

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

May 2, 2012

A one-day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on May 2, 2012, 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 (see Appendix).

The meeting opened with reports from the BSC food safety and antimicrobial resistance working groups, followed by brief updates on *Dual-Use Research and H5N1* and the *Affordable Care Act and Healthcare Transformation*. Next, the meeting focused on selected issues of special concern from CDC's infectious disease national centers: *Safe Water and Improved Hygiene* from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID); *Immunization Infrastructure* from the National Center for Immunization and Respiratory Diseases (NCIRD); and *Gonococcal Antimicrobial Resistance* from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP).

OPENING REMARKS

BSC Acting Chair Dr. Ruth Berkelman called the meeting to order and was joined by Dr. Rima Khabbaz, CDC Deputy Director for Infectious Diseases and Director, OID, in welcoming participants and facilitating introductions.

Dr. Khabbaz welcomed the new BSC members and thanked the board for providing strategic advice and consultation. She provided brief updates on the following:

- **Bioinformatics Planning.** Bob Cottingham joined OID in January as a bioinformatics consultant to help CDC develop a strategic plan and a business plan for bioinformatics. In addition to his CDC assignment, he also provides expert advice on bioinformatics for the Department of Energy.
- **Non-Culture Diagnostics.** APHL and CDC hosted the *Culture-Independent Diagnostics Forum: Charting a Path for Public Health*, in Atlanta, April 25-26. (http://www.aphl.org/conferences/2012AM/Documents/CIDT_Draft_Agenda_3-19.pdf).
- **CDC Laboratory Report.** At the request of the U.S. Senate Committee on Appropriations, CDC issued a detailed report on its internal laboratory activities conducted during FY 2011 (http://www.cdc.gov/osels/lspppo/senate_report.html).

Dr. Khabbaz reported that the proposed CDC base budget for FY2013 is about \$5 billion, which represents a 22% overall decrease from FY2010. An additional automatic government-wide, across-the-board spending cut will be implemented in January 2013, via a process known as "sequestration," unless Congress reaches agreements on deficit reduction and other budgetary issues by December. If no agreement is reached, CDC will need to absorb an additional 9% cut.

Under the proposed FY2013 budget, funding for some infectious disease areas (e.g., HIV/AIDS) will increase while others (e.g., immunization) will decrease. For FY2012, funding from the Affordable Care Act (ACA) Prevention and Public Health Fund (PPHF) has offset funding cuts in some areas.

BSC WORKING GROUP REPORTS

Dr. Berkelman stressed the importance of the working groups to the work of the BSC, and thanked the BSC board members who serve as chairs or members of the working groups.

Food Safety Modernization Act (FSMA) Surveillance Working Group

The charge of the FSMA Surveillance Work Group—which includes members from BSC, CDC, USDA, FDA, academia, consumer groups, industry, and state and local health organizations—is to provide advice and recommendations to CDC and FDA, and through them to HHS on

- Criteria for the designation of Food Safety Integrated Centers of Excellence
- Improvement of foodborne illness surveillance

BSC members include Harry Chen and James Hadler, the working group chair. Dr. Hadler provided updates on issues discussed during the group's first in-person meeting, held November 7-8, 2011:

- **Food Safety Integrated Centers of Excellence.** Criteria developed by the working group were used to develop a Funding Opportunity Announcement (FOA) for the Centers of Excellence. The FOA will be posted in May or June, with applications due in August. Subject to the availability of funds, up to five Centers of Excellence will be designated in September, with funding anticipated for FY2013.
- **Interagency Food Safety Analytics Collaborative (IFSAC).** Input from the working group was incorporated into a draft *IFSAC Strategic Plan for Foodborne Illness Source Attribution* that was vetted at a public meeting in January 2012 and a Food Safety Forum in February 2012. The plan is now operational, with projects underway.
(www.fsis.usda.gov/PDF/IFSAC_Draft_Strategic_Plan_Attribution.pdf).

Dr. Hadler also described priority recommendations identified in the following three areas during the working group's second meeting (April 24-25, 2012):

1) **Evaluating and Improving Surveillance for Foodborne Illness**

- Unify existing food safety surveillance systems and programs (e.g., by developing a strategic plan for integrating information infrastructure that prioritizes national public health food safety surveillance needs)
- Prioritize national public health food safety laboratory needs and ensure that CDC laboratories coordinate with federal, state, and local laboratories to validate new tests (e.g., culture-independent tests) in public health settings
- Develop a business case for—and clearly communicate the value of—public health food safety programs (e.g., use outbreak data to demonstrate the cost-effectiveness of food safety programs, in terms of cases and costs averted)

2) **External Stakeholder Collaboration** (including partners from industry, consumer relations groups, and academia)

- Address legal/cultural/clearance issues that prevent timely sharing of data with external partners
- Provide more timely and granular data to the public
 - Note: Some CDC data sets already do this (e.g., public use data sets from the Behavioral Risk Factor Surveillance System (BRFSS; <http://www.cdc.gov/brfss/>).
 - Partners are particularly interested in outbreak data for imported and organic food. These require written clarification on mechanisms and turnaround times for data requests.

- CDC should develop and routinely use a plan for rapid communication and information sharing during emergencies. The plan should include providing updates to external partners and experts prior to media intervention.

3) Governmental Coordination and Integration

- Develop a strategic plan for integrating public health food safety surveillance systems
 - Use the 2010 Institute of Medicine (IOM) report *Enhancing Food Safety: The Role of the Food and Drug Administration* (<http://www.iom.edu/Reports/2010/Enhancing-Food-Safety-The-Role-of-the-Food-and-Drug-Administration.aspx>) to inform planning
- Explore ways to implement foodborne illness surveillance metrics as measures of state and local performance and quantify the impact of these efforts and metrics
- Develop a national surveillance system to monitor safety of imported foods

The working group has also begun assessing the importance of culture-independent diagnostics on foodborne illness surveillance and outbreak investigation. Future working group topics may include attribution of foodborne illness, antibiotic resistance in foodborne pathogens, workforce training, and use of social media in surveillance for foodborne diseases.

Discussion

In answer to a question on integrating public health and veterinary surveillance for foodborne illness, Dr. Hadler noted that veterinary disease surveillance, including surveillance that monitors the impact on antibiotic resistance of antibiotic use in food animals, is an important factor in ensuring a safer food supply. Dr. Beth Bell, Director, NCEZID, agreed that ongoing dialogue with USDA and FDA—which have representatives on the working group—is essential to ensure that each agency is able to do its part without duplicating efforts.

Although CDC posts surveillance information on its website during outbreaks, some partners (e.g., consumer food safety organizations and academic researchers) are asking for increased access to core surveillance data. Dr. Hadler suggested that in the future CDC could consider providing line-listing data without identifiers (e.g., as in CDC's BRFSS). Dr. Morse stated that CDC is working to develop new methods to improve communication of surveillance information, including RSS feeds for outbreak data, so that partners can be directly notified when an outbreak update has been posted. CDC is also changing the format of routinely posted surveillance data from .pdf to HTML for easier access to data for analysis.

It was suggested that CDC prepare a case study of the recent multi-state outbreak of listeria to identify gaps and review utilization of emergency resources. Dr. Hadler agreed, noting that CDC routinely reviews high-profile investigations and is considering how to streamline and improve its case histories and make better use of existing resources (e.g., by using surveillance data obtained via social media).

During the listeria outbreak, the FoodNet site hosted by the Colorado Health Department facilitated prompt interviews with case-patients and controls. Other states and stakeholders might benefit from having online access to FoodNet tools and data during outbreaks.

