



Minutes from the October 29, 2015

CDC Advisory Committee to the Director

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Advisory Committee to the Director: Record of the October 29, 2015 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on October 29, 2015 at the CDC Clifton Road Campus (Building 21, Conference Rooms 1204 A/B) in Atlanta, Georgia. The agenda included updates from the CDC Director as well as from the Director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) regarding antimicrobial resistance (AR) and the Combating Antibiotic-Resistant Bacteria (CARB) initiative; the Director of the Office of Public Health Preparedness and Response (OPHPR) regarding the Select Agents Program; and the Associate Director for Laboratory Science and Safety (ADLSS) regarding progress on the ACD recommendations on CDC laboratory safety. The agenda also included updates from the following subgroups of ACD: external Laboratory Safety Workgroup (ELSW); Ethical Considerations for Public-Private Partnerships Workgroup (ECPPP WG); Public Health - Health Care Collaboration (PHHCC) Workgroup; Global Workgroup (GWG); State, Local, Tribal and Territorial (STLT) Subcommittee; and Health Disparities Subcommittee (HDS).

Welcome and Introductions

Dr. David Fleming (ACD Chair) called the meeting of the CDC ACD to order at 8:41 am. Those present and participating via telephone bridge or video conference introduced themselves. An attendance roster is appended to this document as Attachment #1. A quorum of ACD members was present, and was maintained throughout the duration of the meeting. The following ACD members disclosed conflicts of interest (COI):

- Dr. Fleming's organization, PATH, receives some funding from CDC. His salary is not directly affected by that funding.
- Ms. Sara Rosenbaum is a professor at George Washington University, which receives grants from CDC.
- Dr. Jewel Mullen is the Commissioner of the Connecticut Department of Public Health and immediate past president of the Association of State and Territorial Health Officials (ASTHO). The Connecticut Department of Public Health, ASTHO, and the Public Health Accreditation Board (PHAB), on which she sits, are CDC grant recipients.
- Dr. Lynn Goldman is a professor at George Washington University, which receives grants from CDC.

CDC Laboratory Safety Progress Update

Dr. Steve Monroe (ADLSS, CDC) explained that the Office of the Associate Director for Laboratory Science and Safety (OADLSS) is a new office within CDC that was envisioned in the fall of 2014 in response to the activities of the external Laboratory Safety Workgroup (ELSW) of the ACD as well as to other laboratory safety reviews. Dr. Monroe began acting in this role in May 2015 and was permanently assigned in September 2015. He provided ACD with an update on progress toward the recommendations made by ELSW, ACD, and other entities. Significant progress has been made across the Agency.

In response to laboratory safety incidents, in July 2014 CDC instituted a moratorium on transfer of material out of its biosafety level (BSL)-3 and BSL-4 laboratories. A process was instituted so that every protocol used to inactivate materials was reviewed. Each

laboratory's procedures were ultimately approved by Dr. Tom Frieden, CDC Director, before work could resume. This activity set the tone for a more deliberate assessment of laboratory practices. Following are highlights of CDC's progress to address the ACD recommendations to CDC regarding laboratory safety in several categories:

Leadership

CDC needed a single point of responsibility and accountability in the agency. The advantage of this position is the opportunity to serve as an advocate for laboratory science and safety at the highest level of the agency, as the ADLSS reports directly to the CDC Director. ACD also recommended establishing a "CDC Way" regarding responsible, safe science. While individual laboratory programs implemented and monitored safety practices in varying ways and to varying degrees, the agency had become fragmented in its approach to laboratory quality and safety. While the solution will take time to be realized fully, work is ongoing regarding the "CDC Way."

Governance

It is important to have a single place where decisions about research safety and quality are made and promulgated. A number of boards and committees either have been established or have been reenergized to consider various aspects of CDC's laboratory safety and quality programs and to ensure that the activities are consistent across the agency. The new OADLSS will ensure that these various committees share information and harmonize their oversight and activities.

Risk Assessments

The review processes revealed that CDC's approach to risk assessment focused specifically on the organism being worked with, the space it was being used in, and the personal protective equipment (PPE) that was being utilized. However, risk assessment should take into account every step of the procedure, where there are opportunities for exposure or other adverse events, and mitigating steps that can be implemented. Risk assessments should also consider alternative approaches. The risk assessment procedures and forms at CDC have been revamped, and training has begun pertaining specifically to risk assessment. To date, 161 staff have been trained, representing a majority of laboratories that work with biological select agents and toxins at the agency.

Laboratory Safety Training

In addition to risk assessment training, revamping of overall laboratory safety training has begun. Existing courses and the approaches to delivering the courses needed to be updated or modernized. A complete review of all laboratory safety training was conducted. The process of updating first focused on courses that impact the most people. A new Laboratory Safety Training Board was established to revamp the curricula. In partnership with the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), the courses are being redesigned to be appropriately delivered to audiences. This process is deliberative, and it will take time. The new Laboratory Leadership Service (LLS) is a two-year program with didactic as well as hands-on elements that is modeled on the Epidemic Intelligence Service (EIS). Much like EIS, it is intended not only to develop safety and quality management skills for people who work in laboratories, but also to develop leadership skills so that LLS graduates can become leaders in laboratory management, with a focus on safety and quality, at CDC and at state and local public health laboratories. **Culture of Safety and Incident Notification**

The agency's approach to incident notification had become fragmented, and there was not a centralized place for event reporting. A unified system for reporting has been instituted. All events are stored so that patterns can be assessed over time. It is critical that laboratorians at the bench view this process as a normal part of their operations. There will not be punitive action for reporting incidents and "near misses"; rather, the approach focuses on building a culture of safety and responsibility. Most incidents are relatively minor, but the agency will learn from them and this may stave off more serious problems in the future.

Biosafety and Occupational Medicine

Deficiencies in CDC's occupational safety programming were recognized. Some of these issues became clear as staff prepared to deploy for the Ebola response. The operations and staffing needs of the Occupational Safety and Health Clinic are being considered.

Progress Reporting and Laboratory Accreditation

There is a need for an external assessment of all of CDC's laboratory programs. Some programs are Clinical Laboratory Improvement Amendments (CLIA)-certified and some laboratories are International Organization for Standardization (ISO)- or College of American Pathologists (CAP)-accredited. Some of the National Institute for Occupational Safety and Health (NIOSH) facilities are certified through the Voluntary Protection Program (VPP) administered by the Occupational Safety and Health Administration (OSHA). Other CDC laboratory programs did not have formal review of their safety and quality. OADLSS is conducting a pilot program using ISO 17025 as a potential accreditation standard for CDC laboratories. They have conducted benchmarking with other laboratories that already have ISO accreditation. There cannot be a "one size fits all" approach to accreditation, but there must be an external standard for all laboratories' safety and quality programs.

Dr. Monroe emphasized that these processes take time. His goal is to meet as many staff members as possible, and he has visited several of CDC's off-site laboratories. He is currently meeting with the leadership of each of the 23 different divisions at CDC that have laboratory activity. Solutions must be "bottom up" so that people at the bench are engaged and enthusiastic about continuing high-quality science.

External Laboratory Safety Workgroup Update

Dr. Joseph Kanabrocki (Chair, ELSW) and Dr. Kenneth Berns (Co-Chair, ELSW) updated ACD on the activities of the ELSW, which has been engaged in reviewing CDC's laboratory safety programs for over a year. The group also reviewed programs at the National Institutes of Health (NIH) and the US Food and Drug Administration (FDA). CDC invited ELSW to return to Atlanta to conduct a one-year follow-up visit, which occurred in October 2015. The visit included discussions with laboratory staff and monitoring progress toward addressing the ACD's recommendations from January 2015.

ELSW includes physicians, scientists, public health officials, environmental health and safety experts, and biosafety experts. The group invested a great deal of time and energy into the review and recommendation process. ELSW proposed several recommendations that were adopted by ACD. During the recent visit, the group assessed progress on the recommendations and created an additional recommendation for consideration.

Leadership

- CDC leadership is clearly engaged and committed to making improvements in laboratory and research safety at CDC. It is a work in progress, but ELSW is pleased with the progress to date.
- There was a substantial allocation of funds for laboratory safety improvements in fiscal year (FY) 2015, and requests for additional funds have been made for FY 2016. The way that funds are allocated and used can be problematic for federal agencies, but ELSW hopes that there can be some freedom in how CDC uses its funds.
- CDC has recently appointed Dr. Steve Monroe as the ADLSS, with Dr. Leslie Dauphin as Deputy Director of OADLSS. Work is underway to ensure that their work is synergized with the Office of the Associate Director for Science (OADS) and the Environment, Safety, and Health Compliance Office (ESHCO).

Governance

- Considerable work remains in the area of governance, particularly regarding the provision of safety services and oversight. It is not clear how these groups interact with, or become part of, OADLSS.
- Three crucial internal groups are involved with lab safety:
 - Institutional Biosafety Committee (IBC), which reviews research projects involving recombinant DNA or organisms
 - Laboratory Safety Review Board (LSRB), which reviews procedures that are used to remove specimens from high-containment to lower-containment facilities
 - Institutional Biosecurity Board (IBB), which conducts reviews of dual-use research of concern (DURC)
- It is encouraging that these groups are active and that their energies are synergized; however, these groups currently have no “home” and limited dedicated resources to support their work.
- ELSW offered follow-up recommendations pertaining to governance:
 - CDC should install a Laboratory Information Management System (LIMS) that will allow for an up-to-date registration process for all 153 laboratories at CDC.
 - LIMS should be deployed as a CDC-wide protocol library providing a description of which pathogens are being managed, where, and by whom.
 - This database would support and augment the entire safety infrastructure by enhancing the capabilities to perform agency level risk assessments, providing insights into training needs, and providing essential capabilities to deploy a rapid response in case of an emergency or adverse event.

Risk Assessments

- Work is in progress to establish an institutional entity and associated processes to perform consistent and thorough risk assessments at the institutional level.
- Training is ongoing in risk assessment, but a common institutional approach should be applied.
- Currently, comprehensive risk assessments are being performed only on new processes or procedures. ELSW recommends that these assessments should include all work performed in BSL-2, BSL-3, and BSL-4 laboratories.
- Institutional level review and risk assessment should not be limited to recombinant DNA, but should include all pathogenic microorganisms managed at CDC. While this is a major task since CDC's portfolio of pathogens is robust, it illustrates the importance of an information management system.

