

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

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

December 6–7, 2017

A one-and-a-half day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on December 6–7, 2017, 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 Center for Global Health (CGH), and the National Centers for Immunization and Respiratory Diseases (NCIRD); HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP); and Emerging and Zoonotic Infectious Diseases (NCEZID)
- Reports from the Advisory Committee on Immunization Practices (ACIP), the Clinical Laboratory Improvement Advisory Committee (CLIAC), the Healthcare Infection Control Practices Advisory Committee (HICPAC), the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC), and the Advisory Council for the Elimination of Tuberculosis (ACET)
- Presentations and discussions on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), on estimating the U.S. burden of waterborne disease, and on U.S. outbreaks of hepatitis A

Following a report from the BSC Food Safety Modernization Act Surveillance Working Group (FSMA SWG), the BSC passed a unanimous motion to approve its 2017 Annual Report to the HHS Secretary.

### Opening Remarks

BSC Chair Dr. Ruth Berkelman, Rollins Professor, Emory University, called the meeting to order and was joined in welcoming participants and facilitating introductions by Dr. Rima Khabbaz, CDC Deputy Director for Infectious Diseases, and Sarah Wiley, the BSC/OID Designated Federal Official. Dr. Khabbaz welcomed members attending their first BSC meeting: Denise Hinton, alternate ex officio member from the U.S. Food and Drug Administration; Mark Riddle, ex officio member from the U.S. Department of Defense; and Susan Philip, liaison representative from the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment. Dr. Khabbaz also conveyed best wishes and many thanks to Dr. Berkelman, who is retiring as BSC Chair.

## NCEZID Update

Rima Khabbaz, OID Director and NCEZID Acting Director, provided the following updates.

### Outbreak Highlights

Over the past year, NCEZID has responded to outbreaks around the world and in dozens of U.S. states and territories. Examples include

- **Outbreak of bubonic and pneumonic plague in Madagascar.** NCEZID participated in a WHO Global Alert and Response Network (GOARN) response team that provided assistance with case-reporting, infection control, and evaluation of transmission risks at ports of entry. The outbreak, which affected about 2,000 people (using a broad case definition), has been contained.
- **Outbreaks of monkeypox in Nigeria and the Republic of the Congo.** NCEZID assisted the Nigerian Ministry of Health in investigating an [outbreak of monkeypox](#) that (as of December 4) involved 167 suspect cases and 1 death. Earlier in the year, the Congolese government invited a team of ecologists from CDC to visit an affected area and help identify animals that carry monkeypox.
- **Outbreak of yellow fever in Brazil.** The Pan American Health Organization and GOARN consulted with CDC on the response to a large outbreak of yellow fever that included cases near large urban areas (Sao Paulo and Rio de Janeiro). NCEZID developed procedures for fractional dosing of yellow fever vaccine (which is in short supply) and prepared a domestic response plan to optimize preparedness for an outbreak in the United States.
- **Salmonellosis in the United States associated with imported papayas.** This summer, CDC and FDA investigated an [outbreak of Salmonella](#) linked to papayas imported from Mexico involving 220 cases in 23 states. This outbreak was one of four separate outbreaks of *Salmonella* linked to papayas imported from four different farms.
- **Brucella RB51 infections in Texas and New Jersey**
  - In July 2017, Epidemic Intelligence Service (EIS) Officers assisted health and agricultural officials in Texas in the investigation of a cluster of infections with *Brucella* RB51, a live attenuated vaccine strain used to vaccinate cattle against brucellosis. The CDC laboratory confirmed a case of RB51 in a pregnant woman who drank raw milk from a nearby farm. Another family member exhibited symptoms consistent with RB51 infection, and milk from the farm tested positive for RB51.
  - In September 2017, the CDC laboratory confirmed *Brucella* RB51 as the cause of illness when a New Jersey woman became sick after drinking raw milk from a company called Udder Milk. CDC is working with New Jersey officials, USDA, and FDA to trace the source of the contaminated milk.
- **A multistate outbreak of *Campylobacter* infections associated with pet store puppies.** As of October 30, the outbreak involved 67 people infected with *Campylobacter* in 15 states. Testing with whole genome sequencing (WGS) indicates that the *Campylobacter* isolates from ill people and from puppies are closely related.

## Emergency Operations Responses

Over the past 6 months, NCEZID has been engaged in two Emergency Operations Center (EOC) activations:

- **Zika response.** CDC deactivated its 20-month-long emergency response to Zika on September 29. Although the number of travel-related cases continues to decline, locally transmitted cases have been reported in Puerto Rico, and one locally transmitted case was reported in Florida, in September. A Zika Coordination and Operations Transition Team (ZCOTT) was established to facilitate ongoing cross-agency collaboration on scientific, communication, and policy issues.
- **Response to Hurricanes Harvey, Irma, and Maria.** The public health response included providing technical support to the Puerto Rico Department of Health and the U.S. Virgin Islands Department of Health and conducting an Epi-Aid investigation of invasive mold infections in Texas.

## Publications and Campaigns

- The 2018 [CDC Health Information for International Travel](#)—the *Yellow Book 2018*—was released in print (in May), online (in June), and in a mobile application (in July).
- The *Get Ahead of Sepsis* initiative, which emphasizes the importance of early recognition and treatment, was [launched in August](#), during Sepsis Awareness Month.
- Advanced Molecular Detection (AMD) Day was hosted by APHL and CDC in September. The keynote speech described rapid field-deployable DNA sequencing, and the workshops and presentations highlighted data visualization, scientific storytelling, and workforce development.
- [U.S. range maps](#) for disease-carrying mosquitoes (*Aedes aegypti* and *Aedes albopictus*) were issued by NACCHO and CDC in October.
- [Be Antibiotics Aware: Smart Use, Best Care](#) was launched in November, during Antibiotic Awareness Week.
- NCEZID also released two brochures:
  - [Emerging and Zoonotic Infectious Diseases](#), which describes NCEZID programs, priorities, initiatives, and innovations. [Fact sheets on specific topics](#) are also available.
  - A revised version of [Innovations to Stop Emerging and Zoonotic Infections](#), which highlights technological innovations such as mobile apps for first responders and laboratories; a new test for *Candida auris*; and CryptoNet, the first U.S.-based system to use molecular detection methods to characterize a parasitic disease
- Other recent publications include
  - [Shiga Toxin–Producing E. coli Infections Associated with Flour](#)
  - [Addressing a Yellow Fever Vaccine Shortage](#)
  - [Community Mitigation Guidelines to Prevent Pandemic Influenza](#)
  - [Surveillance of Waterborne Disease Outbreaks Associated with Drinking Water](#)
  - [Zika Virus RNA Replication and Persistence in Brain and Placental Tissue](#)

## Funding and Budget Updates

### Recent funding announcements include

- [Antibiotic resistance funding announcements](#), which include
  - \$77 million provided to health departments under the AR Solutions Initiative through the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement
  - \$9 million provided to 25 investigators to combat antibiotic resistance. Focus areas include prevention of drug-resistant threats in healthcare settings and studies of the human microbiome.
- **ELC.** The 5-year funding cycle for ELC began August 1, 2014, and runs through July 31, 2019. In 2017 (the fourth year of the funding cycle), ELC disbursed \$302 million, the largest award to local, state, and territorial health departments since ELC began in 1995.
- **Emerging Infections Program (EIP) announcement.** EIP funding will be disbursed in early 2018.

### Budget updates:

- **FY 2018 President's Budget.** The proposed budget includes \$514 million for NCEZID (a decrease of \$70 million from FY 2017), with slight increases proposed for vector-borne diseases and emerging infectious diseases. FY 2018 budget conversations are ongoing.
- **Hurricane supplemental.** On November 17, the administration asked Congress for \$44 billion in emergency aid for areas hit by hurricanes. \$99.2 million was provided to CDC, including
  - \$96 million to “fund public health response activities including support to affected states and territories to address vector-borne, food-borne, water-borne, and other infectious diseases that arise as a result of the hurricanes”
  - \$3.2 million to “fund repairs and other immediate needs at CDC's vector-borne disease facility in San Juan, Puerto Rico.” The NCEZID Dengue Branch in San Juan is getting back on line and continuing to focus on response work, including mosquito control.

## Staff Announcements

Nicki Pesik is the new NCEZID Associate Director for Infectious Disease Preparedness, and Sherry Smallwood is the new NCEZID Management Officer.

## Recent Trips and Visits

- **Congressional briefing.** Over the past few months, CDC Director Brenda Fitzgerald has participated in a Congressional briefing entitled *Ebola, Zika, and AR: Leveraging Diagnostics to Fight Emerging Infectious Disease Threats*. She also visited the Tennessee Department of Health and toured NCEZID laboratories in Fort Collins, Colorado, and San Juan, Puerto Rico.
- **GHSA meeting.** In October, Dr. Khabbaz accompanied Dr. Fitzgerald, CGH Director Rebecca Martin, and HHS/OGA Director Garrett Grigsby on a trip to Uganda to visit the Uganda Virus Research Institute (UVRI) in Entebbe and attend the 4th Global Health Security Agenda (GHSA) High-Level Ministerial Meeting in Kampala. During the GHSA opening plenary, President Yoweri Museveni recognized CDC's support in developing Uganda's national capacity to detect and respond to Ebola and other viral hemorrhagic fevers.

## Preview of 2018

NCEZID activities in 2018 will include

- *Planning the next phase of the ELC Cooperative Agreement.* To build on and modernize the ELC platform, NCEZID will
  - Take stock of newly identified needs at state and local health departments
  - Work with internal and external partners to identify strengths, challenges, and opportunities
- *Updating the NCEZID Strategic Plan*, which will expire at the end of 2017. The updated plan will reflect new priorities and the current needs of external audiences and partners.
- *Working with HHS to establish an HHS Tickborne Diseases Advisory Workgroup*, as required in the 21st Century Cures Act, to “provide expertise and to review all efforts within HHS related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.” The first meeting (scheduled for December 11–12) will include 14 voting members, including 7 who represent federal agencies. Dr. Ben Beard, Division of Vector-Borne Diseases (NCEZID/DVBD), will represent CDC.

## Discussion

### Epidemic Intelligence Service

- EIS has broadened its skill set by admitting scientists and veterinarians in addition to physicians. At the present time, however, EIS is receiving fewer applications from physicians and is considering ways to increase their recruitment (e.g., through loan deferment programs). The overall number of EIS officers has decreased, due to decreased funding.
- After graduation, about two-thirds of EIS officers work in public health at the state, local, or federal level, and about one-third obtain positions in academia or industry. Because the Laboratory Leadership Service (LLS) fellowship is only in its third year, it is too early to evaluate its impact on the public health workforce.
- Dr. Berkelman requested an update on EIS workforce issues at the next BSC meeting.

### Outbreak Responses

- **Plague outbreak.** Investigators responding to the plague outbreak in Madagascar used a rapid assay for plague (based on lateral flow technology) developed by scientists at the Institute Pasteur and/or a [dipstick assay](#) developed at CDC.
- **Salmonella outbreak.** FDA is continuing to investigate farms that might be sources of papayas contaminated with *Salmonella*. In the past, it would not have been possible to determine that four different outbreaks were occurring because it would not have been possible to distinguish among farm-specific strains.
- **Brucella RB51 outbreak**
  - State laws (which vary widely) regulate the sale of raw milk, and CDC assists the states with messaging about potential dangers to health. The [American Academy of Pediatrics \(AAP\) advises](#) pregnant women and children not to consume raw milk products, due to risk of infection with *Listeria*, *Campylobacter*, *Salmonella*, *Brucella*, and *E. coli*.
  - A growing social-media movement encourages people to drink raw milk.