Antimicrobial Resistance Work Group

The Antimicrobial Resistance (AR) Working Group held its first meeting on May 1. BSC members Drs. Bob Weinstein and Andy Pavia serve on the working group, with Dr. Weinstein serving as chair. The

terms of reference for the working group include providing advice and recommendations on the following:

- AR surveillance in support of CDC efforts to
 - Provide information and analysis on the incidence of drug-resistant infections, the prevalence of drug-resistant microorganisms, and the use of antimicrobial drugs (AU)
 - Improve the timeliness of, completeness of, access to, and scope of AR and AU surveillance data
 - Address key barriers at federal, state, and local levels to improving AR and AU surveillance
- AR prevention in support of CDC efforts to
 - Address missed opportunities to implement known prevention strategies
 - Develop prevention strategies where effective strategies are not known or proven
 - Work in critical areas where other groups/agencies/organizations are not currently active
- AR laboratory issues in support of CDC efforts to
 - Improve the effectiveness of clinical and public health laboratories in isolating, identifying, evaluating, and reporting drug-resistant microorganisms and mechanisms of resistance
 - Identify priorities for AR research and translation of research into prevention tools

During the May 1 meeting, the working group developed a 2-year agenda by applying the terms of reference to topic areas suggested by CDC staff. The group decided to focus initially on bacterial and fungal pathogens, emphasizing efforts to prevent the emergence and spread of resistance in humans. The agenda includes the following focus areas and actions:

- Surveillance of antimicrobial resistance
 - Propose criteria for identifying pathogens of greatest public health significance
 - Propose methods to enhance early detection of emerging resistance
- Laboratory methods and diagnosis
 - Propose strategies to enhance laboratory capacity to provide actionable information for public health response
 - Propose approaches for ensuring more rapid international sharing of laboratory data on emergent resistance
- Antimicrobial stewardship (AS)
 - Propose strategies to reaffirm the value of AS in all settings to promote broader acceptance and adoption
 - Propose strategies to enhance ownership of judicious use among individual prescribers
- Interventions to prevent transmission
 - Propose strategies to extend the type of successes seen in infection control in acute care into all healthcare settings and community/other settings
 - Propose criteria for assessing the utility and applicability of prevention strategies in different settings

The CDC AR Office will prepare a summary of the May 1 meeting for working group members and will facilitate communication with AR experts in all CDC Divisions. The working group will convene by conference call within the next 3 months and hold an in-person meeting later this year.

Discussion

In answer to a question about participation by NIH and FDA, Dr. Bell noted that both agencies have identified representatives to participate on the AR working group.

It was suggested that CDC provide information on which AR interventions have been most effective, so that others can build on them. For example, successful interventions to prevent healthcare-associated

infections (HAIs) in hospitals should be extended to other venues, such as long-term care facilities. Conversely, it would be good to know which interventions have not been shown to be effective.

In response to a question about the extent of technical expertise available to the working group, Dr. Bell said that the group had considered inclusion of additional professional organizations but decided to keep the membership small, bearing in mind that many current group members belong to those organizations and are aware of their activities and initiatives. Dr. Pavia noted that the working group plans to invite experts and stakeholders to make presentations and share information on specific topics, as needed (e.g., on development of standard practices for HAI prevention).

It was also suggested that the working group consider how its work can augment or supplement ongoing AR prevention and control efforts by other groups (e.g., the Interagency Task Force on Antimicrobial Resistance; <http://www.cdc.gov/drugresistance/actionplan/taskforce.html>).

DUAL USE RESEARCH AND H5N1

Dual-use research of concern (DURC) is defined by the National Science Advisory Board for Biosecurity (NSABB; http://oba.od.nih.gov/biosecurity/about_nsabb.html) as life sciences research that can reasonably be anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to cause harm. Harold Jaffe, CDC Associate Director for Science, reported on dual-use issues related to research on avian influenza A(H5N1), which have recently been under discussion in the scientific and mainstream press. Dr. Jaffe spoke on behalf of Nancy Cox, Director, Influenza Division, NCIRD; Steve Monroe, Director, Division of High Consequence Pathogens and Pathology, NCEZID; and Jan Nicholson, OID Senior Advisor for Laboratory Science.

Avian influenza A(H5N1) was first detected in Hong Kong in 1997, where it caused sporadic cases of severe and often fatal human illness that ended after 1.3 million chickens were culled. Since its re-emergence in southeast Asia in 2003, H5N1 has become endemic in wild birds and poultry in many countries in Asia, Africa, and Europe, but rarely infects humans. However, concerns remain about the possible evolution of a virulent H5N1 strain that is easily transmissible among humans.

The current controversy involves H5N1 studies conducted at the laboratories of Yoshihiro Kawaoka (University of Wisconsin, Madison) and Ron Fouchier (Erasmus Medical University, Rotterdam) with funding from the National Institutes of Health (NIH) and other organizations. Both studies attempted to identify genetic factors that determine the host range of H5N1, using ferrets as an animal model of human pathogenicity and susceptibility to influenza:

- The Kawaoka laboratory combined a mutated H5 hemagglutinin gene with genes from the 2009 H1N1 virus, used the mutant virus to infect ferrets, and then selected viruses with additional mutations and characterized their transmissibility and virulence. Mutant viruses that were transmissible between ferrets via respiratory droplets were found to be no more pathogenic than the 2009 H1N1 virus.
- The Fouchier laboratory introduced mutations into two genes of a wild-type H5N1 virus, passaged the mutant virus in ferrets, and then selected for viruses that were transmissible between ferrets. At a scientific meeting in Malta in September 2011, Dr. Fouchier reported that the transmissible viruses were highly pathogenic, raising concern about the dangers of this type of research. Several months later, however, in response to questions from WHO and the NSABB (see below), he explained that the selected viruses are not fatal in ferrets when transmitted via respiratory droplets.

After Drs. Kawaoka and Fouchier submitted their findings to *Nature* and *Science*, respectively, in August 2011, NIH referred the manuscripts to NSABB for review. In December, the NSABB recommended that “general conclusions highlighting the novel outcome be published, but that the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm” (<http://www.nih.gov/news/health/dec2011/od-20.htm>). The authors and the journal editors agreed to make the suggested revisions, but requested a mechanism for providing access to the unredacted reports for those who “need to know.” Meanwhile, the topic gained the attention of the national press, generating several articles and comments including an editorial in the *New York Times* (<http://www.nytimes.com/2012/01/08/opinion/sunday/an-engineered-doomsday.html>).

In February 2012, a World Health Organization (WHO) panel of experts reviewed the revised versions of the two manuscripts and met with the authors. The WHO panel favored “full disclosure of the information contained in these studies,” but also supported a voluntary moratorium on related research (http://www.who.int/media/vpc_transcript_2012_02_17.pdf).

In March 2012, the NSABB recommended that the revised Kawaoka manuscript be “communicated in full,”¹ but that the Fouchier manuscript be “communicated, but not as currently written.” By a 12-to-6 vote, the NSABB recommended that the Fouchier manuscript be further revised to include scientific clarifications regarding its data, methods, and conclusions, and should not include “additional information that would enable the construction of an H5N1 virus that is both highly pathogenic and transmissible between mammals through the air” (http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf).

In March 2012, the U.S. National Security Staff issued a new policy on DURC that requires federal departments and agencies that conduct or fund life sciences research to review all current or proposed, unclassified, intra- or extramural research on proposed Tier 1 Select Agents, as well as H5N1 and the 1918 strain of influenza. Any project that meets the definition of DURC requires development of a risk mitigation plan (http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf).

CDC’s DURC policy, which has been in place since 2007, requires determination of dual-use potential during the development stage of all CDC research projects (http://www.cdc.gov/osels/Ispppo/Strategic_Goals/Stewardship/dual_use_research.html). The protocols of three current projects involving Select Agents or 1918 or H5N1 influenza have been reviewed by the CDC Institutional Biosecurity Board, but none were judged to raise DURC issues.

In partnership with other federal agencies, CDC is developing DURC reporting requirements for extramural funding announcements. Other unresolved issues include the following:

- Which risk mitigation strategies should be implemented when DURC issues are identified?
- What is the appropriate role for the U.S. government when DURC is funded by a U.S. agency but conducted in another country, as was Fouchier’s work in the Netherlands?
- If publications are redacted, how can the confidentiality of the original manuscripts be maintained?

¹ Masaki I, Watanabe T, et al. Experimental adaptation of influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets. *Nature* (2012) doi:10.1038/nature10831 (<http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10831.html>).

Of note, this experience has stimulated public discussion and international engagement on DURC, leading to a consensus (though not complete agreement) about the need to investigate genetic factors that influence the host range of H5N1. It has also helped improve U.S. policy and process for addressing DURC.

Discussion

In regard to a question about the potential disincentive effect of this controversy on influenza investigators, BSC member Dr. Carole Heilman noted that some investigators believe that H5N1 research is critical for the health of the U.S. public, while others want to avoid involvement with DURC. Dr. Monroe thought that younger researchers might be discouraged from working in this area, even though important questions remain to be answered. Dr. Pavia said that it is important that benefit be balanced against risk. In addition to its own Agency requirements, CDC is participating in the voluntary moratorium.

Dr. Pavia noted that NSABB provided NIH with balanced options that took into account both scientific value and the risk of societal harms. Dr. Jaffe stated that although NSABB was set up for this purpose, it is not clear that it will continue to play this role. Dr. Monroe noted that NSABB views itself as the court of last resort for unresolved DURC issues, with institutional biosafety boards conducting most DURC reviews. Dr. Heilman agreed that research institutions rather than NSABB or other government entities are primary drivers for DURC oversight. Dr. Monroe said that current review procedures apply only to government-funded research and not to privately funded research.

