

**Meeting of the Board of Scientific Counselors, Office of Infectious Diseases
Centers for Disease Control and Prevention
Tom Harkins Global Communication Center
Atlanta, Georgia**

May 6, 2015

A 1-day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on May 6, 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).

The meeting included reports from the BSC Food Safety Modernization Act (FSMA) Surveillance Workgroup (FSMA SWG) and the BSC Infectious Disease Laboratory Workgroup (IDLWG), along with updates from OID, the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), the National Center for Immunization and Respiratory Diseases (NCIRD), and the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID).¹ The meeting also included presentations on the CDC Surveillance Strategy and the Global Health Security Agenda (GHSa) and a conversation with CDC Director Thomas Frieden.

During the discussion that followed the NCEZID update, the BSC approved a motion to send a letter to the HHS Secretary in support of the Antimicrobial Resistance Initiative in the President's FY2016 budget request.

➤ **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. Dr. Berkelman reviewed the terms of the BSC charter, which states that

The Board of Scientific Counselors, Office of Infectious Diseases, shall advise the Secretary, Department of Health and Human Services (HHS); the Director, CDC; the Director, Office of Infectious Diseases (OID), CDC; and the Directors of 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), CDC, concerning strategies, goals, and priorities for the programs and research within the national centers and monitor the overall strategic direction and focus of OID and the national centers.

The board may also administer and oversee peer review of scientific programs. The board may also perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the national centers.

¹Comprehensive updates from NCHHSTP, NCEZID, and NCIRD were provided to the BSC members in advance of the meeting. The presentations addressed selected topics on which BSC guidance was requested.

➤ **OID Updates**

Dr. Khabbaz noted that detailed updates from NCHHSTP, NCIRD, and NCEZID were provided to the BSC members before the meeting, and that each National Center update would focus on a few selected topics on which BSC input is most needed. OID updates included the following:

The President's Proposed Budget for FY2016. As compared to FY15, the following funding increases are proposed:

- *Infectious diseases issues*, including antimicrobial resistance, the National Healthcare Safety Network, viral hepatitis, and domestic HIV/AIDS
- *Global and domestic threats*, including the Strategic National Stockpile, global public health capacity, polio eradication, the Select Agent Program, and health threats due to climate change
- *Leading causes of disease, disability, and death*, including drug overdose prevention, the National Violent Death Reporting System, gun violence prevention research, and rape prevention and education
- *Monitoring health*, including healthcare surveillance and the *Community Guide* (www.thecommunityguide.org/), public health workforce capacity, and laboratory safety and quality

Decreases are proposed for funding lines on Immunization and State and Local Preparedness and Response, as well as Preventive Health and Health Services Block Grants; Cancer Prevention and Control; Racial and Ethnic Approaches to Community Health; NIOSH Education and Research Centers and the National Occupational Research Agenda (NORA) Agriculture, Forestry and Fishing; Partnerships to Improve Community Health; the Environmental and Health Outcome Tracking Network; Workplace Wellness; and High Obesity-Rate Counties.

The Laboratory Safety and Quality Initiative. Interviews are underway to fill the newly established position of CDC Associate Director for Laboratory Science and Safety. In addition, CDC staff continue to meet with the External Laboratory Safety Workgroup of the Advisory Committee to the Director. Progress includes

- Completion of
 - The “Clean Sweep,” a search of ~1,000 rooms of lab-related space to ensure proper storage of select agents and toxins
 - A box and vial-by-vial inventory of more than 7 million samples in long-term storage
- Increased engagement with CDC laboratory scientists on safety improvements, through surveys and meetings, and installation of cameras as part of the “secondary verification” process to ensure appropriate execution of essential steps in a protocol
- Expansion of external accreditation for CDC laboratories to implement quality management systems across the Agency, as well as implementation of enhanced procedures for custodianship of specimens, roll-out of a new electronic specimen inventory management system, and development of an updated curriculum for biosafety training
- Implementation of standardized disinfection practices using validated and approved disinfectants
- Initiation of safety reviews of laboratory protocols used in BSL-3 and BSL-4 laboratories
- Establishment of the Laboratory Leadership Service (LLS), a new fellowship program, modeled on the Epidemiologic Intelligence Service, to train laboratory management experts. The first class of seven fellows will begin in July.

The Ebola Response. There have been no new cases of Ebola virus disease (EVD) in Liberia for 2 weeks; cases in Guinea have declined after a resurgence; and there has been a continued steady decrease in cases in Sierra Leone. CDC is coordinating the Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE), as a collaboration with the Sierra Leone Ministry of Health and Sanitation and the

Sierra Leone College of Medicine and Allied Health Sciences. STRIVE is a combined Phase 2 and 3 clinical trial to assess safety and efficacy of the rVSV-ZEBOV candidate Ebola vaccine. The current plan is to enroll approximately 6000 healthcare workers in five districts.

Dr. Khabbaz noted that more than 10 times as many cases of Ebola have occurred during the current Ebola epidemic than during all other known outbreaks combined.

Influenza. Updates include:

- **Seasonal influenza vaccine.** The influenza vaccine was less effective during the 2014-15 influenza season, due largely to genetic changes in circulating H3N2 viruses. The vaccine provided little protection against drifted H3N2 viruses but did protect against A/Texas/502012 (H3N2) -like and B viruses (<http://www.cdc.gov/flu/news/updated-vaccine-effectiveness-2014-15.htm>)
- **H5N2 and H5N8 in poultry.** Highly pathogenic avian influenza H5 infections (predominantly H5N2) have been reported in 18 states, affecting poultry flocks in 13 states and wild birds in 5 states. No human infections have been reported. The most highly affected states include:
 - Minnesota, 72 outbreaks (most on turkey farms), with 3.9 million birds lost
 - Iowa, 21 outbreaks, affecting about 6 million layer chickens and thousands of turkeysCDC has issued *Interim Guidance for Specimen Collection, Processing, and Testing for Patients with Suspected Infection with Novel Influenza A Viruses Associated with Severe Disease in Humans* (<http://www.cdc.gov/flu/avianflu/h7n9/specimen-collection.htm>).

A New Global TB Branch at CDC. Efforts to increase collaboration and coordination of CDC's global TB activities over the past 3 years included the appointment of a Global TB Coordinator and the establishment of a Global TB Steering Group. This spring, CDC will also establish a new Global TB Branch within the Division of Global HIV/AIDS (DGHA) in the Center for Global Health (CGH).

Leadership Changes

- Greg Armstrong joined NCEZID in March as Director of the Office of Advanced Molecular Detection (OAMD). Greg previously served as Director, Polio Eradication Branch, in the Global Immunization Division and as Incident Manager of CDC's Polio Eradication response.
- Dave Daigle has accepted the position of Associate Director for Communication (ADC) in NCIRD. Dave currently serves as ADC of the Office of Public Health Preparedness and Response (OPHPR).
- Allison Mawle, NCIRD Associate Director for Laboratory Science, has begun a detail as the OID liaison representative to FDA in the Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health. In her absence, Tim Barrett from CDC OADS has agreed to serve as Acting ADLS for NCIRD.
- Inger Damon has returned to her position as Director of NCEZID's Division of High Consequence Pathogens and Pathology (DHCPP) after serving >7 months as Incident Manager of CDC's Ebola Response. Dan Jernigan, Deputy Director, Influenza Division, NCIRD, is currently serving as the Ebola Response Incident Manager.
- Eddie Ades, NCHHSTP ADLS, retired at the end of April. Jeff Johnson, microbiologist from NCHHSTP's Division of HIV/AIDS Prevention (DHAP), is serving as Acting ADLS.
- David Swerdlow, NCIRD Associate Director for Epidemiologic Science, is retiring from CDC
- Cindy Weinbaum is serving as Acting Executive Secretary of the Advisory Committee on Immunization Practices (ACIP), following the retirement of Larry Pickering earlier this year
- Lisa Koonin is serving as Acting Director, Influenza Coordination Unit (ICU), replacing Steve Redd who is now Director OPHPR

The International Conference on Emerging Infectious Diseases (ICEID). ICEID, which was postponed because of the Ebola response, will take place this summer, on August 24-26. Keynote

speakers include Dr. Frieden, Dr. Robert Weinstein, Professor of Medicine at Rush University Medical College and BSC member and chair of the BSC AR Working Group, and Dr. Joanne Liu, President of Médecins Sans Frontières.

Emerging Infectious Diseases Journal

In August, the EID Journal will issue a special edition commemorating 20 years of the Emerging Infections Program.