### **C. auris and Other HAIs**

- A trained workforce is the key to early detection and control of hospital outbreaks of *C. auris*. However, state-level capacity for diagnosis of *C. auris* and other fungal organisms is very limited.
- In the future, increased use of common (WGS-based) diagnostic platforms could make cross-training easier.
- Dr. Khabbaz noted the importance of making investments “at the interface of healthcare and public health,” such as the [IDSA Antimicrobial Stewardship Centers of Excellence Program](#).
- Regulators are using NHSN guidelines and definitions to track HAIs in hospitals, and hospital administrators might benefit from additional guidance on how to best use these or other metrics to reduce HAI incidence.

## ***Focused Discussion: Building a U.S. Estimate of the Burden of Waterborne Diseases***

Katie Fullerton, NCEZID Division of Foodborne, Waterborne, and Environmental Diseases (DFWED), described a systems-based approach for addressing waterborne diseases and estimating their burden in the United States. She noted that water safety issues are cross-cutting, collaborative, and complex, and that water-related work is conducted at many different CDC Centers and Offices.

### **A New Paradigm: Waterborne Disease in the Developed World**

- Routine treatment of drinking water—[one of the greatest public health innovations of the last century](#)—led to a [dramatic decline](#) in U.S. deaths from typhoid fever and reinforced the concept of collective “public health” action. Modern water and sewage treatment systems also eliminated cholera (<https://www.cdc.gov/cholera/usa/index.html>).
- Today, our safe, reliable water supply is used in many complex ways that can affect disease transmission. Examples include use of water in
  - Complicated plumbing, heating, and cooling systems in large buildings, including hospitals
  - Agriculture and food production
  - Water parks, splash pads, and other complex recreational water venues
  - Medical procedures
- Modern outbreaks of waterborne diseases may be due to contamination of recreational water, drinking water, or water in the environment (e.g., water used in cooling towers). Routes of exposure include ingestion, inhalation, intranasal exposure, and physical contact. The outbreak-causing agent may be a microbe, chemical, or toxin.
- Recreational water outbreaks may be due to *Cryptosporidium*, which has a high tolerance for chlorine, or *Giardia*. However, most cases of giardiasis or cryptosporidiosis are sporadic, and data are not available at the national level to associate individual cases with a specific source of exposure. Incidence rates of cryptosporidiosis and giardiasis are higher than for coccidioidomycosis, Shiga toxin-producing *E. coli* (STEC) infections, or legionellosis (which is also waterborne).
- Current estimates of the burden of waterborne disease in the United States suggest that between 4 and 33 million episodes per year of acute gastrointestinal (GI) disease are associated with public

drinking water systems.<sup>1</sup> These numbers do not account for waterborne illness among the 15% of U.S. population who obtain water from private wells, for waterborne illness associated with recreational water, or for waterborne diseases that cause non-GI symptoms.

## General Strategy

- Like the foodborne disease estimate issued by CDC in 2011,<sup>2</sup> a waterborne disease estimate could help focus public health resources. It would help identify and address emerging issues and provide metrics to follow over time.
- Ideally, a comprehensive U.S. waterborne disease estimate would take into account all infectious causes of waterborne disease, all disease outcomes, and all exposures to water (food, water, animal-to-person, person-to-person, environmental).
- Starting in 2007, CDC created an inventory of waterborne pathogens and the types of disease they can cause (e.g., GI illness, neurologic infections, liver infections, skin and ear infections, eye infections and irritations, and respiratory illness). The inventory identified more than 50 infectious waterborne agents.

## First Waterborne Burden Estimate

- Development of the first U.S. Waterborne Burden Estimate began by focusing on waterborne pathogens that (1) cause significant morbidity and mortality in the United States and (2) have reliable sources of surveillance data. These included pathogens that are primarily waterborne (*Cryptosporidium*, *Giardia*, Acute Otitis Externa, Free-living amoebae, *Legionella*, and Non-Tuberculous *Mycobacterium*) and pathogens that are partially waterborne (*Campylobacter*, Shiga toxin-producing *E. coli* [STEC], *Shigella sonnei*, *Salmonella*, hepatitis A, *Vibrio*, *Pseudomonas*, and Norovirus). Data sources included large, publicly available databases (e.g., from national health surveys, death certificates, and administrative records that contain billing data) as well as published studies estimating deaths, hospitalizations, and emergency room visits due to waterborne disease.<sup>3</sup>

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<sup>1</sup> Colford JM Jr, Roy S, Beach MJ, Hightower A, Shaw SE, Wade TJ. A review of household drinking water intervention trials and an approach to the estimation of endemic waterborne gastroenteritis in the United States. *J Water Health*. 2006;4 Suppl 2:71–88; Messner M, Shaw S, Regli S, Rotert K, Blank V, Soller J. An approach for developing a national estimate of waterborne disease due to drinking water and a national estimate model application. *J Water Health*. 2006;4 Suppl 2:201–40; and Reynolds KA, Mena KD, Gerba CP. Risk of waterborne illness via drinking water in the United States. *Rev Environ Contam Toxicol*. 2008;192:117–58.

<sup>2</sup> Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. [Foodborne illness acquired in the United States—major pathogens](#). *Emerg Infect Dis*. 2011 Jan;17(1):7–15; and Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM. [Foodborne illness acquired in the United States—unspecified agents](#). *Emerg Infect Dis*. 2011 Jan;17(1):16–22.

<sup>3</sup> Examples include the following: Gargano JW, Adam EA, Collier SA, Fullerton KE, Feinman SJ, Beach MJ. Mortality from selected diseases that can be transmitted by water—United States, 2003–2009. *J Water Health*. 2017 Jun;15(3):438–450; Collier SA, Stockman LJ, Hicks LA, Garrison LE, Zhou FJ, Beach MJ. Direct healthcare costs of selected diseases primarily or partially transmitted by water. *Epidemiol Infect*. 2012 Nov;140(11):2003–13; and Adam EA, Collier SA, Fullerton KE, Gargano JW, Beach MJ. Prevalence and direct costs of emergency department visits and hospitalizations for selected diseases that can be transmitted by water, United States. *J Water Health*. 2017 Oct;15(5):673–683.

- Version 1.0 of the U.S. Waterborne Burden Estimate will
  - Focus on 21 selected pathogens and conditions and employ the modeling approach used to develop the 2011 estimate of foodborne diseases. It will make use of surveillance data, administrative data, and published studies, and include adjustments for under-reporting, under-diagnosis, and under-ascertainment.
  - Include pathogen-specific estimates of the attribution of disease to different sources of exposure (foodborne, waterborne, animal contact, person-to-person, and environmental) ascertained by the Structured Expert Judgment (SEJ) project, a collaboration among the University of Florida; the NCEZID Division of Foodborne, Waterborne, and Environmental Diseases; and the NCIRD Division of Viral Diseases.
  - Include estimates of the annual numbers (and medical costs) of cases, emergency department visits, and hospitalizations due to each pathogen or condition. Deaths will also be estimated, although no cost estimate will be provided for deaths. Estimates will be given for (1) all illnesses caused by the pathogen or condition and (2) the proportion of those illnesses or conditions that are waterborne.
- DFWED aims to publish the first paper in 2018 and is developing a communications plan for its release. The paper’s findings will contribute to a comprehensive CDC plan for addressing water, sanitation, and hygiene issues in the United States. Future versions of the U.S. Waterborne Burden Estimate may include information on chemical as well as infectious contaminants.

## Discussion

Ms. Fullerton was joined by Rob Tauxe, DFWED Director; Michael Beach, NCEZID Associate Director for Healthy Water; and Chris Edens, NCIRD Division of Bacterial Diseases. Dr. Tauxe reported that DFWED is moving forward with an updated estimate of the U.S. burden of foodborne diseases and that the ultimate goal is to combine the data on foodborne and waterborne diseases into a single, comprehensive estimate.

## State and Local Resources for Prevention of Waterborne Illness

- BSC members suggested that
  - A holistic approach to outbreak response—by transmission route rather than by pathogen—may help maximize resources to address waterborne diseases at the state and local levels.
  - The responsibilities of state-level response teams that investigate foodborne diseases might be expanded to include investigations of both foodborne and waterborne outbreaks.
  - State-level capacity for environmental sampling of water specimens (e.g., in hospital biofilms) could be augmented through collaborations with Integrated Food Safety Centers of Excellence and/or academic centers.
- Ms. Fullerton noted that the DFWED Environmental Microbiology Laboratory has received funding under the *National Strategy to Combat Antibiotic Resistance (CARB)* to examine the health risk associated with antibiotic-resistant bacteria in natural and built water systems.

## Waterborne Disease Prevention Issues

- A published estimate of the U.S. burden of waterborne illness could bring greater attention to waterborne disease prevention, just as publication of the foodborne illness estimate brought greater attention to foodborne disease prevention.

- A better understanding of the burden and sources of cryptosporidiosis might suggest ways to prevent contamination of water systems with chlorine-resistant organisms. Dr. Beach noted that input from engineers is essential in identifying solutions for reducing the growth of pathogens in biofilms.
- Another argument in favor of a holistic (non-pathogen-specific) approach to addressing waterborne disease prevention is that water management programs for buildings that aim to impede the growth of one pathogen (e.g., *Legionella*) may not be optimal for other pathogens (e.g., non-TB mycobacteria and pseudomonas).

## Legionellosis

- Dr. Edens reported that current activities to address Legionnaires' disease include
  - Dissemination of a toolkit entitled [Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings: A Practical Guide to Implementing Industry Standards](#)
  - ELC-supported efforts to enhance technical capacity at the state and local levels
  - An EIP project to investigate sources of risk (e.g., from household water systems)
  - A project in New York City to evaluate the impact of existing rules and regulations on disease prevention
- Research questions for *Legionella* and other waterborne pathogens include
  - What are risk factors for sporadic cases?
  - What is the age distribution, and which populations are most affected (e.g., urban or rural)?
  - What is the impact of travel on disease spread?
  - Which components of water-drinking exposures are most important (e.g., from water coolers or from private wells)?

## Algal Blooms

NCEH and NCEZID/DFWED have launched an updated [harmful algal blooms \(HABs\) webpage](#) and the [One Health Harmful Algal Bloom System](#) (OHHABS) to monitor cases of illness (human and animal) associated with algal blooms.

## Update on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Publication of the CDC *Antibiotic Resistance Threats in the United States, 2013* spurred the development of the 2014 *National Strategy for Combating Antibiotic-Resistant Bacteria*,<sup>4</sup> the 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria* (CARB), and the CDC FY16 AR Solutions Initiative. These efforts were cited in a 2017 Presidential Directive that re-established a federal advisory committee to address AR issues: the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB).

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<sup>4</sup> The *National Strategy for Combating Antibiotic-Resistant Bacteria* [was released with an accompanying report](#) from the President's Council of Advisors on Science and Technology (PCAST).

Michael Craig, Senior Advisor, NCEZID Division of Healthcare Quality Promotion (DHQP), provided an overview of the aims and activities of PACCARB. He began by presenting a CARB infographic entitled “Antibiotic Resistance Threatens Every Person, Modern Medicine, and Industries” that conveys these messages:

- Antibiotic-resistant germs avoid the effects of the drugs designed to kill them.
- AR affects all communities and, without action, will continue to get worse.
- AR is not stoppable, but its spread can be contained.
- We still have time to make a difference.
- CDC is the 9-1-1 for emerging antibiotic resistance.
- Resistant germs can be anywhere and can affect every aspect of human life, including healthcare, food, sex, environment, and travel.