In regard to a question about ensuring that dangerous pathogens do not “escape” from laboratory facilities, Dr. Jaffe said that CDC laboratories that work with tier-one select agents like H5N1 are inspected by CDC to make sure there are no biosecurity or biosafety problems.

Dr. Berkelman noted that controversy could have been mitigated if the H5N1 studies had been reviewed by NSABB at an earlier stage, before the studies were funded. Dr. Nicholson said that CDC research proposals are reviewed for DURC issues before studies begin. Dr. Berkelman suggested that consideration be given to DURC review for all studies to assess and mitigate potential risks to populations, as is done for human subjects review to mitigate potential risks to individual subjects. Dr. Nicholson reported that NIAID is developing a DURC guidance document that will be posted in the Federal Register.

THE AFFORDABLE CARE ACT AND HEALTHCARE TRANSFORMATION

[Note: Since this presentation was made, the Supreme Court issued its ruling on the Affordable Care Act, upholding the individual mandate but ruling that the planned Medicaid expansion of coverage to 133% of the federal poverty level (FPL) is optional. States are now in the process of determining if they will expand their Medicaid programs, which will affect the number of persons who will achieve insurance coverage over time. In July 2012, the Congressional Budget Office (CBO) issued new projections of insurance coverage, updated to take into account the Supreme Court decision. The CBO report is available at <http://www.cbo.gov/publication/43472>.]

Dr. Lydia Ogden, Director, CDC Office of Health Reform Strategy, Policy, and Coordination, provided an overview of the 2010 Affordable Care Act (ACA) and its implications for public health. She noted that per capita healthcare spending in the United States is the highest in the world, far higher than in other industrialized countries with similar or better levels of health. Moreover, public expenditures for

healthcare (i.e., Medicaid and Medicare) have increased as the baby boomer generation has aged, placing greater demands at both the federal and state levels.

The ACA was designed to address this fundamental U.S. problem—more spending, poorer health outcomes—through a series of actions designed to produce better care, better health, and lower health spending. Its five key themes are:

1. **Expanding Coverage**

Projections: The population of uninsured will drop by 21 million in 2014, and 95% of Americans will be covered by 2016. *[See note above regarding updated projections]*

- Adult children up to age 26 can be covered by their parents' plans (now)
- Medicaid expanded to 133% of the federal poverty level (+9 million)
- Creation of exchanges where individuals can buy insurance at group rates (+9 million)
- Expanded employer coverage (+6 million)

Bridge programs to 2014 include: the Pre-Existing Condition Insurance Plan (PCIP, <https://www.pcip.gov/>); the Early Retiree Reinsurance Program (ERRP; <http://www.errp.gov/index.shtml>), and the Small Business Health Care Tax Credit for Small Employers (<http://www.irs.gov/newsroom/article/0,,id=223666,00.html>).

2. **Offering New Consumer Protections and Choice**

- Guarantees coverage for children with pre-existing conditions
- Prohibits “rescission” (dropping coverage)
- Includes a ban on lifetime coverage limits and emergency room usage limits
- Ensures the right to choose your own doctor
- Expands consumers' right to appeal denials

3. **Making Health Care More Affordable**

- Closes the “donut hole” in Medicare and decreases the cost of medicines starting in 2014
- Requires rebates for consumers if insurers spend too little on care (the “Medical Loss Ratio”)
- Limits annual cost sharing

4. **Improving Quality**

- Created the Center for Medicare and Medicaid Innovation (CMMI ; <http://www.innovations.cms.gov/>), which is testing new medical models (e.g., Accountable Care Organizations (ACOs), patient-centered medical homes, community health teams, and bundled payments). (CMMI is part of the Center for Medicare and Medicaid Services [CMS; <http://www.cms.gov/>].)
- Created the *National Strategy for Quality Improvement in Health Care* (the *National Quality Strategy*; <http://www.ahrq.gov/workingforquality/nqs/>) and the Partnership for Patients (<http://www.healthcare.gov/compare/partnership-for-patients/>), whose goals include preventing healthcare-associated harms and supporting better care transitions.

5. **Improving Prevention and Public Health**

- Requires new plans and Medicare to cover high-value clinical preventive services without cost-sharing; encourages Medicaid to do so as well.
- Authorizes the first-ever *National Prevention Strategy* (<http://www.healthcare.gov/prevention/nphpphc/strategy/report.pdf>)
- Appropriates \$15 billion over 5 years for the Prevention and Public Health Fund (<http://www.hhs.gov/open/recordsandreports/prevention/index.html>)

- Provides \$11 billion over 5 years to expand Community Health Centers to include new sites in medically underserved areas and expand preventive and primary health care services
- Rebuilds the primary care workforce by providing \$1.5 billion to the National Health Service Corps to increase the number of providers in underserved areas by creating incentives to expand the number of primary care doctors, nurse practitioners, and physician assistants and by providing scholarships and loan repayments for those working in underserved areas.

Implications for Public Health. CBO estimates that 92% of nonelderly Americans will have health insurance by 2017, reducing the need for public health departments to provide basic care as part of the social safety-net. At the same time, ACA has opened up new opportunities to work with medical partners to achieve population health goals. Examples of disease control and prevention activities that can be better integrated into the healthcare system include: counseling and education for individuals (e.g., to reduce smoking and obesity); clinical interventions (e.g., preventive services and coordination of care for persons with co-morbidities); long-lasting protective interventions (e.g., immunizations and screenings); policies that improve health by default (e.g., water fluoridation, essential health benefits packages from insurers, and cigarette taxes); and efforts to address social determinants of health (e.g., poverty reduction and improved education).

As part of these efforts, CDC is working to engage on policy decisions, educating partners, conducting strategic planning under conditions of uncertainty, staying abreast of new information, creating new partnerships, and building capacity (e.g., related to the public health and medical workforce, information technology, and care coordination). Dr. Ogden noted that public health activities must take into account fiscal and budgetary constraints, demographic pressures, public opinion, and political constraints. Another challenge is that state and local resources for healthcare activities do not match up well with public health needs. Typically, most resources support traditional medical needs (e.g., linking people to personal health services) rather than population health needs (e.g., monitoring health, mobilizing community partnerships, and informing and educating the local population). Moreover, the factors that currently influence health system priorities are not ideal, although some of them will change as ACA is implemented. Current drivers include money, uninsured people and safety net needs, regulations (federal, state, and local), and local leaders' priorities. Ideal drivers, from a public health perspective, would include local health needs, evidence-based practices, and state-level strategies that are informed by local perspectives.

Dr. Ogden underscored the need for public health leadership and collaboration to ensure that population health goals are achieved through health reform. Issues under discussion by CDC and partners include the following:

- Provision of direct services by local health agencies, once 95% of the U.S. population is insured
- Use of public health funding for services for insured individuals, such as
 - immunization services (see page 16)
 - HIV, STD, TB, and hepatitis screening and treatment
 - pre-Exposure prophylaxis for HIV prevention
 - breast and cervical cancer early detection
- Reimbursement of public health dollars from payers, public or private
- Engagement of new partners by CDC and state and local health department
- Capturing public health data from the health care system
- New knowledge, skills, and abilities needed by public health practitioners

Dr. Ogden noted that health transformation will facilitate patient-centered holistic care; link clinical and community-based services to achieve comprehensive prevention, care, and treatment; and provide the public health community with new sources of data for decision-making and new sources of revenue. On

the other hand, it may cause additional fragmentation in an already fragmented system and create competition among for-profit, non-profit, and other public health care providers.

To address these challenges, CDC has established:

- The Office of Health Reform Strategy, Policy, and Coordination--headed by Dr. Ogden--to monitor ACA implementation and identify opportunities and develop policies that advance public health goals.
- The Office of Prevention Through Healthcare--headed by Dr. Chesley Richards--to promote integration of preventive services and community health interventions into clinical care

Discussion

In answer to a question about how CDC is using ACA as a framework for interacting in new ways with the healthcare system, Dr. Richards noted that CDC is working closely with CMS to leverage resources and activities that advance the three ACA aims: better care, better health, and lower health spending. CDC has a liaison at the CMS Office for Clinical Standards and Quality (<https://www.cms.gov/About-CMS/Leadership/ocsq/index.html>) and is working closely with CMMI, which plans to award \$10-\$30 million over 3 years to medical partners who change the way care is delivered, in accordance with the three ACA aims. CDC is helping to review the CMMI applications and will oversee implementation of some of the innovation awards.

