

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

December 11-12, 2013

A 1½ day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on December 11-12, 2013, 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 updates from OID, the Influenza Coordination Unit (ICU), the Center for Global Health (CGH), and CDC's three infectious disease national centers: the National Center for Emerging and Zoonotic Diseases (NCEZID); the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP); and the National Center for Immunization and Respiratory Diseases (NCIRD). Each update was followed by discussion. Reports were also provided by the two BSC/OID working groups. The Food Safety Modernization Act (FSMA) Surveillance Working Group presented its annual report for Board approval, and the Antimicrobial Resistance Working Group provided information regarding their discussions on prevention and control of carbapenem-resistant Enterobacteriaceae (CRE) and on a subset of public health actions to improve antimicrobial use (Antimicrobial Stewardship).

Presentations were also made on five topical issues: 1) changes in immunization programs at the state level; 2) a new government-wide initiative on Global Health Security; 3) polio eradication efforts; 4) CDC's school-based surveillance systems and NCHHSTP's Division of Adolescent and School Health (DASH) prevention programs; and 5) the FY 2014 Advanced Molecular Detection (AMD) initiative. The AMD presentation included information about the new BSC Infectious Disease Laboratory Working Group, whose establishment was approved at the May 2013 BSC meeting.

DAY 1: DECEMBER 11

➤ **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 OID/BSC Designated Federal Official. Dr. Berkelman welcomed two new BSC members: Dr. Susan Sharp, Kaiser Permanente Northwest; and Dr. Jose Montero, New Hampshire Department of Health and Human Services. Dr. Berkelman also welcomed Dr. Judith Bossé, Assistant Deputy Minister, Health Promotion and Chronic Disease Prevention Branch, Public Health Agency of Canada (PHAC), who is replacing Dr. Rainer Engelhardt, as PHAC's liaison representative to the Board.

➤ **OID UPDATES**

Dr. Khabbaz provided updates on the following topics:

- **The Government Shutdown.** The U.S. government was closed for the first 16 days in October, due to the absence of Congressional appropriations. At CDC, operations were limited to addressing emergency situations, defined as "imminent threats to life or property." Two-thirds of CDC staff were furloughed, and most disease surveillance and laboratory activities were halted. However, members of the Commissioned Corp remained at work, and certain functions supported by mandatory

funding continued. For infectious diseases, these included the World Trade Center Health Program (<http://www.cdc.gov/wtc/index.html>), the President's Emergency Plan for AIDS Relief (PEPFAR; <http://www.pepfar.gov>), and the Vaccines for Children program (VFC; <http://www.cdc.gov/vaccines/programs/vfc/index.html>).

One week into the shutdown, CDC was allowed to recall 30 staff members to respond to a foodborne disease outbreak of *Salmonella* Heidelberg (see below), as well as to address specific issues related to influenza, TB, polio, and drug resistance.

- **The Budget.** The Continuing Resolution (CR) continues through February 15. If the FY2014 budget is passed before that date, the CR will expire. Under the CR, CDC grants to states and cities cover about 30% of FY2013 amounts, and CDC has limited abilities to hire and to host (or send attendees to) conferences. If sequestration continues in 2014, CDC will be subject to additional formula-based cuts. The deadline for a new agreement by Congress is December 13, with January 15 the deadline for enactment.
- **OID Staff News.**
 - Jan Nicholson, OID Senior Advisor for Laboratory Science, is retiring at the end of December. OID will hold a retirement celebration for her on December 16. Michael Shaw, Associate Director of Laboratory Science in NCIRD's Influenza Division, has agreed to fill in for Dr. Nicholson until a replacement is found.
 - Joanne Cono, OID Special Officer for Science Integration, is on detail to the Office of the Associate Director for Science as Acting Director of the Office of Science Quality.
 - Tonya Martin, OID Senior Advisor for Informatics, is on detail to the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) as Acting Director, Division of Health Informatics and Surveillance.
 - In conjunction with the Council of State and Territorial Epidemiologists (CSTE), Alexandra Levitt, OID Special Advisor for Strategic Information Assessment, has published *Deadly Outbreaks*, a book on outbreaks investigations (written as an "outside activity" with permission from the CDC Ethics Office). In addition, Polyxeni Potter, former managing editor, *Emerging Infectious Diseases*, has published *Art in Science, Selections from Emerging Infectious Diseases*—a compilation of *EID* cover art and accompanying essays. Proceeds from the *EID* cover book benefit the CDC Foundation.

DISCUSSION: OID UPDATES

A suggestion about issuing an official BSC statement regarding the public health and safety issues caused by the government shutdown generated the following responses:

- Dr. Khabbaz said that CDC was able to recall furloughed employees to respond to a multistate outbreak of *Salmonella* Heidelberg associated with chicken (see page 12). Although the recall caused some delays, state and local health departments kept CDC informed about the *Salmonella* outbreak and other emergencies.
- Dr. Beth Bell, NCEZID Director, said that in some cases state and local public health workers did not inform CDC about local health issues because they thought CDC was closed. It was also difficult to make plans without knowing how long the shutdown would last.
- Dr. Anne Schuchat, NCIRD Director, said that, like many academic and business institutions, CDC has a Continuity of Operations Plan (COOP) that is periodically updated and exercised. However, the shutdown presented special administrative difficulties, requiring the re-interpretation of laws and regulations to figure out what could be done under these unique circumstances.

- Dr. Jesse Goodman, Deputy Commissioner for Science and Public Health, Food and Drug Administration (FDA), said that a significant part of the year was “eaten up” by the shutdown. Many ongoing processes, including contracts and collaborative projects, were put on hold or otherwise disrupted.

Following this discussion, BSC members concluded that:

- The BSC should use its “political arrows” wisely, focusing on funding as the more pressing issue.
- CDC should be commended for continuing to support state and local partners during the shutdown.

➤ **ICU UPDATE**

Dr. Steve Redd, ICU Director, provided updates on human cases of avian influenza A(H7N9) in China and on avian influenza A(H5N1) around the world:

- **Avian Influenza A(H7N9).** At the time of the May BSC meeting, the spring outbreak of avian influenza A(H7N9) in China was nearly over, although that was not clear at the time. The first wave ended at the end of April, after health authorities closed live bird markets in affected locations. The outbreak affected 8 contiguous provinces in eastern China, two municipalities (Beijing and Shanghai), and Taiwan—an area that includes about 10% of the world’s population. At the time of the BSC meeting, 143 human cases were reported, of whom 47 (about one-third) died.

Only a few human cases of H7N9 occurred over the summer, but 7 cases were reported in the fall, also associated with live bird markets. Fortunately, sustained human-to-human transmission has not been detected. The spring outbreak included five possible instances of one generation of human-to-human transmission or common-source or simultaneous infection, but without ongoing transmission. Current efforts are directed towards disease surveillance and monitoring.

- **Avian Influenza A(H5N1).** Since its re-emergence in 2003, 648 human cases of avian influenza A(H5N1) have been reported in 15 countries (mostly in Asia and the Middle East); 384 (59%) were fatal. More cases occur during the winter months than during the summer, with exposure to poultry remaining the predominant risk. There is no evidence of sustained human-to-human transmission. In 2013, cases were reported in 5 countries: Cambodia, China, Egypt, Indonesia, and Vietnam.

Cambodia, which has reported a few H5N1 cases each year since 2005, experienced 26 cases in 2013, across 11 provinces; 23 people were hospitalized and 14 (54%) died. The increased number of cases might reflect a greater number of exposures to infected birds and/or improved disease surveillance. Previously, an H5N1 strain belonging to the 2.3.2.1 clade had been circulating in the Mekong Delta area; however, the strain detected in Cambodia in 2013 has HA and NA genes from clade 1.1 and internal genes from the 2.3.2.1 clade. It is possible that this reassortant virus is more transmissible in poultry, resulting in increased human exposure.

- **Pandemic Preparedness.** Three guidance documents are under revision to incorporate lessons learned during the H1N1 pandemic:
 - 1) *Stockpiling antiviral drugs.* The former guidance document recommended that businesses and other institutions consider stockpiling antiviral drugs for prophylaxis, post-exposure prophylaxis (PEP), and treatment. The new document will recommend stockpiling antivirals for PEP only, in situations where people are likely to be exposed.

- 2) *Allocating vaccine during a pandemic.* Changes include incorporating a new tool to measure pandemic severity (the Pandemic Severity Assessment Framework [PSAF]¹) and placing greater emphasis on the need to tailor response activities to the actual situation.
- 3) *Community mitigation.* The 2007 *Community Mitigation Strategy* (http://www.flu.gov/planning-preparedness/community/community_mitigation.pdf) is being revised to incorporate the PSAF, as well as research findings on the effectiveness of non-pharmaceutical interventions (NPIs) implemented during the H1N1 pandemic.

DISCUSSION: ICU UPDATES

H7N9 Exposure in Live Bird Markets. The avian H7N9 virus is difficult to track in birds. The virus has low pathogenicity in birds, so they do not become ill. Thus, human (rather than avian) disease implicates live bird markets in the spread of H7N9 influenza. One intervention might be to close the markets during the time of year when outbreaks are most likely to occur. Others might be to close the markets periodically; to designate one day every week when no new birds are accepted; or to ensure that birds are not moved from one market to another (the “one-way path” intervention). Better disinfection of bird stalls is also important. Because interventions need to be sustained over time and be economically viable, permanent closure of affected markets is not a viable option. The virus appears to be more transmissible among market birds (chickens, quail) than among wild birds. The route of transmission appears to be respiratory rather than fecal.

Dual-Use Research. In regard to research at CDC to identify biological determinants of influenza virus transmission to humans (“gain-of-function experiments”), Dr. Redd noted that CDC has protocols for intensive review of “dual use” experiments and for implementation of biosafety controls. Dr. Nancy Cox, Director, Influenza Division, said that CDC is no longer doing gain-of-function work. However, the results obtained to date have provided a road map for molecular surveillance that is being used by a CDC Epi-AID team in Cambodia working to ascertain the reason for the recent increase in human H5N1 cases in that country (see page 3). Dr. Carole Heilman, Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), said that work on influenza gain-of-function experiments has slowed in the United States (not only at CDC). However, it is ongoing in laboratories in other countries that may or may not employ optimal biosafety and biosecurity measures.

Stockpiling Influenza Vaccines. Dr. Redd reported that the National Strategic Stockpile currently includes about 20 million vaccines for use against different clades of H5N1. The current plan (still under discussion) is to use these vaccines if and when human-to-human H5N1 transmission is detected. In the future, other uses of stockpiled vaccine might be considered (e.g., to vaccinate persons with potential occupational risk for exposure to H5N1, such as laboratory workers or CDC staff working in Cambodia).

H7N9 Vaccines. Development and planning for the production of H7N9 vaccines is ongoing, with the expectation that H7N9 vaccines will be stockpiled along with H5N1 vaccines. The H7N9 vaccine currently under development might require administration in two doses, with adjuvant. Although much has been learned about rapid production of influenza vaccines, a two-dose regimen will be challenging, and it is not clear how long immunity will last.

¹Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. *Emerg Infect Dis* 2013;19(1):85-91.

➤ **NCIRD UPDATE**

Dr. Anne Schuchat, Director, NCIRD, reported on activities that address three health priorities identified by CDC Director Thomas Frieden (<http://www.cdc.gov/about/leadership/director.htm>):

1) **Improving health security at home and around the world**

Health security challenges addressed between May and December 2013 included:

- **Middle East Respiratory Syndrome (MERS).** The ongoing outbreak of MERS that began in April 2012 (caused by the coronavirus MERS-CoV) has affected 164 people, killing 71. Most cases were reported in Saudi Arabia between April and November 2013. Other affected countries include Qatar, the United Arab Emirates, Jordan, Oman, and Kuwait. In addition, travel-associated cases have been reported in France, Italy, Tunisia, and the United Kingdom.

CDC has developed a real-time reverse transcriptase polymerase chain reaction (rRT-PCR) assay for detection of MERS-CoV that has been deployed to public health facilities around the world. These include diagnostic laboratories in 19 countries in the WHO Eastern Mediterranean Region (WHO/EMRO); 3 countries in the WHO African Region (WHO/AFRO); and 5 countries in the Americas (through PAHO). The rRT-PCR assay has also been provided to 9 laboratories operated by the Department of Defense (DOD) Global Emerging Infections Surveillance group (GEIS) and to 6 CDC Global Disease Detection (GDD) Centers. The MERS-CoV assay was created and validated in collaboration with affected countries, and reagents were provided to public health laboratories through the Laboratory Response Network (www.bt.cdc.gov/lrn/). Dr. Schuchat thanked Dr. David Swerdlow, NCIRD Associate Director for Epidemiologic Science, for leading the CDC effort.

- **U.S. Outbreaks of Legionnaires Disease.** Over the past 6 months, NCIRD has confirmed 9 travel-associated clusters of Legionnaires disease (LD) and consulted with state and local partners on 11 additional clusters and outbreaks. As part of these efforts, NCIRD has conducted field investigations in Ohio (39 cases in a retirement community, associated with water in a contaminated cooling tower); Georgia (3 cases in a hotel, associated with a contaminated whirlpool spa); and Alabama (15 cases in a long-term care facility, with no source identified). The reasons for the increased LD burden are unknown, but might be related to weather, flooding, or improved local disease surveillance.
- **Meningococcal B Disease at Universities.** Between 2008 and 2012, CDC was consulted on five clusters and outbreaks of meningococcal serogroup B disease, including three that occurred at Ohio University (13 cases), the University of Pennsylvania (3 cases), and Lehigh University (2 cases). Between March and November 2013, an outbreak involving 8 confirmed, (non-fatal) cases (7 undergraduates and one visiting high school student) was reported at Princeton University. All of the undergraduates lived in dormitories. All 8 isolates exhibited the same subtype using pulsed-field gel electrophoresis (PFGE).

Vaccines against meningococcal B disease are not yet licensed in the United States but are currently approved for use in Australia, England, and Canada. Once evidence of sustained transmission was obtained (with additional cases detected after the summer break), CDC worked with FDA to provide meningococcal B vaccine under an Investigational New Drug (IND) protocol for expanded access.

Vaccination was offered to about 5750 persons at Princeton, including undergraduates, students living in dormitories, and persons with high-risk conditions such as asplenia and complement component deficiency. The first dose was given in December; the second one is scheduled for February. CDC (including the Immunization Safety Office) worked with Princeton, Novartis, and the FDA to develop a vaccine safety surveillance plan. The vaccination effort—which received considerable positive media attention—required major collaborative efforts by the state health department, the vaccine manufacturer, the university, and CDC.

A second university cluster of meningococcal B disease—involving 4 cases—occurred in November among undergraduates living in dormitories at the University of California, Santa Barbara. The causative strain was not the strain detected at Princeton. At the present time, CDC field investigators are reviewing the epidemiology of the outbreak and assessing the potential benefits a vaccination campaign might offer.

- **Resurgence of Pertussis.** As reported at the May 2013 BSC meeting, the recent resurgence in pertussis cases has been associated with waning immunity over time in persons who received the acellular pertussis vaccine (which is administered as the pertussis component of DTaP vaccine). However, a recent study suggests another explanation for decreased vaccine effectiveness: an increase in *Bordetella pertussis* isolates that lack pertactin (PRN)—a key antigen component of the acellular pertussis vaccine. A study that screened *B. pertussis* strains isolated between 1935 and 2012 for gene insertions that prevent production of PRN found significant increases in PRN-deficient isolates throughout the United States.² The earliest PRN-deficient strain was isolated in 1994; by 2012, the percentage of PRN-deficient isolates was more than 50%.

To assess the clinical significance of these findings, CDC used an IgG anti-PRN ELISA and other assays (PCR amplification, sequencing, and Western blots) to characterize 752 *B. pertussis* strains isolated in 2012 from six Enhanced Pertussis Surveillance Sites³ and from epidemics in Washington and Vermont. Findings indicated that 85% of the isolates were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains. Moreover, when patients with up-to-date DTaP vaccinations were compared to unvaccinated patients, the odds of being infected with PRN-deficient strains increased, suggesting that PRN-bacteria may have a selective advantage in infecting DTaP-vaccinated persons.

- **Severe Respiratory Disease in Puerto Rico.** CDC assisted the Puerto Rican Health Department in a mass influenza vaccination campaign conducted in response to an outbreak of severe respiratory disease that turned out to be influenza. Puerto Rico has low influenza vaccine coverage rates, due to financial and policy issues.

Updates on responses to global health security challenges related to avian influenza and polio were addressed by Dr. Steve Redd (pages 3-4) and Dr. Steven Wassilak (pages 36-38), respectively.

²Pawloski LC, Queenan AM, Cassidy PK, et al. Prevalence and molecular characterization of pertactin-deficient *Bordetella pertussis* in the United States. *Clin Vaccine Immunol* 2014;21(2):119-25.

³To investigate and monitor the increased number of pertussis cases, CDC is partnering with seven states in the Emerging Infections Program network (CO, CT, GA, MN, NM, NY, and OR) that have established Enhanced Pertussis Surveillance Sites (<http://www.cdc.gov/pertussis/surv-reporting.html>).

2) Reducing the leading causes of death.

Dr. Schuchat provided these updates on NCIRD activities that address the leading causes of respiratory and vaccine-preventable illness, disability, and death:

- **Seasonal Influenza.** A CDC study published in *Plos One* found that a significant burden of influenza disease has been averted over the previous 6 years through vaccination, and that additional impact is achievable through higher coverage rates or more effective vaccines.⁴ A second study, published in the *MMWR*, reports that vaccination during the 2012-13 flu season prevented about 6.6 million influenza illnesses, 3.2 million medically-attended illnesses, and nearly 80,000 hospitalizations.⁵
- **Vaccine-preventable childhood diseases, including pneumococcal pneumonia and rotavirus.**
 - Childhood vaccinations in the U.S. prevent almost 20 million cases of disease and save 42,000 lives every year. From a societal perspective, ten dollars are saved for every one dollar spent.
 - The new rotavirus vaccine has rapidly reduced the incidence of rotavirus gastroenteritis, preventing 200-250,000 hospitalization in children under age 5 years between 2008 and 2012, and saving about \$900 million in direct medical costs (including hospitalizations and ER visits).
 - Since the introduction of the first generation pneumococcal conjugate vaccine in 2000, rates of invasive pneumococcal disease have dropped dramatically in children younger than age 5 years. The use of the vaccine in children has also reduced transmission to unvaccinated infants and adults, more than doubling the impact of vaccination.
 - Internationally, CDC continues to support efforts by ministries of health, GAVI, WHO, and UNICEF to increase the use of childhood vaccines (e.g., against *Haemophilus influenzae type b*, rotavirus, pneumococcal disease, and meningococcal disease) in GAVI-eligible countries.
- **Respiratory Syncytial Virus (RSV).** A special edition of the *Journal of Infectious Diseases—Surveillance for Respiratory Syncytial Virus in CDC’s Global Disease Detection Network: Epidemiology, Disease Burden and Clinical Characteristics* (http://jid.oxfordjournals.org/content/208/suppl_3.toc)—provides RSV surveillance data from six countries that host CDC GDD Centers (China, Guatemala, Egypt, Kenya, South Africa, and Thailand) This burden-of-disease data will be a valuable resource when RSV vaccines become available.