Discussion

In response to questions about the Ebola response, Beth Bell, NCEZID Director, reported that

- Interagency discussions are underway about possible changes regarding screening travelers from Liberia, assuming that no new cases are reported by May 9-10 (which is 42 days after the last burial). The CDC Travel Notice for Liberia has been lowered from Level 3 to Level 2 (<http://wwwnc.cdc.gov/travel/notices>).
- WHO and the U.S. Government are planning after-action reports on the Ebola response that are likely to include recommendations on priorities for Ebola research. At the present time, CDC is continuing to facilitate research efforts in affected countries, including the STRIVE vaccine trial; however, CDC's primary focus remains on getting to zero.

In response to questions about recent outbreaks of avian influenza, Anne Schuchat, NCIRD Director reported that

- ACIP is discussing whether to issue recommendations for vaccination of persons at high-risk for avian influenza, due to contact with infected poultry. An adjuvanted vaccine (GSK's Q-Pan H5N1) is licensed for use in persons aged 18 and older at high risk of exposure.
- CDC is helping to identify strains that could be used to develop vaccines against these strains of avian influenza, if needed

Dr. Weinstein, chair of the BSC AR Working Group (who attended by phone), suggested that the BSC write a letter in support of the Antimicrobial Resistance Initiative. Discussion of this topic was resumed later in the day (see page 22).

- **NCHHSTP: Updates and Discussion Topics.** Jonathan Mermin, NCHHSTP Director, provided the following updates:

Organizational Changes

- A new Program and Performance Improvement Office has been established to enhance efficiency, outcomes, and impact. Initial activities include
 - Awarding a new cooperative agreement on epidemic and economic modeling with Harvard University, Emory University, and the University of California, San Francisco
 - Issuing performance indicator reports, which provide grantees with rapid feedback to improve outcomes

Division of HIV/AIDS Prevention.

- The proportion of persons with HIV who know their HIV status is at the highest level ever (86% in 2011)
- The annual rate of new HIV diagnoses decreased 33% between 2002 and 2011, with declines in people who inject drugs (PWID; ~70%) and persons infected through heterosexual contact (~35%). However, young MSM had increased rates.

Recent DHAP achievements include the release of

- New FOAs to advance HIV prevention for MSM and transgender persons.
- First-ever estimates of HIV transmission at each stage of HIV care:
 - 9 in 10 new HIV infections are transmitted by persons not receiving regular care (e.g., not diagnosed or not in care): 30% by persons not diagnosed and 60% by HIV-infected persons not in regular care.
- New guidance documents:
 - Guidelines on use of pre-exposure prophylaxis for HIV prevention (PrEP) (<http://www.cdc.gov/hiv/guidelines/preventing.html>).
 - *Updated Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States* (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a9.htm?s_cid=mm6349a9_e)
 - A new HIV laboratory testing algorithm
 - Draft recommendations and public comments on recommendations on male circumcision for HIV prevention

Division of Viral Hepatitis. From 2010-2013, reported cases of acute HCV infection increased by 152%. Examples of recent achievements include the following:

- Analyses of the cost-effectiveness of HCV testing and treatment found that
 - Full implementation of CDC HCV testing recommendations could avert 320,000 deaths
 - At current market prices, treating all HCV-infected patients rather than delaying treatment until patients develop more severe liver disease would achieve <\$40,000 per quality-adjusted life year saved.
- Launch of the second phase of the *Know More Hepatitis* campaign
- Implementing projects to improve testing and linkage-to-care for patients with chronic HBV or HCV
- Providing technical assistance to countries with high burdens of HCV, including Egypt and Georgia

Division of STD Prevention. Since release in mid-2013, the *STD Treatment Guidelines* App has been downloaded 830,000 times—about as many times as the main CDC App. The *2015 STD Treatment Guidelines* are coming soon. Examples of recent activities include the following

- Testing novel compounds for efficacy against *Neisseria gonorrhoeae*, including a proprietary compound that might have efficacy against ciprofloxacin-resistant isolates
- Providing the evidence base for ACIP recommendations on HPV vaccination (*MMWR Recommendations and Reports*, August 2014)
- Using Medicaid data obtained through an interagency agreement with Centers for Medicare & Medicaid Services (CMS) to estimate rates of STD testing and morbidity in Medicaid-insured populations.
- Working with Prevention Training Centers to implement provider- and clinic-based interventions to increase STD preventive services for MSM in 31 HIV care clinics in 14 states.
- Providing technical assistance to the Detroit Department of Health and Wellness Promotion to improve access to quality STD services. Wayne State University has established a new STD clinic in Detroit.

Division of Tuberculosis Elimination. TB cases in the U.S. are at an all-time low. 9,412 new TB cases were diagnosed in 2014—a 2.2% decrease from 2013. Recent achievements include

- Completion of the iAdhere study by the TB Trials Consortium. The study found that

- 85% of U.S. patients receiving 3HP treatment² for latent TB through directly observed therapy (DOT) completed the treatment regimen
- 78% of U.S. patients receiving self-administered 3HP completed the treatment regimen. See: http://www.cdc.gov/tb/publications/newsletters/notes/tbn_4_14/tbtrials.htm.
- Completion of the pilot-year of surveillance under the Large Outbreaks of TB in the US (LOTUS) project, which identifies large TB outbreaks based on analysis of genotyping data and reports from programs.

Over the course of the year, LOTUS detected 16 confirmed, probable, or suspected outbreaks. Half of the probable and confirmed outbreaks were detected through genotyping alone, and not reported by disease surveillance programs. At the present time, LOTUS is assisting in the response to an ongoing multistate outbreak of INH-resistant TB among homeless persons.

Division of Adolescent and School Health. Recent achievements include

- Release of *Youth Risk Behavior Surveillance – U.S., 2013*, which summarizes the results of the 2013 National Youth Risk Behavior Survey conducted among >13,000 students grades 9–12, found that the proportion of students who have ever had sexual intercourse declined from 1991 (54 percent) to 2001 (46 percent) and has stabilized (47 percent in 2013)
- Development of a Web-based Performance Measurement System for Program Evaluation for funded partners
- Release of the first Cost-Benefit Study of School Nursing Services, which estimated that Massachusetts realized a \$98 million net benefit from its school nurse program

High priority activities for 2015 include finalizing a research agenda; developing national, state and grantee-level indicators; developing an MMWR Surveillance Summary on Sexual Minority Youth; conducting a Public Health Grand Rounds session on Adolescent Health; and completing a dataset on state-level sexual-health education laws, regulations, policies, and standards.

NCHHSTP Topics for Discussion. Dr. Mermin presented four topics for discussion:

1. **HIV and HCV among people who inject drugs.** An investigation in a small southeastern community in Indiana (population 4200) identified about 150 persons with HIV, more than 90% of whom were co-infected with hepatitis C virus (HCV). The HIV infections were associated with injection of the opiate oxycodone, and the majority of infections were recently acquired.

CDC issued a health advisory on April 24, 2015, and alerted health departments and healthcare providers. CDC is working with the states to identify other areas at risk for clusters of HCV and HIV infection. Overall, there has been a 150% increase in 4 years in acute HCV cases in the United States, primarily due to injection drug use.

Question for BSC members: *What would be the most efficient and accurate way to identify, control, and prevent potential outbreaks of HIV and HCV among PWID?*

Discussion

- Local indicators of potential outbreaks of HIV and HCV among PWID might include a large increase in the number of addicted persons and/or of deaths due to overdoses, especially in rural areas with many people who live below the poverty line. Another possible indicator might be an increase in

²The 3HP regimen is a 3-month, 12-dose regimen for latent TB infection in which isoniazid (H) and rifapentine (P) are given once weekly by directly observed therapy (DOT) for 3 months.

traffic accidents on rural highways. Dr. Mermin noted that CDC has begun using data on substance abuse and treatment to identify areas at risk for hepatitis (see: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a1.htm>).

- A multi-sector response, involving state and local government, healthcare, public health, and law enforcement, is required to control outbreaks among PWID. Multiple control activities are needed including needle exchanges, improved testing and linkage to care, and ensuring community members have a safe place to obtain information.
- It is especially important to create a sense of trust in an affected community (e.g., by passing Good Samaritan laws, making naloxone available to treat overdoses, and gaining community buy-in for treatment programs and needle exchanges). To change attitudes in a rural community typically requires engagement by the local police chief, mayor, and school principal, who can disseminate the message that disease-appropriate treatment is available.
- Research confirms that needle exchanges and other harm reduction efforts reduce disease transmission without increasing drug use. Dr. Mermin noted that the Governor of Indiana issued an emergency order (and the Indiana state government passed a law) allowing emergency use of needle exchanges.
- CDC has issued a grant opportunity on *Prescription Drug Overdose Prevention for States* (http://www.cdc.gov/drugoverdose/states/state_prevention.html), and many states regulate prescriptions of pain killers and identify multiple prescriptions issued to the same person within a short period of time. However, as prescription opioids become more difficult to obtain (as well as more expensive), heroin use is increasing in response, leading to a greater number of injection-related blood-borne infections like HIV and HCV.
- Treatment is key, in terms of health, costs, and social outcomes. However, there is insufficient capacity for substance abuse treatment and in many rural areas clinicians lack experience with HIV and HCV. Public health officials should work with family practice physicians, who are often the only physicians in poor, rural areas. These physicians require training in provision of care to patients with both substance abuse issues and blood-borne infections.
- Social outcomes of substance abuse treatment may include prevention of adverse childhood experiences and decreased neonatal syndromes due to maternal drug use. One approach might include more consistent screening pregnant women who use opioid drugs for HIV and HCV.