CDC is also building staff relationships with the Health Resources and Services Administration (HRSA) to support the recommendations of the Institute of Medicine report *Primary Care and Public Health: Exploring Integration to Improve Population Health*, which was sponsored by CDC, HRSA, and the United Health Foundation (<http://www.iom.edu/Reports/2012/Primary-Care-and-Public-Health.aspx>). Recommendations include training primary care and public health professionals in aspects of each other's fields; promoting collaborations between public health departments and community health centers (e.g., to improve the provision of preventive clinical services to Medicaid recipients); and encouraging hospitals to make primary care and community health major priorities. A major challenge is to ensure that vulnerable populations gain access to effective and cost-effective care. Dr. Richards said that he would welcome input from BSC members on how to identify community health providers with expertise in infectious diseases who can provide high-quality, low-cost care.

In regard to a question about conducting research to evaluate ways to achieve better care at lower cost, Dr. Ogden agreed that research (or "implementation science") is essential. However, CDC does not have funds for this purpose. At the present time, NIH is planning a meeting on implementation science, and Dr. Tanja Popovic, CDC Deputy Associate Director for Science, is involved in the planning, working with Dr. Alex Blum, NIH Office of Behavioral and Social Sciences Research.

In response to a question about CDC's role in providing guidance to health departments on caring for uninsured and underinsured persons during the transition, Dr. Ogden noted that public health departments already care for these vulnerable populations. As health departments move away from providing clinical care (as many have already begun to do), the goal will be to move these individuals to patient-centered holistic ("whole-person") care. Once 90% or more of people are insured, those who remain (who may have disproportionate health needs and costs) will also need to be integrated into the healthcare system. The provision of clinical care by public health departments to these individuals is no longer a cost-effective or politically viable solution.

Other roles for CDC might include:

- Providing public health education for healthcare providers and developing clinical training models that advance the ACA primary care model. One suggestion was to provide training via federally

funded healthcare training centers (<http://www.aidsetc.org/aidsetc?page=ab-04-00>). Dr. Ogden reported that her office is working with the CDC Office for State, Tribal, Local and Territorial Support (OSTLTS) to launch a program that provides population health training to medical residents throughout the country.

- Disseminating lessons learned from health departments in the Northeast who made the transition from providing healthcare to performing a quality-assurance role more than a decade ago
- Providing evaluation data for state and local health departments to help them identify evidence-based and cost-effective clinical practices. In the area of infectious disease care, CDC will continue to gather data on best practices and on adherence to infection control guidelines (e.g., on HAI prevention).
- Translating evidence-based care guidelines into best practices that can be implemented at clinics
- Working with community hospitals to improve people's health before they get to the hospital (e.g., promoting healthy diets and exercise and discouraging use of tobacco)
- Working with CMS and insurers to improve reimbursement for clinical microbiology tests. Loss of these tests due to non-reimbursement is a growing problem for infectious disease surveillance.

Dr. Pavia noted that much can be accomplished through changes in public policy that advance the ACA aims. He said that he has seen a vast change over the years in pediatric practice, due to immunization policies that eliminated infectious diseases that used to be major problems.

Dr. Berkelman requested that updates on implementation science projects and CMMI-supported innovations be provided at future BSC meetings.

UPDATES AND PRESENTATIONS FROM THE NATIONAL CENTERS

➤ NCEZID Updates and Presentation on *Safe Water and Improved Sanitation*

Dr. Bell provided NCEZID updates, followed by a presentation from Dr. Michael Beach, NCEZID Associate Director for Safe Water, on *Safe Water and Improved Sanitation*.

NCEZID Updates

- **Measles Prevention among Refugees.** A longstanding disease prevention issue related to refugee resettlement work was finally resolved when the State Department agreed that U.S.-bound refugees should be vaccinated against measles before (rather than after) they enter the United States. The vaccines will be purchased with assistance from UNICEF.
- **Lyme Disease.** NCEZID is in conducting a multistate trial to determine whether tickborne diseases like Lyme can be prevented through targeted use of pesticide in people's backyards.
- **Rocky Mountain Spotted Fever (RMSF).** NCEZID is conducting a pilot project on tribal lands in Arizona to prevent RMSF (a bacterial disease carried by dog ticks) by removing feral dogs and working with dog owners.
- **Healthcare-associated infections.** The 2010 National and State HAI Standardized Infection Ratio Report (<http://www.cdc.gov/hai/national-sir-jan-dec-2010/results.html>) records a 32% reduction in central-line bloodstream infections and recommends intensified focus on surgical site and *C. difficile* infections. The National Healthcare Safety Network plans to extend HAI reporting next year to 3400 dialysis facilities.
- **Non-Culture Diagnostics.** As Dr. Khabbaz mentioned earlier, NCEZID and APHL held a conference on culture-independent diagnostics in April. The conference included discussion on

transitioning surveillance systems like PulseNet (www.cdc.gov/pulsenet/) from culture-dependent to non-culture dependent tests.

- **Smallpox Laboratory Inspection.** An inspection of the CDC Smallpox Laboratory will take place on May 7, in accordance with World Health Assembly Resolution 60.1. The aim of the inspection is to ensure that conditions of storage of the virus and of research conducted in the laboratories meet the highest requirements for biosafety and biosecurity.
- **Peer Review of the Emerging Infections Program (EIP).** A panel of public health experts, chaired by Dr. David Fleming, Director of the Seattle and King County Public Health Department, will review the EIP program on May 3-4.
- **Listeria Outbreak.** CDC is developing an issue of *Vital Signs* that will present information on foodborne diseases and describe lessons learned from the 2011 multistate outbreak of listeriosis associated with cantaloupes.

Safe Water and Improved Sanitation

Dr. Beach provided an overview of the NCEZID Global Water, Sanitation, and Hygiene (WASH) Program (<http://www.cdc.gov/healthywater/global/>).

International WASH partners include ministries of health, USAID, the Kenya Medical Research Institute (KEMRI), Population Services International, and the Proctor & Gamble Company. WASH activities are also part of global Neglected Tropical Disease control programs (<http://www.cdc.gov/globalhealth/ntd/>).

Within CDC, WASH partners include:

- *The Center for Global Health (CGH)*, which is responsible for international emergency response to waterborne outbreaks and is currently working in Haiti.
- *The National Center for Environmental Health (NCEH)*, which focuses on community-level water systems and water safety plans (<http://www.cdc.gov/nceh/ehs/GWASH/wsp.htm>)

WASH objectives include the following:

- **Making water safe to drink and use**

The CDC Safe Water System (SWS) was developed in response to the cholera epidemic in Latin America in 1991-94. It focuses on water-safety interventions that can be used in communities that lack piped-in water (e.g., treatment of water in the home, use of specially designed water storage containers, and promotion of hygiene improvements and changes in water-handling behavior).

SWS, which is used in more than 30 countries, has led to 22%-84% reduction in diarrhea in at-risk populations. Currently, SWS is testing new technologies for use in the home (e.g., ceramic filters and antimicrobial towels) and working with partners to extend SWS interventions to schools and clinics, including clinics that provide prenatal care.

- **Improving hygiene and sanitation**

The WASH program conducted a study in Pakistan to evaluate the impact of a school-based handwashing-promotion program on students and their households. The study confirmed a substantial health impact on both students and their household members. Households of students who received multi-component interventions—a lesson, hand-outs, access to soap, and instruction from a classmate

(peer hygiene education)—had lower rates of healthcare visits, and the students’ parents had lower rates of work absenteeism due to illness.

- **Responding to complex international emergencies and outbreaks**

CDC continues to provide technical assistance to address water-related outbreaks. Examples include

- Acute febrile illness associated with intestinal perforations determined to be typhoid fever-related (Uganda, 2009-2011)
- Cholera outbreak associated with contaminated water, bucket chlorination intervention methods ineffective (Cameroon, 2010)
- Typhoid fever outbreak associated with improperly sited wells created to supply high-density urban suburbs in Harare (Zimbabwe, 2011)

- **Controlling and eliminating disease**

CDC is developing an assessment tool to evaluate the relative contributions of water, sanitation, and hygiene improvements in preventing non-enteric diseases (e.g., trachoma or respiratory diseases) and parasitic enteric diseases (e.g., schistosomiasis and infections caused by intestinal helminthes). The goal is to develop recommendations for sustainable integration of WASH activities into ongoing efforts to control or eliminate trachoma (<http://www.cartercenter.org/health/trachoma/index.html>), schistosomiasis, (<http://www.cartercenter.org/health/schistosomiasis/index.html>), and other diseases.