According to the Description of Duties laid out in Executive Order 13676, PACCARB provides advice, information, and recommendations to the President, via the HHS Secretary, about programs and policies intended to

- Preserve the effectiveness of antibiotics by optimizing their use
- Advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship
- Strengthen surveillance of antibiotic-resistant bacterial infections
- Prevent the transmission of antibiotic-resistant bacterial infections
- Advance the development of rapid point-of-care and agricultural diagnostics
- Further research new treatments for bacterial infections
- Develop alternatives to antibiotics for agricultural purposes
- Maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers
- Improve international coordination of efforts to combat antibiotic resistance

PACCARB includes 15 voting members who are special government employees; 5 non-voting members who represent nongovernmental organizations; and 10 non-voting ex officio members who represent the agencies of HHS, DoD, and USDA. It establishes standing and ad hoc working groups that prepare reports and recommendations that are approved by PACCARB before release. PACCARB meetings have included the following:

- **September 2015:** Inaugural public meeting. Agencies provided updates about objectives and milestones for implementation of the *National Action Plan for Combating Antibiotic-Resistant Bacteria*.
- **March 2016:** Discussion of a draft report (developed by PACCARB working groups) entitled *Initial Assessments of the National Action Plan for Combating Antibiotic-Resistant Bacteria*
- **June 2016:** Discussion of (1) incentives for the development of vaccines, diagnostics, and therapeutics and (2) the intersection of the environment and antibiotic resistance
- **September 2016:** Discussion of infection prevention and control, stewardship, and innovative approaches to controlling resistance to protect human and animal health

- **January 2017:** Discussion of infection prevention and control for human health
- **May 2017:** Discussion of infection prevention and control for animal health
- **September 2017:** Discussion of stewardship and updates on objectives and milestones for implementation of the *National Action Plan on Combating Antibiotic Resistant Bacteria*

PACCARB working groups included the following:

- **2016:** Antibiotic Stewardship; One Health Surveillance; Diagnostic Innovations; Treatment, Prevention and Control Research and Development; International Collaboration
- **2017:** Incentives for Vaccines; Incentives for Diagnostics; Incentives for Therapeutics and Anti-Infectives
- **Planned for 2018:** Infection Prevention and Stewardship

Mr. Craig noted that

- PACCARB has a One Health Focus, which includes environmental aspects of AR as a key component. All PACCARB working groups include experts in both human and veterinary medicine.
- PACCARB voting members include a former member of the BSC (Robert A. Weinstein) and a former CDC Center Director (Lonnie King). Mr. Craig has served as the ex officio member representing CDC.<sup>5</sup>
- Information on key investments in states and communities made through the AR Solutions Initiative can be found on the CDC webpage entitled [Antibiotic Resistance Investments](#).

## Discussion

### One Health Issues

- PACCARB's co-chairs are an epidemiologist (Martin Glaser) and a veterinarian (Lonnie King).
- The 2018 Infection Prevention and Stewardship Working Group, which plans to discuss use of antibiotics in agriculture and food animals, may also consider issues related to companion animals and veterinary medicine.
- Beth Lautner, USDA/APHIS, reported that USDA is supporting projects to enhance laboratory-based surveillance of drug-resistant diseases among both food animals and companion animals. Other APHIS activities include analyses of antibiotic use on farms and of AR trends that can inform long-term guidance for animal disease surveillance.

### Workgroups

- Additional PACCARB working groups are likely to be established in 2018. Each workgroup has a year to submit a report and recommendations for PACCARB approval.
- The Executive Order caps the number of persons who can serve at any one time. Discussion is underway about how to ensure that PACCARB includes sufficient environmental expertise. PACCARB members serve for 2-year terms, and as members rotate off, persons with environmental expertise may be invited to join.

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<sup>5</sup> Dr. Khabbaz is currently serving as the ex officio member representing CDC on PACCARB.

- At present, PACCARB has few liaison members from pharmaceutical and diagnostics industries. However,
  - Representatives of industry umbrella groups participate in PACCARB’s public meetings.
  - Two voting members, Kent Kester and John Rax formerly worked at AstraZenica.
  - BARDA, which sends an ex officio member to PACCARB, works closely with industry partners.
- BSC members also noted that
  - Voting member Angela Caliendo provides expertise in laboratory diagnostics.
  - Pediatricians—who are major prescribers of antibiotics—should be involved. Mr. Craig reported that AAP has provided suggestions for pediatricians who may serve as future members of PACCARB.

### International AR Issues

- PACCARB provides policy input on global health issues to the administration, Congress, and the World Health Assembly. Future PACCARB meetings may consider international issues such as cross-border spread of resistant pathogens.
- The BSC (or a BSC working group) could help PACCARB review international issues and/or identify international partners.

### Other Comments

- Denise Cardo, DHQP Director, reported that CDC is updating the *Antibiotic Resistance Threats in the United States, 2013* and that WHO is updating its list of AR pathogens.
- Emily Erbeling, NIH/NIAID, reported that CARB-X, a “biopharmaceutical accelerator” to spur pre-clinical product development, has made awards to academic and industrial researchers.<sup>6</sup> CARB-X was created in 2016 as a partnership among BARDA, NIAID, and Boston University.

## Brief OID Update

Dr. Khabbaz conveyed best regards to the BSC from Brenda Fitzgerald, the new CDC Director, who was on travel the week of the BSC meeting. On November 11, at an All-Hands Meeting for CDC staff, Dr. Fitzgerald referred to CDC as “the common defense of the country against health threats” and proposed an organizational refocus around four “communities of practice,” dedicated to science, surveillance, and service. The communities of practice will be led by CDC Deputy Directors with responsibility for Non-Infectious Diseases, Infectious Diseases, Public Health Science, and Public Health Services. Dr. Fitzgerald has asked Dr. Khabbaz (who is currently serving as both OID Director and Acting Director of NCEZID) to remain at NCEZID as Director.

Dr. Khabbaz provided OID updates on

- **Budget.** The Continuing Resolution that funds the federal government will expire on December 9 and might be extended at that time.

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<sup>6</sup> In March 2017, the US Government and the Wellcome Trust announced the first 11 projects to receive CARB-X funding (8 in the U.S. and 3 in the U.K.) to develop new antibiotics. [In July 2017](#), a second round of funding was made to 7 scientists in India, Ireland, France, Switzerland, the U.S., and the U.K.

- **ICEID.** Planning for the next International Conference on Emerging Infectious Diseases (ICEID) is underway. The conference will take place in Atlanta on August 26–29.
- **BSC working groups**
  - Since the disbandment of the Antimicrobial Resistance Working Group, the BSC now has two active working groups:
    - **Food Safety Modernization Act Surveillance Working Group** (FSMA SWG; report summarized below)
    - **Infectious Disease Laboratory Working Group** (IDLWG). Co-chairs Jill Taylor and Susan Sharp reported that IDLWG will meet early in the spring to discuss (1) the Advanced Molecular Detection (AMD) initiative and (2) culture-independent tests (CIDTs). Some IDLWG members will participate in a May 2–3 meeting hosted by the Pew Research Center that will bring together public and private sector experts to consider the epidemiologic and laboratory implications of increased use of CIDTs.
- **Joint OID/NCEH working groups**
  - **Vectorborne diseases.** In May 2016, the BSC voted in favor of establishing a joint OID/NCEH Working Group on Vectorborne Diseases, details of which are in development. BSC member James LeDuc, director of the Galveston National Laboratory, University of Texas Medical Branch in Galveston, will serve as the BSC/OID co-chair, along with a co-chair from the Board of Scientific Counselors, NCEH/ATSDR; Ben Beard, NCEZID Division of Vector-Borne Diseases, will serve as workgroup designated federal official, along with a counterpart from NCEH/ATSDR. Dr. Beard, who participated by phone, hopes that the new working group will help advance strategic planning to build U.S. capacity to address mosquito-borne and tickborne threats. Dr. Berkelman added that the group can consider issues and concerns about pesticide use. She suggested inviting another BSC/OID member to join the new group to represent the state and local perspective.
  - **Waterborne diseases.** Once CDC has published a new estimate of the U.S. burden of waterborne diseases, the BSC might suggest that CDC consider the potential benefits of establishing a joint OID/NCEH Working Group on Waterborne Diseases with a combined focus on infectious and chemical contaminants.

## NCHHSTP Update

Jonathan Mermin, NCHHSTP Director, provided the following updates.

### HIV/AIDS

NCHHSTP has issued

- [Vital Signs on HIV Testing](#), which reported that
  - One in two people with HIV were infected for at least 3 years before diagnosis.
  - Seven in 10 people at high risk for HIV visited a healthcare provider during 2015 but were not tested for HIV. These healthcare visits represent lost opportunities for HIV diagnosis and treatment.
- A July 2017 [HIV monitoring report](#), which reported progress in reaching goals for prevention, care, and treatment of HIV/AIDS, with positive trends in 9 of 16 HIV indicators

- The [HIV/AIDS prevention strategic plan for 2017–2020](#), which incorporates advances in prevention science, including pre-exposure prophylaxis

## Viral Hepatitis

- Multiple outbreaks of hepatitis A occurred in 2016 and 2017 among homeless people and people who inject drugs. These included outbreaks in California and Utah, involving 477 hospitalizations and 21 deaths, and outbreaks in Michigan, involving 457 hospitalizations and 20 deaths.
- A rise in the number of new hepatitis C infections (which have tripled since 2010) is associated with the opioid crisis in rural areas. NIDA, CDC, SAMHSA, and the Appalachian Regional Commission have awarded nine 5-year grants to develop comprehensive approaches to prevent and treat the consequences of opioid injection, including overdose, substance use disorder, HIV, hepatitis B and C infections, and sexually transmitted diseases.
- A [state-level analysis](#) of hepatitis C incidence and preventive services laws and policies found that
  - Maine, Nevada, and Utah have the most comprehensive laws for prevention.
  - 19 of 50 states fall into the least-comprehensive category (i.e., no laws to authorize syringe exchange programs, or other measures).
  - 24 states have Medicaid restrictions that require a period of sobriety before an addicted person can receive HCV treatment.

## STDs

- STDs are at a record high in the United States, with more than 2 million reported cases of chlamydia, gonorrhea, and syphilis in 2016. The number of syphilis infections is increasing, especially among men who have sex with men (MSM) and among women, with over 600 reported cases of congenital syphilis. Gonorrhea has increased by 22% in men.
- Nine state and city health departments have received CDC grants (for a total of \$4 million) to strengthen local capacity to address congenital syphilis. The awardees are Ohio, Maryland, Georgia, Los Angeles, Chicago, Florida, Louisiana, Texas, and California.
- CDC has provided states and localities with an [STD infographic](#) that can be edited to highlight each jurisdiction’s “State of STDs.”
- CDC has posted a YouTube video to raise awareness of drug-resistant gonorrhea entitled [CDC: Gonorrhea drug treatment loses effectiveness](#).

## School and Adolescent Health

- The [School Health Policies and Practices Study](#) (SHPPS) reports improvements in prevention of violence, bullying, and suicide. More improvements are needed in health education, substance use prevention, and HIV and STD services.
- The 2016 [School Health Profiles report](#) found that
  - The median percent of schools teaching 19 sexual health topics in middle school is 14%.
  - The median percent of schools teaching all topics in high school is 38%.
- The **National Youth Risk Behavior Survey, 2005–2015** reports that more 9<sup>th</sup> and 10<sup>th</sup> graders are postponing their first sexual experience.

- [Communication products](#) developed with data from the **Youth Risk Behavior Surveillance System** (YRBSS) include two infographics for healthcare providers and a palm card for public health and education professionals.

## Tuberculosis

- The [TB Surveillance Report](#) found significant progress toward TB elimination in the United States, although the current rate of decrease is too slow to achieve elimination in this century. As of 2016, there were 9,272 cases of active TB disease in United States, with a national incidence of 2.9 per 100,000 (a 2.9% decrease from 2015). The highest numbers of cases were in California, Texas, New York, and Florida.
- CDC has posted a YouTube video entitled [5 Things to Know about Tuberculosis](#), which is aimed at general audiences and can be shared via social media.

**In conclusion**, Dr. Mermin reported that the *American Journal of Public Health* (AJPH) is planning to publish a theme issue entitled *Monitoring Disparities in Prevention and Treatment of HIV, Viral Hepatitis, STDs, and TB in the United States*. AJPH has issued a call for papers with a January 31, 2018, deadline for submissions.

### **Dr. Mermin suggested these questions for discussion:**

- How can we implement truly routine LTBI, HIV, viral hepatitis, and STD screening in hospitals, clinics, and emergency departments?
- How can we best implement comprehensive community opioid and infectious disease prevention, including syringe services programs?
- What is the best use of resources to reduce STD incidence?