2. **Latent TB infection in the U.S.** As noted above, 9,412 new cases of TB were reported in 2014. This reflects a rate of 3 cases per 100,000 persons, which represents the fewest cases since systematic recording began in 1953. Nevertheless, this rate is also 30 times greater than elimination target of 1 case per million (300 cases total).

About 75% of new cases resulted from reactivated latent TB infections (LTBI). Key risk groups for LATBI include

- Foreign-born persons, whose LTBI case-rate is 14 times higher than for U.S.-born persons, accounting for 67% of cases.
- Racial/ethnic minorities. More TB cases are reported among Asian Americans than any other group (2,961 cases).

Key areas for addressing LTBI include

- California, Florida, New York, and Texas, which reported >500 cases each and accounted for 51% of all U.S. cases in 2014
- Mexico, Philippines, Vietnam, China, and India, which are the top 5 countries-of-origin for foreign-borne persons with LTBI.

Question for BSC members: *How would we most effectively detect and treat LTBI to accelerate TB elimination?*

Discussion

- Detection of active TB is not a problem in the United States. However, the estimated 12 million people in the U.S. with latent TB are not diagnosed and treated unless their disease progresses to active TB. CDC has asked U.S. Preventive Services Task Force to consider inclusion of screening and treatment of latent TB as part of preventive services.
 - Most clinicians do not know how to screen for latent TB or that a treatment regimen is available. Patients—if they are aware of it at all—think that latent TB treatment involves 9 months of therapy, during which they cannot drink alcohol.
 - A possible “marketing approach” might involve encouraging persons with risk factors to be screened and treated so as not to pass on their infection to family members. However, as illustrated by past efforts to screen Asian-Americans for hepatitis B, it can be difficult to address campaigns to high-risk groups without increasing stigma. A positive campaign with input from community leaders and community health centers is essential.
 - Individuals who have received BCG vaccine and then have a positive test for latent TB often assume the positive test signal is due to vaccination. Wider availability of the QuantiFERON-TB Gold Test—which is not affected by BCG status—will be valuable.
 - Latent TB is not reportable, and many health departments are reluctant to add it to the reportable list unless the cost-effectiveness of LTBI detection and treatment can be documented. Some states already track LTBI but do not have funds and manpower for follow-up and treatment.
 - Limited resources might be better used to educate healthcare providers. LTBI testing should be encouraged, but carefully targeted to people with risk factors.
 - Beth Bell, Director, NCEZID, reported that significant progress has been made in treating immigrants and refugees with active TB before they enter the United States (see: <http://www.cdc.gov/media/releases/2015/a0316-tb-screening-guidelines.html>). CDC is considering expanding the TB screening program to include long-term visa-holders (e.g., students).
 - WHO has issued guidelines that recommend screening and treatment for LTBI in high-risk groups (e.g., persons living with HIV, contacts of active TB cases, prisoners, healthcare workers, immigrants from high TB burden countries, homeless persons and illicit drug users). See: http://www.who.int/tb/features_archive/LTBI/en/.
- 3. Syphilis among men who have sex with men (MSM).** Syphilis rates for men increased from 5.1 to 9.8 per 100,000, between 2005 and 2013, and men accounted for 91% of all syphilis cases in 2013. The proportion of male cases attributed to MSM increased from 77% in 2009 to 84% in 2012. About half of new syphilis cases are among MSM with HIV, and preliminary data from 2014 show a continued increase in syphilis cases among MSM.

Question for BSC members: *What are the most effective actions that CDC and the nation should take to address increasing syphilis rates among MSM?*

Discussion

- Social media should be used to reach at-risk teens. For example, it might be possible to link messages from “hook-up” apps to public health messages about using condoms to reduce the risk of acquiring STDs, including syphilis and HIV.
- Although it may not be possible to block minors from accessing hook-up apps, it might be possible to use these apps as a vehicle for public health interventions.
- Explore legal means for restricting minors from accessing high-risk apps

4. **Substance Abuse as Risk for HIV, Hepatitis, STDs among Teens.** Substance abuse is a risk factor for HIV, hepatitis, and STDs among teens. Although less than 2% of teens inject drugs, data from selected states and cities indicate that rates of injection drug use among sexual minority youth are up to 7 times greater than rates among heterosexual teens. Many studies show that alcohol and drug use are associated with behavior that puts teens at risk for HIV and STDs. Another contributing factor may be internet dating sites (or “hook-up” apps) that bring together teens living with AIDS, who may not be aware that they should use condoms to prevent against additional infections.

Question for BSC members: *What if any role should DASH have in addressing substance use risks for HIV, STDs, and Hepatitis among teens?*

Discussion. Information about the three risks (substance abuse, tobacco use, and infectious diseases) and how these risks are inter-related should be provided to young people to help them make healthy decisions.

➤ **Food Safety Modernization Act (FSMA) Surveillance Working Group**

The FSMA Working Group, which was established in 2011 by the Food Safety Modernization Act, 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 representatives from the BSC, CDC, USDA, FDA, academia, consumer groups, industry, and state and local health organizations. Current BSC members include Harry Chen, Kristy Bradley and Tim Jones.

Harry Chen, Chair of the FSMA Surveillance Working Group, reported on the May 2015 Workgroup meeting, whose goals were to

- Provide advice and recommendations regarding the improvement of foodborne illness surveillance to the HHS Secretary
- Review and comment on initiatives (see below) to address gaps in foodborne illness surveillance with emphasis on
 - Environmental surveillance, including surveillance for environmental antecedents and contributing factors
 - Surveillance and response for *Vibrio*

Initiatives of the CDC National Center for Environmental Health (NCEH). The ultimate goal for public health and food safety officials is not just stopping foodborne disease outbreaks once they occur, but preventing them from happening in the first place. Long-term prevention of foodborne outbreaks involves the actions of many partners along the farm-to-fork continuum. NCEH presentations to the Workgroup described the following

- **Environmental Data for Foodborne Illness and Outbreak Surveillance.** NCEH encourages and supports state and local food safety programs in their conduct of foodborne illness outbreak environmental assessments that describe how the environment contributes to the introduction and transmission of illness causing agents by
 - Identifying contributing factors (to learn how the outbreak occurred)
 - Identifying environmental antecedents (to learn why the outbreak occurred), and
 - Generating recommendations for informed interventions and policy development.
- **NCEH Environmental Surveillance Initiatives.** At the present time, contributing factors are reported for only 40% -45% of foodborne outbreaks; environmental antecedents are rarely reported. In April 2014, NCEH launched two initiatives to remedy this situation:

- **National Voluntary Environmental Assessment Information System (NVEAIS)**, whose goals are to
 - Discover the underlying environmental factors—including contributing factors and environmental antecedents—that cause foodborne outbreaks, and
 - Use this information to prevent outbreaks.
- **E-Learning on Environmental Foodborne Illness Outbreaks.** This training program, which has more than 2000 users to date
 - Provides web-based training to improve foodborne outbreak investigation practices, which can lead to information that will help prevent foodborne outbreaks
 - Provides training on recommending appropriate control measures
 - Assists outbreak response teams in investigating foodborne illness outbreaks
 - Identifies an outbreak’s environmental causes

In response to questions regarding how to promote and encourage participation in NVEAIS and eLearning, Workgroup members stated that it is important to

- Demonstrate the impact and value of NVEAIS and eLearning
- Engage state and local officials in these initiatives and gain their buy-in
- Leverage partnerships to promote training (e.g., partnerships with Centers of Excellence, FoodCORE, OutbreakNet, and EHS-Net)
- Integrate and streamline NVEAIS and the National Outbreak Reporting System (NORS). For example, NVEAIS and NORS survey tools should be harmonized.