3) Strengthening public health and health care collaboration.

This priority is relevant to all of CDC’s immunization activities that work to reduce antimicrobial resistance. Two current focus areas include

- **Connecting Immunization Information Systems and Electronic Health Records.** NCIRD is working to modernize immunization practices through information technology (IT) initiatives that involve working with:
 - *Clinical partners* to promote meaningful public health use of electronic health records (EHR) and ensure the interoperability of immunization information systems and EHR.
 - *Vaccine manufacturers and providers* to promote the use of 2-D barcoding to capture information on vaccine type, manufacturer, lot number, and expiration date. Merck, for example, plans to

⁴ Kostova D, Reed C, Finelli L, et al. Influenza illness and hospitalizations averted by influenza vaccination in the United States, 2005–2011. *PloS One* June 2013;8:e66312.

⁵CDC. Estimated Influenza Illnesses and Hospitalizations Averted by Influenza Vaccination — United States, 2012-13 Influenza Season. *MMWR* 2013;62(49):997-1000.

barcode all vaccine products by the end of 2014, and GSK and Sanofi have committed to converting their products as well.

- *Public health partners* to modernize vaccine ordering and inventory management at the provider and program level

The goal of these collaborations is to use IT technology to improve vaccine coverage and expand access to immunization. To aid in these efforts, an inter-governmental Immunization Information System (IIS) Executive Board has been chartered to help CDC update its IIS strategic plan and sustain a national leadership role in the future direction of immunization information systems. The IIS Executive Board, which held its first meeting on November 19, 2013, includes federal, state, and local governmental members, including representatives from the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services (CMS), the Indian Health Service, and state-level cancer registries.

- **Human Papillomavirus Vaccine Initiatives.** The HPV vaccine is already having a significant impact in the United States, despite low coverage rates. Thus far, the prevalence of vaccine-type HPV has been reduced by 56% in girls aged 14-19 years, with a 3-dose series vaccination rate of about 30%. An additional 50,000 cases of cervical cancer could be prevented if the coverage rate were raised to 80%. Every year of delay in increasing vaccination rates to this level means that another 4,400 women will develop cervical cancer.

Dr. Frieden is leading the charge to take advantage of this huge opportunity for disease prevention. CDC is mobilizing partners and stakeholders; providing tools and information to clinicians; increasing public awareness of HPV vaccination as cancer prevention; focusing on priority states; addressing vaccine safety concerns at every opportunity; and using systems approaches to improve vaccine coverage. Specific activities include:

- **Mounting public health campaigns (including social media efforts) and disseminating communication tools to providers.** Tools for providers include the *You are the Key to Cancer Prevention* campaign (<http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html>) and *Tips and Time-savers for Talking with Parents About HPV Vaccine* (<http://www.cdc.gov/vaccines/who/teens/for-hcp/tipsheet-hpv.html>).
- **Promoting provider outreach by the American Academy of Pediatrics (AAP; www.aap.org).** A 15-month CDC contract, initiated in November, supports local AAP chapters in efforts to improve coverage rates through HPV vaccine promotion activities such as webinars and other clinician-training projects.
- **Awarding grants from the Prevention and Public Health Fund (PPHF)⁶ to increase HPV vaccination coverage.** Awardees include Minnesota, Massachusetts, New York, New York City, Philadelphia, District of Columbia, Ohio, Chicago, Georgia, Utah, and Arizona. Activities include working with immunization stakeholders to develop jurisdiction-wide initiatives; implementing comprehensive public health campaigns; sending electronic messages to remind adolescents to return for second and third doses; evaluating rates of completion of the 3-dose HPV vaccine series; and helping providers to
 - Increase knowledge about HPV-related cancers and HPV vaccination safety and effectiveness
 - Improve skills needed to deliver strong, effective HPV vaccination recommendations
 - Decrease missed opportunities for timely HPV vaccination and series completion
 - Increase administration of HPV vaccine doses consistent with current ACIP recommendations.

⁶ The Prevention and Public Health Fund was established under the 2010 Affordable Care Act (<http://www.hhs.gov/open/recordsandreports/prevention/>).

- **Building partnerships between immunization and cancer prevention programs and coalitions.** CDC is supporting a project with the National Foundation for Infectious Diseases (NFID; www.nfid.org), to support clinician training and mobilize partners in cancer prevention programs. In addition, CDC is forming new partnerships with Tamika and Friends (a group of cervical cancer survivors) and the Society of Gynecological Oncologists (SGO).
- **Developing metrics to monitor administration of HPV vaccine doses among adolescent girls and boys.** CDC will review coverage rates and other available data monthly, via a CDC HPV Vaccine Dashboard.

CDC has also issued a *Call to Action* that encourages state and local health departments to consider developing HPV vaccine coverage plans. Resources may be found at: <http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html>.

NCIRD Staff News. Dr. Schuchat concluded by providing these updates on NCIRD staffing changes:

- Dr. Melinda Wharton is the new Director of the Immunization Services Division
- Dr. Daniel Feikin is the new Chief of the Epidemiology Branch, Division of Viral Diseases

DISCUSSION: NCIRD UPDATES

MERS-CoV. Dr. Schuchat confirmed that MERS-CoV is not as infectious as the SARS virus. CDC is partnering with the ministries of health of Saudi Arabia and Jordan to learn more about this disease (e.g., whether MERS involves a spectrum of disease that includes mild or asymptomatic cases). CDC participated in the WHO team that conducted the initial MERS delegation to Saudi Arabia and continues to provide diagnostic tests and participate in regional WHO meetings.

HPV Vaccine. It was suggested that HPV vaccination to prevent cancer may be one of today's most important public health opportunities. Issues raised for discussion included

- **Promoting vaccination of boys.** Dr. Schuchat noted that marketing HPV specifically to boys could backfire. A key communications strategy is to “mainstream” HPV vaccines by advising clinicians to talk about HPV vaccines as they do about all other vaccines. HPV vaccination should be routine for all teenagers (boys and girls), administered along with the Tdap and meningococcal vaccines, as part of “three-star” programs or visits. Dr. Schuchat also mentioned that a 2013 HEDIS measure requires three doses of HPV vaccination to be administered to girls by age 13. There is as yet no HEDIS measure yet for boys, because the vaccine recommendation for boys was only issued in 2011.
- **Impact of the new 9-valent vaccine.** Dr. Lauri Markowitz, Team Lead, Division of STD Prevention, NCHHSTP, said that CDC and partners will be paying close attention to the vaccine's effect on strain-types and disease outcomes. At the current time, CDC is helping to draft a consolidated ACIP policy statement on HPV vaccines that will address issues related to the HPV2 and HPV4 vaccines and be used as a backbone for future updates when the 9-valent vaccine is licensed.
- **The importance of outreach to non-physician providers.** Dr. Schuchat agreed that pharmacists are a key partner, especially in regard to providing a second or third dose. One strategy is to have providers provide the first dose in a series and have pharmacists provide the rest. (In the future, improved coordination between pharmacies and state registries will allow patients and doctors to track how many doses have been given.) CDC first reached out to pediatricians and family physicians, and is now reaching out to medical assistants and physician assistants, and also to obstetricians and gynecologists, who can remind their patients about the importance of having their children vaccinated to prevent cervical cancer.

- **Global Issues: HPV and AIDS**

- Globally, HPV vaccine is being administered in a few underdeveloped countries, through donations and/or through GAVI, which has helped support demonstration projects in 9 countries, including Rwanda, where HPV vaccine is provided in schools.
- Recent international studies suggest that HPV infection may increase the risk of AIDS acquisition.^{7,8} Dr. Jonathan Mermin, NCHHSTP Director, said that the relationship between HPV and HIV needs to be addressed. Further research may help advance a discussion about whether HPV vaccination should be introduced into PEPFAR countries.

Other Vaccine Issues

- **Few People Opt out of Vaccination.** Dr. Schuchat noted that vaccine coverage is tracked as part of the metrics for Healthy People 2020, which indicate that the rate of toddlers who get no vaccines continues to be less than 1%.
- **Vaccine Hesitancy.** It was suggested that the meningitis outbreak at Princeton could provide a “teachable moment”--illustrating the societal costs of vaccine hesitancy. Dr. Schuchat observed that to move from hesitancy to confidence requires reinforcement of vaccination as a social norm. There are always questions about the value of vaccines, and because there is less evidence of illness the benefits of vaccination are less obvious. For example, infection with *Neisseria meningitidis* is very severe but also very rare, making it more difficult to explain who was at risk and why vaccines were offered to certain groups of people at Princeton under the IND protocol.
- **Seasonal Influenza Vaccines.** Dr. Schuchat said that any confusion stemming from the variety of new influenza vaccine products currently on the market has had no apparent effect on vaccine coverage. She also stated that CDC has no preference among these products. In the future, ACIP may examine the efficacy of different influenza vaccines in children and older people.
- **IIS Executive Board Activities.** In regard to involving the private sector in efforts to promote meaningful public health use of EHR, Dr. Schuchat said that although the IIS Executive Board does not include representatives from private companies, CDC and partners do conduct meetings with vaccine vendors and other private stakeholders. In addition, the IIS Board is well-connected with other national and international groups and initiatives.

➤ **NCEZID UPDATE**

Dr. Beth Bell, Director, NCEZID, provided the following updates:

- **Chikungunya virus: Transmission Reported in the Western Hemisphere.**
 - Last Friday, WHO reported the first cases of chikungunya fever in the Americas, involving a cluster of cases (first thought to be part of a dengue outbreak) on the French side of St. Martin. As of December 10, the Institut Pasteur had reported 2 confirmed cases, 4 probable cases, and 20 suspected cases. Control measures include destroying mosquito breeding sites and advising people about protecting themselves from mosquito bites.
 - Over the past few years, CDC has been working with PAHO to prepare public health laboratories for the possible introduction of chikungunya virus into the Americas. Activities included

⁷ Smith JS, Moses S, Hudgens MG, et al. Increased risk of HIV acquisition among Kenyan men with human papillomavirus infection. *J Infect Dis* 2010;201(11):1677-85.

⁸ Houlihan CF, Larke NL, Watson-Jones D, et al. Human papillomavirus infection and increased risk of HIV acquisition. A systematic review and meta-analysis. *AIDS* 2012;26(17):2211-22.

- providing trainings and proficiency evaluation programs, building a stockpile of laboratory reagents, and developing and evaluating new protocols for PCR and serologic testing.
- The intercontinental spread of chikungunya fever highlights the need to maintain U.S. surveillance for mosquito-borne diseases (i.e., via ArboNet), despite cuts in public health funding. In the United States, the chikungunya virus can be transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes, whose range includes parts of the U.S. southeast.
- **Dengue Virus: rRT-PCR Assay**
 - The DENV-1-4 rRT-PCR assay developed at CDC is the only FDA-approved molecular diagnostic assay for dengue fever. It detects all four dengue serotypes, in serum and in plasma, and runs on the same diagnostic equipment as CDC's RT-PCR assays for influenza.
 - Since June 2013, CDC has distributed 291 test kits in the U.S. and 238 internationally. At the present time, more than 110 laboratories are running the assay in 48 countries.
 - PAHO is sponsoring a dengue diagnostic course for national laboratories and has approved funds to assist countries in implementing the assays. All Regional WHO Reference Labs have incorporated the assay.
 - Private companies might be interested in manufacturing the assay for clinical use in the detection of acute dengue infection. At the present time, a pharmaceutical company is planning to use the assay in Phase 3 Trials of a new dengue vaccine.
 - **Antibiotic Resistance.** The new CDC report *Antibiotic Resistance Threats in the United States, 2013* (<http://www.cdc.gov/drugresistance/threat-report-2013/>) provides a comprehensive analysis of serious drug-resistant threats that each year sicken an estimated 2 million people and kill at least 23,000. With the assistance of the BSC Antimicrobial Resistance (AR) Workgroup (page 21), the 18 most important AR threats have been ranked as *urgent*, *serious*, or *concerning*. To address these threats, the report identifies steps for preventing drug-resistant infections, tracking their spread, improving antibiotic use, and developing new drugs and diagnostics.
 - **Heartland Virus Infection.** The new tickborne infection caused by the Heartland virus is a classic example of an emerging infection. Although the first cases (discovered in Missouri) were originally thought to be the result of infection with *Ehrlichia* bacteria, whole-genome sequencing (WGS) led to identification of a new virus as the causative agent. CDC has developed PCR-based diagnostic tests for the Heartland virus and disseminated them to the Missouri Department of Health, which is conducting hospital-based surveillance for additional cases.
 - **Salmonella Heidelberg Outbreak.**
 - The 2013 *Salmonella* Heidelberg outbreak affected 23 states and Puerto, with the greatest number of cases (74%) in California; 38% of ill persons have been hospitalized, and no deaths have been reported.
 - Epidemiologic, laboratory, and trace back investigations conducted by local, state, and federal officials indicate that consumption of Foster Farms brand chicken is the likely source of the outbreak.
 - The outbreak strains of *Salmonella* Heidelberg are resistant to several commonly prescribed antibiotics. Although these antibiotics are not typically used to treat *Salmonella* bloodstream infections or other severe *Salmonella* infections, antibiotic resistance can increase the risk of hospitalization in infected individuals.
 - **Monkeypox Outbreak**
 - Since the first cases were reported in October 2013, a monkeypox outbreak in the Democratic Republic of the Congo (DRC) has caused 65 suspected cases, including 8 deaths. Last month, the

- DRC National Laboratory in Kinshasa reported that 24 out of 25 clinical specimens tested positive using an orthopoxvirus-specific PCR assay developed by CDC in collaboration with a private sector partner.
- Since November 30, a CDC response team has been assisting the DRC Ministry of Health in defining the extent of the outbreak and recommending control measures in community and health care settings.
- **National Healthcare Surveillance Network (NHSN).**
 - NHSN receives data on healthcare-associated infections (HAIs) from thousands of hospitals and provides quarterly reports to CMS for use in their Inpatient Quality Reporting program. Nearly all participating facilities (about 12,000) met the November 15, 2013, deadline for reporting central line-associated bloodstream infections, catheter-associated urinary tract infections, and/or surgical site infections. This data will be posted on the CMS Hospital Compare website (<http://www.medicare.gov/quality-care-finder/>). Starting next month, hospital-specific data on methicillin-resistant *Staphylococcus aureus* (MRSA) and *C. difficile* infections will also be included.
 - CDC continues to work with CMS to offer incentives for electronic (as opposed to manual) reporting and to provide hospitals with tools and resources to help them integrate their electronic reporting systems with NHSN.
 - **Rocky Mountain Spotted Fever (RMSF).** Project RMSF Rodeo is an integrated pest management program implemented on tribal lands in Arizona to reduce an increased incidence of RMSF. The 2-year project—which combines health education, use of pesticides and tick collars, and efforts to control the dog population—has achieved a sustained reduction in brown dog ticks, leading to fewer fatal human cases of RMSF. CDC is planning to work with two additional reservations in 2014.
 - **Valley Fever.**
 - More than 20,000 cases of Valley Fever (VF) were reported in 2011, which represents a ten-fold increase in reported cases since 1998. Twenty-eight states have reported cases, with the majority in California and Arizona.
 - In September 2013, CDC participated in a 2-day symposium on VF in Bakersfield, California, on disease trends and solutions (<http://www.cdc.gov/features/valleyfevercalifornia/>).
 - Current CDC activities include enhancing VF surveillance; deploying an Epi-Aid team to investigate VF outbreaks in the California prison system; and identifying potential sites for conducting an NIH-sponsored clinical trial to determine whether early antifungal treatment improves outcomes of primary VF pneumonia.
 - **Culture-Independent Diagnostic Technologies (CIDT).**
 - Diagnostic testing of cultured pathogens (culture-dependent testing) is a basic public health tool, used by PulseNet and other public health programs to monitor disease and drug resistance and track the progress of disease prevention efforts. At the present time, however, these tests are being replaced by rapid, sensitive molecular diagnostic tests that do not involve growing organisms in culture.
 - Until these new, culture-independent diagnostic technologies (CIDT) are adapted to public health purposes, there is concern that (due to lack of isolates for culture-based testing) public health agencies, regulators, and industry partners will not have the information needed to detect foodborne outbreaks, monitor trends in antibiotic resistance, or assess threats posed by new pathogens or new drug-resistant strains.
 - CDC and partners are working toward solutions to bridge this gap. The short-term goal is to preserve public health capacity to obtain clinical isolates by building state-level capacity to

culture CIDT positives and working with industry and regulatory partners. The long-term goal is to adapt CIDT methods for public health purposes. This involves, for example, building a new infrastructure for PulseNet, based on WGS techniques, and developing metagenomic methods for identifying and characterizing pathogens in stool (see pages 14 and 50).

Note: CIDT issues were also discussed by the FSMA Surveillance Workgroup (page 17-19) and during the discussion of CDC's AMD activity (page 48).

- **External Review of the *Emerging Infectious Diseases (EID) Journal.*** A report describing the conclusions of an November 2013 external review of CDC's *EID* journal will be shared with CDC leadership in early 2014. Preliminary conclusions were
 - The linkage between CDC and *EID* benefits both. *EID* provides a way for CDC to demonstrate leadership in the field of infectious diseases, while the CDC brand reinforces *EID*'s reputation for high quality
 - *EID* is not broken, and does not need to be "fixed," but CDC should not be complacent. Improvements and modernization are needed to maintain *EID*'s high ranking among open-access infectious disease journals. To ensure continued success, *EID* should pursue forward-thinking strategies that
 - Use electronic devices and innovations to engage the next generation of public health practitioners
 - Keep *EID* at the forefront of efforts to increase the accessibility, timeliness, and quality of data on infectious diseases
- **Distinguished Honor Awards**
 - The CDC Multistate Outbreak of Fungal Meningitis and Other Infections Response Team received the Samuel J. Heyman Service to America (Sammie") Medal during a White House ceremony, as well as an HHS Distinguished Service Award
 - The CDC Dengue Branch, Division of Vectorborne Diseases, also received the HHS Distinguished Service Award, for its work on detection and prevention of dengue.