## Discussion

### HIV/AIDS

- With fewer U.S. deaths caused by HIV/AIDS—due to better diagnosis and treatment—the number of people living with HIV/AIDS in the U.S. has doubled and the prevalence of HIV/AIDS has increased.
- Disparities continue in some geographic areas and populations, including persons in correctional institutions and persons who inject drugs.
- In the gay community, two factors—increased risk of sexual transmission and high prevalence—work together to increase the incidence of HIV/AIDS. For black MSM, the numbers are going down in all age groups; this is not yet the case for Latino MSM.
- As HIV/AIDS has become a chronic disease, the general level of public health information about HIV/AIDS and HIV/AIDS prevention has decreased.

### Tuberculosis

- About 85% of cases of TB in the U.S. are due to reactivation of latent infections. The majority of people with TB disease who were born outside the U.S. lived in the U.S. for more than 5 years before experiencing active TB.

- The availability of interferon-gamma release assays (IGRAs) has made routine screening and treatment of LTBI more feasible. IGRAs are typically administered in physicians' offices, with results available within 24 hours. Moreover, IGRAs reduce the rate of false-positives in people previously vaccinated with BCG vaccine.
- Six to 13 million people in the United States have LTBI. It is not yet known how to identify persons with LTBI who are likely to progress to active TB disease.
- Public health planning to make LTBI screening routine might draw on experience from the early days of the AIDS epidemic. CDC and partners might engage nongovernmental organizations, publish best practices for healthcare providers, and draft a Healthcare Effectiveness Data and Information Set (HEDIS) measure.
- CDC may consider promoting similar LTBI strategies abroad as in the United States.

### The Opioid Crisis

- The October issue of the *American Journal of Public Health* includes an article on the “epidemic of despair” among rural white Americans.<sup>7</sup> Most increases in death rates in this population are attributable to self-destructive behaviors (e.g., suicide, overdoses, and liver disease due to alcohol and hepatitis C infections) likely related to underlying social and economic factors.
- Many persons became addicted to opioids after receiving pain prescriptions from their doctors.<sup>8</sup> CDC has issued [guidelines](#) on prescription practices and other approaches to pain management. However, as overdoses due to prescription drugs have decreased, overdoses due to illegal drugs have increased.
- Efforts to address the crisis of heroin and fentanyl use (which is increasing) would benefit the associated epidemic of HCV infections.
- CDC has developed preventive messages about opioid use that are directed to students, doctors, and the general public—as well as messages about treatment directed to those who are already addicted.
- Participation in syringe services programs (SSPs) reduces disease transmission, does not increase the number of overdoses, and increases the chance of treatment. Nevertheless, SSPs are not available in many jurisdictions affected by the opioid epidemic.
- CDC should consider developing a state-level legislative toolkit, or community guide, that describes the benefits of SSPs, in terms of health, costs, and community participation.
- In [June 2017](#), the American Medical Association endorsed the development of pilot facilities where people who use intravenous drugs can inject them under medical supervision.

### Health Disparities

- CDC has developed “vulnerability maps” that identify counties at high risk for opioid use and associated disease transmission in multiple states and has shared mapping information with NACCHO and CSTE.

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<sup>7</sup> Stein EM, Gennuso KP, Ugboaja DC, Remington PL. [The Epidemic of Despair Among White Americans: Trends in the Leading Causes of Premature Death, 1999–2015](#). *Am J Public Health*. 2017 Oct;107(10):1541–1547.

<sup>8</sup> See: S. Quinones. *Dreamland: The True Tale of America's Opiate Epidemic*. Bloomsbury Publishing USA, 2015.

- The work of CDC often involves a balance between working in large populations to achieve the largest magnitude of effect and working in smaller communities that are disproportionately affected to reduce disparities. Unless this is monitored carefully, focusing on places where CDC can have the largest magnitude of effect has the potential to increase disparities.

### **A Comprehensive Approach**

- CDC should think creatively about management of complicated patients, who may have multiple health issues and substance abuse problems.
- Efforts to address the opioid crisis—like efforts to address HIV—must take into account mental health issues. Mental health issues are a major reason why people who are diagnosed with HIV or hepatitis C do not receive (or remain in) treatment.
- CDC should consider expanding the continuum-of-care approach to HIV to include TB and HCV, perhaps by creating comprehensive, multi-disciplinary public health programs. These programs could be linked to SSPs and offer care to people addicted to opioids. Dr. Mermin noted that cascades of medical services that comprise continuums-of-care for TB and HCV (unlike for HIV) can end in cure. CDC is developing a “cascade to cure” for people with LTBI, using infectious disease models to develop state-level targets and estimate savings in lives and money.
- Large systems like Kaiser that take a holistic view of health can play a major role in developing a comprehensive approach. The Veterans Administration, which conducts routine screening for HIV and hepatitis C, may be the first health system to eliminate hepatitis C among its patients.

### **Sex Education**

- The reason for the National Youth Risk Behavior Survey finding that 9<sup>th</sup> and 10<sup>th</sup> graders are postponing their first sexual experiences is not known. Dr. Mermin mentioned these hypotheses:
  - Comprehensive health education programs are having an impact, over time.
  - Teens are spending more time alone, on their computers.
  - Black youth have more hope for the future and are engaging in fewer risky behaviors.
  - Youth of all ethnic groups have more hope for the future—due to the improved economy—and are engaging in fewer risky behaviors.
  - Adolescent girls are feeling more empowered and more able to express their needs and wants.
- Although the survey does not define the word “sex,” the same question (with the same wording) has been asked for several years.
- CDC might compare national data on this topic with state-level data and with data from other countries.

## **Reports from Advisory Committees**

### **Advisory Committee on Immunization Practices**

Nana Bennett, [ACIP](#) Chair, reported that

- The October ACIP meeting included votes on recommendations for both the Adult and the Child and Adolescent Immunization Schedules, the recommendation of a third dose of mumps vaccine during outbreaks, and the approval of the use of the new Herpes Zoster subunit vaccine for adults over the

age of 50. In addition, the ACIP recommended the preferential use of this vaccine over the previous live Herpes Zoster vaccine.

- Topics of discussion at the February ACIP meeting will include updating recommendations on hepatitis A vaccine and reviewing data on the new hepatitis B vaccine (assuming it is licensed by February), and reviewing new data regarding LAIV.
- ACIP adopted the GRADE process several years ago for evaluating evidence. Over the next year, ACIP will consider
  - Which processes to use in cases where the evidence base is insufficient to apply GRADE
  - Factors to take into account in moving from a GRADE-based evaluation to formulation of a vaccine recommendation. The implementation of an evidence-to-recommendation framework is underway. In addition, the committee is making a number of administrative changes to improve function and transparency.

Dr. Bennett also noted that

- Amanda Cohn, CDC/NCIRD, is the new ACIP Executive Secretary.
- ACIP is considering how to ensure a smoother, more transparent pathway for nominating new ACIP members.
- The ACIP charter is up for renewal in 2018 and may be updated.

## Clinical Laboratory Improvement Advisory Committee

Sheldon Campbell, [CLIAC](#) member, reported on the November CLIAC meeting, which included updates from CDC, CMS, FDA, and the Institute of Medicine, as well as reports on laboratory testing and telemedicine and on CIDTs. Highlights included

- FDA updates on
  - The [CDC and FDA Antimicrobial Resistance Isolate Bank](#)
  - The [Database for Reference Grade Microbial Sequences](#) (FDA-ARGOS)
  - An FDA workshop on [Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices](#), held on September 13, 2017
  - The FDA “breakthrough pathway” for [coordinated development of antimicrobial drugs and antimicrobial susceptibility test devices](#)
- CDC updates on
  - **Laboratory science issues.** CDC has launched quality initiatives to improve laboratory procedures, biosafety, and workforce development, as well as emergency preparedness efforts (e.g., working with clinical laboratories to improve public/private coordination and with FDA and CMS to improve development and deployment of Emergency Use Authorization (EUA) tests.
  - **Antibiotic susceptibility testing of new antibiotics.** CDC and partners are evaluating ways to shorten the gap between approval of a new antibiotic and the availability of reference testing methods to support its use. As part of these efforts, CDC is working with the [Antibiotic Resistance Laboratory Network](#) (ARLN) to ensure regional availability of testing capacities, as well as capacities for electronic ordering and reporting.

– **Culture-independent tests (CIDTs)**

- Widespread use of CIDTs is causing the loss of isolates and affecting public health evaluation of disease trends. Strategies for addressing the transition to CIDTs include
  - Current strategy: Use reflex culture to obtain isolates
  - Short-term strategy: Use WGS to develop a sequence-based national infrastructure, while continuing to use reflex cultures to obtain isolates
  - Long-term strategy: Use metagenomic techniques to develop methods for direct-from-specimen, sequence-based pathogen characterization
- Questions under consideration include
  - What guidance is needed by clinical laboratories, industry partners, and public health officials to address CIDT issues? Can reflex culture testing be mandated? Can laboratories obtain workload credit for conducting reflex culture testing?
  - What mechanisms are available to monitor CIDT performance characteristics and detect genetic changes that might occur if pathogens evolve in response to the use of CIDTs?
  - How can HHS facilitate development of best practices for public health uses of CIDTs (e.g., test-of-cure assays during outbreaks and reflex cultures)?
  - Can information on methodologies used by CLIA-regulated laboratories be provided to public health authorities to help make adjustments in trend models?
- CLIAC has prepared a draft recommendation on CIDTs, which says
  - In clinical microbiology, CIDTs are rapidly supplanting culture-based tests, but cultures are indispensable for surveillance and outbreak prevention, which are both cost-effective and vital to public health and national security. CLIAC recommends that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDT on public health surveillance and to recommend impactful solutions that are brought to the attention of agency and government leaders.
- Updates were also provided on
  - The NIH [Antimicrobial Resistance Diagnostic Challenge](#)
  - The development of interoperability standards for communicating-device coding and microbiology coding of laboratory tests. This activity is a collaboration among the NIH National Library of Medicine, the Office of the National Coordinator for Health Information Technology (ONC), FDA, and other partners.

### Comments/Discussion

- The 6th edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) will include a chapter on clinical laboratory safety.
- FDA continues to consider issues related to potential regulation of laboratory-developed tests<sup>9</sup> for diagnosis of chronic and infectious diseases.
- The FDA-CDC AR Isolate Bank provides researchers with panels of organisms, with information about their antimicrobial susceptibility.

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<sup>9</sup> A laboratory-developed test (LDT) is a type of diagnostic test that is designed, manufactured, and used within a single laboratory.

- CLIAC is not currently involved in discussions about distinguishing between infection and colonization.
- No pathway is envisioned for maintaining culture-based tests as part of clinical practice.

## Healthcare Infection Control Practices Advisory Committee

[HICPAC](#) was chartered in 1991 to advise CDC and HHS on disease prevention and control, surveillance, and issues related to healthcare-associated infections (including antimicrobial resistance), across U.S. healthcare settings. HICPAC consists of 14 voting members, 6 ex officio members from federal agencies, and liaison members from 21 organizations. It holds public meetings three times a year.