In response to a question regarding what NEVAIS data is most important to share, Workgroup members emphasized that

- NEVAIS data should be representative, timely, and actionable
- The most important data for sharing depend on the audience (e.g., regulators, policy-makers, the public), and NEVAIS should conduct assessments to determine the needs of these audiences

The Environmental Health Specialists Network (EHS-Net). EHS-Net is a collaborative network of federal, state, and local environmental health and food safety specialists that focuses on retail food safety policies and practices. Its objectives include

- Improving our understanding of environmental factors linked to foodborne illness outbreaks
- Strengthening federal, state, local, and industry food safety policies and practices
- Reducing foodborne illness

As part of these efforts, EHS-Net conducts Retail Food Safety Studies to

- Identify food safety policy and practice gaps (e.g., undercooked hamburgers at restaurants)
- Identify ways to address these gaps
- Make policy and practice recommendations

In response to a question on how to better disseminate EHS-Net data to public health and industry partners, Workgroup members emphasized that EHS-Net should

- Engage with partners in “their space,” by
 - Attending the annual Integrated Foodborne Outbreak Response and Management (InFORM) Conference and annual meetings of groups such as the National Restaurant Association and the National Environmental Health Association
 - Providing information through social media
- Target communications and marketing efforts to specific partners
- Engage educational organizations

In response to a question on how to formalize EHS-Net's relationship with industry, Workgroup members emphasized that EHS-Net should

- Engage the senior leadership of trade organizations
- Join the CIFOR industry workgroup

Other Examples of Initiatives to Collect Foodborne Illness Environmental Surveillance Data

The May 2015 Workgroup meeting also included a panel discussion that emphasized the importance of collaboration among epidemiologists, laboratorians, and environmental health specialists in investigating foodborne disease outbreaks. An example highlighted at a recent InFORM meeting, concerned a 2012 outbreak of *Salmonella* involving 425 cases in 28 states. State and local health departments, FDA, and CDC traced the source of the outbreak to a contaminated food product—imported frozen raw scraped ground tuna product (<http://www.cdc.gov/salmonella/bareilly-04-12/>).

Groups and projects that collect foodborne illness environmental surveillance data include

- **NORS**, which has found that U.S. foodborne disease outbreaks are associated with a wide range of foods and that the majority of such outbreaks are associated with restaurants
- **Foodborne Centers for Outbreak Response Enhancement (FoodCORE)**, whose environmental health activities include conducting environmental assessments, participating in trace-back efforts, and providing training for local specialists
- **FDA Rapid Response Teams (RRTs) and Training Programs**, which aim to
 - Develop and maintain multi-jurisdictional rapid response teams that support integrated all-hazards prevention, response and recovery efforts
 - Unify and coordinate federal/state/local emergency response efforts
 - Capture, develop, and support adoption of best practices and encourage mentorship
 - Ensure alignment with national priorities, including those of FSMA
- **FDA Coordinated Outbreak Response and Evaluation (CORE) Network**, which conducts in-depth after-action evaluations of outbreaks responses (<http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272347.htm>).
- **FDA Environmental Assessments**, which provide
 - An in-depth, multi-disciplinary, systems-based approach to determining how contamination may have occurred so it can be prevented in the future
 - A way to determine how the “environment” contributed to the introduction, transmission, and proliferation of pathogens or other hazards that caused illness or contamination
- **USDA/FSIS *Listeria monocytogenes* Environmental Sampling Program**
- **USDA/APHIS/Veterinary Service (VS) Role in Pre-harvest Food Safety**

Presentations were also made on

- *The Environmental Health Investigator Perspective* (National Environmental Health Association)
- *CIFOR Environmental Guidelines* (Council of State and Territorial Epidemiologists [CSTE])
- *Environmental activities of the Integrated Food Safety Centers of Excellence (CoEs)*, including trainings (e.g., to improve awareness and performance) and the identification of major threats facing the food industry, including
 - Pathogen contamination of raw ingredients
 - Scale of production and distribution that can turn minor errors into large outbreaks

- Food-handler contamination of ready-to-eat foods
- *Contributing Factor Data: One of the Keys to Using Outbreak Data to Drive Attribution Models* (Craig Hedberg, University of Minnesota)
- *An Agricultural Perspective on Environmental Activities* (Association of Food and Drug Officials [AFDO])

In response to a question regarding how to better integrate and improve our environmental foodborne surveillance data, Workgroup members stated that better collection, integration, and use of environmental foodborne disease surveillance data requires

- Mapping and documenting ongoing surveillance efforts by all partners
- Collaboration and integrated efforts to
 - Provide training in collection and use of environmental health data. Current trainings are provided by CoEs, Epi-Ready (a collaboration by NEHA and CDC), E-Learning, and by FDA and USDA (for food-safety inspectors).
 - Develop data collection guidelines. This effort can be led by CIFOR.
 - Conduct investigations. Coordination can be facilitated by the Interagency Foodborne Outbreak Response Collaboration (IFORC).

Vibrio Surveillance. According to FoodNet, *V. parahaemolyticus* is responsible for about 85% of foodborne *Vibrio* infections in the United States. Overall, there is a general upward trend in the number of reported cases of *Vibrio* (all species) and *V. parahaemolyticus*.

Data from Japan suggests that *V. parahaemolyticus* outbreaks can be reduced by rapidly chilling shellfish on ice as soon as they are caught (i.e., on board harvesting vessels). Pilot tests in 2014 by Connecticut and New York that used this approach to harvest oysters were very successful.

Workgroup members were asked what efforts should be undertaken to improve foodborne *Vibrio* illness surveillance. Members emphasized that CDC and partners should

- Monitor the effects of culture independent diagnostic tests (CIDT) on *Vibrio* illness surveillance
- Continue education of physicians
- Assess the effects of state-level interventions on industry
- Continue to disseminate surveillance information to public health and industry partners

General Discussion

- *Vibrio* surveillance, like other animal-health-related issues, is a One Health issue.
- Social media might be used to help people protect themselves from *Vibrio* infections, perhaps using a model such as *text4baby*, which aims to improve maternal and child health. CDC and state health departments might consider linking *Vibrio*-related health messages to food-industry and other private sector websites.
- Dale Morse, Associate Director for Food Safety, NCEZID Food Safety Office, reported that CDC has participated in several food safety Twitter chats. Other vehicles for reaching people through social media might include Yelp, Facebook, and texts that provide foodborne-outbreak alerts.
- The incorporation of environmental data into outbreak investigations provides additional complexity. Therefore interagency coordination—involving agencies with different approaches to food safety—will continue to be very important.

➤ **CDC Surveillance Strategy**

Chesley Richards, Director, Office of Public Health Scientific Services, provided an overview of the *CDC Surveillance Strategy* (<http://www.cdc.gov/ophss/docs/cdc-surveillance-strategy-final.pdf>), which was developed in response to

- Congressional FY 2015 budget language that requires CDC to “develop a timeline for a cloud-based and flexible IT public health data reporting platform for CDC programs”
- A request from the Council of State and Territorial Epidemiologists (CSTE) that CDC evaluate the data elements required for public health surveillance and harmonize and standardize those elements across CDC programs.
- A charge from the CDC Director to the CDC Office of Public Health Scientific Services to lead the development of a *CDC Surveillance Strategy*

The *CDC Surveillance Strategy* aims to

- Improve availability and timeliness of surveillance data
- Advance the effective use of emerging information technology
- Identify and amend or retire ineffective or unnecessarily redundant CDC surveillance systems
- Maximize the effectiveness of agency resources and the performance and coordination of CDC surveillance systems

The *Strategy* was informed by input from the CDC Surveillance Leadership Board, the CDC Health Informatics Innovation Consortium, the Health Information Technology (HIT) Policy Committee, a Vendor Forum, and the CDC workforce. Its vision is to have *efficient systems that put the right data and information in the right hands the right time in the right format to take effective public health action.*

Implementation of the *Strategy* includes initiatives to transform collection of 4 types of data:

1. **Mortality Statistics.** The *Strategy* will implement a system of timely electronic death reporting by:
 - Creating a state-based network of enhanced electronic death registration systems (EDRS)
 - Improving physician participation with ERDS
 - Improving quality of cause-of-death information on death certificates
 - Transmitting information to state epidemiologists about specific deaths of interest/concern within 1 day of registration
 - Reporting 80% of all deaths occurring in a state to CDC’s National Center of Health Statistics (NCHS) within 10 days of the date of death
2. **Electronic Lab Reporting.** This topic was addressed later in the meeting by Robert Pinner, Associate Director for Surveillance, Programs and Informatics, NCEZID (see page 14).
3. **Syndromic Surveillance.** The *Strategy* will improve national syndromic surveillance by implementing tools for visualization and analytics. Aims include
 - Improving data access, quality, representativeness, and timeliness
 - Enhancing the capabilities and technology supporting syndromic surveillance data collection, processing, and provisioning
 - Strengthening the National Syndromic Surveillance Community of Practice to promote data sharing and further the science and practice of syndromic surveillance.
4. **Notifiable Diseases.** The *Strategy* will improve electronic reporting of notifiable diseases through the National Notifiable Disease Surveillance (NNDS) Modernization Initiative. At the present time, more than 90 notifiable conditions are reported to CDC through an agreement with CSTE. However,

CDC programs are not receiving the full complement of data and data arrives in varying formats, processed by systems that are decades old. NNDSS requires a modern, interoperable electronic system with standard data and data-exchange mechanisms. This will be achieved through