DISCUSSION: NCEZID UPDATES

Mosquito Control and Budget Issues

- U.S. mosquito control efforts have been decreasing for some time, due to tighter local budgets. CDC does not fund local mosquito control. CDC's vectorborne funding, which supports integrated surveillance in state health departments among other functions was reduced several years ago and again in FY 2013 as part of sequestration.
- Dr. Bell said that (as public health needs increase and budgets decrease) CDC must focus on maintaining laboratories and extramural programs. The President's FY14 budget request for CDC includes increased funding for NHSN and food safety, as well as the AMD initiative.
- It was suggested that CDC combine data on the U.S. burden of all mosquito-borne diseases to determine level of morbidity and mortality due to those diseases. Dr. Bell agreed that combining CDC's surveillance summaries for these diseases is a powerful idea.
 - Dr. Jeffrey Engels, CSTE Executive Director, said that a CSTE state-level survey found a marked reduction in West Nile virus (WNV) surveillance at state and local health departments, including health departments in states with the highest rates of WNV disease (<http://www.cste2.org/docs/VBR.pdf>; and http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a2.htm?s_cid=mm6313a2_w).

- It was suggested that the BSC or another group of advisors, such as the President’s Council of Advisors on Science and Technology (PCAST),
 - Describe the trade-offs involved in making cuts to CDC’s budget (e.g., de-funding Project Rodeo would mean accepting deaths from RMSF)
 - Provide analyses of health impact as the basis for funding decisions

Culture-Independent Diagnostic Technologies

- Culture-independent tests, such as multiplex assays for respiratory pathogens, are increasingly being used in clinical laboratory settings, providing increased sensitivity and lower labor costs.
- Interim bridging strategies are needed to prevent disease surveillance gaps as public health laboratories transition from culture-dependent to culture-independent tests. One strategy is to have diagnostic companies include specimen vials in PCR kits, with instructions for taking a specimen if the PCR test result is positive. Hospital laboratories could then send these positive specimens to state health laboratories for culture-based testing and strain-typing.
- It was suggested that future PCR tests might include primers useful for strain-typing as well as diagnosis. (See also page 19.)
- Next generation sequencing is becoming an important tool, and its cost is plummeting. However, most state and local health departments lack the computer and workforce capacity to analyze the very large amount of data generated by these tools. Developing a reproducible, inexpensive way to identify and sequence the genome of a bacterial pathogen, starting from a stool sample, is the object of an XPrize competition (see page 50).
- In regard to how greater use of CIDT is affecting public health surveillance, Dr. Bell reported that FoodNet sites are already receiving fewer samples—a trend that is expected to increase over the next two years. Samples identified as positives by CIDT do not meet disease surveillance case definitions.
- In addition, the genomes of viruses and bacteria are constantly changing, and molecular diagnostic tests will have to change over time to reflect this.
- Dr. Larry Granger, Director, [Centers for Epidemiology and Animal Health, USDA Animal and Plant Health Inspection Service \(CEAH/APHIS\)](#), noted that CIDT issues are also relevant to USDA’s surveillance work, as well as USDA’s investigations of veterinary outbreaks.

AR Issues Associated with the *Salmonella* Heidelberg Outbreak.

- In regard to the extent to which drug-resistant *Salmonella*, such as the strains associated with the recent *Salmonella* Heidelberg outbreak, are related to the use of antibiotics on the farm, Dr. Bell said that specific information about antibiotic use practices on farms or by particular companies is not generally available. However, in general we know that the widespread use of antibiotics in food animals promotes resistance. Food animals serve as a reservoir of resistant pathogens and resistance mechanisms that can directly or indirectly result in antibiotic resistant infections in humans.
- In regard to whether federal laws should be changed to make industry practices more transparent, Dr. Bell said that industry partners have already started changing the way they use antibiotics, aware that improvements are in their own interest (as well as in the interest of retail outlets). CDC may be in a unique position to help, because it is not a regulatory agency.

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

Dr. Jim Hadler reviewed the history of the FSMA Surveillance Working Group, which was established in 2011 under the Food Safety Modernization Act and charged with providing advice and recommendations to CDC, FDA, and (through them) DHHS on:

- Criteria for the designation of Food Safety Integrated Centers of Excellence (accomplished in 2012)
- Ways to improve foodborne illness surveillance (ongoing)

The 21 working group members include representatives from the BSC, CDC, USDA, FDA, academia, consumer groups, industry, and state and local health organizations, whose responsibilities include developing and submitting an annual report to the HHS Secretary.

Dr. Hadler reported on the outcomes of the working group's meeting on December 8 and 9, as well as on their 2013 Annual Report.

December 8-9 Meeting

The December meeting focused on norovirus infections and included discussion of the CDC *Listeria* WGS Surveillance Project.

1) Guidance on surveillance, prevention, and control of norovirus

Background on Norovirus. Over the past 10 years, the development and use of diagnostic tests for norovirus has led to a growing recognition of their public health impact. The U.S. Gastroenteritis Virus Surveillance System has three major components:

- The National Outbreak Reporting System (NORS; www.cdc.gov/nors/), which conducts epidemiologic surveillance for enteric disease outbreaks
- CaliciNet, a network of state and local public health laboratories, which uses sequence-based typing to characterize outbreak-associated norovirus specimens
- New Vaccine Surveillance Network (NVSN; www.cdc.gov/surveillance/nvsn/), which conducts active, population-based surveillance for acute gastroenteritis at hospitals and emergency departments

Data from these sources have provided a better (and unexpected) picture of norovirus disease burden, epidemiology, and patterns of transmission:

- An estimated 19-21 million cases of norovirus infection occur in the U.S. each year, causing 570-800 deaths. Most outbreaks are spread from person to person in healthcare facilities (64%), and about 19% are transmitted via contaminated food.
- According to NORS data for 2009-10, norovirus is responsible for 79% of enteric illnesses, 65% of enteric disease outbreaks, 41% of hospitalizations due to enteric illness (36% is due to *Salmonella*), and 84% of deaths due to enteric illness.
- One genotype—GII.4—is responsible for most norovirus outbreaks. Most GII.4 outbreaks occur during the winter months in healthcare facilities, causing elevated rates of hospitalization and death in persons greater than 65 years of age. A small number of outbreaks are caused by non-GII.4 genotypes; these foodborne outbreaks are often associated with restaurants or schools, affecting younger persons and causing fewer severe outcomes.
- Even though norovirus is not primarily foodborne, it is the most common cause of foodborne illness (as well as the most common cause of acute viral gastroenteritis) in the United States, responsible for >50% (5.5 million cases) of all foodborne disease every year. It may also turn out to be a significant cause of foodborne disease of unknown etiology.
- A wide range of foods have been implicated in norovirus outbreaks--the most common being leafy vegetables and the next most common being fruits, nuts, and mollusks. Most outbreaks are due to contamination during preparation and service rather than during production and processing—a finding which suggests that strategies to prevent norovirus outbreaks might involve modification or regulation of food preparation practices.

Working Group Advice on Norovirus Surveillance. The Workgroup addressed the following questions about norovirus surveillance:

- *How can norovirus illness and outbreak surveillance, investigation, and data collection be improved?*
The working group recommended that CDC prioritize resources by focusing on sentinel surveillance sites in a few states; maintaining and improving complaint-based surveillance systems; and providing training and education to state and local health departments (e.g., on best practices for assessing norovirus exposures, for proper sample handling and collection, and for communications and outreach). CDC should also strengthen existing surveillance tools and systems, including NORS, CaliciNet, and NoroSTAT,⁹ and standardize procedures for data collection and reporting.

The working group also recommended that HHS agencies conduct 1) environmental assessments to determine the points at which food is contaminated, the percentage of contamination that occurs pre-retail, and the role of aerosolization in viral transmission; 2) attribution studies to learn more about potential sources of food contamination; 3) outbreak investigations that focus on identification of norovirus risk factors and optimal control measures; and 4) evaluations of the role of syndromic surveillance in detection of norovirus outbreaks.

- *What is the utility (and future prospects) for norovirus testing in environmental and food samples for outbreak surveillance?*

Because norovirus testing of environmental and food samples is not standardized, the Workgroup recommended that interpretation of test results be approached cautiously. However, in some situations food-testing data—as well as testing of environmental samples—may be useful in supporting outbreak investigations.

- *How can we improve the data collected to inform source attribution?*

The working group recommended that in-depth studies be conducted in a few states to assess the proportion of illness due to contaminated food or contact with ill food-workers in retail settings. More research is needed to determine the highest risks associated with particular foods, food preparation techniques, and to identify food characteristics and transmission.

The working group also recommended that CDC improve linkages among NORS, CaliciNet, and NVSN.

Working Group Advice on Norovirus Prevention and Control. The working group suggested that

- More research is needed on disinfectants, most of which may be ineffective against norovirus
- Norovirus vaccines may become available within 5-10 years. Challenges to vaccine development include genetic drift and multiple strains. Not enough is yet known about risk groups to target future prevention efforts using vaccines.

In conclusion, the working group noted that norovirus may be “the perfect foodborne pathogen.” It is highly infectious, spreads rapidly and efficiently by a variety of routes, is environmentally stable and resistant to many sanitizers and processing technologies, is constantly evolving, evokes a limited immune response, and is only moderately virulent.

2) The *Listeria* WGS Surveillance Project

CDC’s laboratory strategy for transitioning from culture-dependent testing to CIDT includes

⁹ NoroSTAT—the Norovirus Sentinel Testing and Tracking network—is a sentinel surveillance network of state health departments.

1. Preserving cultures to support continued short-term use of current methods for disease surveillance (e.g., serotyping, antibiotic sensitivity testing [AST], PFGE, and multiple-locus variable-number tandem repeat analysis [MLVA]);
2. Developing public health capacity to use WGS-based diagnostics for surveillance, using cultured pathogens; and
3. Transitioning to metagenomic techniques that do not require growing pathogens in culture.

CDC established the *Listeria* WGS Surveillance Project as a proof-of-concept project to demonstrate real-time use of WGS in disease surveillance. Its goal is to use WGS in parallel with current PulseNet strain-typing methods based on PFGE, characterizing all clinical isolates of *Listeria* in the U.S. during a 1-year period. The project includes epidemiologic follow-up of disease clusters detected through either WGS or PFGE.

The *Listeria* WGS Surveillance Project is designed to answer the following questions:

- Is it possible to sequence all *Listeria* isolates and analyze the sequence data in real-time?
- Which DNA targets have the strongest concordance with epidemiologic factors?
- How can clusters be defined, tracked, and monitored in real-time, using WGS?
- How can strains and isolates be tracked over time, using WGS?
- Which bioinformatics tools and approaches work most efficiently for outbreak detection, delineation, and control?
- Are WGS techniques both fast and accurate?
- How does WGS-based data compare to PFGE data?

Dr. Hadler reported that the preliminary results of this project suggest that WGS duplicates—and can eventually replace—PFGE-based surveillance for *Listeria*.

2013 ANNUAL REPORT

As part of its charge, the FSMA Surveillance Working Group completes and approves an Annual Report each November that is presented to the BSC members for consideration at the December BSC meeting. Pending BSC endorsement, this year's report will be sent to the HHS Secretary in early 2014.

Key topics covered in the 2013 Annual Report include

- Utilizing meaningful performance measures for foodborne illness surveillance
- Responding to public health challenges resulting from the increasing use of CIDT

The report also includes appendices that list CDC accomplishments in implementing FSMA surveillance requirements and describe selected multistate outbreaks of foodborne illness.

Utilizing meaningful performance measures for foodborne illness surveillance. The 2013 Annual Report states that the FSMA Surveillance Working Group

- *Endorses use of meaningful foodborne illness surveillance performance measures at the local, state, and federal levels to: (1) Show progress in reducing foodborne illness, (2) Identify the best evidence-based public health practices; and (3) Encourage programmatic accountability.*
- *Emphasizes the importance of metrics to: (1) Quantify the impact of programs, policies, and regulatory changes; (2) Encourage programmatic accountability; and (3) Track progress and improvements in food safety.*

The Working Group also suggested that

- Performance measures should be prioritized based on the burden and severity of specific diseases and on capacity to collect the data necessary for attributing foodborne diseases to particular food sources

- Implementation in low-resource states could be facilitated by partnering with high-performance states (e.g., Centers of Excellence); linking use to health-department accreditation, and using incentives linked to improvement

Public health challenges due to increased use of CIDT. The FSMA Surveillance Working Group identifies the transition to CIDT as a critically important area requiring national attention. Although the increased use of CIDT in clinical settings offers many advantages, it also presents significant challenges to laboratory-based disease surveillance. In particular, it will result in a dramatic reduction in the number of isolates sent to PulseNet to facilitate detection of outbreaks associated with widely-distributed contaminated foods.

The Working Group therefore recommends the development of a comprehensive strategy for using CIDT to meet public health needs. Its short-term goal should be to maintain culture-based testing for foodborne disease surveillance during the transition to CIDT. Its longer-term goal should be to identify, standardize, and implement public health use of next-generation molecular diagnostic technologies. Achievement of the long-term goal will also require development of public health capacity in bioinformatics.

To advance these activities, the Working Group recommends

- **Short Term Actions:** *Provide resources to state and local public health agencies and laboratories to*
 - Preserve isolates
 - Adapt disease surveillance mechanisms to incorporate new diagnostic methods and technologies
 - Enhance disease surveillance by improving capacity to assess disease exposures (e.g. via improved food histories, environmental assessments of contributing factors, etc.)
- **Long Term Actions:** Invest in infrastructure and research to
 - Develop new molecular methods for disease surveillance (e.g., “NextGen” techniques for PulseNet)
 - Modernize foodborne illness surveillance systems, incorporating new molecular methods for detection of foodborne pathogens

The agenda for the May 2014 meeting of the FSMA Surveillance Working Group will include updates and a discussion of surveillance for drug-resistant foodborne pathogens.

DISCUSSION: FSMA SURVEILLANCE WORKGROUP

CIDT

- In the future, CIDT methods will be used for strain-typing as well as diagnosis. CDC might consider issuing an RFP for the development of molecular typing methods to fill gaps in this area.
- At the present time, CDC and other groups are also considering CIDT issues.

Comments on the Draft Annual Report:

- To make the report less passive in tone, the recommendations should state which agency is responsible for implementing recommended actions and/or which funding mechanisms should support them. Dr. Hadler noted that the Working Group may not request resources for CDC and that the phrasing in the report must reflect that limitation.
- It was suggested that the BSC endorse the recommendations, as they are, and provide a cover letter or appendix that lists strategies in a more direct, prescriptive way. The cover letter might state that there is a need for resources to fulfill the report’s recommendations.
- Table 1 should be reworded to identify some short-term “challenges” (e.g., use of CIDT) as opportunities for the long term.

Dr. Goodman agreed that the report should emphasize that CIDT are a positive development and that the Working Group's goal is to suggest which issues must be addressed to ensure the development of a modernized disease surveillance system that meets (and optimally exceeds) the capabilities of current ones. Dr. Khabbaz added that the report should stress that old public health systems must not be allowed to fail as new ones are developed.

Surveillance of Disease Associated with Imported Food

- The Annual Report does not include recommendations on prevention of outbreaks caused by contaminated foods imported into the United States. Dr. Hadler noted that this topic is on the list of issues to be addressed in depth at future Working Group meetings.
 - Dr. Dale Morse, Senior Advisor, CDC Division of Foodborne, Waterborne, and Environmental Diseases, reported that more than 15% of U.S. food is imported, including more than 80% of seafood, 20% of vegetables, and 40% of fruits and nuts. Recent multistate outbreaks of foodborne disease have often involved imported foods (e.g., mangoes, papayas, pepper, tahini sesame paste, pomegranate seeds).
- One of the aims of FSMA is to give FDA additional authority to ensure the safety of imported food. However, it is often difficult to identify the source of a contaminated food product. CDC is currently working with FDA and USDA to gain greater access to data that would help in making these identifications.

Note: The 2014 Annual Report was endorsed on the second day of the BSC meeting (see page 38).

➤ **Antimicrobial Resistance (AR) Working Group**

Dr. Robert Weinstein, Systems Chair and Department Chair, Department of Medicine, Cook County, Health and Hospitals System, reported on issues discussed at the December 10 AR Working Group meeting, which included discussions on 1) surveillance, prevention, and control of carbapenem-resistant Enterobacteriaceae (CRE) and 2) antimicrobial stewardship.

1) CRE

CRE Diagnostics and Surveillance. Dr. Weinstein noted that CRE presents a complex problem. Whereas MRSA involves one bacterial species and a single resistance gene with a small number of alleles, CRE involves several common bacterial species—e.g., *E. coli*, *Klebsiella*, and *Enterobacter*—and at least three paths to resistance:

- Intrinsic resistance, due to chromosomal resistance genes (e.g., AmpC)
- Plasmid genes that encode carbapenemases (a type of β -lactamase). Examples include the *Klebsiella pneumoniae* carbapenemase (KPC) gene and the New Delhi metallo- β -lactamase 1 (NDM-1) gene.
- Plasmid genes that encode other β -lactamases (e.g., ESBLs) that can cause carbapenem resistance in bacteria by working in concert with chromosomal mutations that remove or alter porin membrane proteins, making it more difficult for antibiotics to enter the cell.

In addition, there are many permutations of bacterial species and carbapenemase or β -lactamase genes.

According to NHSN, the percentage of short-stay hospitals that reported more than one case of CRE involving catheter-associated urinary tract infections or central line-associated bloodstream infections between January and June 2013 was 3.9%. However, the percentage of long-term care facilities that reported cases of CRE within that timeframe was 17.8%. According to data from the Emerging Infections Program (EIP), CRE prevalence is currently tenfold lower than MRSA—which suggests that there is still time to stop the spread of CRE by implementing interventions at long term care facilities.