Deborah Yokoe, HICPAC Co-chair, reported on HICPAC activities to

- Draft guidelines on HAI prevention in neonatal intensive care units (*NICU Infection Prevention Guideline Workgroup*)
- Update guidelines on HAI prevention for healthcare personnel (*Guideline for Infection Control in Healthcare Personnel Workgroup*)
- Advise the CDC National Healthcare Safety Network on HAI surveillance and reporting issues (*NHSN Workgroup*)

The HICPAC workgroups are also working to improve the guideline writing process by revising HICPAC's "Strength of Recommendation" categories and developing a framework for evaluating recommendations about the use of products that are marketed for the prevention of infections. Recent HICPAC guidance documents include

- [Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings](#), published online on March 15, 2017
- [Essential Elements of a Reprocessing Program for Flexible Endoscopes](#), published online January 25, 2017
- [Antibiotic Stewardship Statement for Antibiotic Guidelines](#), published online September 2016 and updated September 21, 2017

## Comments/Discussion

- HICPAC has drafted a White Paper to facilitate discussion of issues that are critical to adequate reprocessing of flexible endoscopes. The current evidence base may not be sufficient to recommend a specific microbiologic method for assessing the adequacy of high-level disinfection for endoscopes.
- HICPAC's infection control activities are in good alignment with those of the [FDA Outbreak Response and Evaluation \(CORE\) Network](#).
- HICPAC might consider addressing
  - The clinical implications of PCR test results for bacterial infections at hospitals that may indicate colonization rather than infection
  - Provider concerns about the appropriateness of NHSN surveillance definitions for pediatric settings

## **CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment**

Susan Philip, Chair of the [CHAC](#) STD Workgroup, reported that CHAC

- Is considering a motion to recommend investment in high-impact interventions in schools (e.g., professional development for middle school teachers to help them support LGBT students, who are at risk for HIV infection)
- Has issued best practices for HIV prevention and treatment in clinical settings, such as Ryan White programs
- Provided guidance to the HHS Secretary on
  - Public health messaging about HIV treatment as disease prevention
  - Public health resources needed to address the opioid epidemic
- Provided recommendations to the CDC Director on removal of barriers to HCV screening, including recommendations for universal (rather than risk-based) screening for pregnant women and for testing of babies at 1–2 months

Dr. Philip also noted that

- Rising U.S. rates of STDs constitute an urgent public health threat.
- The priorities of the CHAC STD Workgroup include disseminating STD treatment guidelines to reduce congenital syphilis and increase capacity for STD screening and treatment in clinical settings.
- Addressing STDs will likely be the focus of the CHAC meeting in May 2018.

### **Comments/Discussion**

- The CHAC HCV Workgroup has drafted a recommendation on universal screening for HCV. The discussion and finalization of this recommendation will take into account a cost-benefit analysis.
- It was suggested that CHAC consider providing guidance on
  - Screening for HIV and syphilis at jails and prisons
  - Overcoming financial issues that impede STD screening of high-risk groups

## **Advisory Council for the Elimination of Tuberculosis**

Barbara Cole, [ACET](#) Chair, reported that ACET has

- Added an amendment to its charter stating that a TB survivor should be included as an ACET member
- Updated a document entitled the *Essential Components of a Public Health TB Prevention, Control and Elimination Program* to include public health information that states and localities can reference in plans to move toward TB elimination
- Increased its collaboration with the [National Tuberculosis Controllers Association](#)

Other ongoing ACET activities include

- Updating guidelines on TB in congregate settings, including correctional institutions, and among homeless populations
- Evaluating ways to improve the availability of TB drugs (e.g., by expanding emergency stocks)
- Providing input for updating the American Academy of Pediatrics (AAP) [Red Book chapter on TB](#) to provide information on TB testing in children and teenagers
- Strategic planning to make LTBI reportable in the U.S. and to update [U.S. technical instructions](#) for TB screening

The next ACET meeting will be held on December 11–12.

### Comments/Discussion

- The GeneXpert TB test is not effective in children and therefore is not approved for pediatric use. Dr. Erbeling reported that NIH/NIAID is supporting the development of other TB tests for use in children.

## Report of the Food Safety Modernization Act Surveillance Working Group

The goals of the FSMA SWG are to

- Provide advice and recommendations on improving foodborne illness surveillance to the HHS Secretary
- Review updates on foodborne illness surveillance activities, including improvements in governmental coordination and integration, evaluation and enhancement of surveillance systems, and collaboration and communication with stakeholders

### 2017 Annual Report

Tim Jones, Chair of the FSMA SWG, noted that the Food Safety Modernization Act (which is primarily focused on FDA activities) created the [Integrated Food Safety Centers of Excellence](#) and the BSC FSMA SWG, which is charged with issuing an annual report to the HHS Secretary.

The 2017 Annual Report includes an introduction; sections on Key Topics, Resources, and Next Steps; and appendices that provide information on FSMA SWG members and implementation of FSMA surveillance requirements. Key Topics include

- CIDTs and whole genome sequencing (WGS)
- A review of foodborne disease surveillance systems and approaches, including [FoodNet](#) and the [National Outbreak Reporting System](#) (NORS)

A motion to approve the 2017 Annual Report passed unanimously following the presentation on the FSMA SWG.

## December 2017 FSMA SWG Meeting

The meeting included the following topics.

- **FSMA implementation**

Signed in 2011, FSMA provided the most sweeping change in FDA's food safety authority in more than 70 years. It includes a broad prevention mandate, a new system of oversight for imported foods, and a farm-to-table approach. FDA's strategic objectives for FSMA implementation include reduced risk of illness

- Attributed to facilities (achieved through implementation of preventive controls)
- Associated with produce
- Associated with imported food

FSMA implementation includes three overlapping phases:

- **Phase 1: Develop regulations, guidance, and policy.** Between 2011 and 2016, FDA finalized seven [rules for food safety standards](#) in such areas as preventive controls for human and animal food; produce safety; and imported foods. Food suppliers of different sizes (large, small, and very small) are subject to different rules and different compliance dates.
- **Phase 2: Identify performance metrics to measure success.** Performance metrics have been identified through a “web of metrics” approach that includes
  - **Public health metrics** that measure reduction in illnesses linked to FDA-regulated foods (e.g., based on data on outbreaks and sporadic illness and data from special studies)
  - **FDA metrics** that measure FSMA implementation (e.g., based on inspection and compliance data, food and environmental testing data, and data from the [Reportable Food Registry for Industry](#))
  - **Industry performance metrics** that measure progress toward creating a strong food safety culture
  - **Segment-specific industry metrics** that focus on specific food-safety areas (e.g., related to produce and imported foods)

Industry data sources include food and environmental testing data and data on “near misses.” FDA efforts to advance industry acceptance and compliance include education, outreach, technical assistance and training, and non-regulatory visits to companies and farms.

- **Phase 3: Implement, monitor, evaluate.** Phase 3 activities include transitioning Phase 2 implementation strategies from design activities to operational activities and monitoring, evaluating, and modifying implementation strategies to ensure achievement of public health and compliance goals.

- **Measuring the public health impact of FSMA**

Use of foodborne disease surveillance data to evaluate FSMA activities is challenging because

- Foodborne illness may be due to multiple hazards.

- A standard way to categorize illness and outbreak data by type of food and to attribute foodborne illness to specific commodities is lacking. The categorization scheme used by the [Interagency Food Safety Analytics Collaboration](#) (IFSAC), for example, is designed to assess the proportion of illness due to broad categories of food (e.g., produce) rather than due to specific types of food (e.g., tomatoes or cucumbers).
- FSMA provisions are typically geared toward conditions and practices. Data from public health sources, such as NORS, do not include information on preparation and processing steps that are important to FSMA evaluation.

Challenges in making use of outbreak surveillance data include questions about

- The relationship between outbreak data and data on sporadic illness. Outbreaks are responsible for a very small fraction of overall illness and may not reflect sporadic risks among different populations.
- Surveillance biases that might reflect regional practices in outbreak investigation and reporting
- The type of outbreaks included in databases on foodborne illness. Although single-state outbreaks are far more common than multistate outbreaks, data from investigations of single-state outbreaks are less likely to be captured by the [Outbreak Response and Evaluation \(CORE\) Network](#). Investigations of multistate outbreaks are more likely to involve FDA investigators, be associated with FDA-regulated facilities, and be due to contamination that occurs at a high point in the chain of production.
- Alignment of food categorization scheme and rules. For example, data on raw agricultural commodities are collected under the FDA Produce Rule, while data on fresh-cut or processed produce are collected under the FDA Preventive Controls Rule.

Analytical approaches to analyzing outbreak data include

- Counting the number of outbreaks or the number of illnesses associated with those outbreaks
- Using outbreak data to estimate the number of illnesses that are relevant to FSMA rules
- Using a variety of statistical approaches to evaluate trends and determine whether illness rates decrease following implementation of an intervention

## Workgroup Guidance

The FSMA SWG recommends that CDC and partners

- Improve data on sporadic cases (as well as outbreak cases) of foodborne diseases
- Evaluate the impact of CIDTs and other factors on the epidemiology of foodborne diseases
- Increase state-level capacity to address foodborne diseases (e.g., informatics capacity)
- Improve sharing of data on foodborne diseases (e.g., with regulators and industry partners)
- Continue to improve collaborations and partnerships

## 2018 FSMA SWG Meetings

Future meetings may address

- CIDTs. This topic may also be discussed at a meeting in Washington, DC, in May, hosted by the Pew Research Center.
- Food safety challenges related to imported foods

- Improving root-cause analyses of outbreaks
- Building state capacity and associated performance measures
- Enhancing integrated data systems in and among CDC, FDA, and USDA
- Updates on interagency collaborations (e.g., IFSAC, IFORC, Gen-FS)

## Discussion

### CIDT Issues

The BSC discussed the transition from culture-based diagnostic tests to CIDTs, which—despite their advantages—pose a special challenge to public health. Until new detection methods come into widespread use, the loss of culture-based techniques could have a significant impact on our ability to detect foodborne outbreaks and identify new patterns of foodborne drug resistance. The transition to CIDTs could also affect estimates of disease incidence and disease trends.

BSC members commented that

- The transition to CIDTs is already affecting foodborne disease surveillance and will eventually affect all infectious disease areas.
- Microbial cultures will always be needed for specific public health purposes, such as characterizing pathogens that cause outbreaks. The immediate concern is loss of the ability to conduct routine strain-typing to detect outbreaks.
- The 2017 Annual Report describes potential ways to address CIDT issues but does not make recommendations. During 2018, the 3-step plan described in the annual report might be updated to
  - Include specific guidance on preserving isolates as a short-term solution (step 1)
  - Document progress in developing a sequence-based infrastructure (step 2)
  - Describe ongoing research efforts to develop metagenomic methods (step 3)
- Additional investments in metagenomics might speed the development of new diagnostic methods, as suggested at a recent FoodNET meeting.
- An overlap in use of WGS and metagenomic methods is likely during the transition to metagenomic methods, similar to the overlap use of PFGE and WGS that occurred during the PulseNet transition to WGS.

### CIDT Recommendations

- The FSMA SWG might draft recommendations on CIDT issues for consideration by the BSC, taking into account
  - APHL’s *Recommended actions for clinical laboratories and public health agencies* ([APHL CIDT Fact Sheet](#), February 2015)
  - Input from a May 8–9 meeting on CIDTs organized by the Pew Research Center to engage subject matter experts from clinical medicine, industry, and public health
  - The estimated costs of taking action at the state and local levels (e.g., to conduct reflex testing)
- The recommendations might include an analysis of the resources required to implement them.

## 2017 Annual Report and Cover Letter

- A motion to approve the 2017 Annual Report passed unanimously. The report will be submitted to the HHS Secretary, with plans for a cover letter that
  - Highlights CIDT issues and explains the importance of preserving cultures, which have been the cornerstone of diagnostic testing
  - Explains that the BSC plans to submit recommendations on CIDT issues to CDC and HHS in early summer
  - Stresses the importance of improving surveillance and control of waterborne diseases

## Other Comments

- CDC should encourage “next-generation thinking” about new opportunities for disease detection and control that may arise as advanced molecular testing methods provide a more complete and comprehensive understanding of the microbial world.
- In the future, social media tools could help enhance foodborne surveillance. For example, tweets about falling ill after a restaurant meal could lead to an immediate public health investigation of the restaurant.
- Use of CIDTs varies among countries. There has been rapid uptake of CIDTs in Australia and Canada, and use of CIDTs may be required in some countries with single-payer systems, such as the United Kingdom and Germany.
- Coordination and data-sharing among U.S. agencies and partners is essential to optimize foodborne disease surveillance and outbreak detection.

## Public Comments

The phone lines were opened for public comments at the end of the day on December 6, but no one spoke.