- **Identifying and characterizing disease**

CDC is participating in the Global Enterics Multi-Center Study (GEMS), led by the University of Maryland and funded by the Gates Foundation, to quantify the burden and etiologies of moderate to severe diarrheal disease among children less than 5 years old (<http://medschool.umaryland.edu/GEMS/>). The results of the study—which involves about 10,000 children in the Gambia, Mozambique, Kenya, Mali, India, Bangladesh, and Pakistan—will guide the development and use of vaccines and other public health interventions.

Based on GEMS data, CDC has designed an intervention trial of household ceramic filters to reduce the burden of cryptosporidiosis acquired through drinking water in Kenya. Partial funding for this pilot study was awarded to NCEZID through an internal CDC innovation competition.

- **Education, training, health promotion, about global water, sanitation, hygiene**

Dr. Beach noted that it can be difficult to “market” WASH activities, because most disease control programs are organized by disease. In general, WASH activities can be highlighted as a component of control programs for diarrheal diseases, which remain a major cause of death in children.

Dr. Beach mentioned that CDC is enhancing its webpages on Global Water, Sanitation, and Hygiene (WASH) (<http://www.cdc.gov/healthywater/global/>); cholera (<http://www.cdc.gov/cholera/index.html>); and the CDC Safe Water System (<http://www.cdc.gov/safewater/>).

- **WASH activities in Haiti**

As of April 2012, the cholera epidemic in Haiti had caused more than 532,925 infections, resulting in about 287,092 hospitalizations and 7095 deaths. CDC is working with the Haitian Ministry of Health and other partners to improve access to clean drinking water and adequate sanitation facilities.

Post-outbreak activities include enhancing the laboratory-based sentinel surveillance system for cholera; evaluating cholera treatment centers (CTCs), in terms of staffing, training, sanitation, and hygiene; developing recommendations and tools for the CTCs; evaluating community health worker trainings and reviewing training materials; conducting a serosurvey to assess levels of cholera exposure and illness; and performing environmental testing for *Vibrio cholera*.

Discussion

Dr. Beach concluded his presentation by asking for advice on ways to amplify CDC's WASH efforts (e.g., through partnerships and identification of best practices) and set priorities for future activities, taking into account the immensity of global needs and CDC's limited resources.

In response to a question about CDC's collaboration with ICDDR, B in Bangladesh (<http://www.icddrb.org/>), Dr. Beach said that when the cholera epidemic began, CDC brought ICDDR, B staff to Haiti to provide consultation and training for local physicians.

In response to a question about how CDC works with non-governmental organizations (NGOs) in Haiti, Dr. Beach explained that CDC conducts "proof of concept" projects to demonstrate interventions that may be implemented by NGOs. CDC also advises NGOs on incorporating evaluation procedures into new programs, so that the most successful programs can be identified and expanded.

In regard to a question about identifying best practices for implementation in low-resource countries, Dr. Beach noted that CDC has considerable experience in that area. CDC's Safe Water System has worked well in many countries in sub-Saharan Africa, including in urban as well as rural areas (though not in the very poorest communities).

In regard to a question about improving water safety by changing behavior, Dr. Beach noted that CDC is evaluating approaches that provide incentives and positive reinforcement (e.g., providing access to other healthcare benefits to individuals who use chlorine tablets to decontaminate water).

Board members expressed concerns that the program has many arms that lack a unifying vision, and also noted the large number of external entities involved in safe water and sanitation. Dr. Beach agreed with these concerns and stressed that it is important for CDC to identify—and focus on—specific areas where CDC can play a unique role.

During discussion by Board members, it was noted that both the availability and quality of water are among the most critical challenges of the future—both domestically and globally. Dr. Khabbaz mentioned that *Safe Water* is an infectious disease issue of special concern, and is included as such in *A CDC Framework for Preventing Infectious Diseases* (<http://www.cdc.gov/oid/docs/ID-Framework.pdf>). Comments and suggestions for CDC from individual Board members included the following:

- Help focus attention on waterborne disease prevention as a major global health issue. Dr. Beach noted that during the 1980s WHO had a sizable budget and staff for waterborne disease, but those resources no longer exist.

- Help move things forward by identifying what works. An analysis of trends in child mortality ([http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)60560-1/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60560-1/abstract)) found that child deaths from infectious disease have declined by 2 million (26%) since 2000, due in part to decreased rates of diarrhea, measles, and pneumonia. CDC can use these data to promote the most effective interventions and programs.
- Focus on implementation research.
- Use CDC's "potent voice" to support individuals and organizations that can have a major impact.
- Transition from a primarily technical ("subject matter expert") voice to a leadership voice that helps advance global water safety.

➤ **NCIRD Updates and Presentation on *Immunization Infrastructure***

Dr. Anne Schuchat, Director, NCIRD, provided Center updates, followed by a presentation from Dr. Melinda Wharton, NCIRD Deputy Director on *Immunization Infrastructure*.

NCIRD Updates

- **Polio eradication.** India was removed from the endemic list for polio--a major milestone in polio eradication (<http://www.polioeradication.org/tabid/461/iid/187/Default.aspx>)
- **Importation of Measles.** More than 70 imported cases of measles were reported in the United States in 2011, most of them from Western Europe.
- **Human papillomavirus vaccine (HPV).** Last December the Advisory Committee on Immunization Practices (ACIP) recommended routine use of HPV vaccine for boys aged 11-12 years (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm>).
- **Global Alliance for Vaccines and Immunization (GAVI).** Thirty-seven additional countries plan to introduce childhood vaccines against rotavirus and pneumococcal pneumonia (<http://www.gavialliance.org>).
- **U.S. Vaccine Supply Chain.** A second-generation version of the CDC Vaccine Tracking System (VTrcks) was deployed to all U.S. states and cities in April 2011 (<http://www.cdc.gov/vaccines/programs/vtrcks/index.html>).
- **2011 Immunization Conference.** The first "virtual" national immunization conference, entitled *Immunization: Access for All!* was held March 26-28 (<http://www.cdc.gov/vaccines/events/nic/>). In the future, NCIRD plans to alternate in-person and virtual immunization conferences as a way of reducing costs.
- **Influenza.** In August, 2011, the CMS published a final rule requiring acute care hospitals to report healthcare provider influenza vaccination rates through the CDC National Health Safety Network (<http://www.hhs.gov/ash/initiatives/hai/hcpflu.html>).
- **FY2013 Cooperative Agreements.** NCIRD has developed a new FOA for an FY2013 cooperative agreement that will emphasize key areas that improve immunization delivery (e.g., coverage rates and vaccine stewardship).
- **National Infant Immunization Week.** During this year's celebration (April 21-28), 39 states honored healthcare workers by providing Childhood Immunization Champion Awards (modeled on the Teacher of the Year Award; <http://www.cdc.gov/vaccines/events/niw/index.html>).

- **Vaccine Toolkit.** NCIRD is expanding the *Vaccine Storage and Handling Toolkit* for healthcare providers (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>).
- **Prevention and Public Health Fund.** PPHF funding provided under ACA during FY2011 helped modernize the U.S. immunization system by increasing vaccination rates among school-aged children and adults, improving vaccine information systems, advancing interoperability of vaccine registries and electronic medical records, and developing the evidence base for ACIP policy recommendations. During FY2012 PPHF funds will also be used to improve vaccine storage and handling practices and to increase HBV vaccination rates among at-risk adults.

Immunization Infrastructure

Dr. Schuchat reported that ACIP has asked CDC to define the elements required for a strong immunization system that protects children and adults. Dr. Wharton’s talk identified and reviewed those elements, which include Surveillance for Vaccine-Preventable Diseases, Response to Outbreaks of Vaccine-Preventable Diseases, Immunization Policy, Vaccine Quality Assurance, Vaccine Management, Vaccine Safety, and Vaccine Information Systems.

Dr. Wharton began by providing a brief overview of the Vaccines for Children (VFC) program. Created in 1993, VFC purchases ACIP-recommended vaccines for American children who are Medicaid-eligible, uninsured, or underinsured (<http://www.cdc.gov/vaccines/programs/vfc/default.htm>). VFC-purchased vaccines (about \$5 billion worth per year) are mostly delivered through the private sector. Funds provided under Section 317 of the Public Health Service Act—which is provided to the states to support vaccine purchase and develop immunization infrastructure—are critical for VFC implementation.