- Message Mapping Guides (MMG) that specify data elements, valid values, and HL7 instructions
- A Message Validation & Processing System (MVPS) that enables receiving, processing, storing, validating, and sharing health-related data
- Provision of technical assistance (TA) to the states (on-site and virtual), focusing on data extraction, mapping to HL7 messages, creating processing routes, and initiating transmission; knowledge and skills transfer; and dissemination of sharable and reusable tools and job-aids. TA pilot programs are underway in several states; training is also provided through the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement.
- Harmonization of data elements

Progress during 2014 included

- Completion of MMGS for hepatitis, congenital syphilis, and STDs; near completion of MMGs for mumps and pertussis
- Ongoing development of MVPS system functionality and role-based security (testing with the jurisdictions to begin in June 2015)
- TA assessments completed in 14 states, in collaboration with CSTE and APHL
- Worked with Michigan to test the MMG for hepatitis and a CDC Message Evaluation and Testing Service (METS) tool

Plans for 2015 include

- Working with 8-10 states who will be sending production data for 3 MMGs (Generic-version 2, Hepatitis, STDs) to CDC.
- Implementing MMGs for mumps, pertussis, and congenital syphilis.
- Initiating development of MMGs for arboviral conditions, varicella, invasive pneumococcal disease

To accelerate progress, CDC will

- Analyze MMG development to identify bottlenecks; increase standardization and structure of MMG templates; and develop MMGs for groups of diseases (e.g., arboviral diseases and enteric diseases)
- Transfer tools and skills to the states to support independent MMG implementation
- Increase dedicated resources to facilitate concurrent development of multiple MMGs and MVPS acceleration
- Accelerate data harmonization by developing standard data table structures for data provisioning (which facilitates MVPS development) and MMG development

Electronic Laboratory Reporting

Dr. Pinner reported on the Electronic Laboratory Reporting (ELR) component of the *CDC Surveillance Strategy*. Its implementation involves

- Support for jurisdictions from the Prevention and Public Health Fund (PPHF) provided through the ELC cooperative agreement.
- Regular communications to offer support, track progress, and resolve issues
- Focused and targeted technical assistance

ELR progress to date is described in a recent MMWR

(<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6412a5.htm>); the current expectation is that 80% of laboratory reports will be transmitted to public health agencies by ELR by the end of 2016. At the present time, large public laboratories (which are 4% of the total number of clinical laboratories) are the source of 39% of ELR reports; public health laboratories (which are 4% of the total) provide 23%; and

hospital laboratories (which are 51% of the total) provide 20%. Dr. Pinner noted that the CMS Meaningful Use Program to advance adoption of electronic medical records has facilitated use of ELR by hospital laboratories.

Areas of emphasis for the ELR Strategy include

- Continuing to provide technical assistance. Over 50 TA requests have been completed and 23 are currently active.
- Working with Quest Diagnostics to assist with ELR implementation. Quest is interested in receiving TA from the APHL TA Team and may adopt APHL's hub as a vehicle for transmitting data from Quest laboratories to state health departments.
- Maintaining a joint focus on delivery of ELR and on its automated uptake into surveillance information systems
- Continuing support for ELR through ELC and through other CDC cooperative agreements

Discussion

- CDC might accelerate participation of clinical laboratories in ELR by
 - Providing grants to clinical laboratories to support implementation of software changes
 - Working with vendors to make ELR requirements part of software packages for clinical laboratories.
- The turn-around times when tests are sent from hospitals to diagnostic companies are often slow, including for rapid molecular tests. In the future, simpler, black-box point-of-care tests will eliminate the need to send specimens out of the hospital for testing. Having immediate results will be a great advantage (e.g., for antimicrobial stewardship). Reimbursement policies should take into account whether testing is rapid and done onsite.
- Other developments that may accelerate testing include self-testing at pharmacies like Walgreens, using FDA-approved tests.
- USDA has had issues with electronic animal-health reporting. One problem has been laboratories that begin using ELR but do not maintain it, as new tests are adopted and systems are not updated.

In regard to whether (and when) CDC's efforts to harmonize data elements will go beyond infectious disease datasets, Dr. Richards reported that

- Once CDC has covered all infectious disease conditions (more than 90) CDC will build off the notifiable diseases datasets to cover whatever falls outside them
- We are both impatient and patient at the same time. Although the problem continues to mushroom, to do it well and to include all stakeholders will take time.
- CDC is having some immediate successes, but is also committed to the longer process required to fulfill the needs of CDC and partners.

In regard to harmonization of data elements, Dr. Richards reported that

- CDC is reviewing infectious disease data under 20 different groupings, looking for opportunities for harmonization. Once variations have been identified under a given grouping, the next step is to figure out how to harmonize them and to propose new standards.
- The immediate outcomes of this process are 1) more transparency about variations, so their number can be reduced and 2) improved discussion with CSTE and representatives from state health departments.
- Some states are ahead of CDC in the process of harmonizing their infectious disease data sets.

In regard to using multiple data sets to address emergency needs and advance prevention efforts (see also discussion about *HIV and HCV among people who inject drugs*, page 6), Dr. Richards said that the vision is to create interoperable data systems—inside and outside CDC—that can be used to analyze and answer

public health questions more efficiently. CDC is committed to getting this effort started over the next four months, keeping the 5-10 year vision in mind.

➤ **BSC Conversation with CDC Director Tom Frieden**

Dr. Frieden thanked the BSC members for their help and advice. He discussed CDC's role in the ongoing response to the Ebola outbreak in West Africa—the largest response effort in CDC history—and also spoke more broadly about global health security issues involving the emergence of diseases in countries that are least prepared to detect and respond to them. He also briefly reviewed the following topics:

- Antimicrobial resistance, which continues to be a major threat to U.S. health.
- The goals and accomplishments of the Advanced Molecular Diagnostics (AMD) initiative
- The public health response to an outbreak of injection-related HIV in a small Indiana town whose incidence of HIV incidence is higher than that of any country in the world (see also page 6).
- CDC's Laboratory Safety and Quality Initiative (see page 2), whose goal is to make CDC laboratories a model for both science and safety.

Discussion

Outbreaks Involving Injection Drug Use

- In regard to outbreak investigations that involve both infectious disease and behavioral issues, Dr. Frieden noted that
 - This type of intersection is more the norm than the exception. As part of the investigation in Indiana, for example, CDC is working with the Substance Abuse and Mental Health Services Administration (SAMHSA) to connect patients with treatment services.
 - CDC is exploring ways to address inter-related communicable and non-communicable disease issues in a synergistic fashion (e.g., linking prevention of HIV and HCV with prevention of prescription drug overdoses). For example, EIPs might collect population-based data about both issues.
- Outbreaks associated with injected prescription drugs present complex issues in terms of access to both healthcare and substance-abuse services for people who are uninsured or medically vulnerable.
- In terms of public health, Dr. Frieden suggested that the prescription-overdose epidemic may be regarded as involving two broad issues: 1) providing substance abuse services to people who are already addicted (several million Americans) and 2) preventing others from addiction. Because most of those now addicted to heroin started on prescription opiates, prevention of opiate addiction may be addressed as an iatrogenic issue.
- The U.S. has experienced a major decline in HIV rates, and local public health programs that address HIV and hepatitis C often handle them like chronic diseases and do not have the resources to detect or respond to outbreaks. A major challenge will be to re-orient these programs to support rapid detection and response.

Ebola and other Global Threats

- In regard to whether CDC staff received adequate support to respond to the Ebola outbreak—as well as to recover from the stresses involved in this effort—Dr. Frieden noted that working weekends and evenings and foregoing vacations takes an enormous toll. CDC has debriefed each staff member who returned from West Africa in an effort to learn more about the personal and scientific aspects of the response.
- Dr. Bell agreed that special efforts have been made to support staff members during the Ebola response and to thank others for doing the extra work needed to continue CDC's core work.
- In regard to developing an overall framework—a consistent “lexicon”—to frame global health security issues, Dr. Frieden noted that

- GHSA has issued a set of measurable outcomes that address global health issues such as childhood vaccination (see also page 20).
- Although it may not be possible to agree on a single lexicon, the principles of good risk communication pertain to many different situations: be ever-green, be first, be right, and be credible.
- As a matter of public policy, long-term funding for disease prevention would likely be more cost-effective than short-term funding for responses to preventable emergencies
- Dr. Frieden suggested that public knowledge about antimicrobial resistance, the Ebola outbreak, and the HIV outbreak in Indiana has led to increased appreciation of public health efforts at the national, state, and local levels.

Other Topics

- In regard to avian influenza in poultry in the Midwest, Dr. Frieden said that CDC is hoping to send a second staff member to USDA/APHIS to provide additional help, if the outbreaks continue.
- CDC should explore ways to partner with clinical laboratories to improve and maintain antibiotic stewardship. As clinical laboratories transition to culture-independent testing, they will need to begin providing public health authorities with DNA data rather than with isolates.