CRE detection and surveillance is complicated by the wide array of CRE, not all of which meet current CDC case definitions for reference testing. In addition, different professionals require different types of surveillance data. For example,

- Clinicians need to know the phenotype of the causative agent (i.e., whether it is susceptible to carbapenems) in order to make treatment decisions
- Infection control practitioners need to know whether hospital patients are colonized by carbapenemase-producing CRE in order to control and prevent hospital outbreaks
- Public health epidemiologists need to know which carbapenemases are being produced by CRE in order to identify new or emerging types of CRE

Methods for detecting carbapenemases include tests that detect carbapenemase activity (e.g., nitrocefin-based and mass-spectroscopy-based tests) and PCR tests (including a test that can distinguish among KPC, NDM, and OXA-48 carbapenemases). In the future, the AR Working Group may review issues related to AR molecular diagnostics in collaboration with the new BSC Infectious Disease Laboratory Workgroup (page 47).

CRE: Prevention and Control. As noted above, action taken now—while CRE levels are relatively low—could stop CRE before it becomes widespread. Dr. Weinstein recalled that early interventions to reduce the spread of vancomycin-resistant enterococci (VRE) by the Siouxland District Health Department in Sioux City, Iowa, prevented regional disease spread in the late 1990s, while VRE prevalence was still low.¹⁰

The 2012 CRE Toolkit *Guidance for Control of Carbapenem-Resistant Enterobacteriaceae* (http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html?s_cid=fb2214) provides recommendations for acute- and long-term care facilities and outlines a regional prevention strategy for implementation by state and local health departments. Recommended core control measures include hand hygiene, contact precautions, education for healthcare providers, minimizing the use of devices associated with HAIs, inter-facility data-sharing of CRE screening results, and improved antimicrobial stewardship (see below). Supplemental control measures include active surveillance involving patient cultures and daily bathing of patients with chlorhexidine.

The goal of the regional CRE prevention strategy is prevention of inter-facility transmission of CRE among acute care hospitals, long-term care facilities, and nursing homes, coupled with enhanced disease prevention measures in long-term care facilities. In 2013, CDC funded three state-coordinated regional CRE prevention programs (in Oregon, Utah, and Michigan), and CDC and NACCHO funded four local health department efforts (in Milwaukee, Philadelphia, DuPage County [IL], and Livingston County [MI]). The Oregon Health Department, for example, instituted the Drug-Resistant Organism Prevention and Coordinated Regional Epidemiology Network (DROP-CRE), which combines rapid diagnostic testing and response to outbreaks; monthly posting of epidemiologic reviews of CRE cases, including information on inter-facility spread; a statewide education campaign; and a CRE toolkit tailored to Oregon responders.

In summary, CDC's goals for CRE prevention are to

- Promote and conduct CRE surveillance in the United States.
- Identify effective definition(s) for CRE surveillance and prevention

¹⁰ Sohn AH, Ostrowsky BE, Sinkowitz-Cochran RL, Quirk SB, Jarvis WR. Evaluation of a successful vancomycin-resistant Enterococcus prevention intervention in a community of health care facilities. *Am J Infect Control* 2001;29(1):53-7.

- Promote identification and dissemination of laboratory techniques for efficient detection and categorization of CRE
- Promote prevention of CRE transmission within and between healthcare facilities
- Support established prevention practices
- Support and identify novel approaches to prevention

Over the next year, the AR Workgroup will try to help move this agenda forward.

2) Antimicrobial Stewardship.

Goals and Action. CDC has developed three goals for improving antimicrobial stewardship:

Goal 1: Monitor and conduct surveillance of both antimicrobial use and the implementation of stewardship activities in the U.S.

Actions:

- Measure antimicrobial use nationally and in individual states
- Develop national and state goals for improvements/reductions in antibiotic prescribing
- Assure continual improvement in clinical lab capacity to accurately and rapidly identify resistant microorganisms, including the accelerated adoption of proven new technologies
- Develop and implement measures of the appropriate antimicrobial prescribing
- Measure the implementation of appropriate stewardship efforts in inpatient settings

Goal 2: Strengthen the scientific base for implementation and evaluation of antimicrobial stewardship activities

Actions:

- Better characterize the appropriateness of antibiotic prescribing according to diagnosis, provider type, and setting for both inpatients and outpatients
- Continue to refine, develop, implement and evaluate specific tools and processes for implementing stewardship activities in all HC settings
- Identify success metrics for each healthcare settings, including process and outcomes measures

Goal 3: Create an expectation that all healthcare providers and organizations will practice stewardship

Actions:

- Continue to aggressively promote communication to both professional and general audiences
- Work with regulators, accreditors, and payers and state health departments to make stewardship activities part of licensing/accreditation/reimbursement
- Promote training and education (e.g., GET SMART) regarding AR across multiple healthcare professions disciplines

In regard to improving surveillance for antibiotic usage (Goal 1), Dr. Weinstein noted that the United States as a whole uses 1-10 times as much antibiotics as the Netherlands. U.S. usage varies by state, with physicians in the highest-use states issuing an average of more than 1 prescription per person each year. Some regional differences may be related to different prescribing practices facilitated by local health insurance plans.

Antimicrobial Stewardship: Educational Activities. Dr. Weinstein reviewed educational activities undertaken as part of *Get Smart about Antibiotics Week* 2013, which included

- Publication by AAP and CDC of “Principles for Antimicrobial Use” in the journal *Pediatrics*:¹¹
 - **Principle 1:** Determine the likelihood of a bacterial infection
 - **Principle 2:** Weigh benefits vs. harms of antibiotics
 - **Principle 3:** Implement judicious prescribing practices
- Recruitment of new partners and new state health departments (especially in high-use areas)
- Hosting CDC Public Health Grand Rounds on “Combating Resistance: Getting Smart About Antibiotics” (<http://www.cdc.gov/about/grand-rounds/archives/2013/November2013.htm>)
- Completion of two Twitter chats on judicious use of antibiotics

Antimicrobial Stewardship Recommendations. CDC’s key recommendation is that all hospitals take action to improve antibiotic use by implementing an antimicrobial stewardship program that will

- Implement policies and interventions to improve antimicrobial use
- Monitor the use of antimicrobial drugs
- Educate providers on optimal antibiotic use and issues in antibiotic resistance

CDC has also proposed development of an Antimicrobial Stewardship checklist for healthcare facilities that includes the following questions:

1. Does this facility have a physician leader identified to optimize antibiotic use?
2. Does this facility have a pharmacist leader identified to optimize antibiotic use?
3. Does facility leadership support efforts to optimize antibiotic use at this facility?
4. Is there at least one intervention to optimize antibiotic use integrated into clinical care at this facility?
5. Does this facility monitor antibiotic use?
6. Is information on optimizing antibiotic use provided to prescribers at least annually?

CDC plans to publish a *Vital Signs* on inpatient antimicrobial use in March 2014.

Next Steps. The AR Working Group plans to hold two conference calls between now and May to review CDC updates on 1) CRE detection and control; 2) AR diagnostics and CDC’s role in increasing national laboratory capacity for AR detection and characterization; 3) promoting interventions to decrease AR; and 4) AR issues related to the animal-human interface. The animal-human interface discussion may include the members of the FSMA Surveillance Workgroup.

DISCUSSION: AR WORKGROUP

Dr. Khabbaz thanked the AR Working Group for ranking the threats in the landmark report on AR (page 11).

CRE Surveillance

- Dr. Weinstein noted that most CRE outbreaks in the United States are due to bacteria that produce carbapenemases (e.g., KPCs or NDMs) rather than to bacteria that have other CRE resistance mechanisms. (NDMs move among species, while KPCs are more clonal, with one major strain type.)
- CRE surveillance requires clear definitions that specify which types of CRE should be reported and which CRE isolates should be collected for surveillance purposes. The CSTE HAI Steering Committee has established a CSTE/CDC workgroup to standardize laboratory testing techniques for AR. CRE case definitions and a position statement will be proposed at the CSTE annual meeting in June.

¹¹ Hersh AL, Jackson MA, Hicks LA. Committee on Infectious Diseases. Principles of judicious antibiotic prescribing for upper respiratory tract infections in pediatrics. *Pediatrics* 2013;132(6):1146-54.

- Col. Kent Kester, Associate Dean for Clinical Research, Uniformed Services University of the Health Sciences, DOD, reported that DOD has begun an initiative to collect and characterize resistant pathogens, conducted in partnership with academic institutions, CDC, and other USG agencies.

Other CRE Issues

- A longitudinal study conducted in Israel found that CRE colonization can last for months to year.¹² Although colonization can be eradicated through administration of oral colistin, this treatment can disturb a person's microbiome (as in *C. difficile* patients), possibly making it easier to become re-colonized.
- In regard to whether CRE has become a “nightmare bacteria,” Dr. Weinstein said that the incidence of CRE varies widely in different states and hospitals and that CRE (at the present time) remains susceptible to colistin.

Antimicrobial Stewardship Programs

- Dr. Weinstein noted that stewardship programs usually have process-oriented goals; in most cases they measure practices and procedures rather than amounts of antibiotic use. Program goals also depend on particular infections and pathogens.
- CDC is supporting a multicenter study of a 3-day “time-out” intervention in which physicians decide on day 3 of an antibiotic regimen whether to continue or stop further antibiotic treatment. A previous HAI study on ventilator-associated pneumonia was so immediately and obviously successful that it was stopped early. Dr. Goodman said that an unpublished study that used a 2- or 3-day approach reduced vancomycin use in a hospital by 70%.
- It is unlikely that stewardship programs alone can reduce antibiotic use in high-use areas. Dr. Bell said that it may be possible to use the CMS paradigm tying performance to hospital payments (as with HAI reduction), using hospital data reported to CDC via the new NSHN module on AR use. Recognition of the high costs of treating AR infections may also drive change.
- Thus far, about 60 hospitals have adopted the new AR module, whose use requires money, electronic capacity, and motivation. NHSN is trying to make the module simpler, and some states may decide to mandate AR hospital reporting of AR infections.
- Dr. Weinstein noted that collaboration among CDC, the Healthcare Infection Control Practices Advisory Committee (HICPAC), the Society for Healthcare Epidemiology of America (SHEA), the Association for Professionals in Infection Control (APIC), and other groups helped reduce device-associated HAIs dramatically over the past decade. The major remaining HAI issues are infections with *C. difficile* and drug-resistant bacteria, including CRE.
- It is important that stewardship programs encourage participation by surgeons and oncologists

➤ **Immunization Changes at the State Level**

Dr. Anne Schuchat, NCIRD Director, reviewed the current status of U.S. immunization programs¹³ and discussed changes in state-level immunization programs that have taken place over the past few years.

¹² Oren I, Sprecher H, Finkelstein R, et al. Eradication of carbapenem-resistant Enterobacteriaceae gastrointestinal colonization with nonabsorbable oral antibiotic treatment: A prospective controlled trial. *Am J Infect Control* 2013;41(12):1167-72.

¹³ The BSC meeting binder included a copy of: Protecting the public's health: critical functions of the Section 317 Immunization Program—a report of the National Vaccine Advisory Committee. *Public Health Rep* 2013;128(2):78-95.

CURRENT STATUS OF U.S. IMMUNIZATION PROGRAMS

Dr. Schuchat reported that

- The incidence of most vaccine-preventable diseases is at record lows, due to high rates of childhood immunization
- Less than 1% of U.S. toddlers have received no vaccines¹⁴
- Many new vaccines have been introduced over the past decade, and disparities in coverage have been reduced.
- The production and availability of annual seasonal influenza vaccines have also been improved.

Sustaining these gains requires ongoing efforts by states, providers, and families. Dr. Schuchat noted that the cost of vaccinating one child with ACIP-recommended vaccines from birth through 18 years of age increased from \$70 in 1990, to \$370 in 2000, to \$1723 in 2013. Nevertheless, the return on investment in terms of lives saved and dollars gained is huge.

In terms of federal immunization resources, the Vaccines for Children (VFC) program provides approximately 50% of pediatric vaccines in the United States each year. Today, the VFC Program is funded at nearly \$4 billion. Although the VFC Program has grown over the years and new vaccines have been introduced, CDC's base discretionary funding to maintain and strengthen the immunization infrastructure has decreased, with PPHF funds, which are potentially less stable, making up the difference. (Funds from the 2009 American Recovery and Reinvestment Act were also used in one-time efforts to upgrade the U.S. immunization infrastructure.) These discretionary funds ensure we have the public health systems and workforce at the local, state, and federal levels that are necessary for achieving our national immunization goals.

In addition to purchasing and distributing publicly-purchased vaccines, public health's role in immunization includes

- Monitoring vaccine impact and strengthening the evidence base for vaccine policy and programs
- Detecting and responding to outbreaks of vaccine-preventable disease
- Improving preparedness to deliver vaccines during public health emergencies
- Improving access to quality immunization services
- Enhancing partnerships with community vaccinators and private providers
- Safely distributing public sector vaccines and managing vaccine supply disruptions and shortages.

Public health's role is also critical in addressing current priority issues, including

- A resurgence of pertussis
- Lagging HPV vaccine coverage rates
- Measles importations and outbreaks
- The short window of opportunity to leverage the electronic health record (EHR) "revolution" to improve public health
- Improvement of vaccine management and quality

CHANGES IN STATE-LEVEL IMMUNIZATION PROGRAMS

Since 2006, major changes in the immunization landscape have included the following:

¹⁴ Source: USIS (1967-1985), NHIS (1991-1993), CDC, NCHS and NIP, and NIS (1994-2012), CDC, NIP, NCHS and NCIRD; no data from 1986-1990 due to cancellation of USIS due to budget reductions.

2006-7	▪ Centralized distribution of public vaccines
2009-10	▪ Immunization against pandemic influenza H1N1
2010	▪ New immunization provisions in the Affordable Care Act (see below)
2010-2013	▪ Rollout of a new Vaccine Tracking System (VTrcks) (http://www.cdc.gov/VACCINES/programs/vtrcks/index.html)
2012	▪ Publication of VFC Program: Vulnerabilities in Vaccine Management, by the HHS Office of the Inspector General (see below) ▪ New CDC policy on use of Section 317 vaccines (see below)
2013	▪ Immunization Cooperative Agreements (2013-17) ▪ New state vaccine purchase policy (see below) ▪ Lapse in federal appropriations (government shutdown)

Dr. Schuchat provided information and updates on these and other changes:

- **Immunization Provisions in the 2010 Affordable Care Act.** Under the Affordable Care Act (ACA)
 - New health insurance plans must provide coverage for ACIP-recommended vaccines without deductibles or co-pays, when delivered by an in-network provider
 - As the new plans are written and existing plans lose their grandfathered status, the number of underinsured children and adults should decrease
 - Although some uncertainties remain, with full ACA implementation over the next several years problems in providing vaccines to underinsured children should be largely resolved
- **New CDC Policy on Use of Section 317 Vaccines.** Starting in FY2013, vaccines purchased with Section 317 funds can no longer be administered to fully-insured children (<http://aapnews.aapublications.org/content/early/2012/10/01/aapnews.20121001-1.full?rss=1>). This change, which has led to a shift in the Section 317 safety-net population from children to uninsured adults, gave rise to a number of questions about the future direction of the program. Dr. Schuchat addressed misunderstandings about the policy, stating that
 - CDC remains committed to childhood immunization. Section 317 will continue to provide funding for the essential public health systems and workforce that support childhood immunization, regardless of who pays for the vaccine.
 - The Vaccines for Children Program and healthcare reforms from the ACA should make vaccines accessible to children, so that Section 317 vaccines can be directed to the uninsured and for use in outbreak response.

Although we anticipate changes in the role of public health in delivering immunization services following full implementation of the ACA, public health will continue to play a major role in

- Building and maintaining the public-private partnership of immunization providers to advance quality assurance, provider education, and the use of immunization information systems
- Providing evidence-based immunization policy that allows us to understand disease burden and assess vaccine risks and benefits
- Conducting surveillance for disease and for safety, as well as for coverage
- Fostering multi-sector partnerships and coalitions to broaden access and awareness
- Responding to outbreaks to protect public health

- **Modernizing Immunization Practices.** A CDC priority for immunization is enhancing information technologies to improve immunization practices, including clinical decision-making, vaccine inventory management, and accountability. CDC investments include efforts to improve interoperability of information systems, including barcoding, EHR, Immunization Information Systems (IIS), and the CDC vaccine ordering and tracking system (VTrckS). The nation has a unique opportunity to leverage health information technologies and systems to meet national immunization goals. As described earlier (see page 8), CDC is developing an IIS Strategic Plan and has established an intergovernmental IIS Executive Board to help CDC prioritize its health IT efforts for immunization.

Note: Efforts to modernize immunization practices were also discussed as part of the NCIRD updates (page 7).

- **2012 OIG Report: VFC Program: Vulnerabilities in Vaccine Management.** This report (<http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>) highlights areas for improvement in the VFC Program in the areas of vaccine storage and handling, inventory management, and accountability.

In response, CDC established an internal steering committee that has identified gaps in the VFC Program. CDC is working to address these gaps through policy changes, scientific and technological research, and education and training. CDC has also entered into agreements with

- The National Institute of Standards and Technology (www.nist.org/) to develop protocols for identifying and operating cold-chain equipment that monitors temperature on a continuous basis and for storing and transporting frozen and refrigerated vaccines.
- NSF International (<http://www.nsf.org/>) to develop standards for vaccine storage units (refrigerators and freezers) and to assist providers in identifying certified vaccine storage units and assessing future technologies to address vaccine storage and handling concerns.

- **New State Vaccine Purchase Policy.** Beginning in FY 2014, CDC made a change in the way that state-funded vaccine purchases are made from the CDC vaccine contracts. This change affected vaccines funded by state appropriations, the Children’s Health Insurance Program (CHIP), and pooled insurance programs. With the decreasing amount of federal Section 317 vaccine purchases and the increasing amount of state-funded vaccine purchases, CDC could no longer provide “advanced credit” with Section 317 for state-funded purchases. This practice allowed states access to state-funded vaccine in advance of having state funds to pay for the vaccines. Starting in FY 14, states are required to provide payment before submitting vaccine orders. This change created considerable communications and program challenges, which were addressed through system changes and outreach and dialogue with key stakeholders, including immunization programs, state and local health officials, and professional associations. As a result of the considerable efforts made to implement this change, CDC was able to continue processing states’ vaccine orders despite the lapse in federal appropriation (the government shutdown) during the first 3 weeks of FY 2014.