CDC is rethinking its investments in immunization infrastructure in light of existing and anticipated changes in healthcare implemented under the 2010 ACA (see pages 7-11 above). In the days ahead, the public health system will continue to work with a range of providers and venues (e.g., medical offices, clinics, schools, workplaces, and pharmacies) to ensure that vaccines are available to children, teens, and adults. Moreover, local health departments will continue to be responsible for stewardship of publicly purchased VFC vaccines administered in both public and private sectors.

The elements of a strong immunization system include:

- **Surveillance for Vaccine-Preventable Diseases**

Surveillance is achieved through state-based systems that receive reports from providers, hospitals, schools, and laboratories. Laboratory-based disease surveillance is essential to monitor the effectiveness of vaccination. For example, disease surveillance following the introduction of the pneumococcal conjugate vaccine (PCV7) in 1998 and the rotavirus vaccine in 2006 demonstrated the effectiveness of those vaccines in decreasing illness among children.

- **Response to Outbreaks of Vaccine-Preventable Diseases**

Epidemiologic investigation is essential to identify disease exposures and routes of transmission, as well as determine if an outbreak is due to inadequate vaccine coverage or to vaccine failure. Depending on the results of an investigation, control measures may include isolation and quarantine, vaccination, and/or antimicrobial prophylaxis.

These efforts are resource-intensive, and most are carried out by state and local health departments. A recent example concerns a measles outbreak in San Diego due to a single imported case involving a child infected in Switzerland who returned to the United States and exposed 839 other people. The child's parents had refused vaccination under California's personal belief exception. The outbreak response, which included quarantine costs for the families of 48 children, involved about \$176,000 in public and private funds.

- **Immunization Policies**

ACIP provides evidence-based recommendations on vaccination that set a national standard of practice for immunization in the United States. Many states also maintain local immunization advisory committees.

- **Quality Assurance and Provider Education**

As the ACA is implemented and more Americans acquire medical insurance, CDC will focus more on quality assurance and less on vaccine delivery. Provider education will be essential to ensure safe and effective immunizations, which require administration of the right vaccine to the right person by the right route of administration at the right time. It also requires appropriate vaccine storage and handling.

- **Vaccine Management by Immunization Providers**

Comprehensive vaccine management has three critical components: reliable and appropriate equipment, knowledgeable staff, and written vaccine storage and handling plans. Those plans must also include instructions for handling potentially compromised vaccines.

- **Management of Vaccine Shortages by CDC**

CDC works with industry to actively manage distribution of vaccine and works with ACIP to issue interim recommendations for vaccine use during vaccine shortages. These efforts require active communication with healthcare providers.

- **Vaccine Information Systems**

Electronic vaccine information systems are essential to track the vaccination status of both vaccinated and unvaccinated populations by recording in immunization registries all vaccinations given to all age groups by all providers in a geopolitical catchment area. Vaccine information systems are also needed to monitor vaccine inventories and identify adverse events. In the future vaccine inventories may be improved through vaccine bar-coding.

CDC and partners are working to make vaccine registries and other vaccine information systems interoperable with other health information systems, including electronic health records. Currently, vaccine providers are being encouraged to report vaccinations to immunization registries electronically as a component of "Meaningful Use" of electronic health records (<http://www.cdc.gov/vaccines/programs/iis/meaningful-use/index.html>).

- **Assessment of Immunization Coverage**

Assessment mechanisms for monitoring immunization coverage include the National Immunization Survey (NIS), including NIS-Teen (www.cdc.gov/nchs/nis.htm), the Behavioral Risk Factor Surveillance

System (BRFSS: www.cdc.gov/brfss/), and the National Health Interview Survey (www.cdc.gov/nchs/nhis.htm). CDC is exploring additional approaches, including surveys conducted via the Internet rather than via telephones.

- **Vaccine Safety**

CDC's ongoing efforts to ensure vaccine safety include

- Conducting ongoing surveillance for adverse events, via the Vaccine Adverse Event Reporting System (VAERS; <http://www.cdc.gov/vaccinesafety/Activities/VAERS.html>)
- Exploring proposed linkages between vaccines and adverse events, via the Vaccine Safety Datalink project (VSD; <http://www.cdc.gov/vaccinesafety/Activities/VSD.html>)
- Rapidly disseminating new information on contraindications and precautions for use of vaccines.

CDC also supports Vaccine Safety Coordinators at state and large local health departments throughout the country who alert CDC to vaccine safety concerns in their state, help respond to vaccine safety issues and emergencies, and serve as a resource for local health departments and vaccine providers in the state.

- **Communication and Partnerships**

CDC is promoting communication and strengthening vaccine partnerships by

- Providing information and advice to health care professionals who recommend and/or administer vaccines. Examples include resources for conducting vaccine conversations with parents, which were developed in partnership with the American Academy of Pediatrics and the American Academy of Family physicians (<http://www.cdc.gov/vaccines/spec-grps/hcp/conversations.htm>)
- Applying communication science and best practices to deliver effective messages, using appropriate formats, channels, and spokespeople
- Building and maintaining immunization coalitions and partnerships
- Increasing attention to vaccine issues and mobilizing partners through events and observances. Examples include National Infant Immunization Week (<http://www.cdc.gov/vaccines/events/niiw/index.html>) and National Influenza Vaccination Week (<http://www.cdc.gov/flu/nivw/>).

In summary, Dr. Wharton stated that it is essential for CDC and public health partners to

- Build and maintain partnerships with immunization providers, by providing quality assurance, provider education, and immunization information systems
- Help develop evidence-based immunization policies, by generating data on disease burden and on vaccine risks and benefits
- Assess the impact of vaccines and monitor the effectiveness of vaccine programs, by conducting surveillance for disease, for vaccine coverage, and for vaccine safety
- Fostering multi-sector partnerships and coalitions to broaden vaccine access and promote awareness of vaccine benefits
- Responding to cases and outbreaks of vaccine preventable diseases to protect public health.

Discussion

Dr. Wharton reported good progress at the state and local levels on achieving interoperability between electronic health records and immunization registries. However, additional agreements are needed to support interoperability between states.

In response to a question about integrating pharmacy data into immunization registries, Dr. Wharton said that this may be possible at the state level. Dr. Schuchat noted that most pharmacy chains currently lack national information systems, although they may develop them in the future.

In response to a question about the role of pharmacies in vaccine delivery, Dr. Schuchat said that CDC has provided pharmacies with guidance on vaccinating adults and is now providing them guidance on vaccinating teens and children. One objective is to ensure that the immunization information is provided to each individual's medical home. With good reporting, it will be possible for a child to receive the first vaccine in a series from his or her healthcare provider and then receive the rest at a pharmacy. BSC member Dr. Steve Ostroff suggested that CDC provide a model policy for pharmacies that administer vaccines.

Some large companies that previously provided influenza vaccinations to employees on site are now giving employees certificates for vaccination at a particular pharmacy. Along the same lines, Emory University asks employees to obtain a vaccination coupon online. Practices such as these that add an intermediary step to vaccination may decrease vaccination rates. Conversely, Dr. Wharton noted that the enthusiasm with which retail chains are promoting vaccination may make up for decreases in the number of worksite vaccinations.

Dr. Chen noted that when pharmacies in Vermont proposed providing vaccines to children local pediatricians resisted. However, Vermont is an exception since nearly all children in Vermont are insured and have a primary physician.

In response to a question about increasing immunization rates for teenage girls, Dr. Wharton said that CDC is working with obstetricians and gynecologists, who may become immunizers or may refer their teenage patients to vaccine providers.

Dr. Schuchat reported that the biggest barrier to HPV vaccination is miscommunication. Although the ACIP recommendation is for three doses by age 13, some providers are telling parents that it is fine to wait because the child is not yet sexually active. Perhaps the inclusion of teen-age boys in the HPV recommendations will help increase rates for both sexes.

BSC member Dr. Frank Cockerill reported that the Mayo Clinic is developing ways to recover HPV from throat samples in order to identify HPV infections that can lead to oral cancers. He suggested that CDC engage ear-nose-and-throat (ENT) physicians in HPV vaccination campaigns. Dr. Cockerill also mentioned recent studies in Ethiopia that found high rates of cervical cancer in some communities, suggesting an urgent need for HPV vaccine (http://apps.who.int/hpvcentre/statistics/dynamic/ico/country_pdf/ETH.pdf). Dr. Schuchat noted that the GAVI alliance is ready to help countries like Ethiopia integrate HPV vaccine into their immunization programs.

Due to recent funding cuts, funds from the ACA/PPHF are supporting core programs in addition to one-time products (e.g., establishment of new billing systems). If PPHF is canceled, the impact on the U.S. immunization infrastructure may be substantial. Insurance will not cover non-delivery functions, and vaccine infrastructure funding is limited. BSC member Dr. Bruce Gellin (Director, HHS National Vaccine Program Office) asked the BSC members for advice on explaining to the public what will happen if "the bridge collapses" and our long-standing immunization infrastructure is undermined.

