provided updates to the Advisory Committee’s External Laboratory Workgroup (during bi-weekly conference calls) and to HHS (on a monthly basis)
- Posts information on laboratory safety on internal and external OADLSS websites
- ***Pursue external review and accreditation for CDC laboratories.*** OADLSS
  - Initiated a pilot project to begin the process of achieving accreditation from the International Organization for Standardization (ISO). Pilot laboratories are applying ISO standards and sharing lessons learned about their implementation.
  - Completed benchmarking site-visits to state and federal laboratories to identify best practices for pursuing ISO accreditation.
  - Is producing a standardized, ISO-compliant Quality Manual template for use by pilot laboratories and future CDC laboratories seeking ISO accreditation

Dr. Monroe concluded by noting that core CDC laboratory safety functions related to chemical safety, radiation safety, and select agent compliance may in the future be moved to OADLSS. He also mentioned that a Public Health Grand Rounds on [“Strengthening a Culture of Laboratory Safety”](#) will take place next week.

## DISCUSSION

- CDC’s mission depends on its laboratories
- CDC should consider
  - Sharing laboratory risk-assessment mechanisms and methods (when finalized) with state laboratories
  - Assigning LLS trainees (like EIS trainees) to state health departments
- OADLSS has responsibility for coordinating development and implementation of government-wide laboratory policies on such issues as gain-of-function research
- Dr. Lautner, USDA/FSIS, reported on USDA efforts to improve laboratory safety. Challenges include incorporating (and maintaining) new laboratory activities and procedures without additional funding or staffing. Another challenge is to create a non-punitive environment in which individuals are comfortable in bringing forward safety issues that need to be addressed. This is a challenge that CDC is also addressing.

## Closing Remarks

Dr. Berkelman thanked the BSC for its leadership and specifically recognized Dr. Heilman, who will be retiring in early 2016, and thanked her for her invaluable service on the Board.

## APPENDIX: Meeting Participants

### BSC Members

Ruth Berkelman	Carole Heilman	Scott Ratzan
Jack Bennett	Tim Jones	Lee Riley
Nancy Bennett	Beth Lautner	Guillermo Ruiz-Palacios
Luciana Borio <i>(representing FDA)</i>	Mike Loeffelholz	Susan Sharp
Kristy Bradley	Ruth Lynfield	Jill Taylor
Mike Brady	Beth Marlowe	Judy Wasserheit
Harry Chen	José Montero	
	Andy Pavia	

### Partners and Public Visitors

Meredith Allen <i>(Association of State and Territorial Health Officials)</i>	Jeff Engel <i>(Council of State and Territorial Epidemiologists)</i>
Catherine Cairns <i>(Association of State and Territorial Health Officials)</i>	Lilly Kan <i>(National Association of County and City Health Officials)</i>
Andres Camacho-Gonzalez <i>(Pediatric Infectious Diseases Society)</i>	Kelly Wroblewski <i>(Association of Public Health Laboratories)</i>

### CDC Staff

Grace Appiah	Cherie Gray	Rebecca Martin
Greg Armstrong	Rachel Greenberg	Tonya Martin
Tim Barrett	Marta Gwinn	Jeff Mercante
Ann Bauman	Stephen Hadler	Jonathan Mermin
Ben Beard	Marsha Houston	Nancy Messonnier
Beth Bell	Angela Jiles	Rebecca Miller
Gail Bolan	Taccara Johnson	Sara Mirza
Pat Breyse	Kathleen Keyes	Steve Monroe
Ellen Brown	Rima Khabbaz	Brittany Moore
Sharunda Buchanan	Natalia Kozak-Muiznieks	Matt Moore
Heather Carleton	Debra Kuehl	Dale Morse
Joe Carpenter	Jasen Kunz	Robin Moseley
Evelyn Cater	Caroline Lagoy	Jeff O'Kelley
Cody Clemmons	Collette Leaumont	Angela Oliver
Amanda Cohn	Alexandra Levitt	Mark Pallansch
Laura Cooley	Art Liang	Bob Pinner
Kim Distel	Ruth Link-Gelles	Kristin Pope
Kathleen Dooling	George Luber	Sam Posner
Laurel Garrison	Claressa Lucas	Brian Raphael

**CDC Staff (cont.)**

Steve Redd  
Sheila Riggs  
Helen Rogers  
Melissa Rolfes  
John Sarisky  
Stephanie Schrag

Michael Shaw  
Sharon Slocumb  
Jean Smith  
Eija Trees  
Julie Villanueva  
Matthew Westercamp

Melinda Wharton  
Cyndy Whitney  
Jonas Winchell  
Jonathan Yoder

*I hereby certify that to the best of my knowledge, the foregoing minutes of the proceedings of the meeting of the Board of Scientific Counselors, Office of Infectious Diseases, on December 9–10, 2015, are accurate and complete.*

/S/  
Ruth Berkelman, M.D.  
Chair, BSC, OID

03/29/16  
Date