Laboratory Safety Training

- It is clear that the CDC has accepted the responsibility for further developing and delivering its own laboratory safety training program.
- Efforts are underway to broaden the available online training and to develop subsequent lab-specific, directly observed training for local laboratories.
- Funds for a laboratory safety training facility at CDC have been requested.
- The LLS has been established, and it is critical for bringing scientists to the profession of laboratory safety. ELSW looks forward to seeing these fellows serve the community as leaders in safety.

Incident Reporting

- Apprehension about the possibility of retribution when reporting accidents or safety concerns was expressed by some.
- There is a sense from some staff that the CDC reaction to accidents has been to initiate extra paperwork.
- Communication is critical and leadership is aware of its importance. Regarding public communication, it is important to promote the science that CDC conducts and its value to public health more actively. Internal communication is also very important. Leadership should inform the CDC community about efforts and progress in laboratory safety.
- One of the new strategies has been the use of cameras for verification of procedures. The cameras were received with mixed reviews in that some staff find them to be helpful, while others view them as a gimmick. These tools should be employed strategically.

ESHCO and Occupational Medicine

- An intense internal review of ESHCO is being conducted. It will be determined which functions should move to OADLSS and which should remain with ESHCO.

- Previous ESHCO leadership was not provided with adequate administrative support to facilitate improvements.
- The occupational medicine group still appears to be understaffed and unsure of its role or ability to respond to incidents, especially large-scale incidents.

Progress Reporting and Laboratory Accreditation

- ELSW strongly encourages the implementation of a LIMS to include:
 - Registration of data on protocols and pathogens
 - Information on laboratory incidents and near-misses
 - Facilitate an institutional risk assessment process
 - Provide a basis for determining task/agent-specific training needs
 - Track progress in the development of lab safety programs
- ELSW recommends external accreditation. ISO may or may not be the best tool for a research laboratory setting. The American Biological Safety Association (ABSA) accreditation should be considered. CDC should choose carefully which accreditation agency would best support CDC lab safety improvement efforts.

Dr. Berns added that when bad things happen in government organizations, it is common to appoint an external panel, whose recommendations frequently are not implemented. This scenario has not been the case with ELSW at CDC. Dr. Frieden has done an excellent job of responding to the problems and to the recommendations of the internal and external groups. Although changing an organization the size of CDC will take time, a great deal of progress has been made in only one year of effort. These issues demand continued monitoring in order to be effective.

Dr. Kanabrocki thanked Sarah Wiley for her support as the Designated Federal Officer (DFO).

Discussion Points

Dr. Fleming thanked Drs. Kanabrocki and Berns for their work on ELSW, recognizing that the group offered clear recommendations that have made a significant difference at CDC.

Dr. Frieden offered his gratitude to ELSW. He acknowledged that the workgroups of ACD have been enormously helpful in the past, and this group is no exception. He stressed that the biggest unheralded secret to CDC's success is its laboratories, which are important to everything the agency does. CDC's credibility and ability to provide definitive answers to public health questions relies on the laboratories. CDC works with dangerous pathogens, as do other agencies and institutions. CDC is unique because it has a broad scope and frequently works under time pressures that are not common in other laboratory settings. The diversity of the laboratory work creates challenges. The more that entities external to the public sector are invested in CDC and provide advice and monitoring, the better for the agency. Progress is moving as rapidly as possible on the ESHCO issues. The LLS is a strong new program that has been stood up quickly. The risk to CDC's reputation from the laboratory issues is significant. The agency will continue to improve as rapidly as possible. He agreed with the need for continued

monitoring. Regarding risk assessment, the term is not widely understood. He hoped for examples of how it has been done effectively.

Dr. Kanabrocki agreed and noted that “risk assessment” can be an overused term that takes on different meanings in different contexts. In his experience, the IBC process illustrates risk assessment. The evaluation considers the host, how it is manipulated, the environment and types of experiments being conducted, and the staff and their experience with the pathogen. The review also considers Dual Use Research of Concern (DURC) concerns. Alternative approaches, such as the use of surrogate organisms or attenuated strains, might be suggested, especially given staff training and facility capability questions. This review process should be done at an institutional level to ensure consistency.

Dr. Berns added that the work done in laboratories has risk associated with it. The challenge is to appreciate the risk, understand it, and to mitigate and manage it as much as possible.

Dr. Chu commented on parallels between this work and the quality and patient safety movement in healthcare delivery. Some facilities have utilized cameras, for instance, to monitor handwashing for infection control. Laboratory safety may learn from the “trials and tribulations” in the healthcare delivery world. When healthcare workers are surveyed about the culture of safety, freedom from retribution, and other similar issues, it is clear that these issues are not easy to address. The “CDC Way” is probably the appropriate approach, as it can be a culture that looks for opportunities to improve and to learn from near-misses. Leadership is the key to this work. In the medical setting, incidents are often approached internally, which does not allow for open-minded consideration. The leadership can make it manifest from the outset that these incidents are learning opportunities. Leadership can also encourage people to report incidents and avoid punitive actions. Transparency of information is also important so that incidents, lessons learned, and processes that are changing as a result are shared broadly throughout the system. These approaches support the idea that a safety culture is good.

Dr. Frieden asked about healthcare examples that might be transferable to CDC’s laboratory settings. The agency made some approaches manifest, but some laboratories felt attacked.

Dr. Chu does not feel that cameras work, as they perpetuate the “gotcha mentality.” The “CDC Way” can create a culture that focuses on working in the safest way possible, and on finding ways to improve. The laboratory directors are highly trained professionals, but no one person can do everything. There should be collective mindfulness to see the potential of all of the things that can go wrong. It can be challenging for these professionals to receive external advice, but dialogue is critically important.

Dr. Frieden clarified that the laboratory cameras serve as secondary verification of certain critical steps. The options are to have a second person in the room when the steps are being performed, or for a person to review the film before the next step is performed. The cameras have a freeze frame system that allows an hour-long procedure to be reviewed quickly. They are a validation rather than checking up; however, they may be perceived differently.

Dr. Berns offered examples of scrub nurses or other inspectors who check periodically to ensure that the checklists are being completed. When there are high-consequence procedures, there should be frequent monitoring.

Dr. Chu said that in a high safety organization, inspectors are often invited to observe. The process is not perceived as a test. There is a difference in the overall approach and receptivity.

Dr. Mullen noted that surgeons use checklists to drive down medical errors. As a state regulator for hospitals, she focuses on the idea that “never events” sometimes occur. The available tools help minimize their possibility, and when they do happen, lessons can be learned. The work requires that people move beyond their individual selves and think about the bigger picture.

Regarding the LIMS recommendation, Dr. Rima Khabbaz commented that CDC has worked for many years on installing one for the infectious disease laboratories. The process and resources have been challenging, but progress is being made. It is important for many reasons.

Dr. Kanabrocki agreed that establishing LIMS is not easy, as it integrates many different components. He has experience with building one from the ground up, which took two years. He also has experience with a LIMS product that was purchased. It was expensive, and it took a year to be made useful for the institution. The process is difficult and costly, but the benefits are huge because LIMS drives all other efforts in laboratory safety. LIMS identifies issues, training needs, and facility deficits.

Dr. Harold Jaffe said that when his office became involved in assessing the laboratory incidents, laboratory supervisors commented that clinical microbiologists know about safety because it is part of their jobs, but research scientists and molecular biologists do not view safety as a primary responsibility. He asked if there was truth in this generalization and, if so, how it should be taken into account.

Dr. Kanabrocki replied that there is truth in the statement, but he has observed changes and new trends in that younger scientists are more accustomed to oversight and compliance. They are also more comprehensive in how they approach a problem. Clinical laboratories have to be certified in order to operate. Until the select agent program, there was relatively little regulation in the realm of laboratory safety related to microorganisms. Safety does represent a new culture for many of these investigators. The establishment of a culture of safety must incorporate contributions from the “top-down” as well as “bottom-up.” Strong leadership is necessary, and front-line staff also have to be educated. Academia has historically failed in training scientists when they are students about their responsibilities in safety. The issue is ultimately about conducting responsible and thoughtful science, which should be promoted from an ethical perspective. This approach also makes communication with the public about laboratory safety easier. The research realm has lagged in this area, but there have been great improvements.

Dr. Berns agreed that research has lagged in laboratory safety, but the issue is generational. Students are trained in an environment where it is recognized that there are correct ways to work and they are more cognizant. There have been significant improvements in the approach to biosafety in research laboratories. Their challenge regards how to encourage those changes.

Dr. Kanabrocki stressed that it is important to articulate the rationale supporting recommended practices in the realm of lab safety. Scientific insight and data are important to make these arguments for scientists. Historically, data have been missing as well.

Dr. Frieden indicated that CDC's clinical laboratories go through the CLIA certification process, but they have struggled with the best way to certify the research laboratories. Some pilots have been conducted. Though 72 pages of tests are conducted in CDC laboratories and are reported out, many are not fully vetted. CDC is trying to distinguish between what actually will be useful, and what may be unnecessarily bureaucratic and expensive.

Dr. Kanabrocki said that some external accreditation evaluates procedures, which is a more tactical than strategic approach. The best accreditation or type of review is strategic and pertains to how an agency or institution is approaching and managing laboratory safety. ABSA has a program that accredits non-select-agent, high-containment laboratories. From his personal experience, his institution has had two reviews. One was external and one was internal, but they were both ad hoc. He thought CDC's approach of assembling internal and external groups was on target and valuable, and that it would be wise to conduct these kinds of reviews periodically.

Dr. Frieden asked how such an internal review might work.

Dr. Kanabrocki replied that the group can step back and look from a high level to assess what works, what does not work, and what might be missing. An auditing function should occur more closely to the activities. The value of an external or internal group is its perspective on the big picture.

Dr. Berns emphasized that scientific organizations always benefit from having an external review. Many of CDC's centers have a Board of Scientific Counselors (BSC). This approach falls into the same category of periodically reviewing how a system is working and is beneficial.