➤ The Global Health Security Agenda

All of the World Health Organization's 194 member countries committed to International Health Regulations in 2005. However, as of 2014, only 30% fully prepared to detect and respond to pandemics. Kashef Ijaz, Deputy Director, CGH Division of Global Health Protection, provided an update on GHSA, which aims to strengthen national capacities to

- Prevent infectious disease catastrophes
- Detect threats early, and
- Respond rapidly and effectively to outbreaks.

The GHSA partnership—which includes nations, international organizations, and civil society groups—has developed 11 Action Packages to develop national capacities in specific areas. CDC supports implementation of all 11 Action Packages. CDC's "core four" are

- The **Laboratory Action Package**, to build national reference laboratories and specimen referral networks
- The **Surveillance Action Package**, to build national surveillance for three core syndrome and increase capacity to analyze and link data for functional, real-time biosurveillance
- The **Emergency Operations Action Package**, to facilitate activation of national Emergency Operations Centers (EOCs), based on Incident Management Systems (IMS)
- The **Workforce Development Action Package**, to facilitate national workforce development and planning, aiming for a minimum of 1 trained field epidemiologist per 200,000

CDC has received emergency funding for fiscal years 2015 to 2019 to address the international Ebola response, improve domestic preparedness and response for Ebola, and advance global health security via GHSA. The GHSA funds will support capacity-building work in 17 countries, including 7 either affected by or at risk for Ebola (Liberia, Sierra Leone, Guinea, Cote d'Ivoire, Mali, Senegal, and Burkina Faso), plus Bangladesh, Cameroon, Ethiopia, India, Indonesia, Kenya, Pakistan, Tanzania, Uganda, and Vietnam.

GHSA priorities in Liberia, Sierra Leone, Guinea include:

- **Disease Surveillance and Epidemiology:** Tracking and isolating Ebola Virus Disease (EVD), ensuring appropriate contact-tracing and reporting, and building emergency response capabilities

- **Capacity Building/Workforce Development:** Providing support and training for Ministry of Health staff in epidemiology, logistics, health management, analytics, and other support functions
- **Laboratory:** Strengthening diagnostic capacity and improving EVD specimen transfer to facilitate active surveillance
- **Infection Prevention and Control (IPC):** Strengthening active surveillance in healthcare facilities and assisting with case-monitoring, contact-tracing, and community-level infection control activities

GHSA flagship projects in other countries might include efforts to

- Reduce the incidence of malaria in Nigeria
- Reduce the incidence of TB in Uganda, Ethiopia, and/or India
- Reduce the incidence of vaccine preventable diseases
- Build EOCs in Cameroon and/or Senegal
- Prevent disease spread in Mali during the Hajj, through improved integration of emergency operations, disease surveillance and laboratory capacity
- Establish event-based disease surveillance in Vietnam

Next steps and targets include

- In 2015: Get to zero, stay at zero, and build back better in Liberia, Sierra Leone, and Guinea
- Over the next 3-5 years: Expand GHSA activities in countries at risk for Ebola
- By 2020: Implement GHSA activities in 30 countries, protecting 4 billion people

Suggested topics for BSC discussion on GHSA included

- Challenges associated with starting large scale initiatives and advice/suggestions/insights on dealing with these challenges
- Factors to consider in facilitating sustainability for programs in the long-run within the ministries of health
- Challenges associated with integrating horizontal capacity building into strengthening vertical programs

Discussion

GHSA Planning, Evaluation, and Partnerships. CDC should

- Establish well-defined steps and a robust evaluation process to ensure that monies are well spent
- Set goals, determine what is realistic, and evaluate each activity on an ongoing basis
- Demonstrate short-term successes within the long-term process of achieving difficult and complex goals
- Foster partnerships for long-term capacity building. Partners should include universities, schools of public health, and private sector partners (e.g., corporations) that have a stake in maintaining stable societies.
- Focus on building core capacities. Efforts that build on existing public health infrastructure (e.g., using polio eradication infrastructure to address malaria) should be encouraged.

Education, Training, and Sustainability

- When GHSA ends, it should leave behind a young, well-trained workforce
 - The number of people trained and re-trained is a good metric of success
 - About 80 CDC staff (new hires) are likely to participate in GHSA activities, working with locally employed staff in partnership with ministries of health. CDC's aim should be to train the trainers and program managers (who are often FETP graduates). Afterwards, CDC should maintain in-country partnerships and provide technical assistance, as needed.

- Many FETP programs have a good track record in terms of the number of graduates hired and retained by ministries of health. In some high-population countries like Bangladesh, the focus should be on basic (rather than advanced) training, to build the number of junior people with public health training.
- Affordable technologies are key
 - Do not build systems that depend on technologies that cannot be sustained
 - Acknowledge the need for cultural acceptance and adaptation

Other Comments

- The Ebola outbreak is an example of what can happen when a dangerous pathogen enters highly populated urban areas. Research and planning are essential to prevent this from happening again.
- Be forward-thinking, make use of new technologies for education and communication, and be aware of the potential impact of environmental change on infectious disease spread in poor countries.

➤ NCIRD: Measles Elimination and Vaccine Hesitancy

Anne Schuchat, NCIRD Director, noted that the elimination of measles in the U.S. was achieved in 2000 through high vaccine coverage rates, high-quality measles surveillance and response, and improved measles control throughout the Americas. However, imported cases of measles and limited spread occur every year:

- In 2014, for example, measles cases in the U.S. rose above the 1 case per million threshold achieved in 2000, due in part to low vaccine coverage in certain communities. Since 2000, outbreaks have typically occurred when an infected person returning from Europe or Asia came into contact with a community that had low coverage rates. An outbreak of this type occurred in 2014 when a missionary infected in the Philippines returned to his Amish community in Ohio. The people in the affected community accepted the measles vaccine as part of the response to the outbreak.
- A total of 668 cases of measles from 28 states were reported in the U.S. in 2014, including 60 imported cases. 99% of the cases were importation-associated, 86% were outbreak-associated, and 77 cases (12%) required hospitalization. Of 658 cases that involved U.S. residents, 76% occurred in unvaccinated persons and 16% in persons whose vaccination status was unknown. Among unvaccinated persons, 80% were unvaccinated due to personal belief exemptions, and 8% were too young to be vaccinated.
- Of 166 cases of measles identified thus far in 2015, two-thirds are associated with an outbreak that began in Disneyland last December and spread to at least seven states. This outbreak changed the public conversation by demonstrating what can happen to “innocent bystanders” when significant numbers of people remain unvaccinated. As a result, the demand for vaccination increased among both children and adults.

Dr. Schuchat emphasized that every measles case requires investigation and follow-up by state and local health departments. CDC supports these efforts by providing technical assistance, evaluating data on confirmed cases, testing specimens to help with difficult diagnoses, and using AMD methods to identify viral genotypes and strains. CDC also develops and disseminates tools and materials for public health professionals, healthcare professionals, and the public.

Dr. Schuchat concluded with these key points:

- Measles was eliminated from the U.S. in 2000—but is still a plane ride away
- Astute clinicians need to recognize ‘old’ diseases
- Public health infrastructure is critical
- Improved immunization abroad will reduce risk in the U.S.

- Clinicians play key roles in parental vaccine acceptance by parents
- State requirements can keep vaccination as the default option and protect communities
- Improved immunization histories for adults (i.e., via Immunization Information Systems) can help us understand the changing epidemiology of vaccine preventable diseases

Discussion

Adult Vaccination

- The Adult and Influenza Immunization Summit will take place on May 12-15 (<http://www.izsummitpartners.org/>).
- Because ACA-insured children have access to all ACIP-recommended vaccines, with no co-pay, CDC can shift vaccine resources previously targeted to children to uninsured adults.
- The HHS National Vaccine Office issued a draft *National Adult Immunization Plan* (http://www.hhs.gov/nvpo/national_adult_immunization_plan_draft.pdf) in February (during the Disneyland outbreak), which emphasizes the need for registries to track adult vaccination and provide data to evaluate the health impact of adult vaccines
- CDC should partner with pharmacies and chain stores in providing adult vaccines. These stores market vaccines directly to consumers and can provide electronic data to physicians and to vaccine registries, using Immunization Information Systems (IIS). This type of collaboration is already underway in New York City, where many pediatricians and pharmacies use electronic medical record systems that provide harmonized data sets. The key is to provide clinical decision support and ensure that systems used by doctors and pharmacies are interoperable with state or city registries.