BSC member Dr. Judy Wasserheit noted other challenges for the U.S. immunization infrastructure:

- Transitioning from one to two critical times for vaccination: (1) Newborn to five years old and (2) adolescence.

- Eliminating cervical cancer through vaccination and other interventions aimed at different age groups. In the United States, the elimination of cervical cancer will involve close coordination among CDC centers that address chronic and infectious diseases.

➤ **NCHHSTP Updates and Presentation on *Gonococcal Antimicrobial Resistance***

Dr. Kevin Fenton, Director, NCHHSTP, provided Center updates, and Dr. Gail Bolan, Director, NCHHSTP Division of STD Prevention, presented information on *Gonococcal Antimicrobial Resistance*. *NCHHSTP Updates*

- **HIV/AIDS**
 - Developed a new FOA on HIV prevention programs for health departments (<http://www.cdc.gov/hiv/topics/funding/PS12-1201/>)
 - Conducted nearly 2.8 million HIV tests under the 3-year Expanded HIV Testing Initiative, resulting in the identification of more than 18,000 HIV-positive persons (<http://www.cdc.gov/hiv/resources/factsheets/HIV-ETP.htm>).
 - Launched the *Testing Makes Us Stronger* campaign to increase HIV testing among black men who have sex with men (MSM) (<http://hivtest.cdc.gov/stronger/about/index.html>)
- **Hepatitis**
 - Helped develop the *HHS Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (<http://www.cdc.gov/hepatitis/HHS-ActionPlan.htm>)
- **Tuberculosis**
 - Issued guidelines on 12-dose therapy for latent TB, based on results from an NCHHSTP-sponsored trial (<http://www.cdc.gov/nchhstp/newsroom/LatentTBPressRelease.html>)
 - The CDC TB Laboratory is now able to provide drug-resistance results within 2 days, using molecular tests. The traditional culture-based method takes about 42 days.
- **STDs**
 - Tracked and raised awareness of gonorrhea drug resistance.
- **Adolescent Health**
 - The Division of Adolescent and School Health (DASH), which moved to NCHHSTP this year, completed an external expert review of its STD prevention and sexual health portfolio.
- **Improved Access to Surveillance Data**
 - NCHHSTP has created an interactive, web-based tool that will increase public access to U.S. surveillance data on HIV, viral hepatitis, STDs, and TB (<http://www.cdc.gov/nchhstp/atlas/>). As part of this effort, NCHHSTP has developed guidelines to ensure data security and confidentiality.

Antimicrobial Gonococcal Resistance

Dr. Bolan described the growing threat of untreatable antimicrobial gonococcal (GC) infections and public health efforts to address it. She noted that gonorrhea is the second most commonly reported nationally notifiable disease. An estimated 600,000 U.S. cases occur each year, the vast majority of which are asymptomatic. Left undetected and untreated, gonorrhea can lead to pelvic inflammatory disease (PID) and adverse reproductive outcomes such as infertility and ectopic pregnancies. Gonorrheal infection also facilitates HIV transmission. The direct U.S. medical costs due to gonorrhea are estimated at \$138 million per year.

The bacteria that cause gonorrhea—*Neisseria gonorrhoeae*— have progressively developed resistance to sulfonamides, penicillins, tetracyclines, and (most recently) fluoroquinolones, leaving cephalosporins as drugs of last resort (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5614a3.htm>).

In 2010, with U.S. gonorrhea rates at a historic low (about 100 cases per 100,000 people) but with drug resistance rising, CDC issued new treatment guidelines that recommend dual therapy for GC infections, with ceftriaxone (an injectable cephalosporin) or another cephalosporin, cefixime, administered if ceftriaxone is not an option, plus either azithromycin or doxycycline as first-line treatment. Dual therapy was recommended because treatment failures with cephalosporin mono-therapy (involving cefdinir, cefixime, or ceftriaxone) were reported during the 2000s in Hawaii, Japan, Australia, and Western Europe. In 2010 and 2011, additional treatment failures using the oral cephalosporin cefixime were reported in Norway, Sweden, UK, Austria, France, and China. Azithromycin has been a recommended second line regimen for the cephalosporin allergic patient. Spectromycin is no longer a second-line option because it is currently not being manufactured in the United States.

CDC monitors trends in GC antimicrobial drug susceptibility via the Gonococcal Isolate Surveillance Project (GISP; <http://www.cdc.gov/std/gisp/>), which includes 26-29 STD clinics that serve as GC sentinel surveillance sites. Each site collects 25 urethral gonorrhea specimens each month from symptomatic men and sends them to regional laboratories for culture-based susceptibility testing, followed by confirmatory testing at CDC. The most recently published GISP data suggest that susceptibility to cefixime and ceftriaxone is decreasing in the U.S., especially in the western United States and among MSM. The isolates with decreased susceptibility to cefixime remained susceptible to azithromycin (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a2.htm>).

CDC and public health departments face many challenges in responding to the threat of GC resistance, including a lack of alternative treatment options, with few new antibiotics in the pharmaceutical pipeline. GC control efforts are also adversely affected by declining public health resources, which have led to fewer positions for STD intervention specialists to investigate untreated persons and their partners as well as to closures of STD clinics at state and local health departments, which provide drop-in, on-site diagnosis and treatment. While GISP is an inexpensive sentinel surveillance system, it covers only about 4% of the population and does not collect cervical, rectal, or pharyngeal GC specimens. Since the inception of GISP in 1987, CDC provides GISP clinic and local public health laboratories with \$5000 a year to support collection of specimens and epidemiologic data from 300 patients and processing and shipment of isolates to regional GISP laboratories antimicrobial susceptibility testing. Over the years, local public health resources have covered the increasing GISP operational costs due to COLAs and the change in GC diagnostic standard of care from culture-based testing to nucleic acid amplification tests (NAATs).

CDC's response to the growing threat of multidrug gonococcal resistance includes

- **Working with domestic and international partners to raise awareness of the problem of GC resistance globally and among clinicians, industry, researchers, and the public in the U.S.**

Examples include:

- Disseminating a media fact sheet on *Antimicrobial Resistance and Neisseria gonorrhoea* as part of the *Combat Antimicrobial Resistance* information packet disseminated by WHO on World Health Day, April 7, 2011²

² The fact sheet states: "Antimicrobial resistance has become a serious problem for treatment of gonorrhoea (caused by *Neisseria gonorrhoeae*), involving even "last-line" oral cephalosporins, and is increasing in prevalence worldwide. Untreatable gonococcal infections would result in increased rates of illness and death, thus reversing the gains made in the control of this sexually transmitted infection. (http://www.who.int/world-health-day/2011/WHD201_FS_EN.pdf).

- Publishing an MMWR article on recent GC cephalosporin susceptibility trends (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a2.htm?s_cid=mm6026a2_w)
- Publishing an article on *The Emerging Threat of Untreatable Gonococcal Infection* in the February 2012 issue of the *New England Journal of Medicine*
- Disseminating the *U.S. Cephalosporin-Resistant Gonorrhea Response Plan* (<http://www.cdc.gov/std/gonorrhea/arg/CephOutbreakResponsePlan.pdf>)

- **Scaling up provider and patient gonorrhea prevention and education**

CDC is providing technical guidance and consultation to state and local health departments, clinical providers, medical associations and other partners involved in the provision of health care services regarding screening at-risk persons; ensuring optimal care and treatment of persons diagnosed with GC; preventing infection by offering condoms and prevention counseling to GC-positive persons and members of at-risk groups (e.g., non-Hispanic blacks, young persons, and MSM); ensuring that patients' partners are treated to prevent re-infection of the patient and further spread of GC in the community; and remaining vigilant for treatment failures.

- **Expanding local and regional gonorrhea laboratory capacities**

CDC is working with state and local partners to increase local access to laboratories that conduct culture-based testing for diagnosis of drug resistance; developing molecular assays to detect GC resistance; and working with CMS and health plans to ensure reimbursement for both molecular and culture-based testing at the same visit when a treatment regimen fails.

- **Enhancing global collaboration**

CDC helped develop and is helping to implement the *WHO Global Action Plan to Control the Spread and Impact of Antimicrobial Resistance in Neisseria gonorrhoeae*, which will be launched on May 17, 2012 (<http://www.who.int/reproductivehealth/publications/rtis/9789241503501/en/index.html>).