Motion

Dr. Fleming called for a motion to approve the ELSW report and associated meeting minutes. It was moved and seconded to approve the ELSW report and associated meeting minutes. The motion carried unanimously with no abstentions.

Dr. Fleming noted that ELSW is approaching the end of its charge.

Ms. Carmen Villar said that when ELSW was chartered, it was charged to look across the US Department of Health and Human Services (HHS) at three different operating divisions.

Ms. Sherri Berger said that they have sought additional clarification from HHS on the expectations for the group, but this report is the last official step for the CDC portion of the ELSW's work.

Ms. Villar thanked ELSW and the CDC staff who were involved in standing the group up and supporting it, and Dr. Fleming led a round of applause from ACD for the work of the ELSW.

Director's Update

Dr. Tom Frieden (CDC Director) provided ACD with updates on key CDC global and domestic activities. He noted that while Ebola is out of the headlines, CDC has never left the front lines. CDC has over 130 staff members working in every community in West Africa where there are suspected or confirmed Ebola cases. They are increasingly working to build systems, and it is not easy to make progress in the context there. Parts of CDC are having trouble keeping up because so many of their staff have deployed to respond to Ebola. Close to 4000 CDC staff members have worked on the Ebola response, with 1300 deployed to West Africa and spending more than 60,000 work days. This response has been the largest in CDC history. The epidemic is coming under control, but there is still more to do.

In terms of staff updates, Dr. Frieden welcomed Dr. Anne Schuchat as the new CDC Principal Deputy Director; Ms. Dena Morris, the new director of CDC's Washington office; Dr. Stephen Redd, Director of the Office of Public Health Preparedness and Response (OPHPR); Dr. Rebecca Martin, Acting Director of the Center for Global Health (CGH); and Dr. Steven Monroe, ADLSS.

Dr. Frieden pointed out that the CDC budget is its work plan. The program budget, which varies by year, is approximately \$7 billion. The President's Budget request has increased from approximately \$6.9 billion to \$7.1 billion. The Senate budget was lower than the President's Budget. The House of Representatives budget was at the level of the President's Budget, but with a proposal to cut the tobacco program in half. This change would not allow CDC to continue the "Tips From Former Smokers" campaign, which has been rigorously documented to prevent at least 16,000 deaths per year and to save at least \$375 million in healthcare costs per year. The House leaders speak of CDC and NIH as being nonpartisan and an area where the two political parties can work together; however, the Senate did not take that approach.

The world is safer than ever from global health threats thanks to better tools, better communication, and better diagnostics. At the same time, the world is at greater risk than ever from global health threats because of the greater interconnectedness of the world and the power of technology to do harm as well as good. GHS is a main focus and organizing principle to strengthen the world's ability to find and stop health threats. Significant new resources, proposed as part of the Ebola response, are available and are broader than Ebola. They are intended to prevent the "next Ebola." The inter-agency and leadership issues are complex. CDC likes working under the chief mission authority in countries. Ambassadors are key as they can serve as advocates and provide context. Because "you get better at stopping outbreaks by stopping outbreaks," more work needs to be done in countries. The EIS training program is an important resource for the number of outbreaks in the world.

In the Severe Acute Respiratory Syndrome (SARS) outbreak a decade ago, there was a delay in reporting and detection. The outbreak resulted in \$40 billion in economic costs. Dozens of countries were involved in the outbreak response. CDC worked with China for 10 years. When H7N9 avian influenza emerged, there was prompt detection and reporting, global collaboration, and rapid control. With genomic sequencing, a

diagnostic test and vaccine were developed. The Ebola outbreak in West Africa experienced delays in reporting and slow response. The World Bank (WB) has estimated \$15 billion in economic costs. Using the polio eradication infrastructure, Nigeria had prompt detection and reporting of Ebola as well as rapid response and control of the virus.

Ebola could have been much worse than it was. The modeling of exponential increase of the virus was occurring one year ago. Export to multiple countries in the region was taking place. If it had gotten out of control in Nigeria, Ebola undoubtedly would have gotten out of control in Africa. CDC surged staff to Nigeria quickly and the response was robust and effective, but it was volatile for several weeks. Lagos has a population approximately 50 times larger than Monrovia, Liberia. Had Ebola been out of control in Nigeria and then Africa, the global implications and impact to economics, political stability, and health would have been significant. People died of malaria during the Ebola outbreak because the malaria systems stopped functioning. The Ebola outbreak could have reversed years of progress in AIDS, tuberculosis (TB), malaria, immunization, and maternal mortality in Africa and parts of Asia.

Ebola illustrated three main lessons:

- In terms of GHS, every country's ability to find, stop, and prevent health threats must be strengthened. This work includes workforce, laboratory capacity, surveillance systems, and emergency response capacity.
- The international community needs to have the ability to surge rapidly. CDC has created a Global Rapid Response Team (GRRT), and the World Health Organization (WHO) is considering how to improve their rapid response capacity. Even with these efforts, there is still a need to strengthen individual countries' capacity.
- Healthcare infection control is a continuing challenge everywhere in the world. Infection control is important to protect health workers, report diseases, and prevent disease transmission and control spread. Ebola, Middle East Respiratory Syndrome (MERS), and SARS are indicator diseases.

The Global Health Security Agenda (GHSA) has three broad areas: Prevention, Detection, and Response. Laboratory systems are pivotal to GHSA, and CDC is working closely on this issue. Independent assessments are also crucial, and there must be transparency. Currently there is no validated, transparent, objective tool to determine whether countries are prepared. A tool has been developed and should be strong as it is adopted globally. Uganda is an example of a country that has made strong progress, but the tool can identify specific areas for additional improvement. Over the next five years, it is hoped that countries will identify their gaps and steadily fill them. The pre-Ebola status quo, a combination of non-accountability from countries and a lack of global assistance, cannot be tolerated.

Turning to prescription drug overdose (PDO) and abuse, Dr. Frieden lamented that PDO and abuse is one of the few health problems in the US that is worsening. The problem has quadrupled in 15 years, with 160,000 deaths from opioid overdoses, largely among young people. Increased drug use may bring the next phase of HIV. In Indiana in 2015,

a community of 4300 people had 181 cases of HIV. This situation could be repeated in other places in the US.

The approach to motor vehicle crashes is collaborative among public health, law enforcement, and communities, including families who are active and advocating. The approach has reduced traffic fatalities by half. The same results are possible in prescription opioid abuse. There is a 1:1 correlation between more prescriptions for opioids and more people dying from them.

A heroin epidemic is ongoing as well. There is an easy misconception that the increase in heroin use is due to the focus on prescription opiates. While that may be the case in individual instances, the trends are independent overall. Three out of four people reporting heroin use in the past year took prescription opioids first. The opioids are gateway drugs to heroin. Also, the heroin industry has improved its supply chain management. Heroin is cheaper and more widely distributed across the US. Opioid prescribing is driving the heroin problem in different ways in different parts of the US. The US population can be divided into two groups: 1) those who are currently addicted to or dependent on opioids. Many have access to services. These people need opioid reversal with naloxone and medication-assisted treatment (MAT) with methadone, buprenorphine, or naltrexone, which are underutilized; and 2) everyone else who is at risk for addiction or dependence.

Doctors and the clinical system are the main drivers of opioid use in the US. They prescribe the medicines without realizing their risk/benefit ratio. The National Center for Injury Prevention and Control (NCIPC) is finalizing Opioid Prescribing Guidelines for chronic pain outside the end-of-life setting. Programs have been strengthened in opioid abuse throughout the US. CDC is considering a technical package for improving prescribing; improving treatment; reducing the availability of illicit drugs; promoting social awareness and economic development to reduce initiation and continuation of drug use; and rigorous, real-time monitoring and appropriate action in a feedback loop to develop effective programs.

Part of improved prescribing pertains to guidelines. Risk cannot be reduced to zero, but the risk/benefit ratio can be publicized. The risks with opioid use are clear. A few doses of these drugs can lead to addiction for life, and an overdose can lead to death. The benefits of these drugs for chronic, non-cancer pain are not proven. There are similarities to antibiotic resistance (AR) in the overtreatment of symptoms and undertreatment of causes. Physicians and other clinicians often write prescriptions without considering resistance or the possibility of addiction that could occur as a result.

In terms of drug-resistant bacteria, modern medicine is at risk not only from infections, but from procedures such as chemotherapy, organ transplant, chronic conditions, and others that are often complicated by infections. Increasingly, organisms are resistant to all or nearly all antibiotics, which is a major challenge that risks turning back the clock 100 years. Rapid progress can be made, and dollars and lives can be saved. Antibiotic stewardship is an important part of the process, as is working in a coordinated approach across hospitals. With these collaborative approaches, there can be more substantial decreases in resistant bacteria than a facility can accomplish alone. Public health is the key nodal entity to make this work happen.

HIV is CDC's largest global health program, and that significant progress is being made. Despite the progress and increases in life expectancy, Dr. Frieden emphasized that there is a five-year "window of opportunity" in which HIV infections can be reduced significantly. It is important to be specific about where treatment should be scaled up and to consider global use of pre-exposure prophylaxis (PrEP). Without making these changes, costs may rise substantially. Data needs to drive where programs are located.

In conclusion, Dr. Frieden stressed that laboratory safety and quality is the number-one priority for CDC. He acknowledged that there is a balance between focusing on safety while not making the laboratory staff feel beleaguered.

Discussion Points

Ms. Rosenbaum asked, given the agreement recently reached by Congress and the White House, how the agreement may translate to CDC's budget for FY 2016.

Dr. Frieden replied that the agreement is good for CDC, as CDC's proposed budget is not less. The budget agreement is lower than the overall President's Budget request by approximately \$5 billion in areas other than defense. It will be difficult, but not impossible, to achieve the \$7.1 billion requested for CDC. The agency has Congressional support. He was hopeful that the House proposal to decimate CDC's tobacco program will be rejected by the Senate. The proposal for PDO is likely to be approved for \$54 million, and funded at \$50 million by the House given concern about that issue. CDC requested \$264 million for drug resistance. The House budget is \$120 million in this area, and the Senate budget is \$30 million.