The Disneyland Outbreak and Vaccine Hesitancy

- Measles transmission in Disneyland did not lead to explosive outbreaks, most likely because high rates of immunization in most U.S. communities provide a significant degree of herd immunity
- Despite study after study showing no linkage between autism and vaccination—including a new study involving children with autistic siblings (a group at high risk for autism)³—a recent survey on attitudes toward autism still gives “vaccine use” as an option for the cause of autism. Dr. Schuchat noted that
 - It is human nature to link events that are close in time, such as vaccinations and autism diagnoses
 - Surveys of parents who delay or refuse vaccination most often reveal concerns about how many shots are needed and what the timing should be. Pediatricians must be ready to answer these questions, because the autism myth will not disappear.
 - However, the Disneyland outbreak shifted the conversation to demonstrating why we need vaccines
- CDC has begun to map areas of high and low vaccine coverage and to provide resources to the states (via cooperative agreements) to support outreach to areas where coverage is poor. Peer-to-peer interventions may be useful for raising confidence in vaccines (e.g., mothers talking to each other at schools) in contexts where trust in health care providers is low
- This approach to disease prevention—i.e., through outreach to communities at-risk for measles outbreaks because of low vaccination rates—may present some parallels to previously discussed efforts to prevent HIV and HCV outbreaks through outreach to communities at risk because of substance abuse issues (see page 6).

Global Immunization Measures

- In regard to developing global measures of vaccine coverage, Dr. Schuchat noted that GHSA uses first-dose “measles coverage” as a sentinel marker of each country’s immunization system.

³ Jain A, Marshall J, Buikema A, Bancroft T, Kelly JP, Newschaffer CJ. Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. JAMA 2015 Apr 21;313(15):1534-40.

Pertussis Vaccines

- In response to questions about pertussis vaccines, Dr. Schuchat noted that
 - Two new papers suggest that although the vaccines currently in use are not ideal, they do prevent the worst outcomes. One paper reported short-term effectiveness that waned over a few years;⁴ the other confirmed that vaccination reduced infant hospitalizations and deaths.⁵
 - CDC's current focus is on providing protection for infants who are too young to vaccinate by vaccinating their mothers during pregnancy so that they passively receive antibodies.
- BSC member Dr. Carole Heilman, Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, NIH, noted that multi-component acellular pertussis vaccines contain three target antigens, including pertactin protein. Although the pertactin gene has been deleted in some pertussis strains, the other two vaccine target antigens remain.

➤ **NCEZID: Antimicrobial Resistance and Chikungunya Fever**

Antimicrobial Resistance. Dr. Bell reported on the following documents and events:

- *Antibiotic Resistance Threats in the United States, 2013*, developed by CDC with input from the BSC AR Workgroup (<http://www.cdc.gov/drugresistance/threat-report-2013/>)
- *National Strategy to Combat Antibiotic-Resistant Bacteria (CARB)* and an accompanying Executive Order (both released in September, 2014), which lay out a set of federal actions and goals for reducing major AR threats over the next 5 years (<http://www.cdc.gov/drugresistance/federal-engagement-in-ar/national-strategy/index.html>)
- *Combating Antibiotic Resistance*, issued by the President's Council of Advisors on Science and Technology (PCAST) in September 2014, which makes policy recommendations for sustaining strong federal leadership, effective surveillance and response, fundamental research on antimicrobial resistance, increased clinical trials and economic incentives for the development of antibiotics, limitations on the use of antibiotics in animal agriculture, and effective international coordination (<https://www.whitehouse.gov/blog/2014/09/18/pcast-releases-new-report-combating-antibiotic-resistance>)
- The *CARB Action Plan*, issued in March 2015, outlines steps to implement the *CARB Strategy* and address the policy recommendations of the PCAST report, providing significant outcomes expected by 2020 (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf). A companion action plan to combat drug-resistant TB is under development.

To maintain momentum, CDC has developed an AR Solutions Initiative for FY16 that lays out aggressive, cost-saving interventions to reduce the projected burdens of infections with resistant organisms. Implementation of the Initiative's three components—*Detect & Respond*, *Protect*, and *Innovate*—would improve processes and outcomes such as comprehensive tracking, rapid detection, faster outbreak response, better patient care, and improved prescribing.

As part of the first component, *Detect & Respond*, CDC and partners will advance comprehensive tracking of AR by

⁴ Acosta AM, DeBolt C, Tasslimi A, et al. Tdap vaccine effectiveness in adolescents during the 2012 Washington State pertussis epidemic. *Pediatrics* 2015 Jun;135(6):981-9.

⁵ Tiwari TS, Baughman AL, Clark TA. First pertussis vaccine dose and prevention of infant mortality. *Pediatrics* 2015 Jun;135(6):990-9.

- **Defining populations at risk.** The Emerging Infections Program (EIP) will lead efforts to determine the national and community prevalence of AR infections and will provide a platform for epidemiologic studies.
- **Advancing Quality Improvement.** Collection of data by the NHSN will enable real-time tracking of AR infection and antibiotic usage (AU) at healthcare facilities that leads to targeted quality improvement.
- **Ensuring Early Warning.** A regional laboratory network will be established to conduct sentinel monitoring of novel AR resistance mechanisms

Because patients often move from one healthcare facility to another, an outbreak in one hospital can have a regional impact on health.⁶ As part of the second component—*Protect*—CDC plans to establish State AR Prevention (Protect) Programs in states that will build local capacities to address the spread of resistant infections across healthcare settings, with an emphasis on AR and infection control. State-level core capacities will be strengthened in these areas: improving regional awareness of AR threats, assessing and improving infection control, assessing and improving prescribing behaviors, and protecting patients from infectious threats, including AR threats.

CDC will also support antimicrobial stewardship programs that improve and reduce AR by:

- Providing data about antibiotic use to better understand prescribing
- Setting national standards of antibiotic use to improve use and reduce resistance
- Ensuring that all hospitals have effective stewardship programs
- Understanding state-by-state differences in antibiotic prescribing rates
- Evaluating intervention strategies to improve antibiotic prescribing
- Creating state-level programs to improve antibiotic prescribing in hospitals and the community

As part of the third component—*Innovate*—CDC will conduct applied epidemiologic investigations related to the human microbiome and will also support Prevention Epi-Center studies. Examples of innovations that are helping to reduce AR include widespread adoption of:

- Chlorhexidine as an antiseptic for hospital use—a best practice identified and tested by the Prevention Epi-Centers
- A “bundled” group of prevention strategies to reduce CRE colonization and infection in long-term care acute hospitals.

Current CDC efforts include

- Participating in planning and leading the White House Stewardship Forum to strengthen partnerships and identify new prevention opportunities
- Creating an AR isolate library, in partnership with FDA
- Collaborating with NIH and the Broad Institute to sequence the genomes of drug-resistant bacteria and identify and track new resistance mechanisms
- Refining NHSN AU and AR modules for use by long-term care facilities and hospital networks.
- Supporting AR activities conducted under GHSA.

Proposal: A Letter to the HHS Secretary to Support the AR Initiative. Dr. Weinstein proposed that the BSC and/or the Workgroup draft a letter to policymakers explaining that today’s technical advances provide a special opportunity to prevent drug-resistant infections in ways that were not possible in the past. Dr. Berkelman suggested that the letter be sent to the HHS Secretary and that it support the AR

⁶ Lee BY, McGlone SM, Wong KF, et al. Modeling the spread of methicillin-resistant *Staphylococcus aureus* (MRSA) outbreaks throughout the hospitals in Orange County, California. *Infect Control Hosp Epidemiol* 2011 Sep;32(9):938).

Initiative in the President's FY16 budget request. Once the letter is delivered, it could be shared with other interested groups.

BSC members suggested that the letter should

- Support the AR initiative as a whole, including actions by all HHS agencies
- Mention that state and local health officials are represented in the BSC and on the Workgroup
- Mention the importance of preventing over-use of antibiotics and improving infection control.
- Include microbiome research on the list of opportunities

Action: The BSC approved a motion to send the HHS Secretary a letter in support of the AR Initiative in the President's FY16 budget request. The letter will be signed by the BSC chair and the chair and co-chair of the BSC Antimicrobial Resistance Working Group, which will meet on May 7. (As follow up, a letter from the BSC chair and AR Working Group chairs to Secretary Burwell was sent on May 11, 2015.)

Chikungunya. Dr. Bell reviewed the natural history of Chikungunya, a mosquito-borne alphavirus that causes a disease characterized by high fever and severe arthralgia. Most infected persons become symptomatic; mortality rates are low but morbidity high, with symptoms lasting from months to years. In contrast to dengue virus, there is only one serotype of chikungunya virus (CHIKV), and it is believed that lifelong immunity follows infection. In tropical climates, large, explosive outbreaks typically continue until a large proportion of the population has been infected and community transmission can no longer be sustained. There is no curative treatment and no licensed vaccines; prevention relies on avoidance of mosquito bites and mosquito control.