- **VPD Laboratory Reference Centers.** As part of the trend towards greater laboratory regionalization, the Association of Public Health Laboratories (APHL; www.aphl.org/) and CDC have worked with the states to establish regional VPD Reference centers, including:
 - Bacterial and viral testing centers in Minnesota and Wisconsin. The Wisconsin reference center also provides test-proficiency panels
 - Viral testing centers in California and New York State

The viral testing centers can subtype viruses that cause measles, mumps, rubella, varicella-zoster, and rotavirus; the bacterial testing centers can identify and characterize bacteria that cause infections with

B. pertussis, *S. pneumoniae*, *N. meningitidis*, and *H. influenzae*. To date, 30 state laboratories and 9 local public health laboratories have enrolled as “submitting sites” in the regional VPD Laboratory Center program. Shipping and testing costs are supported by the CDC Immunization Cooperative Agreement.

- **Performance Evaluation Panels.** A bacterial Meningitis Performance Evaluation Exercise involving 12 state laboratories was held in April 2013, and a Measles/Mumps Performance Evaluation Panel exercise involving 45 laboratories was held in September 2013. All laboratories that completed the measles/mumps exercise passed with scores of 90% or greater.

CDC IMMUNIZATION PRIORITIES FOR FY2014

CDC’s immunization priorities are

- Preserving core public health immunization infrastructure at local, state, and federal levels
- Making strategic investments to modernize immunization infrastructure, address key gaps in evidence base, and improve efficiency
- Maintaining adequate vaccine purchase as safety net for uninsured adults, VPD outbreaks, and other urgent needs

Future challenges and opportunities include

- Strengthening accountability
- Improving vaccine handling and inventory management
- Enhancing immunization information systems and health IT (e.g., EHRs and health information exchanges)
- Improving key vaccine indicators (e.g., lagging HPV vaccine coverage among teens)
- Harnessing the ‘immunization neighborhood’ (e.g., pharmacies, work places, community sites, and medical homes)

DISCUSSION: IMMUNIZATION CHANGES AT THE STATE-LEVEL

317 Funds

- It is important that CDC be able to use 317 funds to strengthen the U.S. immunization infrastructure, as the public health community transitions away from using these funds to purchase vaccines. As in the past, the 317 funds should be used where the need is greatest.
- NIH congratulated CDC on its efforts to work with partners to transition the immunization program as the vaccine safety-net target population shifts from children to uninsured adults

Adult Immunization

- CDC should continue to
 - Work to increase workplace immunization and immunization of marginalized adult populations
 - Strengthen the “immunization neighborhood” model, which uses workplaces and community sites as platforms for both adult and teen immunization. In the past, immunization primarily involved children, but now vaccination of adults and teens are “frontier issues.”
 - Recognize pharmacists as a major partner and encourage pharmacies to make their IT systems interoperable with state vaccine registries and state health departments.
 - The 2014 annual meeting of the National Adult and Influenza Immunization Summit will be held in Atlanta, Georgia, at the Hyatt Regency hotel on May 13–15, 2014 www.preventinfluenza.org. Topics will include consideration of the roles of health insurance organizations, workplaces, and pharmacies in increasing vaccination among insured and safety-net populations of adults.

- For influenza, the workplace model has worked well because influenza vaccine is inexpensive, and employers are often willing to pay for it. However, that model may not work as well for other adult vaccines. Dr. Carolyn Bridges, the CDC Associate Director for Adult Immunization, is coordinating efforts to expand and improve immunization for adults.

School-based Immunization for Adolescents

- Dr. Schuchat noted that efforts have been made to improve influenza vaccination of school-age children through school-located vaccination programs. However, U.S. communities differ widely in their attitudes about school-based vaccination.
- This is also true for different countries. For example, Peru routinely provides vaccines at schools. On the other hand, during an HPV vaccine demonstration project in Vietnam, school-associated vaccination was found to be less acceptable than vaccination through health facilities.

Technical Innovations to Modernize Immunization Practices

- Consumer-based IT can help build acceptance of teen and adult immunization as a social norm. One idea is to create an electronic “yellow card” that can be used from any site. Another idea is to develop an interactive scheduling tool that works on mobile devices. The device would provide a reminder about when to return to a clinic or doctor’s office for vaccination.
- These efforts should be advanced in tandem with the upgrading of state-level interoperable immunization information systems (registries). CDC must be strategic in a very technical and dynamic situation in which many “pieces” are changing.
- The office of the National Coordinator for Health Information Technology (ONC) can help drive these changes.

IT Workforce Issues

- Effective use of IT is a major challenge at many state health departments. It is not uncommon for IT workers at public health departments to leave for jobs in the private sector.
- Dr. Chesley Richards, CDC Deputy Director for Public Health Scientific Services, has identified IT workforce gaps as a major public health issue that requires CDC attention.

➤ CGH Updates

The CGH update included presentations on the following topics:

- *Highlights of 2013 CGH activities*, by Deputy Director Patricia Simone
- *The global health security initiative*, by Dr. Scott Dowell, Senior Advisor for Global Health Security, and Dr. Eric Kasowski, Chief, Global Health Security Branch
- *Polio eradication*, by Dr. Steven Wassilak, Senior Medical Epidemiologist, CGH Global Immunization Division

2013 Highlights

- **Yak Tsie Botswana Combination Prevention Project (BCPP).** CDC is working with the Botswana Ministry of Health (MOH) and the Botswana-Harvard Partnership of the Harvard School of Public Health to determine whether a combination of community-level prevention interventions will decrease HIV incidence. The interventions—which will be evaluated over 3 years via a randomized trial in 15 pairs of communities—include expanded coverage of services for HIV testing and counseling, voluntary male circumcision, prevention of mother-to-child HIV transmission, and antiretroviral treatment.

- **Global Maternal and Child Strategy.** At the request of CDC country directors, CGH has developed a *Global Maternal and Child Health Strategy for 2013-16* that builds on the government-wide Global Health Initiative (<http://www.cdc.gov/globalhealth/ghi/>). The strategy emphasizes an integrated approach to maternal and child health that stresses the need to work with country counterparts to identify priorities and evaluate progress on an ongoing basis.
- **Multistate Cyclosporiasis Outbreak Response.** Between June and October 2013, the Division of Parasitic Diseases and Malaria helped investigate an outbreak involving 631 cases of cyclosporiasis in 25 states and New York City. The outbreak involved restaurant- and grocery store-associated clusters linked to a bagged salad mix and fresh cilantro (<http://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html>).
- **Malaria Vaccine Update.** Vaccine trial results released on October 8 indicated that the candidate malaria vaccine RTS,S/AS01 reduced cases of malaria by nearly half in children and by one-third in young infants. CDC will continue to work with the Kenya Medical Research Institute (KMRI) to oversee one of 11 study sites. The trial will also evaluate the utility of providing booster shots at 18 months.
- **Infection control to prevent the spread of TB.** Improved TB infection control is a global health imperative that can be advanced through increased use of relatively simple, inexpensive—and already proven—infection control strategies. The CDC Director’s call to prioritize and accelerate efforts to strengthen TB infection control emphasizes that an integrated response to rapid identification and interruption of nosocomial transmission can have a large public health impact, reducing disease and saving lives.

Elements of this initiative include assisting countries with high burdens of TB, MDR-TB, and/or dual infections with TB and HIV/AIDS to improve infection control in healthcare facilities by addressing “TB Basics”:

- Developing rapid and robust TB infection assessment tools, tailored to local needs
- Implementing TB infection control intervention packages that address identified gaps
- Developing monitoring and evaluations plans (including indicators and benchmarks)
- Answering key programmatic and operations research questions

Training and capacity-building efforts to advance the TB infection control initiative are conducted in partnership with ministries of health, healthcare staff, Field Epidemiology (and Laboratory) Training Programs (FETPs and FELTPs), and other stakeholders and implementing partners.

- **Non-communicable Disease (NCD) activities.** Current projects include
 - Strategic cross-center program planning and implementation, conducted in partnership with FETPS, emphasizing health issues related to tobacco, hypertension, and motor vehicle injuries
 - Addressing global NCD surveillance needs (e.g., conducting surveys in Rwanda and Kenya and developing tools for capacity assessment)
 - Conducting pilot projects in key areas, such as global standardized hypertension treatment projects in Colombia and Barbados (<http://www.cdc.gov/globalhealth/ncd/hypertension-treatment.htm>) and sodium reduction studies in China and Thailand.
 - Providing technical guidance to WHO and Ministries of health on NCD issues (e.g., assisting the Brazilian Ministry of Health in evaluating hypertension reduction efforts)
 - Helping to develop USG positions on public health issues in global NCD agreements

- **National Public Health Institutes (NPHI).** CDC is working in partnership with the Emory University School of Public Health and FETPs to assist countries in building national public health agencies. For example, CDC has provided technical assistance to China’s public health agency (“China-CDC”) to strengthen its disease surveillance network and influenza response capacity. China-CDC’s ongoing surveillance for avian influenza H7N9 reflects the progress made in international reporting and cooperation since the SARS outbreak in 2003 (see below).
- **Improving Public Health Management for Action (IMPACT).** CDC has received a 2-year grant from the GATES Foundation to develop a cadre of highly-trained public health advisors at ministries of health. Objectives for the first year include learning about countries’ management needs and priorities; evaluating existing data and training programs; and designing a pilot program for training public health advisors. Patrick McConnon (former CDC public health advisor and former Executive Director of CSTE) is leading this project.

Global Health Security Initiative: Overview

Ten years ago, the response to the international outbreak of SARS was hampered by delays in global disease detection and reporting, as well as by failures in laboratory-based disease surveillance and public health communications. Recognition of these failures led to increased global collaboration to improve surveillance and response to emerging threats, including the adoption of a revised set of International Health Regulations in 2005 and increased diplomatic consideration of health as a global security issue.

In 2007, the World Health Assembly Report formally defined Global Health Security (GHS) as “the activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries.” In the United States, GHS issues were addressed in

- The *National Strategy for Countering Biological Threats* (<https://www.hsdl.org/?view&did=31404>)
- The HHS *National Health Security Strategy* (<http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Pages/default.aspx>)
- The Department of Defense *Quadrennial Defense Review* (<http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Pages/default.aspx>).

CDC Efforts to Enhance Global Health Security. The integration of health and security issues presents opportunities and challenges for public health. In the decade since the SARS outbreak, CDC has expanded its Global Disease Detection (GDD) program, which currently includes 10 Regional Centers, in China, Bangladesh, Guatemala, Egypt, Georgia, India, Kazakhstan Kenya, South Africa, and Thailand. The Centers--which were established in partnership with each country’s ministry of health--are helping to expand national and regional public health capacity in such areas as outbreak response, leadership training, laboratory diagnostics, and the detection of new pathogens. U.S. investment in these Centers has led to public health investments by the host countries. In Thailand, for example, where U.S. GDD investments have been level, public health investments by the Thai government have risen steadily since 2008, leading (for example) to improvements in influenza surveillance and vaccination.

Other examples of ongoing CDC activities that enhance global health security include

- **Ebola outbreak detection in Uganda.** With assistance from CDC, the Uganda Virus Research Institute has improved detection and monitoring of Ebola outbreaks. As a result, response times have greatly improved. During an outbreak in 2000, 38 days elapsed between detection of the first known outbreak case and initiation of an investigation, while in 2011 the interval between detection and

investigation was only 1 day. In general, for all infectious diseases in all parts of the world, the time from the start of an outbreak to its discovery is shrinking.¹⁵

- **Investigation of the Middle East Respiratory Syndrome (MERS).** CDC is assisting ministries of health and WHO in investigating MERS, which causes severe pneumonia with renal failure (page 5).

In September, 2013, CGH launched 2 GHS demonstration projects that build on existing activities in Uganda and Vietnam. The projects focus on:

- **Laboratory strengthening** to increase national capacity for detection, specimen referral, and laboratory confirmation of priority pathogens
- **Developing national Emergency Operations Centers (EOCs)** to provide central points for epidemic response and information exchange
- **Improving Information Technology** to support integration of data sources from disease surveillance, laboratory, and EOC dashboards to guide public health decisions during a crisis

In Vietnam, the primary goal is to improve the national EOC, by training MOH staff on EOC systems, procedures, and exercises, and upgrading the EOC's physical layout and equipment. In Uganda, the emphasis is on laboratory capacity to monitor Ebola, cholera, and TB, and to strengthen laboratory biosafety and biosecurity, with assistance from the DOD Defense Threat Reduction Agency (DTRA).

The new GHS Initiative. It is evident that

- Globalization has led to increased health risks that do not respect borders
- These risks also threaten the economic and social welfare of the U.S. and other countries
- Most countries are not able to respond effectively
- Inadequate links to global detection systems pose threats to other countries, including the U.S, yet less than 20% of the world is prepared to respond to global health threats, as judged by compliance with the provisions of the IHR.¹⁶

In response, the U.S. Government is launching a GHS initiative that involves

- **Department of Health and Human Services:** Office of Global Affairs; Office of the Assistant Secretary for Preparedness and Response; CDC; FDA
- **U.S. Agency for International Development (USAID):** Emerging Pandemic Threats Program
- **Department of Defense (DOD):** Office of the Assistant Secretary for Global Affairs; Office of the Assistant Secretary for Nuclear, Chemical, and Biological Defense Programs; DTRA; Armed Forces Health Surveillance Center
- **Department of State:** Biosecurity Engagement Program; Office of International Health and Biosecurity; Biological Policy Office

The interagency GHS initiative includes three elements:

- **Prevent** avoidable catastrophes, by
 - Creating safer, more secure laboratories
 - Ensuring a safer food and drug supply
 - Slowing the pace of drug resistance
 - Immunizing against epidemic-prone diseases
 - Promoting evidence-based policies and decision-making

¹⁵ Chan EH, Brewer TF, Madoff LC, et al. Global capacity for emerging infectious disease detection. Proc Natl Acad Sci USA. 2010;107(50):21701-6.

¹⁶ By the June 2012 deadline, only 16% of the 194 countries committed to the IHR reported being fully prepared to detect and respond to pandemics. Many countries asked for a 2-year extension, and some did not submit information.

- **Detect** threats early, by
 - Strengthening nationwide laboratory systems (target: 5 core tests in 80% of districts)
 - Improving surveillance systems
 - Training field epidemiologists whose data analysis supports evidence-based policies
 - Building capacity to investigate outbreaks
 - Conducting event-based surveillance
- **Respond** effectively, by
 - Strengthening emergency operations centers
 - Full activation within 2 hours
 - Build local emergency response expertise
 - Improving border safety and quarantine measures
 - Establishing or strengthening the public health workforce
 - Scaling-up information management and technology infrastructure
 - Supporting executive decision-making

In conclusion, Dr. Dowell noted that

- Much remains to be done to improve the prevention, detection, and response to epidemics
- Security is a fundamental role for government
- Health security requires strengthening the fundamentals of public health: surveillance, laboratory diagnostics, response, prevention
- CDC's demonstration projects have helped make the case for GHS concrete and compelling
- The GHS initiative is a U.S. Government and international priority
- CDC will play a central role in the this complex interagency and international initiative

Global Health Security Initiative: Implementation of Plans and Projects

Dr. Kasowski reported that Global Health Security is the second goal of CDC's 2012-2015 *Global Health Strategy* (<http://www.cdc.gov/globalhealth/strategy/>). Implementation involves strengthening country capabilities to prepare for and detect emerging threats and public health emergencies; to respond to international public health emergencies, and to help improve in-country response capabilities.

CDC's contributions to the interagency GHS initiative include

- Providing public health leadership among U.S. GHS partners
- Enhancing disease-specific and event-based surveillance and laboratory capacity to better detect threats to global health
- Building emergency management capacity and response expertise in host countries
- Serving as the WHO Collaborating Center for IHR Implementation
- Helping to establish and strengthen National Public Health Institutes (page 31)
- Establishing or strengthening FETP/FELTPs

CDC's plans for 2014 include

- Building on GHS demonstration projects in Uganda and Vietnam
- Aligning GHS activities with GDD Center priorities
- Collaborating with
 - DoD/DTRA, to lay the groundwork for a global GHS network (see below)
 - State Department, to improve GHS preparedness in selected Tier 1 and 2 countries¹⁷

¹⁷The Biosecurity Engagement Program of the Department of State (BEP; <http://www.bepstate.net/>) conducts activities in these countries:

- USAID, to strengthen pathogen detection, through the Emerging Pandemic Threats (EPT-II) program (<http://www.usaid.gov/news-information/fact-sheets/emerging-pandemic-threats-program>)

CDC is using lessons learned from the GHS demonstration projects in Vietnam and Uganda to develop a model, integrated approach to GHS implementation that builds on existing collaborations and prioritizes development of core public health capacities required under the IHR. In each country, CDC's GHS work must meet the following:

- Be tailored to MOH priorities and have MOH commitment
- Fill gaps not covered by other health programs
- Complement efforts already underway under other multilateral frameworks (e.g., the IHR and the Asian-Pacific Strategy for Emerging Diseases (APSED); http://www.wpro.who.int/emerging_diseases/APSED2010/en/)

CDC and DTRA have developed an interagency Partnership Strategy that aims to improve the protection of at least 2 billion people over the next 5 years. Its objectives include

- Improving and expanding a global GHS network that provides accurate and timely awareness of public health threats
- Building a reliable and sustainable capacity to detect, prevent, attribute, report, respond to, and recover from public health threats, as early as possible for the US and international partners

To lay the foundation for a global GHS network that will advance the three objectives of the GHS initiative (to prevent avoidable catastrophes, detect threats early, and respond effectively)—CDC and DTRA will partner with

- Ethiopia, Kenya, South Africa, Tanzania, and Uganda (WHO/AFRO)
- India, Philippines, Thailand, and Vietnam (WHO/SEARO)
- Jordan (WHO/EMRO)
- Kazakhstan and Georgia (WHO/EURO)

Initial efforts will focus on the same areas as the GHS demonstration projects: laboratory strengthening, laboratory biosecurity and biosafety, EOC development, and IT improvements. To advance these efforts, CDC will provide technical guidance to CDC country teams to work with ministries of health to build a USG plan that supports their IHR (2005) priorities. The aim is to establish a country-owned, Embassy-led, interagency-supported process similar to the processes involved in PEPFAR's country operational planning or PMI's malaria operational planning.

Dr. Kasowski concluded by emphasizing the following:

- The GDD Centers have a significant role in the GHS initiative
- Robust in-country ownership is a critical component of a global GHS network
- The newly established CGH Division of Global Health Protection will promote integration and coordination of agency-wide efforts to enhance GHS

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- Tier 1: Yemen, Iraq, Pakistan
 - Tier 2: Afghanistan, Libya, Egypt, India, Indonesia, Saudi Arabia, Jordan, Morocco, Somalia, Malaysia, Algeria.