Ms. Dena Morris added that CDC could have had a worse outcome from the agreement. The existing budget caps had zero net gain, and it was difficult for CDC to improve without another agency or program losing. The agreement lifts the caps somewhat, but provides little new money and not as much money as requested in the President's Budget. The funds are also front-loaded, with more in FY 2016 than in FY 2017.

Regarding tobacco control, Dr. Farley expressed shocked and disappointment at the perception that it is "yesterday's problem" that has been solved. There is little interest in new energy and action in tobacco control. This observation aligns with Congress proposing to decimate CDC's tobacco control budget. He asked whether this change was due to pressure on Congress from the tobacco industry or whether public health has erred in not maintaining the visibility of this issue, which is still the number one killer in America.

Dr. Frieden said that it is apparent that the tobacco industry is relentless in marketing, lobbying, and influencing of the social discussion. There is also a tendency for society to move on to the next problem. People need to be reminded that tobacco is still a major problem in the US, and a number-one killer. There is increasing segregation of smokers in society, which has led to a lack of understanding about the significance of the problem. The House program cut is likely due to pressure from the tobacco industry.

Dr. Lynne Richardson recalled that the last ACD meeting included updates on efforts in hypertension. She asked about its current place in CDC's priorities and plans.

Dr. Frieden answered that the Million Hearts® initiative is a key focus area for CDC. The 6|18 Initiative is CDC's primary means for intersecting with the healthcare field.

Hypertension is a major problem in the US and is a major health equity issue. Sodium reduction is important as a societal effort, and lessons are being learned from healthcare systems around the US that have made a difference in hypertension control. A global team is working on improving hypertension treatment, as it is an undertreated condition globally. Information management is challenging, as the number of patients who need to be treated is massive. Pilot projects are needed to show how prevention efforts can be scaled effectively.

Dr. Ursula Bauer (Director, National Center for Chronic Disease Prevention and Health Promotion [NCCDPHP]) said that with so many priorities at CDC, it is difficult to describe all of them. CDC is focused on hypertension, increasingly globally as well as domestically. Million Hearts® is a key area of work, and the entire Division of Heart Disease and Stroke Prevention (DHDS) is focused on deploying its expanding resources to address hypertension, also with a health equity lens.

Dr. Mullen wondered if the cuts to tobacco funding could be a means for pre-empting ongoing advocacy against electronic nicotine delivery systems. There is increased uptake in these systems. Within CDC's budget, she noted that NCIPC has an appropriate focus on PDO. She asked about firearm safety as part of CDC's work.

Dr. Frieden agreed that e-cigarettes are a significant issue. There has been Congressional action to limit what FDA can do about e-cigarettes. Regarding gun violence, NCIPC has expanded the National Violent Death Reporting System (NVDRS). The state-run system includes every suicide and homicide in the US. States determine what to do with the data and what to study. President Obama has sent a clear memorandum to the HHS Secretary stating that the law does not prohibit CDC from conducting gun violence research. He has also proposed funding for gun violence research, which will not be passed.

Dr. Fleming recalled the loss of the Community Transformation Grants (CTGs). At the same time, there was encouraging development of new programs to improve community health. He asked whether ACD could help to highlight the importance of community-based prevention work.

Dr. Bauer said that the \$80 million Partnerships to Improve Community Health (PICH) program has been zeroed out in the Congressional budget proposals. PICH was created by Congress, which directed CDC to implement it. NCCDPHP thinks about how to redesign the community health approach and better message it to secure more bipartisan support for the programs, which are in many Congressional districts across the US and benefit many Americans. Congress may prefer reaching communities through state health departments, and CDC is engaging in more of that pass-through funding with added value at the state. The direct partnership approach will not work, so they are determining how best to achieve their community health goals.

Ms. Morris pointed out that these funds are difficult to talk to Congress about. The most effective messengers are the communities and constituents.

Ms. Rosenbaum commented on possible synergy between health agencies and the rethinking of community benefit obligations on the part of hospitals. From the hospitals' perspective, health planning and the upstream investments that flow from it and the Internal Revenue Service (IRS) definition of an acceptable community benefit

expenditure are incongruent. A lot of work is needed from public health to add its voice to the rethinking of what hospitals should get credit for. State law tends to follow federal law on this point, and some state laws have minimum community benefit spending requirements. If the IRS does not define certain activities as countable community benefit expenditures, there is less incentive for a hospital to invest in that direction. Hospitals may not be willing to consider upstream investments for fear that the IRS could reject the investment as not countable. A broader redefinition of “community benefit spending” is needed to include elements that IRS recognizes as community-building, not community benefit.

Mr. John Auerbach (Associate Director for Policy, CDC) said that community-based, total population interventions are difficult to explain with regard to their health outcomes and cost implications because limited data are available in these areas. In the coming months, CDC will evaluate what is known about these programs and package that information in a succinct manner that makes the business case for investing in certain areas for strong outcomes. This exercise will identify where more research is needed to make these arguments.

Dr. Chu reported that his institution is about to undergo the second round of the Community Health Needs Assessment (CHNA) process. The first round was somewhat rudimentary, with community groups listing typical community needs, such as behavioral health and diabetes. The process did not show where funds could leverage other funds for impact. There are gaps in using community benefit and community investment to maximize health. Guidance is needed in this area, not only from the IRS, but also regarding focus areas. The American Hospital Association (AHA) has convened a series of community dialogues, and many hospitals are struggling with where to spend money, not just individually, but collectively to make impact. A collective picture can be made to show the effects that directed spending could have on different problems. For instance, Kaiser has worked to educate physician staff and to monitor prescribing patterns of opioid use, but an individual in a community will go to different facilities. Other hospitals convened to address the problem. Community-wide problems need community-wide solutions, and CDC could help in this area.

Dr. Bauer noted that behavioral health has been a challenging area that affects all of CDC’s priorities, including chronic disease prevention, disease management, PDO, HIV, and others. Each of these problems needs upstream prevention through behavioral health.

Dr. Frieden indicated that CDC would follow up on the ideas regarding the IRS and its definition of “community benefit.” He was not sure how to make the second round of the CHNA more effective. The issue of community-wide intervention is key. No one institution can make a tangible impact on its own in AR, PDO, tobacco, hypertension, and other problems. He recently spoke with a front-line CDC worker who was pivotal in Ebola control and Nigeria and Liberia as well as to polio elimination in Nigeria. When the worker and CDC arrived in these areas, there was no coordination of the various activities and organizations working there. A great deal of effort is needed to coordinate everyone so that they are looking at the same data and agree on who is doing what in the context of an approach that is either proven to work and can be scaled up, or is coordinated and specific and will be evaluated. That community-wide coordination and prevention is critical to responding to emergencies and to working on leading problems in a community.

Ethical Considerations for Public-Private Partnerships Workgroup Update

Ms. Sara Rosenbaum (ACD member; Chair, ECPPP WG) presented an interim progress report of the work of the ECPPP WG regarding conflict of interest (COI) at CDC. The workgroup was established during the April 2015 ACD meeting in response to specific cases that raised potential conflict of interest concerns when working with the private sector. The workgroup includes ACD members and outside experts with strong experience in the questions of appropriate financial relationships with the private sector and how to manage them. The group has reviewed current CDC policies and guidelines and has engaged in discussions with CDC Foundation staff. The workgroup produced a background document to capture the nature of current CDC oversight of financial relationships with the private sector and CDC's relationship with the CDC Foundation, a legally and functionally separate entity. The group has begun drafting a series of observations and principles, and recommendations flowing from them.

One case example involves a large coalition effort, funded at a large level by one or two principal funders to increase public awareness of Hepatitis C and the importance of treatment. The principal funders stood to potentially gain from this increased awareness and treatment. The other case example involves an investigation into whether certain industry practices were harming workers in the industry. The investigation was funded by an industry association. Both cases were widely reported in the media. Dr. Frieden realized the importance of these issues to CDC and requested a workgroup to assess the issues and make recommendations. Their work was grounded in the evidence, as well as the challenges associated with dealing with ethically complex questions about private financial relationships.

The ECPPP WG's initial key observations include the following:

- In any activity, maintaining the public trust is paramount. Not just the public perception, but the public trust of CDC is such that its words and research matter, and it operates in the interests of the population, not of itself.
- Donor cultivation and relationship-building occurs over time and takes many forms. The process is iterative, and it is important to be aware of the dynamic throughout it. The point at which donor cultivation becomes more formal must be managed.
- CDC is prohibited from explicitly soliciting funds.
- Congress sanctioned the development of private financial relationships through the CDC Foundation, and CDC can also directly accept gifts from private donors.
 - There are complexities in the CDC-CDC Foundation Relationship:
 - There is no common, shared set of standards for reviewing COI or for the process of identifying areas where the conflict is so great that no review is needed.

- The entities are legally separate, but intertwined. They do not have to be operationally separate and can work in a more coordinated fashion than they have been.
- CDC Foundation guidelines are under revision.
- Currently, there are no “bright lines” that absolutely prohibit funding from a particular type of donor or for a particular activity.
- In developing outside financial support for CDC projects, there is not always a consideration of the level of priority that a particular project holds for the CDC mission. Many things in public health are worthwhile to pursue, but when funding supports CDC in a principal role, there is a need for common priorities.
- Because there is no clear set of priorities of which projects to fund via outside sources, it is not possible to know what is considered important, but low-priority.

The workgroup created four guiding principles that are enduring in the realm of ethics and managing financial relationships:

Transparency

- There should be transparency between the CDC Foundation and CDC as well as between CDC and the public.
- Written funding priorities will help both sides understand CDC’s expectations regarding highly important areas that need outside funding.
- A review process should be aligned with the priorities. CDC and CDC Foundation should work together more smoothly.
- Public access to information is extremely important. Information about CDC’s projects that are funded through partnerships with outside organizations, and why the partnership is important for the public good, is not readily available. Some information is available through the partners.

Public Trust

- There is a difference between public trust and public perception. CDC has a public trust standard.

Core Mission

- Anything the CDC does with outside funding should speak to its core missions.
- CDC has to be a nimble responder to public health crises when they arise.
- CDC conducts vital research and investigations.
- The agency does seminal work in health promotion.
- CDC tests and evaluates interventions.
- The agency engages in professional development.
- CDC sets standards.