Dr. Bell reported that

- As of March 2015, 44 countries or territories in the Caribbean, Central America, South America, and North America have been affected, with a total of 1,310,925 suspected or confirmed cases. The expectation is that CHIKV will continue to spread to new areas in the Americas.
- Historically, an average of 28 persons per year tested positive for recent CHIKV infection in the U.S. (range 5–65 cases per year), nearly all of them in travelers. At the present time, however, 47 states and the District of Columbia are reporting cases, including 2,549 travel-associated cases (18% in Florida and 30% in New York) and 12 locally-acquired cases (all in Florida).

Since 2009, CDC has worked with PAHO and state health departments to improve capacity to diagnose chikungunya fever, to estimate the risk of CHIKV importation and local transmission, and to address gaps in state and local capabilities to detect and respond to outbreaks, currently especially along the U.S.-Mexico border. CDC activities have included

- Assisting assist state and local health department with CHIKV outbreak investigations
- Distributing laboratory testing reagents and providing training in laboratory methods
- Dissemination of guidelines, information, and educational materials to Customs and Border Protection officials, the cruise ship industry, public health partners, and healthcare providers
- Providing information to the public through the CDC website, social media, and Travelers Health advisories
- Providing information to healthcare providers through the CDC website, the Health Alert Network, Yellow Book/Travelers Health updates, Medscape Expert Commentaries, diagnostic testing guidelines, webinars, MMWR articles, and fact sheets

Large numbers of infected travelers are likely to arrive in the U.S. this summer. As CHIKV spreads through the American tropics and into Northern Mexico, there will also be an increased risk of locally

transmitted infections, particularly in Florida and in border states such as Texas, California, New Mexico, and Arizona. However, local transmission is possible in all states with *Aedes* vector mosquitoes.

Discussion

- Mexico has experienced large, explosive chikungunya outbreaks that spread very fast across the Pacific Coast through Sonora to Mexican states along the U.S. border. The spread of the disease in Mexico—and the impact on the local economy—differs from that of dengue fever. Because the disease is painful and debilitating, people tend to stay home for the duration of the outbreak, which is typically around 3 weeks.
- Differences in living patterns and behaviors (e.g., use of screened windows and air conditioning and less crowded living conditions) might lead to smaller, less explosive outbreaks in U.S. border states compared to those seen in Mexico and Puerto Rico.
- The CHIKV outbreak in Puerto Rico caused widespread illness. Many infectious disease doctors were infected, as were many staff members at the CDC Dengue Branch in San Juan. The literature suggests a broad range in how long symptoms last, with some persons experiencing pain for months or years. The CDC sentinel surveillance system for dengue is also being used to track chikungunya fever, better characterize the disease and its impact (e.g., on the elderly), and identify risk factors. The CHIKV outbreak in Puerto Rico involved some deaths, and CDC is also analyzing possible risk factors of those who died.
- In regard to mosquito control, Dr. Bell said that the mosquitoes that carry CHIKV are daytime biters that live indoors and can breed in tiny volumes of water. Unlike with West Nile virus, night-time outdoor spraying has little effect. Control efforts in the U.S. are likely to include putting screens on windows and eliminating breeding sites.
- The Mexican Ministry of Health and CDC continue to work together to address infectious diseases along the Mexico-U.S. border. At the present time, the National Institute of Public Health of Mexico (INSP) is conducting research to improve and focus mosquito control and identify areas at greatest risk of CHIKV outbreaks.
- In the United States, rates of tick-borne diseases are also rising. Both mosquito-borne and tick-borne diseases require more attention.
- In regard to whether reporting bias (e.g., the need to protect tourism) influences CHIKV surveillance, Dr. Bell noted that there has been no evidence of systematic under-reporting in Puerto Rico or in border states since chikungunya fever became a reportable disease in January 2015.

➤ **Infectious Disease Laboratory Working Group (IDLWG): AMD Update**

BSC member Susan Sharp, Director of Laboratories, Kaiser Permanente Northwest, and IDLWG Co-chair, reviewed the Workgroup's observations about the establishment, progress, and future activities of CDC's Advanced Molecular Diagnostic (AMD) initiative (<http://www.cdc.gov/amd/>).

AMD Evaluation. The first year of the AMD initiative went well in terms of acquiring hardware but more slowly in terms of workforce development. Major efforts include

- *Re-training laboratory staff.* A major challenge is to acquire new skills while retaining old ones, which continue to be needed
- *Establishing the APHL Bioinformatics Fellowship Program.* This program, which is funded through cooperative agreements with APHL, includes both master-level and postdoctoral fellows. To date, three post-doctoral and seven masters-level fellows have been recruited. Several graduates have transitioned to more permanent roles. However, the Fellowship's stipend is not competitive with other employment opportunities in bioinformatics

AMD Focus Areas. The IDLWG might help advance AMD by providing guidance and oversight in the following four areas:

1. Quality Assurance:

- Developing standardized protocols applicable to different types of specimens and sequencing equipment
- Creating common bioinformatics pipelines
- Maintaining curated microbial genome sequence reference databases
- Adapting existing programs (e.g., proficiency testing) to assure that data are valid, reproducible, and standardized

2. Efficiency and Effectiveness:

- Developing metrics for evaluating the impact of AMD on costs and outcomes
- Evaluating centralized vs. de-centralized laboratory capabilities (e.g., specialized “centers of excellence”)
- Leveraging existing knowledge and capacities within CDC and the public health community

3. Workforce Development and Communications:

- Developing training fellowships and competitive grants
- Creating a standardized vocabulary for communication on AMD issues

4. Public Health – Partner Cooperation:

- Increasing partnership engagement (e.g., by professional societies, universities, industry colleagues)
- Working with test manufacturers and clinical laboratories to develop diagnostics that meet both clinical and public health needs.

The next in-person IDLWG meeting will take place in late summer or fall of 2015.

Discussion

In response to questions about reference databases, Dr. Michael Shaw, OID Senior Advisor for Laboratory Issues, reported that CDC is helping to establish two curated databases:

- A reference database for developing diagnostic assays, developed with NCBI and FDA
- A public health database that includes genomic sequences of well-characterized organisms, developed with extensive interagency input.

In response to questions about the MALDI-TOF mass spectrometry, Dr. Sharp noted that

- Diagnostic use of MALDI-TOF mostly involves testing organisms grown in culture. Unlike diagnostic techniques based on metagenomics, MALDI-TOF has not been adapted for use in detecting multiple organisms in blood or stool specimens.
- The IDLWG will continue to consider diagnostic options involving both isolates and primary specimens.

➤ **Upcoming BSC/OID meeting**

The BSC/OID will convene for its next in-person meeting on December 9-10, 2015.

APPENDIX

Meeting Participants

BSC Members

Ruth Berkelman
Jack Bennett
Luciana Borio (*representing FDA*)
Judy Bossé
Kristy Bradley
Mike Brady
Harry Chen
Frank Cockerill
Jim Cummings (*representing DoD*)
Dawn Fukuda
Bruce Gellin
Carole Heilman
Tim Jones
Beth Lautner
Ruth Lynfield
José Montero
Andy Pavia
Scott Ratzan
Guillermo Ruiz-Palacios
Susan Sharp
Jon Temte
Bob Weinstein (*byphone*)

Partners and Public Visitors

Chris Aldridge (*National Association of County and City Health Officials*)
Celia Hagan (*Association of Public Health Laboratories*)
Lilly Kan (*National Association of County and City Health Officials*)
Peter Kyriacopoulos (*Association of Public Health Laboratories*)
Jennifer Lemmings (*Council of State and Territorial Epidemiologists*)
Christy Phillips (*Pediatric Infectious Diseases Society*)
Jill Stevens (*Social and Scientific Systems*)
Kathy Talkington (*Association of State and Territorial Health Officials*)

CDC Staff

Larry Anderson
Greg Armstrong
Ann Bauman
Beth Bell
Elise Beltrami
Rae Benedict
Gail Bolan
Byron Breedlove
Evelyn Cater
Bob Cottingham
Kim Distel
Peter Drotman
Priscilla Golden
Tom Gomez

Marta Gwinn
Rita Helfand
Michael Iademarco
Kashef Ijaz
Rima Khabbaz
Lisa Koonin
Alexandra Levitt
Allison Maiuri
Tonya Martin
Karen Mason
Jonathan Mermin
Nancy Messonnier
Steve Monroe
Dale Morse

Robin Moseley
Tony Moulton
Aime Nisler
Bob Pinner
Kristin Pope
Steve Redd
Chesley Richards
Larry Schonberger
Eric Sergienko
Michael Shaw
Sharon Slocumb
Serena Vinter
John Ward
Cindy Weinbaum

CDC Staff (cont.)

Sarah Wiley

Michelle Wilson

Stephanie Zaza

Barb Zehnbauer

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 May 6, 2015, are accurate and complete.

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

10/13/15
Date