DISCUSSION: GHS INITIATIVE

AR as a Global Health Threat. Dr. Dowell said there is broad agreement that AR is a global threat and that more work is needed to establish international goals and metrics. CGH has been working with DHQP's Antimicrobial Resistance Office to develop specific GHS goals for improved laboratory capacities to detect and trace drug-resistant microbes on the WHO list of seven drug-resistant pathogens of concern.¹⁸

GHS Resources and Sustainability

- Dr. Kasowski said that the duration of GHS funding for each partner country will vary, and that country buy-in is critical to the sustainability of GHS efforts. CDC will encourage each country to take resources into account in setting GHS goals, which might range from setting up a single laboratory to establishing a National Public Health Institute. Dr. Dowell added that the plan is to help translate intense interest into long-term sustainable support to build public health fundamentals.
- Although USG resources for GHS initiative are likely to be limited, Dr. Dowell said that the expectation is that host countries will invest their own resources from the beginning and that those investments will grow over subsequent years.

GHS and Humanitarian Efforts

- The timing of the new U.S. GHS initiative is in good accord with the transition from **Millennium Development Goals** to Sustainable Development Goals (<http://sustainabledevelopment.un.org/index.php?menu=1300>).
- In regard to current thinking about how to sustain humanitarian response efforts over the longer term, Dr. Dowell said that efforts to improve health and address health emergencies are closely related, because the capacities and resources they depend on overlap.

GHS Partnerships. Regarding the need to involve academic partners (e.g., the Consortium of Universities for Global Health; <http://www.cugh.org/>), Dr. Dowell said that engagement of universities and NGOs will be part of the GHS roll-out over the next weeks and months. Attracting private sector partners and resources will require multisectoral engagement, political will, and the ability to report the achievement of measurable outcomes over time. In regard to interagency partnerships, CDC is working with USAID and other USG partners to ensure that each agency has an appropriate role in implementing the interagency strategy.

CDC Investments in Global Health

- Dr. Schuchat, who recently served as CGH Acting Director, noted that the increased global work is transformative for CDC, which currently has \$2 billion investments in global health, primarily related to PEPFAR.
- Dr. Simone said that when PEPFAR began, the rapid growth in overseas investments led CDC to develop better monitoring systems to ensure good stewardship and management.

¹⁸ The WHO list of drug-resistant pathogens of concern includes:

- *Escherichia coli*: resistance to 3rd generation cephalosporins (ESBL) and to fluoroquinolones
- *Klebsiella pneumoniae*: resistance to 3rd generation cephalosporins (ESBL) and to carbapenems,
- *Staphylococcus aureus*: methicillin resistance (MRSA)
- *Streptococcus pneumoniae*: resistance (non-susceptibility) to penicillin
- Non-typhoid *Salmonella* (NTS): resistance to fluoroquinolones
- *Shigella* species: resistance to fluoroquinolones
- *Neisseria gonorrhoeae*: reduced susceptibility to 3rd generation cephalosporins

- Dr. Schuchat added that local management issues have in the past been a challenge for some global efforts, such as polio eradication, and that accountability is vital.

POLIO ERADICATION

Dr. Wassilak reviewed the history and current status of the Global Polio Eradication Initiative (GPEI), which began with a 1988 World Health Assembly Resolution. The GPEI is a public-private partnership led by WHO, Rotary International, CDC, and the United Nations Children’s Fund (UNICEF). In recent years, GPEI has also received strong support from the Bill and Melinda Gates Foundation.

During the 1990s, the incidence of polio declined by 99%. Polio was eliminated from the Western Hemisphere and all Western Pacific countries, and the wild poliovirus (WPV) serotype 2 (one of three poliovirus serotypes) was eradicated. After further progress, by 2006, only 4 endemic countries remained (Pakistan, India, Nigeria, and Afghanistan). More recent updates include the following:

- WPV from endemic countries continued to cause sporadic outbreaks in non-endemic countries in Asia and Africa, sometimes leading to sustained transmission and re-establishment of endemic transmission
- India has become polio-free (last reported case in January 2011)
- There have been successes since 2010 in rapidly ending outbreaks in Africa and a geographic narrowing of cases in Pakistan and Nigeria
- There has been a reduction in confirmed cases of indigenous (as opposed to imported) polio in Afghanistan in 2013
- The last case of polio to date caused by WPV type 3 (WPV3) globally was detected in November 2012, which suggests that WPV3 may be eradicated or close to it
- Current polio cases involve either WPV type 1 (WPV1) or circulating vaccine-derived polioviruses (cVDPV)—rare emergence of strains that have reverted from live, attenuated oral poliovirus vaccine (OPV) strains circulating in areas with low immunization coverage. Outbreaks of cVDPV type 2 strains are of special concern, because the bivalent vaccine predominantly used in supplementary immunization since 2010 targets only WPV1 and WPV3. However, trivalent OPV used in routine childhood immunization and the inactivated poliovirus vaccine (IPV) both target all three polioviruses.

Despite this progress, however, imported WPV has continued to cause sporadic outbreaks in non-endemic countries in the Middle East and Africa (see below). In 2011, the GPEI Independent Monitoring Board stated that “The programme is not on track for its end-2012 goal, or any time soon after, unless fundamental problems are tackled.” In 2012, the WHO Executive Board issued a resolution declaring that polio eradication is “a programmatic emergency for global public health, requiring full strategy implementation, strong national oversight and accountability, and vaccination recommendations for travelers to and from infected areas.” This resolution led to the activation of the WHO Strategic Health Operations Centre and the CDC Emergency Operations Center (EOC; see below).

GPEI Status in 2013. The international spread of polio continued in 2013, with reintroduction of WPV1 occurring in Cameroon, in countries in the Horn of Africa (Ethiopia, Kenya and Somalia), and in Syria (where immunization efforts are limited because of the civil war). There were also serious issues in endemic countries, including Nigeria (attacks on healthcare workers, anti-vaccine campaigns), Afghanistan (decreased vaccination in eastern insecure areas and cross-border importations from

Pakistan), and Pakistan (attacks on healthcare workers and a ban on OPV in North and South Waziristan). In addition, WPV1 was detected in sewage in Egypt, Israel, the West Bank, and Gaza.¹⁹ Managing these new risks involved making logistical adjustments to ensure safety and security, leveraging broad Islamic community support, and emphasizing the importance of disease containment in endemic countries. Ongoing GPEI activities in non-endemic countries included sustaining population immunity through vaccination and maintaining surveillance for acute flaccid paralysis. The activation of CDC's EOC facilitated CDC participation in these intensified polio eradication efforts, enabling CDC to provide expanded technical assistance to ministries of health in affected countries, working with WHO and UNICEF, as well as FELTP programs and CDC Country Offices.

Innovation and Research. In 2008, CDC convened an external expert panel to review polio research priorities. At that time, polio research projects were funded and implemented on an ad hoc basis. In 2011, the CDC Global Immunization Division instituted a systematic approach to polio research, with dedicated funds and competing proposals that were prioritized by public health impact, objectives, and feasibility. Working in partnership with WHO, CDC conducted

- Studies in India on polio seroprevalence in infants in Uttar Pradesh and Bihar; on polio vaccine responses and viral shedding; and on frequency of WPV positivity in individuals older than 5 years of age
- Studies in Sudan and Kenya on limitations in the reverse cold chain specimen transport system and on the duration of WPV survival in laboratory specimens
- Studies in Nigeria on risk factors for the emergence of cVDPV, on polio seroprevalence in young children in Kano, and on the reasons for the failure to deliver OPV to children, including children in nomadic populations
- A synthesis of the literature on the waning of intestinal immunity after live poliovirus and polio vaccine exposure, including modeling studies on the role of older persons in polio transmission
- A modeling study of the relative roles of OPV and IPV in the GPEI “endgame”

In 2012, CDC undertook additional studies, as part of a GPEI Interagency Innovation Working Group on Polio. Projects included

- Expanding the age group for immunization during supplemental immunization activities in response to WPV outbreaks in previously polio-free areas (in collaboration with WHO)
- Piloting the use of Lot Quality Assurance Sampling (LQAS) methods with expanded sampling to identify areas where additional efforts to deliver polio vaccine are needed (in collaboration with WHO)
- Expanding use of short message services (SMS) and smart phones to enhance surveillance (in collaboration with WHO) and enhance monitoring of vaccine use (in collaboration with WHO and UNICEF)

CDC also identified polio network innovations within countries and summarized best practices for delivering vaccination services during conflicts and times of political change. Recent and ongoing projects include

- Improving cold-chain carriers for vaccine transport (and reverse cold-chain carriers for specimens)
- Implementing SMS services to enhance community-based and provider-based surveillance in Northern Nigeria and Nepal

¹⁹ Tulchinsky TH, Ramlawi A, Abdeen Z, Grotto I, Flahault A. Polio lessons 2013: Israel, the West Bank, and Gaza. *Lancet* 2013;382(9905):1611-2.

- Entering into a cooperative agreement with Kid Risk, Inc., to model the health and economic outcomes of GPEI policies
- Using Geographic Information Systems (GIS) to improve micro-planning and GPEI team performance in Nigeria (in collaboration with WHO, with support from the Bill and Melinda Gates Foundation)
- Conducting seroprevalence studies in selected polio-free countries, including populations of children in Mozambique and Myanmar and young adults in Uganda and Namibia
- Studies to assess
 - The use of dried blood spots or oral fluids (as compared to sera) in seroprevalence studies
 - The effect of diarrhea on immune responses to OPV
 - The use of coverage surveys to ensure optimal use of IPV in routine immunization programs
 - The effectiveness of providing fractional doses of IPV under an alternate immunization schedule
 - Responses to bivalent and trivalent OPV

The Way Forward. GPEI has issued a Polio Eradication and Endgame Strategic Plan 2013–2018 (<http://www.polioeradication.org/resourcelibrary/strategyandwork.aspx>), whose goal is to complete the eradication of polio by the end of 2014 and certification in 2018. Objectives include 1) poliovirus detection and interruption; 2) immunization systems strengthening, including eventual withdrawal of all OPV use (to prevent further emergence of cVDPV), and incorporation of at least one dose of IPV into routine childhood vaccination series; 3) containment and certification; and 4) legacy planning to ensure that the health gains of GPEI persist. The strategic priorities of the plan including 1) stopping transmission in Syria, Somalia, and Cameroon; 2) using immunization campaigns to reduce vulnerability to polio infection in the Middle East, the Horn of Africa, and Western and Central Africa; and 3) enhancing access to immunization services in Pakistan and Nigeria.

DISCUSSION: POLIO ERADICATION

cVDPV. Dr. Wassilak confirmed that the WPV2 virus currently in circulation is an OPV vaccine-strain virus that has reverted to wild-like characteristics. The current plan for routine vaccine programs is to provide each child with IPV and begin to withdraw the OPV vaccine starting with removing type 2. Before that is done, however, large booster campaigns of the OPV may be necessary in the most-vulnerable countries.

Virus in Sewage. In regard to the detection of wild-type WP1 virus in Israeli sewage, Dr. Wassilak noted that Israel has good polio environmental surveillance, and no disease has been found in its population which is well vaccinated with only IPV, since 2005. It was thought that shedding of virus in stool (as well as in oral secretions) would not substantially occur in a person immunized with IPV who is subsequently challenged with wild virus. However, intestinal immunity is not complete after vaccination with IPV and some viral shedding occurs, and (as indicated here) can lead to ongoing transmission. Other countries that test for virus in sewage and use IPV only, including Finland, Netherlands, and Slovakia among others, have not found any WPV. Regardless, in countries contemplating a change to IPV for routine vaccine use—particularly areas where vaccine coverage is incomplete—it may be best to give IPV followed by OPV to get the advantages of both: high seroconversion to all serotypes with few doses (IPV) and intestinal immunity (OPV).

Civil Unrest and Outbreaks of Vaccine-Preventable Disease

- Many Syrian refugee children are receiving care (and are under disease surveillance) in camps in Jordan and Turkey. These children are being vaccinated against polio. WHO recommends that travelers from countries with polio transmission be vaccinated.

- In regard to prevention of VPD outbreaks in global “hot-spots,” Dr. Wassilak noted that Syria and Libya will be high-risk areas for the foreseeable future. Measles and polio vaccines are being provided to refugees from these countries, as well as to Sudanese refugees in Chad and to Somali refugees in Kenya and Ethiopia. At the present time, due to civil unrest, the Central African Republic is also at high risk for WPV and cVDPV outbreaks.
- As to whether existing (and future) “hot-spots” will make polio eradication impossible, Dr. Wassilak said that vaccine coverage rates do not have to be perfect to stop transmission. Poliovirus is not as transmissible as measles virus, so local elimination can be achieved with reasonably good coverage, especially in parts of the world where population density is less than in India. Modeling studies predict, for example, that 80% coverage would be sufficient to eliminate polio from Nigeria. At this time, however, lack of access to Borno State in northeast Nigeria (due to civil unrest caused by Boko Haram militants) remains a significant impediment.

DAY 2: DECEMBER 12

➤ UNFINISHED BUSINESS: 2013 FSMA Surveillance Working Group Annual Report

Dr. Hadler reviewed final changes to the 2013 FSMA Surveillance Working Group report and stated that it would be accompanied by a cover letter highlighting areas that the BSC wishes to emphasize.

Additional Discussion

- It was noted that CIDT methods have important implications for basic science as well as public health and that HHS should invest in efforts to develop and coordinate them.
- Dr. Granger suggested that in the future the Working Group might consider how to address risks at the production and processing end of the food industry that involve contamination of produce by animal-origin fecal material.

The BSC passed (by hand vote) a motion to submit the report to the HHS Secretary.

➤ NCHHSTP UPDATE

Dr. Jonathan Mermin, who has served as NCHHSTP Director since summer 2013, noted that NCHHSTP addresses diseases—HIV/AIDS, viral hepatitis, STDs, and TB—that are associated with stigmatization and health disparities and that disproportionately affect marginalized and medically underserved people. The political and social context in which these diseases occur raises special public health challenges.

- **Division of HIV/AIDS Prevention.**
 - Published the 2013 *National HIV Prevention Progress Report*, which found that 62% of the Divisions targets have been met or exceeded. New HIV infections decreased 15% among heterosexuals, 21% among African American women, and 22% among injection drug users from 2008 to 2010. Moreover, the percent of people with HIV who knew their HIV status increased from 81% in 2006 to 84% in 2010. However, from 2008 to 2012, new HIV infections increased 12% among men who have sex with men (MSM).

- Conducted a study in Thailand which found that pre-exposure prophylaxis (PrEP) can prevent HIV among people who inject drugs. A daily dose reduced the risk of HIV acquisition by 49%.²⁰ In June, CDC issued updated interim guidance for PrEP for the prevention of HIV infection among injecting drug users (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm>).
 - Published *HIV Testing and Risk Behaviors Among Gay, Bisexual, and Other MSM—United States*, which reported (based on a 21-city study) that knowledge of HIV status among people with HIV was associated with 60% less transmission risk behavior. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6247a4.htm>
 - Continued the Care and Prevention in the U.S. (CAPUS) program, which awards \$45 million to 8 states over 3 years. The focus is on reducing obstacles to diagnosis and access to ongoing care, based on research indicating that the largest gap in the continuum of HIV care from detection to viral suppression involves people not being diagnosed and falling in and out of care (e.g., due lack of insurance, incarceration, or other reasons).
 - Released the first Rapid Feedback Report for awardees of the Funding Opportunity Announcement (FOA) on *HIV Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color* (<http://www.cdc.gov/hiv/policies/funding/announcements/ps11-1113/index.html>). For each participating community organization, the Report indicates progress in such areas as the number of people tested and the number of new positives linked to care. The goal is to provide feedback to help grantees measure their progress and learn from other grantees. In addition, CDC can use this information to provide prompt assistance, if needed, or to stop funding, if an organization is unable to implement the prevention program.
 - Issued a new 5-year FOA for partner organizations who can provide capacity building assistance (CBA) for high impact HIV prevention, with awards to be made in spring 2014 (<http://www.cdc.gov/hiv/dhap/cbb/cba.html>). Awardees will participate in a national CBA Provider Network that will serve health departments, community-based organizations, and healthcare organizations. This FOA represents a major shift from mostly behavioral interventions to engaging healthcare providers.
 - Launched Reasons/Razones (<http://www.cdc.gov/features/REASONS-RAZONES/>) as the first national bilingual campaign to encourage HIV testing among Latino gay and bisexual men
- **Division of Viral Hepatitis**
 - In association with state health departments and FDA, CDC led an investigation that traced the source of a multi-state outbreak of hepatitis A to eating frozen foods with contaminated pomegranate seeds imported from Turkey. Illness was confirmed in 162 persons, of whom 71 were hospitalized (<http://www.cdc.gov/hepatitis/outbreaks/2013/a1b-03-31/index.html>).
 - In partnership with the Hepatitis B United Coalition (<http://www.aapcho.org/projects/hep-b-united/>), CDC launched “*Know Hepatitis B*,” a national multimedia campaign aimed at Asian and Pacific Islanders (<http://www.cdc.gov/knowhepatitisb/>). The campaign includes more than 1500 TV PSA spots (in English, Chinese, Vietnamese, Korean), and a website that has been accessed more than 26 million times.
 - CDC released the 2011 Viral Hepatitis Surveillance Report (<http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/PDFs/2011HepSurveillanceRpt.pdf>).

²⁰ Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381(9883):2083-90.

- **Division of STD Prevention**

- **Treatment of Gonorrhea Infections.** In view of growing antibiotic resistance, there is an urgent need for new treatment options for gonorrhea. A clinical trial supported by CDC and NIH identified two new treatment regimens: 1) injectable gentamicin with oral azithromycin and 2) oral gemifloxacin with oral azithromycin. Injectable gentamicin/oral azithromycin was 100% effective in curing genital gonorrhea infections, while oral gemifloxacin/oral azithromycin was 99.5 % effective. Both combinations cured 100% of throat and rectum infections.
- **HPV Vaccine Impact.** Since HPV vaccine was introduced in 2006, vaccine-type HPV prevalence has decreased 56% among female teenagers 14-19 years of age (see also page 8). Dr. Mermin noted that OIG coordinates a monthly CDC-wide HPV Winnable Battle Meeting.
- **New STD Treatment Guidelines App.** A free CDC app for Apple and Android electronic devices that provides clinicians and other providers with reference information on the identification and treatment of STDs is available at <http://apps.usa.gov/std-treatment-guide.shtml>, as well as iTunes and Google Play.