Accountability

- Accountability applies to all personnel, not only low-level staff but also higher-level staff who are likely to be in a position to cultivate donors.

The workgroup has begun drafting specific recommendations, which will be refined based on feedback. The group plans to apply the recommendations to case examples to determine what the recommendations suggest regarding standards and processes. Preliminary recommendations in each area follow:

Transparency

- In terms of mission relevance, a clear statement is needed about why any financial relationship is being entered into and how it aligns with CDC's mission.
- What is the primary benefit to the public that is leading to the establishment of a financial relationship? Are there detriments to the relationship?
- What are the clear and measurable benefits expected from the relationship?
- Where the CDC Foundation is involved, final determination should be made by CDC. Due diligence should originate with the CDC Foundation and CDC so that the agency's decision is based on a record that was built regarding how a project advances the mission of CDC, can be managed properly, is good for the public, and any potential detriment to the public is outweighed by the benefit.

Clear Standard for COI Review

- Each time a review is conducted, there should be clear, measurable public benefits that flow.
- Consider the potential for adverse impact on public trust.
- Weight is given to the question of whether the partner will benefit, and if so, how and how much? This question is important for managing the public trust.
- There must be management of the relationship.
- The level of CDC Foundation review should be addressed.

Comprehensive Review Process

- A comprehensive review process should be jointly developed by CDC and the CDC Foundation.
- The relationship of funding to the CDC mission should be articulated.
- The review process should begin at the earliest points of donor cultivation.
- The CDC Foundation must conduct due diligence.
- Information-sharing mechanism that ensures that CDC has the benefit of the CDC Foundation's work and that CDC Foundation has the benefit of CDC's prioritization activities.

- There should be CDC deliberation.
- Manage, reduce, and eliminate COI. There are issues to manage in any financial relationship.
- Manage COI between CDC and CDC Foundation, given their financial relationship.

Managing COI in Research and Programs

- There must be a firewall with the funder.
- The CDC Foundation should have a clear sense of CDC's priorities, and both should be transparent in those situations in which they receive external funding.

Prohibited Sources of Outside Funds

- There was a range of opinions among the workgroup members in this area. Some members felt that there are some sources of funds that should never be accepted given their relationship to harm to the public's health which, such as tobacco, even if the use of the funds is purely humanitarian. Others felt that under certain, narrow circumstances or rare situations, it could be possible to accept funding that otherwise would not be accepted.
- The general sentiment tipped toward an absolute prohibition on very few, narrowly defined sources of funding.
- Another prohibited source of funding would be any funder that essentially would gain the public's endorsement of its products or services from the association with CDC.
- Any situation in which the funder would provide real or perceived influence over the conduct of CDC.
- Funds should not be accepted that conflict with CDC's mission or reputation, or with laws.

Prohibited Activities with Outside Funds

- The workgroup agreed that certain activities cannot be carried out with outside funding. These activities reach to the core of the governmental purpose of CDC.
- In terms of standards and guidelines development, standards guide insurance coverage decisions and there must be a "bright line" between their development and funding.
- Regarding investigation into public health risks, if a specific industry or activity is being investigated because of its risks, the subject of the investigation should not be anywhere near it.
- Health promotion campaigns with donor product interest should be prohibited, especially if a dominant entity is eclipsing the effort with their funds or their presence.

- In terms of funder involvement in research, it should be clear what happens when the award is made regarding the research process and results.

Discussion Points

Mr. Doug Nelson (Chair, CDC Foundation) thanked the workgroup for their work, and indicated that senior staff at the CDC Foundation have been working on these issues for over a year.

Dr. Farley thanked Ms. Rosenbaum for summarizing the workgroup's complicated discussions and diverse views. He is a believer in hard lines and "bright lines" because CDC, deservedly, has a stellar reputation that enables it to engage in many important efforts simply by speaking. Other federal agencies and experts do not have this ability or the reputation of always speaking for the best in science and public health. It is crucial to maintain that reputation, so when there are judgment calls, it is best to avoid anything that might compromise it. Bright lines are needed because the situations are complicated, and the decision-making process for accepting funds is complicated. If the guidelines are all "shades of gray," there are too many opportunities for surprises. Having simple, clear rules that everyone at CDC and the CDC Foundation understands will avoid such situations. These approaches will require difficult decisions. For instance, he does not believe that CDC should accept tobacco money, even to help with the Ebola crisis. Even if a company's motives are largely benevolent and it wants to support an initiative that CDC thinks is worthwhile, if the company will benefit financially, CDC should not enter into a financial partnership with it. The long-term reputation and public trust of CDC is crucial. Other workgroup members had different opinions on this point.

Mr. Nelson said that the CDC Foundation shares the workgroup's and CDC's recognition that protection of the public trust in CDC is the highest moral and functional obligation that the CDC Foundation has. Increased alignment between the way that CDC and the CDC Foundation make judgments about donor appropriateness is a priority aspiration on both sides. As much communication should take place as possible at the highest levels possible between these two entities that share a common purpose. It is important to remember that approximately 80% of the resources that come through the CDC Foundation to advance the goals and mission of CDC come from philanthropic donors as opposed to from corporate or for-profit entities. The eminent need for the highest level of judgment about donor appropriateness is, in most cases, a different exercise of judgment between those two categories of private funding. This difference is implicitly recognized in the workgroup recommendations. The problem of "getting wise and right" all the time is becoming more challenging with respect to funders who have commercial interests, commercial purpose, and shareholders. The recommendations also recognize that there are some questions about the appropriateness of corporate donors that do not easily lend themselves to a "bright line" or "checking the box" approach to decision-making. Judgment is required, so standards for judgment as opposed to compliance with easily-articulated guidelines represent a challenge to arriving at final recommendations and improved practice. There are examples, such as donors who are involved in tobacco promotion, of donors who constitute reputational risk and risk to CDC's public trust. The decision-making can be simplified in these instances; however, there are gradations of the risks and rewards in some projects that will not be addressed completely by "bright line" criteria. The structure of due diligence as well as the

presentation and sharing of the findings represent opportunities to improve the process. He looks forward to continued conversations among the workgroup, CDC staff, and senior management at the CDC Foundation. There is work left to do to create common decision-making standards for instances about donor appropriateness where there are no easy “bright lines,” but where the CDC Foundation and CDC must come to a conscientious weighing of risk and reward to public health.

Dr. Richardson asked about the existing processes for the CDC Foundation to cultivate and accept gifts. There are concerns about monies that are directed to specific initiatives and projects. She asked if donations are always directed, or whether there are unrestricted gifts to the CDC Foundation to support CDC.

Ms. Becky Payne (Deputy Chief of Staff, CDC; DFO, ECPPP WG) said that CDC receives funds directly from the CDC Foundation. The foundation was established by Congress to help build public-private partnerships. The support received is often, but not always, financial. There is flexibility and speed in working with the CDC Foundation, where funds that come directly to CDC are like federally-appropriated dollars and are confined by federal regulation. CDC’s experts are always interacting with others in the larger world. Many people and groups want to collaborate with CDC on projects that further the agency’s mission. When these conversations progress, they transition to the CDC Foundation, which helps develop priorities and concepts and consider funding. The CDC Foundation works with CDC to help these projects come to pass. The CDC Foundation has worked with some donors for many years. These donors may become interested in other projects at CDC and ask to become involved. These situations can result in blurring regarding mission. It is likely that any project proposed by such a donor will be important and could have potential impact, but the discussion about mission relevance addresses the question of how strongly CDC can acknowledge a good idea that is not the most important thing to do and that might make take them “off point.” CDC must be comfortable with this position within its own organization and with its ambitious scientists and with its partners. In other cases, a CDC staff member may generate an idea about an area of public health impact for which CDC does not have sufficient federally-appropriated dollars. The staff member writes concepts that are reviewed and cleared by CDC leadership and forwarded to the CDC Foundation, which works on securing a donor.

Dr. Frieden noted that the CDC Foundation can accept unrestricted funds, but they are not generally offered by donors.

Ms. Rosenbaum said that she, workgroup member Dr. Eric Campbell, and Ms. Payne tried to create a visual aid to show the ways in which money develops at CDC. Funds can develop because the CDC Foundation has, or develops, a relationship with an entity that is interested in supporting CDC’s high mission work. There can also be situations in which the beginning of the relationship is not through the CDC Foundation, but in more informal interactions between CDC staff and the world. The potential funder is directed to the CDC Foundation, which can work more nimbly. As funds are received, they tend to be for project-specific work.

Dr. Mullen asked whether the public trust guiding principle, which addresses clear benefit, is also vetted by the population, community, or country where the work is proposed to be done, not just through a CDC lens. In terms of trust, it may send a strong message to convey that CDC’s funding and work is considered by both sides.

The President's Bioethics Commission considered these issues related to Ebola and potential research on an Ebola vaccine.

Ms. Rosenbaum said there could be mention of how public trust is weighed and how CDC and the CDC Foundation arrive at the conclusion that public trust is present to reflect that this process involves more than CDC's opinion.

Dr. Chu said that until the workgroup began to understand the process and relationships involved, they could not conceive of a better process. The background and supporting work that occurred before the workgroup calls was on target and helped them focus their discussions. It is evident that there has not been a clear process, adherence to core principles, or certainty that funding was related to CDC's core mission. It was assumed that CDC's public trust is paramount, but that value was not reflected operationally. There were also issues associated with internal or inter-entity COI. These issues needed to be made apparent before the workgroup could create recommendations. More important than defining "bright lines" is the notion of the transparency of the process, with a rigorous way to assess potential COI and risk assessments. One person's bright line may not be another person's bright line. For instance, are sugary drinks a bright line of prohibited funding? Openness and transparency are important, as well as procedures that clearly articulate the thinking process.

Ms. Rosenbaum has concluded that if every partnership were prominently displayed on the CDC and CDC Foundation sites, it would have a tremendous impact on making it possible to recognize certain bright lines and situations immediately. She agreed that transparency is the major issue.

Dr. Fleming stressed that standards and guidelines development is one of the hardest areas to find internal funding to support. If, for instance, the Bill and Melinda Gates Foundation (BMGF) wanted to provide CDC financing to develop Ebola guidelines in a certain setting, he wondered whether the guidelines would prohibit it, even though it is an example of a philanthropic organization providing financing for an initiative that is clearly within CDC's mission.