## NCIRD Update

Nancy Messonnier, NCIRD Director, provided the following updates.

### Leadership Changes

- Kristin Pope is the Deputy Director for Management and Operations.
- Erin Connelly is the Associate Director for the Office of Health Communication Science.
- Sarah Wiley is the Acting Associate Director for Policy.
- Melinda Wharton, Director of the Immunization Services Division, is also serving as Acting Director, National Vaccine Program Office in the Office of the Assistant Secretary for Health, HHS.

## October 2017 ACIP Meeting

- **Recommendation on shingles vaccine.** The Shigrix subunit vaccine (licensed in October 2017) is
  - Recommended for healthy adults aged 50 years and older
  - Recommended for adults who previously received the current shingles vaccine ([Zostavax<sup>10</sup>](#))
  - The preferred vaccine for preventing shingles and related complications
- **Recommendation on mumps vaccine.** Anyone previously vaccinated with two doses of a mumps-containing vaccine who is identified by public health officials as at increased risk for mumps because of an outbreak should receive a third dose of a mumps-containing vaccine to improve protection against mumps disease and related complications.
- **Childhood immunization schedule.** ACIP is simplifying the footnotes to the childhood immunization schedule by removing unnecessary text while preserving all pertinent information and maintaining clarity.

## Vaccine Updates

- Data from the National Immunization Survey (NIS) indicate that less than 1% of American toddlers received no vaccines in 2016.<sup>11</sup>
- HPV vaccine coverage among adolescents is lower than expected (about 40%). However, the recommended change from 3 to 2 doses is likely to have a significant impact over the next few years. HPV vaccine coverage has risen more rapidly in males than females (though starting 5 years later), and coverage rates in males and females are converging.
- Influenza activity is increasing in many parts of the United States, with H3N2 (which tends to be severe in the very young and very old) as the predominant strain. A report in Australia suggested that the 2017 vaccine is only 10% effective against H3N2; in the United States, overall Flu VE efficacy has been measured as 30%.
- A sixth wave of severe human infections with avian influenza A(H7N9) has begun in China. The main risk factor is the same as before: contact with chickens.
- CDC is investigating a recently reported association between influenza vaccination and miscarriage. Earlier studies did not find such a linkage.
- Two-thirds of pregnant women in the United States do not receive the influenza vaccine, in spite of recommendations from the American College of Obstetricians and Gynecologists (ACOG).

## Division Reviews Portfolio

### Division of Bacterial Diseases (DBD)—*focus on Global*

DBD conducts about 70 projects in more than 40 countries, involving collaboration with many partners, including WHO, MSF, Gavi, and the African Society for Laboratory Medicine. DBD goals include

- Determining disease burden, including the proportion that is vaccine preventable

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<sup>10</sup> Zostavax is a live attenuated virus vaccine licensed in 2006.

<sup>11</sup> Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Kang Y. [Vaccination Coverage Among Children Aged 19–35 Months—United States, 2016](#). MMWR Morb Mortal Wkly Rep. 2017 Nov 3;66(43):1171–1177.

- Developing and implementing cutting-edge diagnostic tools for multi-pathogen detection and characterization
- Expanding the use of AMD technology in disease detection and outbreak surveillance

Examples of DBD projects include

- The [Child Health and Mortality Prevention Surveillance](#) (CHAMPS) network, a network of disease surveillance sites in Sub-Saharan Africa and South Asia that collects data on the causes of child mortality. CHAMPS sites are using TaqMan Array Cards (TAC)<sup>12</sup> to identify diseases that cause different types of clinical syndromes (e.g., pneumonia and diarrheal disease).
- MenAfriNet, an international consortium supported by the Gates Foundation to monitor meningitis disease and evaluate the impact of meningococcal A conjugate vaccine. MenAfriNet has established case-based surveillance in 102 districts in 5 priority countries (Burkina Faso, Niger, Mali, Chad, and Togo) and implemented real-time PCR in 8 national reference laboratories.

### **Division of Viral Diseases (DVD)**

DVD Global projects focus on

- Assessing the disease burden due to vaccine-preventable diseases. Examples include working with partners to
  - Estimate the burden of rubella virus infection and congenital rubella syndrome (CRS) in the Democratic Republic of the Congo and the potential impact of vaccination
  - Profile rubella and CRS epidemiology in Zambia
  - Review hospital discharge registries and national data sources to evaluate trends in diarrhea deaths
- Assessing the disease burden due to non-vaccine-preventable diseases. CDC is providing technical support to evaluate disease burden due to RSV and other respiratory pathogens, enteric pathogens (e.g., rotavirus and norovirus), picornaviruses (e.g., enterovirus A71), and cytomegalovirus.
- Conducting research to improve diagnostics for MERS and Rubella/CRS, develop rotavirus vaccines, and evaluate new methods for vaccine delivery (e.g., microneedle patches) and for shipping specimens (e.g., UNEX cards)

### **Immunization Services Division (ISD) Reviews/Partner Engagement**

- ISD works with core partners (e.g., ASTHO, NACCHO, and ACS) to provide strong and consistent messages about vaccine-preventable diseases.
- ISD partnerships to advance adult immunization include
  - Organizational partnerships supported by the Prevention and Public Health Fund. Participants include the National Association of Community Health Centers (NACHC), ACOG, the American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS), and the American Academy of Family Physicians (AAFP)

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<sup>12</sup> TaqMan Array Cards are high-throughput, simple-to-use tools for quantitative analysis of mRNA or miRNA transcripts using a real-time PCR protocol. They utilize a microfluidic card with 384 reaction chambers and 8 sample loading ports.

- Partnerships with 10 state and local health departments that are working with pharmacies, community health centers, and large health systems to implement [Standards for Adult Immunization Practice](#)
- ISD partners in reducing immunization disparities include public health departments in Chicago, South Carolina, Michigan, West Virginia, and Louisiana; NACHC; the National Academy for State Health Policy; Every Child By Two; CMS; and the CDC Rural Health Work Group.

## Outbreaks and Technical Assistance

- In fall 2017, NCIRD
  - Investigated 62 human infections with novel influenza A viruses, performing genetic and antigenic analyses of each virus. All were associated with swine exposure, including several associated with agricultural fairs.
  - Deployed staff to Saudi Arabia to provide technical assistance during investigations of cases of MERS-CoV, as part of an ongoing collaboration with the Saudi Arabian Ministry of Health
- Over the course of the year, NCIRD activities to address Legionnaire’s disease (LD) have included
  - Providing more than 100 consultations on clusters and outbreaks of LD in the U.S., including a cluster of about 25 community cases in Philadelphia
  - Developing LD prevention programs for use in Veterans Health Administration healthcare facilities
  - Publishing [Vital Signs: Health Care–Associated Legionnaires’ Disease Surveillance Data from 20 States and a Large Metropolitan Area—United States, 2015](#)
  - Posting a Federal Register Notice entitled [Effective Methods for Implementing Water Management Programs \(WMPs\) To Reduce Growth of Transmission of Legionella spp.](#)
  - Assisting CMS in developing a rule that requires Medicare-certified healthcare facilities to establish water management programs to reduce the risk of the growth and spread of *Legionella* and other opportunistic pathogens
- NCIRD also contributed to a [special supplement](#) in *Clinical Infectious Diseases* on the worldwide burden of group B streptococcal disease.

## What’s Next

Upcoming events include

- 100<sup>th</sup>-year commemoration of the 1918 influenza pandemic
- Publication of updated childhood and adult immunization schedules
- Reconsideration of the live attenuated influenza vaccine (LAIV) by ACIP
- Updating the CDC strategy for influenza and maternal vaccination

## Discussion

### Influenza Vaccine

- A study in Australia that rated the efficiency of the current influenza vaccine as 10% led some hospital employees in the U.S. to question mandatory vaccination of healthcare workers. Jacqueline

Katz, Deputy Director, NCIRD Influenza Division, noted that the vaccine efficacy rate measured in the U.S. was 32% and that the Australian study (which involved a small cohort) gave an efficacy range of 10–30%.

- Vaccine efficacy studies often vary from country to country, perhaps because of population differences. In Australia the influenza vaccine is recommended for at-risk groups only (not for universal use, as in the U.S.), so fewer people are vaccinated.
- Future assessments by the National Immunization Survey (NIS) of vaccine coverage and early-season influenza activity may rely less on telephone surveys and more on data from state-level registries.

### **Research on Influenza Vaccines and Treatments**

- BARDA is supporting private sector efforts to develop monoclonal antibodies that provide protection against Ebola virus, influenza virus, and other pathogens. It was noted that in the future,
  - A cocktail of monoclonals might be used to treat influenza.
  - Monoclonals and/or small-molecule drugs might be used for pre-exposure protection against seasonal influenza.
- In the long term, the identification of monoclonals that are effective against all influenza strains could point the way toward development of a universal influenza vaccine. In the meantime, it is important to continue making improvements in current seasonal influenza vaccines.

### **Influenza A(H7N9)**

- A greater sense of urgency about pandemic preparedness is needed at the state level, in view of the emerging threat of influenza A(H7N9).
- Dr. Katz reported that
  - Most A(H7N9) viruses cause mild or asymptomatic disease in chickens and are therefore classified as low pathogenic avian influenza (LPAI) viruses. However, highly pathogenic avian influenza (HPAI) viruses were recognized in some provinces during the fifth wave of severe human infections with avian influenza A(H7N9).
  - LPAI H7N9 viruses, which have spread more widely than HPAI H7N9 viruses, are less likely to be detected in poultry. The majority of A(H7N9) viruses have molecular features that are consistent with the ability to bind both avian- and human-like receptors, which may enhance their ability to infect humans. The severity of disease in humans appears to be similar for both LPAI and HPAI, but a smaller number of human HPAI H7N9 virus infections have been detected and investigated.
  - The Chinese Government has piloted vaccination of poultry against the H7N9 viruses.
  - CDC, NIH, and other USG agencies are working with local partners in border regions to improve influenza surveillance among wild birds and live bird market poultry. Thus far, influenza A(H7N9) has not been detected in aquatic birds.

## Adult Vaccination

- CDC should consider issuing best practices on adult vaccination for large healthcare organizations.
- Dr. Messonnier concurred and reported that CDC is working closely with multiple large healthcare organizations, especially around utilizing quality measures. She also noted that CDC is developing an estimate of the burden of disease that could be prevented through adult vaccination.

## Public Health Communication

- Figuring out how to use public health messaging to change behaviors is an ongoing challenge.
- Vaccination should be an everyday part of healthcare, for children, teens, and adults. Public health messaging about vaccines should encourage people to get vaccinated but should not scare them.
- CDC typically focuses on providing information to healthcare providers who recommend vaccines to their patients (e.g., pediatricians, obstetricians, and internists). Vaccination of pregnant women is largely an education/communication issue rather than an access-to-care issue, but there may also be system issues.
- National data on vaccination are not always useful at the local level, because reasons for vaccine hesitancy differ from place to place.

## Revaccination and Vaccine Efficacy

- The “antigenic distance hypothesis” (ADH) predicts that in certain cases the immune response triggered by previous seasonal influenza vaccines can interfere with the immune response triggered by a more recent vaccination. It has been proposed that ADH might account for reduced vaccine efficacy against A(H3N2) influenza, as measured in Canada since 2010.<sup>13</sup>
- Dr. Katz reported that CDC and partners are continuing to study this phenomenon, which may vary in impact among different age groups and populations.

## Other Comments

- **Group B strep.** CDC might evaluate whether the implementation of molecular testing for group B streptococcal disease has been a cost-effective way to reduce the incidence of infection.
- **Mumps vaccine.** The initial efficacy of the mumps vaccine is high (though not as high as for measles vaccine), but wanes over time.
- **Shingles vaccine.** Studies are underway to assess the impact of using different adjuvants with the new Herpes Zoster vaccine.
- **Global laboratory issues.** Most projects that aim to improve national capacities to detect particular pathogens (e.g., by implementing advanced technologies) also address “horizontal” (non-pathogen-specific) issues of laboratory quality and sustainability.