- **Division of TB Prevention**

- The *2012 TB Surveillance Report* found 9,945 new TB cases in 2012, a 6% decrease from the previous year and lowest rate in history of United States. There is a consistently higher rate in foreign-born persons, due to reactivation of latent TB in this population (<http://www.cdc.gov/tb/statistics/reports/2012/default.htm>). Current efforts to eliminate TB exposures in the United States focus on treatment of latent TB in foreign-born persons and on assisting their countries-of-origin with TB prevention efforts.
- CDC issued guidance on
 - The use of bedaquiline, the first new drug approved specifically for TB since 1968, which provides another tool against multidrug resistant TB (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6209a1.htm>)
 - 12-week therapy with isoniazid and rifapentine to treat latent TB infection, based on a CDC-supported clinical trial showing that 3-month, once-weekly isoniazid and rifapentine (3HP) is as effective as 9 months of isoniazid in preventing TB disease (<http://www.cdc.gov/tb/publications/lb/treatment.htm>). CDC also led a post-marketing surveillance project involving 1500 patients to monitor the adoption and success of 3HP for TB prevention.
- CDC is working with FDA to remedy episodic shortages of TB drugs and diagnostics.

- **Division of Adolescent School Health**

- CDC awarded funds for a new 5-year FOA to promote school health, which provided awards to local school districts in states, based on HIV/STD burden, poverty level, and number of students. The FOA includes prevention for young MSM, and the school districts encouraged to provide safe and supportive environment for LGBT youth.
- CDC released an updated Health Education Curriculum Analysis Tool (HECAT) to help school districts and schools analyze health education curricula (http://www.cdc.gov/healthyyouth/HECAT/index.htm?s_cid=tw_eh443).
- The *National Youth Risk Behavior Survey (YRBS) 1991-2011*, found that
 - The proportion of U.S. high school students who had ever had sex declined from 1991 (54%) to 2001 (46%) and has stabilized since that time (47% in 2011)
 - The proportion of sexually active students who used a condom the last time they had sex increased from 1991 (46%) to 2003 (63%) and has stabilized since that time (60% in 2011).

(Note: DASH activities were also discussed in a presentation on CDC's school-based health surveillance and HIV/STD prevention, starting on pages 44-47.)

Other NCHHSP achievements include:

- Releasing an expanded NCHHSTP Atlas that includes county-level epidemiologic data on HIV/STDs as well as state-level data on HIV/STDs, TB, and hepatitis (<http://www.cdc.gov/nchhstp/atlas/>). Emory University's AIDS Vu is also an excellent resource (<http://whsc.emory.edu/home/multimedia/videos/aidsvu.html>)
- Publishing a supplement to *Public Health Reports* on *Applying Social Determinants of Health to Public Health Practice* (<http://www.publichealthreports.org/issuecontents.cfm?Volume=128&Issue=9>).

NCHHSTP DISCUSSION

HIV Cure Initiative. An HIV vaccine is the ultimate goal for HIV prevention in people who are HIV-negative, while a functional or absolute cure is the goal for people who are HIV-positive. As part of the President's HIV Cure Initiative (<http://www.nih.gov/news/health/dec2013/niaid-02.htm>), NIH is re-directing \$100 million over the next 3 years for research on HIV cures, and CDC is helping NIH with laboratory and animal-based research.

Reduction of Hepatitis C

- Chronic hepatitis C infection is becoming a treatable infectious disease, with new oral treatment regimens approved this month. The current role of public health departments, therefore, is to ensure that people get access to treatment and get cured—which is similar to the public health role in addressing TB. In contrast, HIV remains a chronic disease, requiring lifetime care and ongoing services to suppress the patient's viral load and ensure that the virus is not transmitted to others.
- Reduction of chronic viral hepatitis represents an important opportunity, but with challenges (e.g., identification of infection, access-to-care) similar to ones involved in HIV prevention efforts. Successful application of the “baby boomer strategy”—HCV testing all persons born between 1945 and 1965—is essential to save the lives of millions of persons, many of whom (if left untreated) will eventually have end-stage liver disease and require liver transplants.

STD Burden, Surveillance, and Clinics

- Dr. Gail Bolan, Director, NCHHSTP Division of STD Prevention, reported the following:
 - International work on sexually transmitted infections is a major priority for CDC.
 - CDC is helping to update the *WHO Sexually Transmitted Infections (STI) Treatment Guidelines*, which will focus on five STIs and include an economic analysis of the global STI disease burden. CDC health economist Harrell Chesson will contribute to this analysis.
- In regard to the adequacy of the current gonorrhea surveillance system, Dr. Bolan explained that
 - The Gonococcal Isolate Surveillance Project (GISP; <http://www.cdc.gov/std/gisp/>)—which began in 1987 as a model system, based on culture-dependent testing—helps identify trends but does not provide timely data. Now that molecular tests are replacing culture-based tests, GISP (like PulseNet) is receiving fewer samples.
 - Surveillance of growing drug resistance in *N. gonorrhoeae* is a major concern; the currently recommended treatment is effective but has side-effects, is expensive, and involves an injectable drug. CDC is also concerned about the changing healthcare environment, with most STD clinics being closed, eliminating another major source of surveillance data on gonorrhea and other STDs.
 - CDC is considering how to re-focus and prioritize STD surveillance activities to support detection and treatment. One approach is to repurpose the remaining STD clinics to 1) focus on syphilis prevention and infertility reduction and 2) provide public health laboratories and CDC with isolates of gonorrhea and other pathogens of public health concern.
- Dr. Goodman agreed that STD work is changing rapidly, as the public health community transitions from health-department-supported, disease-specific STD clinics—the classical model of the 20th

century—to a more dispersed model where STDs (as well as many other public health issues) will need to be addressed through the health system. These changes are having a huge impact on behavioral health campaigns and infectious disease surveillance systems.

Grant Awards for HIV Prevention Projects

- In regard to the practice of de-funding FOA awardees who perform poorly, Dr. Mermin explained that this does not apply to awards made to state and local health departments. Instead, it applies to nongovernmental grantees, and, in this case, to a specific FOA (PS11-1113)²¹ that provides awards to community organizations. Significant efforts are made to improve program results, including extensive technical and administrative assistance.
- In awarding grants to state and local health departments, NCHHSTP generally gives priority to states with high HIV burdens. However, awards are sometimes made through a competitive basis to less-burdened states that pilot innovative programs or test new strategies. The Seattle-King County Health Department, for example, conducted an innovative surveillance project that used surveillance data to improve individual care of people with HIV.
- NCHHSTP has stationed epidemiologists in 3 states that requested personnel assistance in addition to financial assistance.

TB Prevention and Treatment

- More than half of TB-infected foreign-borne persons in the United States come from a small number of countries where TB is prevalent.²² Dr. Bell said that CDC has revised its screening and treatment guidelines for incoming refugees and immigrants from these high-risk TB countries. The impact of this change should be evident within the next 2 years. CDC is also working with state and local health departments to increase TB testing and treatment among persons from those countries.
- CDC is considering whether to establish a stockpile of TB drugs and reagents for public health use. Such a stockpile would address immediate drug-shortage problems but would require up-front funds to purchase the stockpiled materials.
- Dr. Goodman said that many drug shortages involve inexpensive generic drugs or diagnostic tests for which health departments pay little, so incentives for producing them are reduced. Although manufacturers are required to notify FDA when shortages are anticipated, other sources of supply may be lacking or have quality issues. The situation is improving, but remains very difficult.
- It was suggested that the adequacy of supplies of drugs and reagents (not just for TB) might be addressed as a GHS issue for the United States.

Measuring the Impact of Public Health Campaigns

- The online/social media component of CDC's campaigns—which are developed through communications research -- is measured by recording the number of “clicks” (each one representing a visit to an informational website).
- For an anti-smoking campaign, for example, the number of “clicks” indicates how many people are sufficiently interested to seek information online, rather than the number of people who actually stop smoking. Similarly, it is difficult to measure the direct health impact of the “Let's Stop HIV

²¹ FOA PS11-1113: Human Immunodeficiency Virus (HIV) Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color (<http://www.cdc.gov/hiv/policies/funding/announcements/PS11-1113/index.html>).

²²Over 70% of foreign-born TB cases reported in the United States in 2009 were in persons born in 12 countries: Mexico, Philippines, Vietnam, India, China, Haiti, Republic of Korea, Guatemala, Peru, El Salvador, Ethiopia, and Honduras (http://www.cdc.gov/Features/dsWorldTBDAY/index.html?s_cid=w_c_ds_cont_001).

Together” campaign, which is intended to decrease stigma, mobilize the community, and create an “enabling environment” where people are open to discussion.

- Dr. Mermin suggested that it might be possible to incorporate a quantitative indicator into a public health campaign whose goal is to increase infectious disease screening (e.g., by comparing testing rates in cities where the campaign took place vs. rates in cities where it did not take place). In that case, the indicator would need to be incorporated into the initial design of the campaign.
- CDC is a partner in the USAID-hosted Population-Based Behavior Change Evidence Summit on Global Health (<http://plbcevidencesummit.hsaccess.org/home>), which will review data on evidence-based behavioral change methodologies, including methodologies for effective media campaigns.

Public Health and the Healthcare System

- Dr. Mermin spoke about the increased public health role in quality assurance and monitoring required under ACA. This role must be incorporated into (and implemented within) the healthcare system. For example, in the future, healthcare workers might be responsible (as part of quality assurance) for identifying and assisting persons who fall out of care for diseases like AIDS or diabetes and helping them re-engage and receive effective services.
- Although not all public health issues involve the healthcare system (e.g., food production and sanitation), a closer relationship with the healthcare community is essential. Much more can be done to improve the public’s health by incorporating preventive care into healthcare. *Strengthening public health & health care collaboration* is one of three CDC priorities identified by Dr. Frieden (<http://www.cdc.gov/about/leadership/director.htm>; see also page 5).
- Dr. Bolan said that CDC is helping to integrate primary care and public health through partnerships with the National Association of Community Health Systems (<http://www.nachc.com/about-our-health-centers.cfm>), ASTHO, and NACCHO. Goals include supporting the healthcare system with risk assessment and better treatment; retaining STD clinics that serve vulnerable, marginalized groups; and working with academic clinical centers to train nurses and doctors.
- Many ongoing public health activities (e.g., serving people without access to care and conducting outbreak investigations) are not paid for by the healthcare system, but might be in the future.
- The public health community must change with the times and take advantage of new opportunities.

➤ **CDC’S SCHOOL-BASED HEALTH SURVEILLANCE AND HIV/STD PREVENTION**

The mission of NCHHSTP’s Division of Adolescent and School Health (DASH) is to reduce “priority sexual health risks and related health behaviors among youth that result in HIV and other sexually transmitted infections and in unintended pregnancy.” Dr. John Moore, the acting division director, said that fulfillment of this mission involves fostering collaboration between the public health and education sectors, federally and locally, through a coordinated school-health model that promotes a healthy and safe school environment by engaging a range of school-based programs (e.g., health services, physical education, nutrition services, health education, and counseling, psychological, and social services).

As part of these efforts, DASH provides assistance to school administrators and health councils on assessment and planning and on the implementation of multiple, coordinated, evidence-based strategies to address disease risk factors—and increase protective factors—that affect young people. Those strategies include

- Monitoring sexual health risk behaviors and school policies and practices to address them
- Providing funding and technical assistance to state and local education agencies and NGOs to support delivery of effective HIV/STD/teen pregnancy prevention programs
- Conducting behavioral research to help provide the science base for effective policies and programs

- Providing evidence-based guidance for adolescent and school health programs to prevent HIV/STD/teen pregnancy

DASH employs 3 school-based systems that monitor risk behaviors:

1. **The Youth Risk Behavior Surveillance System (YRBSS;** www.cdc.gov/yrebs/), which 1) measures health risk behaviors among youth that contribute to the leading causes of mortality and morbidity; 2) determines how health risk behaviors change over time; and 3) provides comparable data among various subsamples of youth. Categories of risk behaviors tracked by YRBSS include: behaviors that contribute to unintentional injuries and violence; sexual behaviors; alcohol and other drug use; tobacco use; unhealthy dietary behaviors; inadequate physical activity; and such conditions as asthma, overweight, and obesity. YBRSS has three components:
 - The *National school-based YRBS*, which has been conducted biennially since 1991, surveys public and private schools (grades 9-12), with oversampling of African American and Hispanic students. Data are gathered via a self-administered questionnaire that includes about 88 multiple choice questions; participation is voluntary and anonymous. The average sample size per question is about 14,500.
 - *The State, territorial, and local (STL) school-based YRBS*, which is conducted in 47 states, 21 cities and counties, and 6 territories, through funding to public health or education agencies. (In addition, 3 non-funded states conduct their own surveys.) The 2013 YRBS results will be released in early summer of 2014.
 - *Global YRBS surveys*, which have been conducted by 90 countries, including some countries in each WHO Region.
2. The **School Health Profiles (Profiles;** www.cdc.gov/healthyyouth/profiles/), which assess policies and practices in states, territories, and school districts. Profiles' surveys are conducted biennially by education and health agencies via questionnaires administered to middle and high school principals and lead health education teachers, by mail or online. Profiles' topics include health education; physical education and physical activity; practices related to bullying and sexual harassment; policies related to HIV/AIDS, tobacco use, and nutrition in schools; health services; and family and community involvement in school health. Profiles' surveys are conducted in the same cities, counties, and territories as the STL YBRSS.
3. **The School Health Policies and Practices Study (SHPPS;** <http://www.cdc.gov/HealthyYouth/shpps/>), which is designed to assess school health policies and practices at the national level, has been conducted every 6 years in the past. In 1994, 2000, and 2006, SHPPS was conducted at the state, district, school (elementary, middle, and high), and classroom levels. Beginning in 2012, the SHPPS data collection process switched to a biannual survey and was reduced in scope due to limited resources. The 2012 SHPPS (released in 2013) involved online questionnaires administered at the state-level (to assess how states assist school health programs) and at the school-district level (to assess school health policies and practices). The 2014 SHPPS will involve data collection at the school and classroom levels, conducted on site (e.g., taking photographs of food sold in school vending machines).

Dr. Moore also provided updates on

- **Use of School-Based Health Data.** DASH has created a Youth Online website (<http://apps.nccd.cdc.gov/youthonline>) that allows anyone to conduct their own analyses of the YBRSS data. YBRSS data are also used to measure Healthy People 2020 Objectives, while School Health Profiles are used to monitor progress in achieving CDC performance measures associated with FOAs, including:
 - HIV/STD prevention among youth (FOA 1308), 9 Performance Measures
 - Chronic disease prevention (FOA 1305), 12 Performance Measures

- **The NCHHSTP cooperative agreement to promote adolescent health through school-based HIV/STD prevention and school-based surveillance.** (FOA 1308; August 1, 2013 – July 31, 2018). FOA 1308 supports the implementation of 4 DASH strategies:
 1. ***School-Based Surveillance for STL Education or Health Agencies.*** Awards are provided to implement the STL YRBS and School Health Profiles.
 2. ***School-Based HIV/STD Prevention.*** Awards are provided to districts and schools to address HIV and other STD prevention through: 1) Exemplary Sexual Health Education; 2) Key Sexual Health Services for Students and Staff; 3) Safe and Supportive Environments; and 4) Educate Decision Makers on Policy and Implement and Track Policy. In the past, awards were made to state or local education agencies in most states and territories; due to budget constraints, the 2013 awards were made to agencies in 19 states and 17 cities.
 3. ***Capacity Building Assistance for School-Based HIV/STD Prevention.*** Awards are provided to NGOs to support sustainable initiatives for school-based HIV/STD prevention, working in coordination with a DASH contractor.
 4. ***School-Centered HIV/STD Prevention among Black and Hispanic/Latino YMSM.*** Awards were made to one NGO, three local education agencies, and one evaluation contractor (ICF International) to reduce HIV infection and other STDs by educating teen YMSM in reducing sexual risk behaviors; increasing the number of teen YMSM who are tested and treated for HIV and STD; and reducing absenteeism and school drop-out among teen YMSM.
- **School Health Research.** Activities include providing
 - Research synthesis, on such topics as strategies for increasing protective factors among youth (<http://www.cdc.gov/healthyyouth/adolescenthealth/connectedness.htm>) and for involving parents in school health activities (http://www.cdc.gov/healthyyouth/adolescenthealth/parent_engagement.htm)
 - Practical tools and research-based guidance to help schools implement effective policies and practices. Examples include HECAT (see above) and an adaption of the *Testing Makes us Stronger* HIV prevention campaign targeted to teens (<http://hivtest.cdc.gov/stronger/>).
 - Technical assistance for grantees in evaluating school programs. Tools include the Performance Evaluation Reporting System (PERS) and the School-Level Performance Measures in the School Health Profiles. DASH also provides online tools to help schools with program planning, evaluation, planning, data collection and analysis, and ways to use data to improve school health programs.

DISCUSSION: CDC'S SCHOOL-BASED HEALTH SURVEILLANCE AND HIV/STD PREVENTION

Engaging Teens, Parents, and Teachers

- From a health system perspective, teens represent a forgotten population, as well as an opportunity for effective public health action. Early adolescence is a time when many behaviors—whether risky or healthy—are formed.
- A CDC study that surveyed teenagers, parents, and healthcare providers found that 66% of teens were concerned about their health. (Interestingly, only 20% of parents thought their kids were concerned.) Engagement of all groups—students, teachers and parents—is essential.

Vision for DASH

- DASH has traditionally been concerned with adolescent health in general, but has been re-conceptualized to focus primarily on HIV/STD and teen-pregnancy prevention.
- DASH is the division of adolescent and *school* health, rather than adolescent health. DASH funds state and local education agencies directly, while other CDC Centers and Divisions address adolescent health issues in ways that are less directly linked to schools.

- DASH encourages collaboration between state health and education agencies. DASH also encourages schools to reach out to state health departments and other community partners.
- Regarding taking advantage of school-based programs to advance public health goals (e.g., improving HPV vaccine coverage), Dr. Moore said that CDC is exploring both school- and community-based venues where CDC can increase its work to advance teen health.

YRBS Data

- State health officials rely on YRBSS data for guidance in reaching out to students and their families to promote disease prevention.
- In regard to helping health officials describe the value of teen health programs to school administrators, Dr. Moore said that research has shown that better health leads to better school achievement.