Ms. Rosenbaum explained that uppermost in the workgroup's mind when crafting that prohibition was the 20% of funding that comes to the CDC Foundation from a corporate entity with direct interests in a guideline. In terms of setting standards, the processes that support bringing people together with all declared conflicts on the table in a fully public process are important. She feels that when there are operating standards in place, a foundation might support collecting information from the field when they are put into practice. However, the act of setting standards that will have a legal effect on how services are delivered and paid for is an area of concern. The workgroup will create examples in this area to provide their best sense of how the recommendations will be operationalized.

Dr. Fleming encouraged the workgroup to take the example of BGMF, as it will be important. The issue is also likely to arise with the work of the *Community Guide*.

Mr. Nelson pointed out that there is a significant distinction between philanthropic funding and its motivation and the character of any COI, as opposed to corporate funding for the five activities that were preliminarily identified by the workgroup. He urged caution in developing a procedure and standards for judgment on this matter,

particularly because investigations into public health risk and standards and guideline development are the two areas that have benefited CDC by the presence of philanthropic resources. The subjects are sensitive and require significant objectivity to be credible, but much of the development is not likely to find public funding to support them to the necessary degree. Much of what CDC does to understand public health risk has historically, and could in the future, benefit from access to appropriate private resource to enhance, deepen, and accelerate their ability to move. Areas such as employment and health promotion campaigns with donor product interest are simpler to perceive as appropriately prohibited. They should be careful to come to a conclusion that would not allow for benefit from the right kind of private partnership in the other areas.

Dr. Schuchat said that the draft recommendations state that the areas are prohibited from utilizing outside funds. The statement does not differentiate the source of the funds. The description of CDC employment is somewhat narrow in terms of consultation, but many projects funded by outside sources are projects that need staffing. There has been internal debate regarding whether the resources generated from outside sources could only support contractors or could be legitimately applied to full-time employee (FTE) salaries.

Ms. Rosenbaum indicated that the workgroup considered projects that are similar to projects at a university, which literally buy a portion of a person's time to serve as Principal Investigator (PI) on a funded project. The issue of CDC employee payments pertains to consultation to an outside organization where the individual receives compensation of one kind or another as an individual, not that the employment time is being bought. Regarding the philanthropic question, the issue is complex, but the term "philanthropic" needs a fair amount of contemplation. If there are areas in which outside funding is acceptable as long as it is philanthropic, it should be considered how far away from a donor's intent the funds have to be in order to be considered philanthropic. These are important areas for the workgroup to consider in their examples.

Ms. Berger suggested that the wordsmithing process could clarify some questions, especially if the recommendations use the terms that CDC legally uses, such as "gift funds" and "consultation services," which are different from gift fund dollars. The Congressional appropriation allows CDC to use gift funds to pay salaries and benefits.

Regarding the concept of a "sunshine website," Dr. Jaffe wondered what might happen post hoc, if donor information is published and subsequent revelations about the donor place a project in jeopardy. He wondered about publishing the donor information before the fact. It could be awkward, but worth considering.

Ms. Rosenbaum said that the workgroup did not consider that question. The notion that the information would be published post hoc would likely increase the certainty and due diligence. The group can explore the issue of publishing before the fact and opening a public comment period on proposed funding.

Dr. Jaffe asked whether the workgroup considered the "nuclear option." That is, should CDC not accept corporate money? If the funding is 20% of the CDC Foundation's total and the risk is so great, perhaps the agency should not accept it.

Ms. Rosenbaum clarified that the CDC Foundation was established to develop partnerships. There are no statutory constraints on the partnerships. There is clearly underlying Congressional interest in the appropriate use of private funds. The CDC Foundation statute also allows the CDC Director and HHS Secretary to turn funding down, but as a legal matter, no total avenue is closed.

Dr. Eric Campbell (Member, ECPWP WG) said that the “nuclear option” has been debated extensively in university settings. He is not aware of a single university that has exercised that option. Most institutions recognize that these relationships, especially in science, are essential. While they often carry significant risks, the purpose of this process is to develop a process and principles that can be applied to mitigate those risks to the extent that the benefits of the relationships can be realized. The only way to fully absolve oneself of any risk related to these partnerships is to ban them, but there are great potential benefits that can result from the relationships. Organizations believe that they can manage the relationships appropriately.

Ms. Rosenbaum pointed out that accepting funds only from philanthropy is not positive either.

Dr. Kanabrocki noted that he and Dr. Berns are working with NIH on a difficult project with many ethical considerations. They found that the use of case studies was helpful, and he encouraged the workgroup to take that path.

Dr. Farley did not think that any member of the workgroup felt that the “nuclear option” is necessary. There are circumstances under which it is appropriate for CDC to accept corporate funds, following clear standards. It would go too far and miss important opportunities to prohibit accepting those funds entirely.

Dr. Frieden thanked Ms. Rosenbaum and the workgroup for their thoughtful work. He said he looked forward to seeing the next iteration of their work, and thought that the interim presentation was helpful even without being final. The CDC Foundation has the motto, “Helping CDC do more, faster.” He agreed that case studies will be very important in working through these ethical issues. The difference between for-profit and not-for-profit funding is significant. It does not mean that for-profits are assumed to be tainted in some way, and non-profits are assumed to be pure, but there are differences between the two. Partner benefit will be a complex issue. If there were no benefits, then partners would not donate. This concept applies to foundations as well as to for-profit entities. The endorsement issue is realistic to consider, as the CDC “halo effect” is desirable. As long as the process is managed clearly and transparently, and there is no COI, then it may be acceptable. He hoped for a case study in areas similar to the global hypertension effort. CDC has thus far not received funding from philanthropy for global hypertension. Perhaps it is not desirable to receive support from one drug company, but if a group of five drug companies all contributed to a global hypertension effort, with appropriate transparency, it might or might not be acceptable. This issue is particularly complex, because there is controversy regarding whether drug treatment versus other strategies for addressing hypertension is better. It may be problematic, therefore, for any drug company to be involved in any manner. The CDC Foundation can provide recent examples to help with the case studies.

Ms. Rosenbaum said that the issue of numerosity arose frequently in the workgroup. The most complicated situations are ones in which there are one or two dominant

funders controlling efforts, as opposed to a large coalition of funders without a single dominant funder that is likely to gain.

Dr. Richardson said that many ACD members have dealt with these complicated issues in various arenas and at the institutional and individual levels. She was troubled by the idea of “bright lines” and “prohibited” sources of funding and activities. The bulleted prohibited activities map to six of CDC’s core missions. While it may be part of a thoughtful process and discussion, if there is a list of prohibited activities, it may in the future be interpreted to include things that never were envisioned when the list was created. This could result in lost opportunities. The safest approach is not to accept funds from anyone, but that approach is not the best one. Activities that are not undertaken or programs that are not stood up because of gifts that are not accepted have to be weighed against the risk to CDC’s reputation. It is not an absolute process. For instance, there is a difference between standards and guidelines. The recommendations will be wordsmithed more carefully, and she hoped that they would include language indicating that some elements require a special category of oversight and review because they are so likely to be problematic.

Dr. Fleming thanked the workgroup, and expressed the ACD’s appreciation for the framework and opportunity to provide comments and suggestions regarding the final document.

Antimicrobial Resistance (AMR) and Combating Antibiotic-Resistant Bacteria (CARB)

Dr. Beth Bell (Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), CDC) described CDC’s progress in AR and the CARB initiative. National momentum in AR has been growing since the publication of CDC’s AR Threat Report in the fall of 2013. Subsequent activities have included inter-agency government work on a strategy and action plan, gathering input from the President’s Council of Advisors on Science and Technology (PCAST). The White House Antibiotic Stewardship Forum was held in 2015, and a Presidential Advisory Council was formed as part of the Presidential order that accompanied the strategy. The council met for the first time in the fall of 2015.

CDC focuses on three core activities regarding AR threats across healthcare-associated resistant organisms as well as foodborne and community pathogens:

Prevention

- Develop evidence-based guidelines
- Assist in outbreak response
- Implement prevention strategies with states and partners
- Conduct applied research to inform prevention

Stewardship

- Track antibiotic use, especially in healthcare settings
- Provide research tools and guidance on improving antibiotic use
- Improve consumer and provider education

Surveillance

- Implement real-time data systems for tracking and quality improvement

- Define risk populations
- Provide national and international laboratory expertise, testing, and diagnostic capacity

AR is an area in which the community perspective that recognizes how health care facilities are connected is important. The August *Vital Signs* published data and applied agent-based models to estimate, using Carbapenem-resistant *Enterobacteriaceae* (CRE) as an example, the potential improvement in CRE that could be achieved by applying a coordinated approach with the health department as the “node” and ensuring that facilities use common methods to track patients and share information. The model indicated that by taking a coordinated approach, up to 70% fewer patients would acquire CRE over five years compared to using good infection control at any individual facility. Considering AR organisms as a community problem is a major focus of the budget request, including empowering the health department to serve as the central point in community AR efforts.

There have been examples of innovation in applied research. The Prevention Epicenters (PE) program is a unique effort in which CDC collaborates with academic investigators to conduct focused, applied research related to infection in health care. The work is connected to filling knowledge gaps that are identified by surveillance data and outbreak responses. For example, one of the Epicenters conducted a study that found that a combination of disinfectant and ultraviolet (UV) light used to clean patient rooms reduced new AR infections by 30% in patients staying in a room where an infected person was previously treated. Other Epicenters are working on using biomarkers to improve prescribing and prevent resistance among intensive care unit (ICU) patients. There is also a project on characterizing the fecal microbiota of CRE-positive patients to improve prevention strategies. Plans are expanding for multicenter studies.