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<sup>13</sup>Skowronski DM, Chambers C, De Serres G, Sabaiduc S, Winter AL, Dickinson JA, Gubbay JB, Fonseca K, Drews SJ, Charest H, Martineau C, Kraiden M, Petric M, Bastien N, Li Y, Smith DJ. Serial Vaccination and the Antigenic Distance Hypothesis: Effects on Influenza Vaccine Effectiveness During A(H3N2) Epidemics in Canada, 2010–2011 to 2014–2015. *J Infect Dis.* 2017 Apr 1;215(7):1059–1099.

## CGH Update

Rebecca Martin, CGH Director, provided the following updates.

### PEPFAR

- PEPFAR's updated epidemic control strategy
  - Accelerates optimized HIV testing and treatment strategies, particularly for reaching men under age 35 and key populations
  - Expands HIV prevention, particularly for young women under age 25 and men under age 30
  - Incorporates
    - Continuous use of epidemiologic and cost data to improve partner performance and increase program impact and effectiveness
    - Renewed engagement with faith-based organizations and the private sector
    - Strengthened policy and financial contributions by partner governments
- PEPFAR aims to achieve control of the HIV epidemic in high-burden countries by the end of 2020, with its 90-90-90 Global Target increased to 95-95-95:
  - 95% of people living with HIV know their status
  - 95% of people who know their status access treatment
  - 95% of people on treatment have suppressed viral loads
- [CDC and partners have supported life-saving antiviral treatment for 7.3 million of 13.3 million persons supported by PEPFAR](#) (35% of all people on antiretroviral treatment), including more than 388,000 children under the age of 15.
- PEPFAR's Population-based HIV Impact Assessments (PHIAs) demonstrate [progress toward HIV epidemic control](#) in many countries, with Lesotho, Swaziland, Malawi, Zambia, and Zimbabwe approaching control of their HIV epidemics.

### Global TB

- CDC is working with ministries of health, USAID, NIH, the Office of the Global AIDS Coordinator, and DoD to advance global TB control in more than 25 countries.
- For example, CDC is assisting the Indian Ministry of Health in improving TB case finding and treatment (particularly for MDR-TB patients), in preventing TB transmission in healthcare facilities, and in improving the quality of TB and MDR-TB diagnostics.
- Global TB efforts build on momentum from the [United States Government Global Tuberculosis Strategy](#), the [National Action Plan for Combating Multidrug-Resistant Tuberculosis](#), and the [Moscow Declaration to End TB](#).

### President's Malaria Initiative (PMI)

- [PMI](#) is expanding into five new countries (Burkina Faso, Cameroon, Cote d'Ivoire, Niger, and Sierra Leone). CGH plans to send CDC Resident Advisors to each of these countries.

- Malaria-endemic countries have made substantial progress, due to scale-up of prevention and treatment interventions. As described in a September 2017 supplement to the *American Journal of Tropical Medicine and Hygiene* on the evaluation of the impact of malaria control interventions,<sup>14</sup> all-cause mortality among children under 5 years of age decreased 40% between 2005 and 2010.

## Global Health Security

- [CDC and partners are supporting countries' efforts](#) to achieve International Health Regulations (IHR 2005) compliance and respond to public health events of international concern (PHEICs), as part of the [Global Health Security Agenda](#) (GHS). Examples of GHS activities include working with ministries of health to
  - Prevent further spread of Zika disease
  - Reduce the worldwide burden of measles by implementing the [“microneedle patch”](#) as a new method for vaccination
- Improvements in global health security provide both health and economic benefits to the U.S. When an outbreak occurs overseas, it can affect U.S. companies and workers in industries that export goods and services to affected countries. In 2015, \$308 billion in U.S. material goods was exported to GHS priority countries; production and transport of these goods supported 1.6 million U.S. jobs. The states with the highest total value of U.S. goods exported to GHS priority countries were Washington (\$28.8 billion), California (\$27.2 billion), and Texas (\$26.0 billion).<sup>15</sup>
- GHS is a 5-year initiative that ends in 2018. Development of GHS 2.0 is under discussion with global partners.

## Global and Domestic Health: Exchanges

- Global health experience gained during the public health response to the 2010 hurricane in Haiti informed the response to the 2017 hurricanes in Florida, Texas, and Puerto Rico.
- Global lessons-learned can be applied domestically in such areas as
  - Development of guidelines
  - Access to affected populations (urban and rural)
  - Community engagement
  - Capacity-building and technology transfer

## Global Health Goals

- CDC is revising its global health strategy, with these three goals under consideration:
  - Health impact: Save lives, improve health outcomes, and foster the health of populations globally

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<sup>14</sup> Rowe AK. Assessing the Health Impact of Malaria Control Interventions in the MDG/Sustainable Development Goal Era: A New Generation of Impact Evaluations. *Am J Trop Med Hyg.* 2017 Sep;97(3\_Suppl):6–8.

<sup>15</sup> Statistics are from “The Relevance of the Global Health Security to U.S. Export Economy,” under review by *Emerging Infectious Diseases*.

- Health security: Improve global public health preparedness and response to protect Americans and populations across the globe
- Global health leadership: Lead and influence the advancement of global public health science and practice
- WHO has published its draft [\*Thirteenth general programme of work 2019–2023\*](#). Its mission is *Promote Health—keep the world safe—serve the vulnerable*, and its strategic priorities include
  - Health coverage: 1 billion more people with health coverage
  - Health emergencies: 1 billion more people made safer
  - Health priorities: 1 billion lives improved

**Dr. Martin suggested these questions for BSC discussion:**

- What are other ideas for implementing global/domestic exchanges?
- In fiscal year 2018, what strategies should CDC undertake internally to continue to strengthen its role and activities in the global health arena?

## Discussion

### Global TB

- Effective, evidence-based strategies are required to address TB and latent TB infections (LTBI) in low-resource countries.
- CDC and global partners might consider supporting national efforts to identify and treat children under 5 with LTBI.
- The elimination of TB in the United States depends on controlling TB abroad and addressing LTBI at home.
- Lessons learned in the U.S. about LTBI treatment might be useful to other countries.
- A method for identifying persons with LTBI who are likely to advance to active disease would be a major advance.
- Few countries currently conduct surveillance for LTBI and drug-resistant TB. Surveillance data are essential to assess disease burden and monitor the impact of interventions.

### Field Epidemiology Training Programs (FETPs)

- Many FETPs provide 2-month programs in outbreak management for county-level officials and 30-day programs for front-line response workers. Thus far, FETPs have trained more than 4,000 front-line workers in rapid detection and response.
- CDC might explore ways to link university programs and FETPs. These collaborations could provide degree programs for FETP trainees, as well as opportunities for operational research (e.g., in detection and treatment of TB).

- Dr. Martin reported that
  - FETP trainees are often government workers, and many FETP graduates work in ministries of health. CGH is considering ways to help FETP graduates as their careers progress.
  - The number of EIS officers from other countries has decreased in recent years, partly due to visa issues. This year’s EIS class may not include any international members.

## Global Health Security

- BSC members commended CDC’s ongoing commitment to global health security.
- Dr. Martin reported that response coordination among U.S. agencies has improved, with good collaboration during the responses to Ebola and Zika. Each agency had its own GHSA funds and budget.
- CDC collaborates with DoD on laboratory diagnostics and capacity building, with USAID on One Health issues, and with DHS and the FBI on public health law issues.
- Private sector partners value “soft diplomacy.” Examples of private sector activities include ExxonMobil’s assistance with malaria prevention efforts in Nigeria and the GHSA Private Sector Roundtable’s work to mobilize industry for action.

## Antimicrobial Resistance

- CDC activities conducted as part of the GHSA AR Action Package include efforts to address MDR-TB, extend e-learning modules on AR issues, and improve hospital infection control in hospitals (e.g., in India).
- CDC is also working with FAO and other partners to coordinate One Health workshops in 11 countries that address AR issues at the interface of animal and human health.
- In regard to classifying AR events (outbreaks involving drug-resistant pathogens) as PHEICs under the IHR, Dr. Khabbaz reported that
  - AR events fall under the IHR framework, and AR remains a priority for WHO.
  - The [Strategic and Technical Advisory Group \(STAG\) on antimicrobial resistance](#) met in fall 2016 and will meet again in February. STAG members receive monthly reports on working group activities to promote national AR action plans and develop a framework for antimicrobial stewardship.
- The change of leadership at WHO might lead to new opportunities to bring forward AR issues.

## Disease Surveillance

- CDC is working with many partners to use new technologies to advance laboratory-based disease surveillance in resource-limited countries.
- Public health information systems are starting to use mobile phones and text message to make laboratory data available at different levels, in real time. In Uganda, for example, PEPFAR partners are using both telephones and bicycle messengers to transmit laboratory results to healthcare facilities and patients in a timely fashion.
- In the future, laboratory diagnostics will be made more sustainable through use of point-of-care multiplex assays.

## Africa CDC

- [Africa CDC](#) was established by the African Union in January 2017. Its director is John Nkengasong.
- Two CGH staff members are detailed to Africa CDC to help develop criteria for Africa CDC Collaborating Centers, to enhance linkages to [National Network of Public Health Institutes](#), and to work with FETP graduates to improve syndromic surveillance and training.

## Global/Domestic Exchanges

- Domestic public health efforts can benefit from applying lessons learned in global health work in such areas as
  - Improving outreach to at-risk communities (e.g., in remote or rural areas)
  - Addressing stigmas that prevent ill persons from seeking treatment
  - Identifying and addressing other factors that impede treatment (e.g., depression or substance abuse)
  - Appreciating the potential roles of different categories of healthcare workers, in addition to doctors and nurses
- These lessons can (for example) help the U.S. public health community address the opioid crisis.

## ***Focused Discussion: Outbreaks of Hepatitis A in the United States***

Monique Foster, NCHHSTP Division of Viral Hepatitis, reviewed the epidemiology of hepatitis A virus (HAV) in the United States and described recent outbreaks related to foodborne transmission and person-to-person contact.

### **Background: Global Patterns of HAV Transmission**

- Countries with high HAV endemicity rarely experience outbreaks, because most adults in these countries were infected as children and are therefore immune. Most early childhood HAV infections are asymptomatic.
- In countries with very low HAV endemicity, such as the United States,
  - HAV infections are sometimes reported in persons who have traveled to HAV-endemic regions.
  - Outbreaks are uncommon. However, when they do occur, they may be large and prolonged, because most adults are susceptible.

### **Hepatitis A in the United States**

- In the pre-vaccine era, cyclical increases in the U.S. incidence of hepatitis A occurred every 10–15 years. Outbreaks typically involved large numbers of children and young adults and continued for at least a year. In non-outbreak years, the annual number of reported cases was about 21,000.
- Hepatitis A vaccine was
  - Introduced for outbreak control and protection of at-risk populations in 1996
  - Used to protect persons living in areas with high incidence rates, starting in 1999
  - Recommended by ACIP for universal childhood immunization in 2006

- Cases of hepatitis A have decreased by 95% since 1999. In the pre-vaccine era, large community outbreaks often began when asymptomatic children infected adult caretakers. Today, adults are more commonly infected through ingestion of contaminated food, contact with infected persons in HAV-endemic countries, or contact with infected individuals in at-risk populations in the U.S.