- **Updating the 2010 gonorrhea treatment guidelines**

The update may include downgrading the oral cephalosporin, cefixime, to a second-line, alternative treatment regimen and may include a recommendation on follow-up testing one week after treatment when an alternative regimen is used.

- **Promoting identification of new treatments**

CDC is promoting development of new GC treatments by:

- Currently collaborating with NIH in GC treatment trials to evaluate the use of existing drugs in dual-drug regimens.
- Planning work with NIH to evaluate future drugs as they become available
- Mining DoD drug stockpiles for potential antimicrobial agents
- Encouraging private-sector drug development through incentives and regulatory change.

Dr. Bolan mentioned that *Neisseria gonorrhoeae* has been proposed as a qualifying pathogen under two legislative initiatives proposed by the Infectious Diseases Society of America: the Generating Antibiotics Incentives Now (GAIN) Act and the Limited Population Antibacterial Drug (LPAD) legislation to expedite development of antibiotics (http://www.idsociety.org/New_Pathway_for_Antibiotic_Approval/).

In conclusion, Dr. Bolan stated that rebuilding public health defenses against GC will require a collective effort, involving public and private sector partnerships.

Discussion

Dr. Heilman suggested that CDC and its partners model the costs of treating GC infections (both resistant and susceptible) to highlight the need for new drug development. NIH and CDC can promote this research by providing scientists with a panel of GC strains.

Dr. Bolan cited the work of a Canadian modeler Christina Chan³ whose findings (based on cases treated with mono-therapy) suggest that GC cases will increase by 6 million over the next 7 years, accompanied by increases in HIV, PID, and infertility. The projected costs will be about \$780 million. She mentioned that modelers in her Division are further refining this model to look at costs related to dual therapy. She agreed that CDC should provide a panel of GC strains for researchers. She mentioned a CDC collaboration with the Harvard School of Public Health to examine the population biology of GC strains (including drug-resistant strains) through whole genomic sequencing and determine how resistant strains evolved.

In response to questions about dual-therapy regimens to mitigate the emergence of resistance, Dr. Bolan noted that additional studies are needed to identify if multiple drug combinations that treat disease can delay or prevent development of resistance. This is a hypothesis that needs testing.

In response to a question about GC prevention strategies, Dr. Bolan said that an important primary prevention strategy in use today for sexually active, at-risk individuals is promotion of condom use in addition to reduction in number of partners for persons not in a mutually monogamous relationship with an uninfected partner. An effective GC vaccine is needed. Secondary prevention focuses on timely diagnosis and treatment of infected individuals and their partners. Because resources are limited, we are working with state and local STD prevention programs to re-prioritize existing resources and scale GC prevention activities.

In response to a question about HIV and gonorrhea co-infection, Dr. Bolan mentioned that HIV status of GC cases reported through the nationally notifiable disease reporting system is not collected. However, an enhanced GC surveillance system, the CDC STD Surveillance Network (SSuN), does collect this information and it has been estimated that overall nearly 6% of GC cases are co-infected with HIV but this rate is much higher among MSM with gonorrhea, for whom about 22% are co-infected with HIV. Gonorrhea causes inflammation, which may facilitate HIV transmission, and the Division is now looking a temporal relationships between GC infections and subsequent HIV acquisition through matched STD and HIV surveillance databases. Dr. Berkelman noted that these finding support the value of a “syndemic” approach to treatment and prevention of HIV, STDS, TB, and viral hepatitis (*see*: <http://www.cdc.gov/nchhstp/programintegration/About.htm>).

In the future, GC resistance may be detected by molecular tests. For now, CDC is asking public health and other laboratories to rebuild and support culture-based testing and antimicrobial-susceptibility testing

³ Chan CH, McCabe CJ, Fisman DN. Core groups, antimicrobial resistance and rebound in gonorrhoea in North America. *Sex Transm Infect* 2012; 88(3):200-204.

of isolates if requested by a clinician. CDC is also asking laboratories that no longer perform culture-based tests to partner with a public health, hospital, or other laboratory when drug-susceptibility testing is available.

In response to a question about whether it is realistic for public health laboratories to maintain capacity for culture-based GC resistance testing—when resources are challenging—Dr. Bolan agreed that it is difficult, because the demand for culture testing may be too low in some areas to make it cost-effective. However, some public health laboratories, especially those in areas where rates of GC infections are high, are maintaining this capacity. CDC is also working with APHL and public health laboratories in establishing billing systems.

Dr. Berkelman said that the need to request assistance from a public health laboratory is a barrier that could decrease clinicians' access to GC drug-susceptibility testing. Dr. Bolan said that the solution might be to work with hospital laboratories and university laboratories to maintain capacity for GC drug-susceptibility testing. CDC is also exploring the possibility of making GC susceptibility-test results reportable, as they have done in New York City.

In response to a question about testing for GC infections that occur at non-genital sites, Dr. Bolan noted that CDC has recently expanded the GISP to involve the collection of specimens from rectal and pharyngeal sites. Since 2006, the CDC STD Treatment Guidelines have also been recommending extra-genital GC screening among MSM. This recommendation has been challenging to implement because the molecular assays (NAATs) that are now commonly used to diagnose GC in most clinical setting are not yet FDA approved for extra-genital sites, and laboratories must perform CLIA-approved validation studies before these tests can be used at these sites for clinical management.

CLOSING REMARKS

Dr. Berkelman and Dr. Khabbaz thanked the Board members for their service and support of CDC's mission.

The next BSC meeting will be held on Wednesday, December 5, 2012. One or more teleconference meetings may be held in the interim.

The meeting was adjourned at 2:30 PM.

**APPENDIX
MEETING PARTICIPANTS**

BSC Members

Ruth Berkelman
Jack Bennett
Luciana Borio (*representing U.S. Food and Drug Administration on behalf of Jesse Goodman*)
Harry Chen
Frank Cockerill
Bruce Gellin
John Gittleman
Tom Gomez (*representing U.S. Department of Agriculture on behalf of Larry Granger*)
Jim Hadler
Carole Heilman
Ned Hook
Shannon Jones
Laurene Mascola
Steve Ostroff
Andy Pavia
Mathu Santosham
Bob Sautter
Ken Scott (*representing Public Health Agency of Canada on behalf of Rainer Engelhardt*)
Kim Smith
Julio Sotelo
Jon Temte (*representing CDC Advisory Committee on Immunization Practices on behalf of Carol Baker*)
Bob Tesh
Judy Wasserheit
Bob Weinstein

Partners and Public Visitors

Jane Getchell (*Association of Public Health Laboratories*)
Joe Hilinski (*Pediatric Infectious Diseases Society*)
Lilly Kan (*National Association of County and City Health Officials*)
Harry Keyserling (*American Academy of Pediatrics*)
Don Low (*Ontario [Canada] Public Health Laboratories*)
Ruth Lynfield (*Infectious Diseases Society of America*)
LaKesha Robinson (*Council of State and Territorial Epidemiologists*)
Kathy Talkington (*Association of State and Territorial Health Officials*)

CDC Staff

Ed Ades	Kevin Fenton	Wendi Kuhnert
Michael Beach	Julia Gargano	Hubert Lee
Beth Bell	Peter Gerner-Smidt	Alexandra Levitt
Elise Beltrami	Jeff Hageman	Jeff Morelli
Gail Bolan	Tom Hearn	Marty Monroe
Sharon Bloom	Rita Helfand	Steve Monroe
Roberta Carey	Kim Hummel	Dale Morse
Evelyn Cater	Michael Iademarco	Robin Moseley
Joanne Cono	William Jackson	Glen Nowak
Nancy Cox	Harold Jaffe	Jan Nicholson
Kim Distel	Beth Karp	Angelica O'Connor
Peter Drotman	Rima Khabbaz	Ciara O'Reilly

CDC Staff (cont.)

Lydia Ogden
Mark Pallansch
Jean Patel
Larry Pickering
Kristin Pope
Steve Redd
Jared Reynolds
Chesley Richards
Sandy Roush
Catherine Sager
Jane Seward

Alvin Shultz
Patty Simone
Sharon Slocumb
Larry Slutsker
Steve Solomon
Bob Spengler
Riley Steiner
Erin Stone
Dave Swerdlow
Rob Tauxe
Carla Willis

John Ward
Eli Warnock
Faith Washburn
Todd Weber
Melinda Wharton
Jean Whichard
Sarah Wiley
Jonathan Yoder

I hereby certify that to the best of my knowledge, the foregoing minutes of the proceedings of the meeting of the Board of Scientific Counselors, Office of Infectious Diseases, on May 2, 2012, are accurate and complete.

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

Date