Challenges and Opportunities

- Public health departments face many challenges in working with schools, due to jurisdictional fragmentation (i.e., the need to work separately with each individual school district) and to local political issues.
- Traditionally, public health departments have coordinated teen health programs (such as teen immunization programs) with departments of education and with school nurses. DASH previously facilitated these efforts by supporting state-level education/health coordinators in some states and by maintaining a close partnership with the federal Department of Education. Dr. Moore said that DASH is working to help foster a close working relationship between health and education agencies by requiring an MOU between those agencies in funded states and cities.
- It was suggested that CDC highlight the critical role of school nurses in improving teen health. Dr. Moore noted that in past years DASH funded teen health projects implemented by the National Association of School Nurses. DASH recently completed a paper highlighting the critical role of school nurses. This paper has been accepted for publication and will be made available to BSC members once it is published.

➤ ADVANCED MOLECULAR DETECTION FOR INFECTIOUS DISEASE PREVENTION AND RESPONSE

New BSC Infectious Disease Laboratory Working Group

Dr. Steve Monroe, NCEZID Deputy Director, reported on the establishment of a new BSC Infectious Disease Laboratory Working Group approved at the May 2013 BSC meeting. BSC members Dr. Jill Taylor, Interim Director, Wadsworth Center, New York Department of Health, and Dr. Susan Sharp, Regional Director, Microbiology, Department of Pathology, Kaiser Permanente Northwest, have volunteered to serve as workgroup co-chairs. The workgroup members are drawn from state health departments, APHL, the Translational Genomics Research Institute (TGen North), clinical laboratories, schools of public health, and the Public Health Agency of Canada.

The terms of reference were provided to the Board in the meeting binder (Tab 13). The charge is “to provide advice and guidance to the BSC/OID regarding CDC’s efforts in enhancing the use of genomic tools, information technologies, and other diagnostic innovations to advance public health.” The workgroup will meet by phone if not in person before the next BSC meeting.

Dr. Taylor noted that CIDT is revolutionizing diagnostics in clinical and public health laboratories, and that the workgroup can assist CDC in helping state and local health departments to use AMD. She

suggested that the issue of limited resources might be turned to CDC's advantage, because it means that CDC must proceed slowly until it is clear what will work best for the long term. In terms of foodborne diseases, for example, CDC has time to consider the lessons learned from the *Listeria* WGS Surveillance Project (pages 17 and 48) and from the use of AMD to support the investigation of the recent multistate *Salmonella* outbreak (page 12). Dr. Sharp emphasized that AMD is a huge, unique, and very challenging project that will "take us to new places." She urged everyone to be open-minded and engaged.

Dr. Khabbaz thanked Dr. Monroe, Dr. Robert Tesh, Professor, University of Texas Medical Branch, and Dr. Marta Gwinn, CDC Office of Public Health Genomics, for help in setting up the new workgroup.

UPDATE ON CDC'S AMD ACTIVITIES

Dr. Duncan MacCannell, Senior Advisor for Bioinformatics, NCEZID, described the Public Health Grand Rounds on December 3, which highlighted examples of CDC's AMD work (<http://www.cdc.gov/about/grand-rounds/archives/2013/december2013.htm>), including

- WGS and genetic mapping of 72 isolates from a TB outbreak investigation in May-July 2013 that identified 103 single nucleotide polymorphisms, 41 genomic types, and 4 clusters (reported by James Posey, Division of TB Elimination, NCHHSTP)
- Deep-sequencing of influenza viruses to identify minor population variants (reported by Michael Shaw, Influenza Division, NCIRD²³)

Dr. MacCannell also provided an overview of the following activities:

- **WGS analysis of PFGE-indistinguishable isolates from the multi-state outbreak of *Salmonella* Heidelberg infections** described by Dr. Bell (page 12). The analysis indicated that different strains were involved in clusters that occurred in Alabama (associated with attendance at a funeral), New York (associated with a childcare facility), and Colorado (associated with a family gathering). Because these three events occurred at the same time and had similar clinical presentations, linkages had been suspected.
- **The *Listeria* WGS Surveillance Project**, initiated in September 2013, to validate the potential use of near real-time WGS as a new PulseNet technique that might replace PFGE (see also; pages 17-18). The *Listeria* Surveillance Project is an ongoing collaboration among FDA, the NIH National Center for Biotechnology Information (NCBI), USDA, and several state public health laboratories. (Potential future partners who have expressed interest in the project include public health agencies in France, the UK, Denmark, Australia and Canada.) Its goal is to use WGS to analyze isolates from all U.S. clinical cases of *Listeria monocytogenes* infection, as well as from food and environmental specimens. Objectives include:
 - Improving the resolution and timeliness of cluster identification and epidemiologic follow up
 - Helping to guide response efforts (e.g., to identify risk factors and exposures and ensure judicious use of resources)
 - Developing a foundational infrastructure and methods for the next generation of PulseNet techniques
 - Developing a platform for AMD-based epidemiology and disease surveillance that might be adapted for use in monitoring any type of infectious microbe

Thus far, CDC and partners have used WGS to confirm 5 clusters of listeriosis, including one that might have been missed (or recognized late) using PFGE. Current challenges include developing a protocol for use and release of public health sequence data and associated metadata, at the local, state, federal, and international levels; identifying criteria for interpreting WGS data (e.g., what defines a

²³ Dr. Shaw recently joined OIG as Acting OIG Senior Advisor for Laboratory Science (see page 2).

cluster?); and improving data management (e.g., standardizing informatics workflows and facilitating use of WGS data during outbreak investigations).

Improvements to CDC's AMD Infrastructure. Additional sequencing instruments have been purchased for the core sequencing laboratory operated by CDC's Division of Scientific Resources and for CDC's infectious disease laboratories. These instruments come from different vendors, and each has advantages and disadvantages and their own pattern of sequencing errors, which must be taken into account (for example) in generating reference sequences. Key investments have also been made in computer equipment and software, with improvements made in computer capacity to record epidemiologic data for each isolate and track each isolate's progress from specimen processing to sequence analysis, providing a unified data management capability for large projects.

The volume of AMD data has grown from about 20 terabytes in 2012 to more than 67 terabytes in 2013. As a result, CDC has increased its scientific computing and data storage capacities and is continuing to expand the number of site licenses and bioinformatics trainings. In addition, CDC's Research Grade Network went live on October 1st, allowing CDC participants to access data at their desktops. Scientific computing support has also expanded, with the installation of new high-performance computing resources and centralized support, training, and information that can be accessed via a common information portal.

AMD Workforce Development. CDC has created a Bioinformatics in Public Health (BPH) fellowship, in partnership with APHL, Georgia Tech, and Emory University's Rollins School of Public Health. In its first year, the program will place bioinformatics students and fellows from Georgia Tech and Emory in CDC laboratories. In subsequent years, the program may be expanded to include students from additional schools, with placements at state and local public health laboratories as well as CDC. There are two categories of fellows: Pre-doctoral (involving a 4- month, semester-long project) and post-doctoral (involving an 18-24 month project). The BPH fellowship program—which has received 15 host laboratory applications and 20 project proposals—plans to place 4-6 fellows during 2014.

Other bioinformatics training opportunities include monthly workshops for CDC staff, involving online training and SOPs for using CDC's computing equipment; day-long introductory and advanced trainings provided by vendors such as CLC Genomics, Schrodinger, and Geneious; and a week-long course in genomics, bioinformatics, and "big data," that will be co-hosted by CDC, Georgia Tech, and INTEL in February or March 2014. CDC has also had a bioinformatics seminar series ongoing for nearly 2 years.

Microbial Reference Sequences. AMD collaborations are underway to establish reference sequences for the genomes of

- *Bacillus anthracis* and *Cryptosporidium cayetanensis* (with NIAID and other partners)
- *Escherichia coli* and *STEC*, *Exserohilum spp.* and *Apophysomyces*, *Klebsiella pneumonia*, and *Staphylococcus aureus* (with TGen North)
- *Listeria monocytogenes* (with FDA, USDA, and NCBI)
- *Mycobacterium tuberculosis* and *Neisseria gonorrhoeae* (with the Broad Institute, the Harvard School of Public Health, and the Wellcome Trust Sanger Institute)
- *Plasmodium spp.*, *Nocardia*, *Actinomyces*, and other unusual pathogens (with the Broad Institute, the Harvard School of Public Health, and Georgia Tech)

These sequences will be used to assess genetic diversity in each pathogen and identify screening targets and mutations that affect drug susceptibility, virulence, and other properties. The sequences will be made available to researchers through MicrobeNet, NCBI, GenBank, and the PathoSystems Resource Integration Center (PATRIC) database.

Other AMD Collaborations. Additional projects to advance public health use of AMD include

- **The Metagenomics and Rapid Pathogen Identification project**, to develop strategies for broad-based pathogen detection and characterization, starting with primary clinical specimens. Partners include the Los Alamos National Laboratory, the Lawrence Livermore National Laboratory, Columbia University, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), European Centre for Disease Prevention and Control (ECDC), and the University of Texas Medical Branch (UTMB).
- **The High Performance Computing and Hardware Acceleration project**, to advance low-level code optimization and hardware acceleration of critical software and algorithms. This project is conducted in partnership with the National Cancer Institute.
- **The CIDT/AMD Challenge**, a competition conducted by the XPRIZE Foundation to develop a way to consistently and reliably recover, identify and characterize STEC from a stool sample, using technology and methodology that is cost-effective, epidemiologically relevant, and feasible for public health use.

New AMD collaborations, on the horizon, include pilot projects to

- Improve pathogen detection, surveillance, and characterization, conducted in partnership with the 10 EIP sites (the EIP Microbial Genomics Project)
- Assess WGS informatics platforms and analytical workflows, working with state and large local health departments
- Improve laboratory support during outbreak responses.

DISCUSSION: AMD

Why does CDC need in-house AMD capacity?

- In response to comments regarding the need to avoid redundancy, Dr. Khabbaz noted that CDC is connecting and leveraging its AMD capacity with other groups, as recommended by the 2011 Blue Ribbon Panel on *Future Strategies for Bioinformatics in CDC's Infectious Diseases Laboratories*, which concluded that CDC's ability to meet its public health mission is threatened by not keeping up with advances in bioinformatics and laboratory technology (<http://www.cdc.gov/amd/pdf/bioinformatics-panel-report.pdf>).
- Dr. MacCannell agreed that CDC's AMD work is being harmonized with that of other agencies, including FDA and USDA, which are partners in the *Listeria* WGS Surveillance Project—a good example of using AMD in a collaborative way to improve public health practice. The goal is to establish common standards and sustain an open dialogue.
- AMD is also important to support outbreak investigations. Dr. Khabbaz noted that during the 2010 outbreak in Haiti CDC relied on colleagues at the Public Health Agency of Canada to analyze WGS data and monitor the causative strains of cholera.
- Dr. Bell said that CDC requires basic AMD capacity and expertise to achieve such public health goals as re-tooling PulseNet as CIDTs replace culture-based tests. Dr. Goodman agreed that CDC needs to build in-house AMD expertise and figure out how best to share data and coordinate AMD activities among USG agencies.
- Dr. Berkelman said that AMD expertise at CDC is a critical resource for the public health community. She noted that the new BSC Infectious Disease Laboratory Work Group can help CDC move forward in this area.

Strengthening and Sustaining AMD Capacity

- Dr. Khabbaz reported that CDC has fulfilled the short-term recommendations of the Blue Ribbon Panel (e.g., establishing a core bioinformatics activity and a research-grade network) and is working on longer-term ones (e.g., building the public health bioinformatics workforce).

- The challenge is to sustain what CDC has achieved so far. The President’s proposed budget includes \$40 million for AMD, and the Senate’s proposed budget includes \$20 million.²⁴
- Thus far, funds have been contributed from many CDC Centers, because CDC regards this effort is transformative and important.

Learning from Partners’ Experience

- It is important that CDC learn from its partners, rather than “reinventing the wheel.”
- NIH began using WGS and related techniques 8-10 years ago. In regard to lessons learned, Dr. Heilman said that:
 - It is not cost-effective to make large capital investments at the beginning, because the technology keeps changing.
 - It is important to focus on core business because enthusiastic investigators can easily pursue new and expensive directions.
 - Also, because internal data storage is expensive, it is important to explore other methods (e.g., cloud storage). NIH is currently trying to figure out how to store data in a cost-effective way.
- USDA has used AMD techniques to lower diagnostic costs during outbreak investigations. Dr. Granger gave two examples:
 - USDA used AMD to link *M. bovis* infections to a specific exposure, so that it was not necessary to conduct serologic testing on all cattle in an affected herd.
 - USDA used AMD to identify the source of human infection with brucellosis during an outbreak in Washington State. The brucellosis strain was traced to a shipment of imported animals, so that it was not necessary to test every farm.
- In the future, the USDA Ames Laboratory might work with CDC’s AMD activity to help identify animal-related origins of foodborne disease outbreaks. Dr. Bell noted that CDC collaborates with the USDA Food Safety and Inspection Service on listeria issues, and with the USDA Ames Laboratory on influenza. She agreed that further CDC/USDA collaboration on AMD would help strengthen surveillance for foodborne disease and antimicrobial resistance.

Building AMD Capacity at the State and Local Level

- AMD collaboration between federal agencies and state and local laboratories is occurring on an intellectual level—but not at the bench. Few if any state health departments have the equipment or workforce capacity to sequence a microbial genome directly from a clinical sample or analyze sequence data using metagenomic techniques.
- In the long run, it will be important to disseminate AMD technology to state and local laboratories, because CDC cannot provide AMD support for all U.S. outbreaks responses.
- A major role for CDC is to standardize AMD tools, procedures, and data pipelines to lay the groundwork for a national AMD infrastructure that facilitates communication between public health and clinical laboratories.
- In developing AMD standards, CDC may consider those proposed by the Global Microbial Identifier project, which is developing a global system to aggregate, share, mine, and use microbiological genomic data to address global public health challenges (<http://www.g-m-i.org/>).
- The use of AMD affects both laboratory and epidemiologic aspects of disease surveillance and outbreak response. At the present time, CSTE is working on epidemiologic issues, while APHL is working on the laboratory side. Dr. MacCannell said that the EIP Microbial Genome project (see page 49) will help ensure that these changes occur in tandem. This project will also help CDC figure out how to bring all 50 states on board.

²⁴ In January 2014, CDC received \$30 million in FY 2014 funding for Advanced Molecular Detection and Response to Infectious Disease Outbreaks.

- Dr. MacCannell also stressed that microbial databases must contain high-quality sequences obtained from isolates with well-defined epidemiologic characteristics. The goal is to create a reliable reference database that can be used to answer epidemiologic questions.
- Dr. Berkelman noted that the Listeriosis Surveillance Project is another opportunity to develop the epidemiologic side in synch with the laboratory side.

AMD Priorities

- CDC's AMD priorities include focusing on core public health business, setting standards (see above), and ensuring open access to AMD data.
- As far as public health practice, the immediate emphasis is on using AMD to provide laboratory support during outbreaks investigations.
- During the multistate outbreak of fungal meningitis, for example, CDC used AMD to conduct the initial characterization of disease clusters. For more sophisticated and in-depth work, CDC relied on an outside group with a proven track record.
- In the future, CDC may expand its AMD capacity further, but for now—especially in view of limited human resources--the emphasis is on basic work to support outbreak responses.

➤ **CONCLUSION**

Dr. Berkelman thanked everyone for their attendance, with special thanks to two BSC members who have completed their terms of service: Dr. Jim Hadler and Dr. Bob Tesh. Dr. Khabbaz also thanked the BSC members for their input into the FSMA Surveillance Workgroup Annual Report and cover letter, and for helping OID (now and in the future) to identify priorities for the AMD initiative.

The meeting was adjourned at noon.

APPENDIX

Meeting Participants

BSC Members

Ruth Berkelman
Jack Bennett
Judith Bossé
Kristy Bradley
Harry Chen
Frank Cockerill
Jesse Goodman
Larry Granger (*representing U.S. Department of Agriculture on behalf of Beth Lautner*)
Jim Hadler
Carole Heilman
Kent Kester
Laurene Mascola
José Montero
Andy Pavia
Scott Ratzan
Bob Sautter
Susan Sharp
Jill Taylor
Jon Temte
Bob Tesh
Judy Wasserheit
Bob Weinstein

Partners and Public Visitors

Michael Brady (*American Academy of Pediatrics*)
Jeff Engel (*Council of State and Territorial Epidemiologists*)
Tom File (*National Foundation for Infectious Diseases*)
Joe Hilinski (*Pediatric Infectious Diseases Society*)
Lilly Kan (*National Association of County and City Health Officials*)
Ruth Lynfield (*Infectious Diseases Society of America*)
Christy Phillips (*Pediatric Infectious Diseases Society*)
Kathy Talkington (*Association of State and Territorial Health Officials*)
Kimberly Walker (*American Society for Microbiology*)
Kelly Wroblewski (*Association of Public Health Laboratories*)

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Beth Bell
David Bell
Elise Beltrami
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Ken Castro
Evelyn Cater
May Chu
Christina Chung
Nancy Cox
Peter Crippen
Inger Damon
Kim Distel
Scott Dowell
Peter Drotman

Yi Fie Fu
Kathy Gallagher
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Marta Gwinn
Stephen Hadler
Tom Hearn
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Marsha Houston
Jennifer Huang
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Nicole Liddon
Duncan MacCannell
Karen Mason
Alison Mawle
Marian McDonald
Jono Mermin
Steve Monroe
John Moore
Gina Mootrey
Dale Morse
Stephen Morse

Robin Moseley
Jan Nicholson
Steve Oberste
Angelica O'Connor
John O'Connor
Alexa Oster
Mark Pallansch
Jean Patel
Yang Peng
Larry Pickering
Kristin Pope
Sarah Poser
Richard Quartarone
Missy Rasmussen
Steve Redd
Chesley Richards
John Ridderhof
Tomas Rodriguez
Sandy Rousch

Brian Santucci
Anne Schuchat
Jane Seward
Sonya Sharpe
Michael Shaw
Liping Shen
Pattie Simone
Sharon Slocumb
Jean Smith
Steve Solomon
Li Tie
Tracee Treadwell
Steven Wassilak
Linda Weigel
Cyndy Whitney
Sarah Wiley
Thelma Williams
Michelle Wilson

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 11–12, 2013, are accurate and complete.

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

Date