The area of stewardship is important, and underlying these efforts is the ability to track antibiotic use. NCEZID is working toward better understanding of prescribing trends and establishing national targets for reducing inappropriate use. This work is an example of an intersection with the work in device-related healthcare-associated infections (HAIs). The ability to benchmark and establish targets, and track progress toward the targets, has been an important driver for progress. To this end, hospital-based reporting of antibiotic use to the National Healthcare Safety Network (NHSN) is being implemented. A risk-adjusted summary measure for antibiotic use has been developed and endorsed by a subcommittee of the National Quality Forum (NQF) and will be considered by the full NQF. This measure will be an important means for establishing targets and tracking trends. CDC is implementing HAI prevalence surveys that include assessments of antibiotic use and resistance in hospital and long-term care settings through CDC’s Emerging Infections Program (EIP). This work will establish a baseline and characterize the landscape of use and resistance patterns.

NHSN is foundational to making progress in tracking antibiotic use and resistance. The NHSN Antibiotic Use and Resistance (AUR) module will allow hospitals to utilize the data for implementation of their own antibiotic stewardship programs and quality improvement efforts. The data will empower facilities to improve prescribing and help health departments in their coordinating roles. It will also allow for national benchmarking. To date, 118 facilities have submitted at least one month of antibiotic use data to NHSN. The process involves the electronic capture of information from

pharmacies and laboratories, and CDC is working with vendors to make it easier for facilities to use the module.

NCEZID has been creating tools and guidance for stewardship, such as CDC core elements for antibiotic stewardship programs for hospitals and nursing homes that have been distributed. The center also works with partners to support innovative approaches to implementing antibiotic stewardship, such as antibiotic “time outs” and helping health departments target problematic areas to develop new partnerships to make local improvements.

NHSN conducted a survey of antibiotic stewardship programs in hospitals. The survey results indicate that 39% of US hospitals report implementing all seven core elements of a stewardship programs. There needs to be a greater sense of what the hospitals mean when they indicate that they are implementing the elements. CDC is collaborating with groups that use CDC’s core elements for hospital antibiotic stewardship programs to assist with dissemination and to learn where some problems with implementation may lie.

Consumer and provider engagement is pivotal to the antibiotic stewardship effort. The White House Forum on Antibiotic Stewardship held in August 2014 included over 150 organizations across human and animal health representing a broad group of stakeholders, including a number of government representatives. There was a great deal of interest and enthusiasm at the forum, which also served as a venue for different groups working in the same sector to interface and discuss collaboration. The annual *Get Smart About Antibiotics Week* has expanded its partnerships in 2015 and provides another opportunity to follow up on White House Forum commitments to antibiotic stewardship.

An AR Isolate Bank was launched by CDC and FDA in June 2015. The bank provides collections of bacteria to support the research and development of new diagnostic tests and antibiotic drugs. It was identified in the PCAST report and other efforts as a gap and a barrier to stewardship. CDC has a significant collection of isolates to bring to bear in this effort. Curated panels from the AR isolate bank can be used to challenge and design the next generation of clinical tests and therapeutic agents. Currently, the bank contains over 220 isolates comprised of first collections of CRE and other multi-drug resistant (MDR) gram-negative rods. There has been a robust level of interest in receiving these collections.

Regarding CARB, it is hoped that funds will be received to jump-start many efforts, especially in the areas of strengthening states and improving communication and coordination at the state level as well as tracking antibiotic use and stewardship.

Discussion Points

Dr. Chu asked whether these efforts are engaging with accreditation bodies such as the Joint Commission to establish a database of antibiotic use by facility in the hospital setting.

Dr. Bell answered that NCEZID is working with the Joint Commission.

Dr. Denise Cardo (Director, Division of Healthcare Quality Promotion (DHQP), NCEZID, CDC) added that they are working with several groups, including Kaiser, to learn not

only how to collect the data, but how the data can be helpful for promoting better quality. The Joint Commission is part of this work. The concept is sound and now is the time to work with partners to make a difference.

Select Agents

Dr. Steve Redd (Director, OPHPR, CDC) described CDC Select Agent Program (SAP). The work that is regulated by the SAP is important. It is necessary for the scientific community to continue to work on these dangerous pathogens and toxins to develop diagnostics, vaccines, and therapeutics. The program regulates that activity so that it is done as safely and securely as possible. The effort represents benefit/risk assessment: the more the work is regulated, the less work will be done and the fewer benefits will be realized.

The Select Agent Program is regulatory. All aspects of regulations are part of the program. It is governed by laws, Executive Orders, and rules. The program was established in 1996, with a much narrower scope that focused on regulating the transfer of agents. The law required that CDC be notified when a list of agents was transferred. The program took its current form after the 9/11 attacks. Two different laws created the structure of registering, inspecting, reporting incidents, and personnel requirements for persons having access to agents. The structure was somewhat modified by an Executive Order that separated some of the most dangerous agents into Tier 1.

The program is responsible for the following:

- Developing and implementing regulations
- Registering facilities that wish to do work on select agents
- Conducting inspections
- Receiving reports of theft, loss, or release
- Conducting investigations, generally collaboratively with state and local health departments and other parts of CDC
- Enforcing by suspending activities, revoking registration, and making referrals to the Office of the Inspector General (OIG) or, when criminal acts are suspected, to the Federal Bureau of Investigation (FBI)

The list of regulated entities, or laboratories, fluctuates. At the peak in 2006, over 400 entities were regulated by the program. Today, 295 entities are registered with the Federal Select Agent Program. A small number deal only with animal or plant pathogens, and another small number deal only with human pathogens. A group of entities are registered to work on either human or animal pathogens. The groups are primarily government and academic institutions. Currently, the program includes 65 identified Select Agents and toxins, with 13 of them designated at Tier 1 agents.

The number of inspections conducted by the program each year varies. The requirement is to inspect every entity at least every three years, and high-complexity organizations are inspected annually. In the last five years, the program has also conducted unannounced inspections, with a target of 25% of the inspections being unannounced. There was a decrease in inspections in 2013 as part of implementing new rules and training entities on them.

The program also receives Form 3 Reports, which address theft, loss, or release of select agents. Approximately 100 of these reports are received per year from registered

entities, and an often-larger number is received from diagnostic laboratories. The range of seriousness in the reports varies, from an infection in a laboratory worker (a very small number of these serious events have been reported) to something relatively trivial, such as a torn outer glove.

There have been a number of program accomplishments to date. A database has been created of registered entities and the select agents they work on. There is a system for receiving reports of incidents. A system ensures that personnel working in laboratories with select agents have undergone a security assessment. And a system is in place for working with the state health departments that have these laboratories and facilities in their jurisdictions.

I'll now provide a brief update on events that have taken place during 2015. At Tulane University this year, two primates were discovered to be infected with *Burkholderia pseudomallei*. Though unclear initially, it became clear that the organisms were being worked on in a laboratory at the same facility, but a different part of the campus. The organisms most likely were transferred from that laboratory to the primates inadvertently through a clinic exposure. Select agent work was suspended on February 11, 2015 and a third animal was subsequently discovered to be infected with *Burkholderia pseudomallei* and symptomatic. Three additional animals were discovered to have seroconverted to Burkholderia.

On May 22, 2015, a private laboratory identified live anthrax spores in a sample that was supposed to have contained killed spores. This incident resulted from a 10-year period of double failure of inactivation of live spores and of the test that was supposed to test that the spores were dead. Ultimately, the program identified 193 laboratories in all 50 states, 3 territories, and 8 countries that had received shipments from this laboratory, a US Department of Defense (DoD) facility at Dugway Proving Grounds. All shipments of *Bacillus anthracis* from Dugway were suspended on June 25, 2015. DoD initiated a 30-day review as part of the response to the incident.

As a recommendation from that 30-day review, environmental specimens were sampled from different laboratory rooms at Dugway. Five of the samples were positive from locations where there should not have been anthrax spores. That finding resulted in a suspension of select agent and toxin work at Dugway on August 28, 2015. It is important to note that no humans became sick in any of these events. There were possible exposures through the shipment of the live anthrax spores, but no human health consequences have been detected as a result of the incidents. They have generated a great deal of attention and identified inappropriate procedures.

In July 2015, Dr. Frieden asked for a 90-day review of the Select Agent Program. The report findings are in the categories of:

Improving the Inspection Process

- Standardize the process and make it clear what is being examined
- Link this work to penalties for elements that are not up to the standard

Improving Incident Reporting

- Identify observations and reports on a continuum of risk
- Understand the things that are really going wrong and not assign the same weight to a torn glove and an infected laboratory worker

- Conduct better analysis of what is being found, which is essential to the corrective action process

Transparency

- Work toward a more transparent system so that people understand what is happening in laboratories

The select agent world seeks analogies in other regulatory programs. For instance, the aviation safety profile has improved dramatically since 1995. What would that ratio look like for laboratory work? Is there a way to have similar improvements in select agent work in 5 to 10 years?

Discussion Points

Ms. Rosenbaum asked about the Select Agent Program's enforcement power. For instance, if a laboratory is having problems, does the program have administrative powers to issue an order to close? What is the process by which the program reaches the point of issuing an order? What happens after the order is issued if the facility wants to stay open?

Dr. Redd replied that this facet of the program's work is straightforward. The program sends a letter to the entity to stop work, and the entity stops work. The letter can be sent immediately when a threat is detected and halting procedures would mitigate that threat. The next step is an inspection or investigation report that outlines the problems and is shared with the facility. The facility then responds with its plans for addressing the problem. The program follows up with the facility and must be satisfied that the necessary changes have been made before the facility reopens. There is no appeal process, and some facilities have indicated that they would like one. Currently, facilities must provide evidence that is sufficient to allow them to reopen.

Dr. Frieden added that there is also not a clear penalty process. The program can close facilities and reopen them, but cannot directly penalize them.

Dr. Kanabrocki has a long history with the SAP, and has long argued that the Form 3 process needs to be better teased apart. In his mind, an occupational exposure is not a theft or a loss, and if it is managed appropriately it is not a release. Those occupational exposures occur in an infectious disease program. It is important for a facility to be prepared for them, for the staff to be trained to respond to them, and to have a response program for them. He encouraged that occupational exposures and illnesses be treated separately from thefts, losses, and releases. "Theft" is the first word, and its negative connotation is sensed by the public. The types of exposures and incidents, and their severity or lack thereof, should be better demonstrated. He applauded the direction of the program.

Dr. Redd said that the idea also fits with the focus on transparency. The way the numbers of Form 3s are reported may give the impression that every instance is dangerous. The incidents are actually evidence that the system is working and that unimportant events that are opportunities to improve are reported.