## U.S. Outbreaks of Hepatitis A in the Post-Vaccine Era

- Between 2003 and 2015, fewer than 200 outbreak cases were reported each year. However, four of the five largest U.S. outbreaks in the post-vaccine era occurred over the past 5 years, and three occurred within the last 18 months. A rise in cases of hepatitis A is also occurring in Europe, with over 11,000 cases reported since January 2017.
- In 2016 and 2017, multiple outbreaks of hepatitis A were associated with either foodborne transmission or person-to-person transmission in at-risk groups.
  - **Foodborne transmission**
    - Foodborne outbreaks of hepatitis A typically occur when susceptible adults ingest contaminated foods imported from HAV-endemic countries. In 2016, large outbreaks were associated with
      - [Scallops](#)
      - [Frozen strawberries](#)
    - Contamination can occur at point-of-service or during growing, harvesting, processing, or distribution. CDC may assist FDA with traceback investigations.
    - Foodborne transmission of HAV is underreported and misdiagnosed.
    - Outbreak responses may include provision of post-exposure prophylaxis.
  - **Person-to-person transmission in at-risk groups**

Population groups at risk for hepatitis A include

    - Men who have sex with men (MSM). Hepatitis A vaccine has been recommended for MSM since 1996.
    - Homeless persons
      - Homelessness has not been confirmed as an independent risk factor for HAV infection because many homeless individuals have other risk factors (e.g., substance use and/or liver disease). However, seroprevalence studies suggest that older age, duration of homelessness, and injection drug use are associated with immunity to hepatitis A.
      - Responses to hepatitis A outbreaks among homeless persons can be hampered by poor hygienic conditions, transience, and poor responsiveness to education and preventive efforts.

## California Outbreak among Homeless Individuals—March 2017 to the Present

- California State officials noted significant increases in reported cases of hepatitis A in March 2017, with the majority of cases associated with injection drug use and/or homelessness.
- As of November 24, the outbreak included 665 cases. Of those, 426 (65%) were hospitalized and 21 (3%) died. The hospitalization rate during HAV outbreaks is typically 25%.

- In San Diego (the site of about 80% of the outbreak cases), the median age of patients was 43 years. Five percent had coinfections with hepatitis B, and 17% with hepatitis C. Epidemiologically linked cases were identified in Arizona and Utah.
- The San Diego Health Department set up an incident command structure (ICS) to coordinate response efforts, and CDC deployed an Epi-Aid team. Handwashing stations were installed, and mass vaccination events were held in a variety of locations, with teams of public health nurses visiting encampments to offer immunizations.
- The epi-curve of the outbreak suggests that cases were present prior to March. Additional cases are likely to be reported, due to the long incubation period of the virus (15–50 days) and lags in reporting.

### **Michigan Outbreak among Injection Drug Users—October 2016 to the Present**

- Michigan state officials noted increases in cases of hepatitis A in October 2016. Although early cases were linked to an infected food handler at a grocery store, the investigators determined that disease transmission was strongly associated with a history of drug use.
- As of November 11 the outbreak included 555 cases. Of those, 457 (82%) were hospitalized and 20 (4%) died. The median age of patients was 42 years. Three percent of the cases have coinfection with hepatitis B, and 38% with hepatitis C.
- The Michigan Department of Health and Human Services set up an ICS, and a CDC field team arrived in October. Mass vaccination events were conducted in collaboration with the Michigan Primary Care Association and drug treatment centers. Because the outbreak did not involve large outside encampments (as in San Diego), hygiene interventions were less important. While most of those infected reported drug use, only 11% were homeless.
- As in California, the outbreak's epi-curve suggested that cases were likely present before the outbreak was detected and that additional cases are likely to emerge before the outbreak is contained.

### **Increased Morbidity and Mortality during the 2016–17 Outbreaks**

- Hospitalizations related to the outbreaks in 2016 and 2017 ranged from 25% in the outbreak associated with frozen scallops to 82% in the Michigan outbreak.
- All-age mortality for HAV infection is typically 0.6%, and no deaths were associated with recent foodborne outbreaks. However, the case mortality rate for the California outbreak was 3% and for the Michigan outbreak 4%.

### **Sequence Analysis of HAV Outbreak Strains**

- Of the seven known hepatitis A genotypes, the most common in North and South America is IA. The strains circulating in the European MSM outbreak and among MSM in the U.S. involve genotype IA.
- The majority of U.S. outbreaks over the last 5 years have been associated with genotype IB. The outbreaks in California and Michigan involved two different IB genotypes.

### **Challenges**

- Different groups within state and local public health departments may be responsible for hepatitis A reporting (e.g., a vaccine group, a foodborne disease group, or a viral hepatitis group).

- During outbreaks of hepatitis A,
  - Vaccination efforts must be mobilized rapidly and must prioritize those at risk rather than the “worried well.”
  - States and localities must decide whether to set up incident command systems.
  - Many states and localities continue to rely on the CDC laboratory for HAV testing.
- Routine vaccination of persons in at-risk groups (as identified by ACIP) is an important component of disease prevention. ACIP may in the future consider whether to classify homelessness as a risk factor for hepatitis A infection.

## Discussion

Dr. Foster was joined by Cindy Weinbaum, Deputy Director, Immunization Services Division, NCIRD.

### Severity of Illness Due to Hepatitis A Infection

- Hospitalizations during the outbreaks in Michigan and San Diego involved long stays because many cases had co-infections or suffered from alcohol-associated liver disease. The high mortality rates were likely due to higher age and damaged livers rather than to a virulent viral strain.
- Deaths rarely occur during foodborne outbreaks of hepatitis A. Although the hospitalization rate during an outbreak associated with ingestion of contaminated pomegranate seeds<sup>16</sup> was high, the severity of disease did not correlate with the rate of hospitalizations, because the hospital stays were short.

### Vaccination against Hepatitis A

- The most effective strategy for increasing vaccination uptake during the California outbreaks was to bring along a person known to the people living in the encampment (e.g., a local police officer or service provider).
- Ongoing efforts are required to identify and overcome obstacles to hepatitis A vaccination of at-risk groups (e.g., stigma associated with infection and confusion about vaccines against hepatitis A and B). Health officials are working with clinics that serve at-risk groups, including MSM<sup>17</sup> and persons living with HIV.

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<sup>16</sup>Collier MG, Khudyakov YE, Selvage D, Adams-Cameron M, Epson E, Cronquist A, Jervis RH, Lamba K, Kimura AC, Sowadsky R, Hassan R, Park SY, Garza E, Elliott AJ, Rotstein DS, Beal J, Kuntz T, Lance SE, Dreisch R, Wise ME, Nelson NP, Suryaprasad A, Drobeniuc J, Holmberg SD, Xu F; Hepatitis A Outbreak Investigation Team. Outbreak of hepatitis A in the USA associated with frozen pomegranate arils imported from Turkey: an epidemiological case study. *Lancet Infect Dis*. 2014 Oct;14(10):976–81.

<sup>17</sup>Latash J, Dorsinville M, Del Rosso P, Antwi M, Reddy V, Waechter H, Lawler J, Boss H, Kurpiel P, Backenson PB, Gonzalez C, Rowe S, Poissant T, Lin Y, Xia GL, Balter S. Notes from the Field: Increase in Reported Hepatitis A Infections Among Men Who Have Sex with Men—New York City, January–August 2017. *MMWR Morb Mortal Wkly Rep*. 2017 Sep 22;66(37):999–1000.

- The Chronic Hepatitis Cohort Study (CHeCS) is monitoring 10,000 HCV-infected patients to learn more about disease progression and the impact of care and treatment on patients' health. As part of these efforts, CHeCS is measuring HAV vaccination rates among persons with HCV infection.<sup>18</sup>

### Homelessness and Hepatitis A Infection

- Hepatitis A infection is not usually associated with homelessness, although lack of housing is a known risk factor for many diseases.<sup>19</sup> The 2017 HAV outbreak among homeless persons in California could be a one-time event or a harbinger of things to come.
- Past HAV outbreaks have been associated with drug use and/or with poor hygienic practices associated with homelessness. During the California outbreak, responders installed public restrooms, encouraged handwashing, and distributed hygiene kits as an incentive for vaccination.
- Hepatitis A prevention among at-risk groups must be addressed at the local level (e.g., by partnering with local homeless services providers, substance abuse programs, and correctional healthcare facilities).

### Other Comments

- Some front-line healthcare workers were infected with hepatitis A during the outbreak in Michigan (e.g., in emergency departments where homeless persons seek care). The San Diego Department of Health and Human Services helped hospitals implement stronger contact precautions.
- The California public health laboratory is working with APHL to share HAV strain data with other public health laboratories via the [APHL Informatics Messaging Services platform](#) (AIMS).

## Public Comments

The phone lines were opened for public comments at the end of the meeting, but no one spoke.

## Upcoming BSC/OID Meetings

The meeting was adjourned at noon. The next BSC meetings will take place on May 2–3 and December 5–6, 2018.

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<sup>18</sup> Forty percent of the HCV patients monitored in the Chronic Hepatitis Cohort Study have no immunity to hepatitis A virus, despite the ACIP recommendation that individuals with chronic liver disease be vaccinated. *See:* Henkle E, Lu M, Rupp LB, Boscarino JA, Vijayadeva V, Schmidt MA, Gordon SC; Chronic Hepatitis Cohort Study (CHeCS) Investigators. Hepatitis A and B immunity and vaccination in chronic hepatitis B and C patients in a large United States cohort. *Clin Infect Dis.* 2015 Feb 15;60(4):514–22.

<sup>19</sup> Kushel M. Hepatitis A Outbreak in California—Addressing the Root Cause. *N Engl J Med.* 2018 Jan 18;378(3):211–213.

## APPENDIX: Meeting Participants

### BSC Members

|                                  |   |                                 |
|----------------------------------|---|---------------------------------|
| Ruth Berkelman                   | Mary Hayden   | Bonnie Maldonado                |
| Jack Bennett                     | Denise Hinton ( <i>by phone; representing FDA</i> ) | Andy Pavia                      |
| Nancy Bennett                    | Tim Jones   | Susan Philip                    |
| Kristy Bradley                   | Salmaan Keshavjee                                   | Mark Riddle ( <i>by phone</i> ) |
| Mike Brady                       | Beth Lautner ( <i>by phone</i> )                    | Lee Riley                       |
| Sheldon Campbell                 | Jim Le Duc  | Guillermo Ruiz-Palacios         |
| Barbara Cole ( <i>by phone</i> ) | Mike Loeffelholz                                    | Susan Sharp                     |
| Jeff Duchin                      | Ruth Lynfield                                       | Jill Taylor                     |
| Emily Erbeling                   |   | Debbie Yokoe                    |

### Partners and Public Visitors

|   |  |
|---|--|
| Meredith Allen ( <i>Association of State and Territorial Health Officials</i> ) | Peter Kyriacopoulos ( <i>Association of Public Health Laboratories</i> ) |
| Andres Camacho-Gonzalez ( <i>Pediatric Infectious Diseases Society</i> )        | Kasia O'Neill Murray ( <i>The Pew Charitable Trusts</i> )                |
| Marla Dalton ( <i>National Foundation for Infectious Diseases</i> )             | Walt Orenstein ( <i>National Foundation for Infectious Diseases</i> )    |
| Jeff Engel ( <i>Council of State and Territorial Epidemiologists</i> )          | Kelly Wroblewski ( <i>Association of Public Health Laboratories</i> )    |
| Lilly Kan ( <i>National Association of County and City Health Officials</i> )   |  |

### CDC Staff

|                |                  |                  |
|----------------|------------------|------------------|
| Michael Beach  | Myrline Gillot   | Jonathan Mermin  |
| David Bell     | Tom Gomez        | Nancy Messonnier |
| Sharon Bloom   | Jackie Katz      | Allison Miller   |
| Gail Bolan     | Rima Khabbaz     | Dale Morse       |
| Elise Caruso   | Dawn King        | Prabasaj Paul    |
| Evelyn Cater   | Muriel Konne     | Bob Pinner       |
| Koo Chung      | Alexandra Levitt | Sam Posner       |
| Bryanna Cikesh | Barbara Mahon    | Sonja Rasmussen  |
| Kendra Cox     | Lauri Markowitz  | Virginia Roberts |
| Kim Distel     | Rebecca Martin   | Raul Romaguera   |
| Peter Drotman  | Tonya Martin     | Michael Shaw     |
| Chris Edens    | Robert McClung   | Brajendra Singh  |
| Monique Foster | Sherri McGarry   | Sharon Slocumb   |