Dr. Kanabrocki agreed that the reports are direct evidence that the system is working.

Dr. Berns asked about the fraction of incidents that are loss, particularly inventory issues. There is pushback in the community regarding the absolute number of vials, even given issues with the FBI and other concerns.

Dr. Redd said that one of the problems with the review is that it does not separate the incidents by type. There are zero supposed thefts. Regarding inventory, frequently institutions can resolve discrepancies, and there are few losses. It is a great deal of work to square the inventory with the database. There are opportunities in information management systems to make the process less onerous and burdensome.

Dr. Kanabrocki stressed that the inventory question needs to be considered. Counting tubes is something of a fallacy when working with replicating organisms. The approach gives a negative impression and does not really address security.

Dr. Frieden pointed out that the challenge with that issue is explaining where specimens of a pathogen are.

Dr. Kanabrocki said he understood the problem, but with infectious materials as opposed to toxins, the inventory should be qualitative as opposed to quantitative. Counting tubes of infectious agents is not likely to be beneficial. Toxins are a different, finite chemical. When it is depleted, it is gone. Keeping inventories of toxins makes sense. Problems with inventory of infectious materials remain, however. The process of counting tubes is interesting, because it requires entering a -80 degrees Celsius freezer, holding the door open and jeopardizing its contents. It may not be worth the time and energy spent on it.

Dr. Redd noted that there could be an alternative to counting vials, such as an information technology (IT) solution such as barcoding.

Dr. Kanabrocki agreed that there will be solutions. Some systems use barcodes, but they do not stick well in the freezer and have their own problems.

Public Health – Health Care Collaboration Workgroup Update

Mr. John Auerbach (Associate Director for Policy, CDC) reported that the Public Health – Health Care Collaboration (PHHCC) has continued to meet on several issues. The workgroup has two new chairs, Dr. Mullen and Ms. Rosenbaum. There has been progress on the PHHCC recommendations that were approved by ACD, particularly on two of the four. The recommendation to support a more coordinated health system that links clinical care with public health is closely aligned with one of CDC's three strategic directions at CDC. The recommendation to fully leverage the Patient Protection and Affordable Care Act (ACA) requirements for non-profit hospitals and community health improvement builds upon the issues related to the IRS and the activities of nonprofit hospitals.

The overall approach to building linkages between clinical care and public health has been to identify how public health adds value to the work that takes place in the healthcare sector. This value lies in three components of prevention: 1) traditional clinical preventive interventions; 2) innovative preventive efforts that are possible under payment reform activities that are taking place as part of the move away from a fee-for-service model and toward value-based contracting; and 3) community- or population-wide approaches.

The first two areas relate to providing assistance and considering what takes place in a clinical setting that is beneficial from a preventive approach. Some may fit within the traditional reimbursable services paradigm, but for one reason or another, there may not be as much uptake or utilization of those services. Other services may be more innovative. In order to have an impact as public health practitioners, it is important for public health to know where discussions are taking place with the healthcare sector. These discussions can be statewide or may take place as local health departments work with local practitioners. It is important to demonstrate that public health can make worthwhile contributions to the proceedings. In order to demonstrate that value, public health must understand the priorities, interests, and procedures where those discussions are taking place. Public health must be prepared to enter those discussions with clear recommendations.

The 6|18 Initiative was developed to assist in those activities. The number refers to six high-burden health conditions and 18 evidence-based interventions that can be presented to providers to have an impact on prevention in a concrete and specific way.

The six health conditions are:

1. Tobacco use reduction
2. Blood pressure control
3. Infection prevention
4. Asthma control
5. Unintended pregnancy prevention
6. Diabetes prevention and control

The conditions were selected based on: 1) burden of disease; 2) cost in terms of illness, injuries, premature death, and economic costs; and 3) what CDC knows within the areas about what works; that is, there must be solid evidence that using interventions within a relatively short amount of time can save money by controlling healthcare costs or by improving healthcare outcomes.

Evidence packages are being developed for each of the 18 interventions. The packages are based not on a typical approach for writing a journal article, but also on what insurers need to be convinced that public health can have an impact in large healthcare systems.

In addition to sharing materials with partners at the local and state level, CDC is directly involved in working with insurers, large providers, and large employers. The activities with commercial providers include inviting leaders of the largest insurance companies to CDC so that CDC staff understand more about their reach. Smaller meetings are arranged with individual divisions for in-depth discussions about what CDC knows about preventive interventions that may be useful for insurance companies as they make decisions about coverage and the way that benefits are structured. These meetings have taken place with Humana and Blue Cross/Blue Shield Association (BCBSA). A meeting is planned with United Health, the largest insurer in the US. In addition to being informative, the meetings are leading to discussion about specific pilots in different locations.

Similar meetings have taken place with representatives from the Medicaid programs in the 50 states. Medicaid operates differently in each state, so CDC is getting to know the Medicaid directors much like the Office of State, Local, Territorial and Tribal Support

(OSTLTS) has gotten to know every state's Public Health Commissioner. CDC is now able to differentiate between the Medicaid programs with interest in working on each of the different health conditions and can provide the evidence packages to them. CDC has contracted with the National Association of Medicaid Directors (NAMD) and the Center for Health Care Strategies (CHCS), which trains the Medicaid directors. CDC is working on a nearly-daily basis with the Centers for Medicare and Medicaid Services (CMS). This work involves having staff based at the CMS Innovation Center in Baltimore, Maryland as well as regular visits. CDC's approaches can be tailored within CMS. For example, long-acting reversible contraception (LARC) interventions are focused on Medicaid, whereas the Diabetes Prevention Program (DPP) targets Medicare. Part of this work involves training staff at CDC so that they are well-informed about the insurance industry and the way that their work can be of use. The training helps staff use the right terminology and seek the right evidence. Four full-day trainings have been held with 80 CDC employees with national experts.

Dr. Jewel Mullen (ACD Member, co-Chair, PHHCC) described the PHHCC recommended opportunities for accelerating the 6|18 Initiative. The suggestions to the question posed, "What does public health have to do with it?" included the following:

- Identify innovative early adopters in the commercial and Medicaid realms who are already working to drive change. They can help lead the way forward, and CDC can learn from them.
- Work has already been done to establish CDC as the subject matter expert (SME). CDC should continue to position itself for a national/state approach.
- Employers and payers are working at the state level, and they should be engaged. In particular, self-insured employers and benefits consultants should be engaged as partners.
- Align new partnerships with existing insurer initiatives. Regarding population health, align with efforts such as the American Heart Association's Life's Simple 7[®] program, which does some of the same work in heart disease risk reduction as CDC's Million Hearts[®].
- Develop a dashboard for national situational awareness and to monitor health system adoption.

Regarding the IRS requirements for nonprofit hospital investments in community health, Mr. Auerbach said that the initial requirement was to conduct a CHNA. In the upcoming requirement, hospitals will re-conduct the CHNA, focusing on gaps. It has been challenging to coordinate those activities with public health. Some communities have good experiences with the public health and community agencies working collaboratively with the hospitals, but many communities have not had as much joint planning and agreement on priorities as had been hoped.

To help with these issues, CDC developed an interactive website that was launched in May 2015. The site provides tools, best practices, and links to resources to encourage a more coordinated approach toward community health. Since the launch, CDC has hosted several well-attended Webinars and has been invited to speak at national

conferences of the National Association of County and City Health Officials (NACCHO) and ASTHO. There were 25,000 views of the website in its first month. The informal feedback has indicated that the site has been helpful for those that are engaged in this work.

CDC has a role in CMS's State Innovation Model (SIM) grants, which is a large investment on the part of the CMS Innovation Center. The Innovation Center was created by the ACA to serve as a laboratory for innovative clinical and reimbursement approaches. It has spent \$1 billion of its \$10 billion budget on the SIM program. Grants are awarded in 34 states, three territories, and the District of Columbia (DC). Recipients of the grants, particularly the testing as opposed to the design grants, are required to focus on ambitious goals of: 1) Achieving 80% of a state's residents to have their insurance paid for by a value-based approach within four years; and 2) Achieving 80% of a state's residents cared for by patient-centered medical homes.

The SIM program also requires a population health component of the statewide efforts to redesign health insurance systems, set new quality standards, and create new incentives. CMS approached CDC, and there has been activity for several years. The focus of the work has often been on obesity, tobacco, and diabetes. The work is broadening to include the full range of issues that states choose to prioritize. The collaboration has been productive between NCCDPHP, OSTLTS, and CDC's Policy Office. There has been a series of telephone conferences with the states' public health leaders to ensure that they are thinking about how to be actively involved with SIM activities. CDC has worked closely with CMS on how to structure the program so that there are opportunities to redesign the healthcare delivery system so that population health is an important component of the design. CDC has been able to advance beyond traditional to innovative preventive measures and to begin work with the states regarding how to consider about prevention statewide via policy approaches that can have impact if they are implemented in conjunction with activities in clinical settings.

Discussion Points

Dr. Fleming suggested that the first and third components could be pooled together. Like many elements of the 6|18 Initiative, clinical intervention may work well for affluent, commercially insured populations. In thinking about how to make the clinical measures most effective for people in the third component, the clinical care system must be willing to engage in an additional set of activities, often in partnership with public health and social services. He asked whether conversations with insurers had progressed to include expanding the scope of what they need to do to reach those populations.

Mr. Auerbach said that those discussions have taken place. Some of the 18 interventions specifically relate to the interventions that are necessary to ensure that lower-income populations or populations with greater disparity will be more likely to access care. One of the proposals is to eliminate cost-sharing with regard to the purchase of certain medications. Data have shown that even what seems to be low-cost shares can be a significant obstacle to getting a prescription filled. In meeting with insurers, CDC has brought up the unevenness with which the burden of illness occurs within communities and the benefits to paying particular attention to the populations where those disparities exist. The insurers may interpret patients in these populations to be more costly or "super-utilizers." If inequity is perceived as potential extra cost, then there can be progress. The way to discuss disparities, when possible and when evidence exists to support it, is to speak in terms of the extra cost that comes with caring

for people who have been diagnosed late or have additional risk factors. This approach brings common ground that did not exist previously.

Dr. Mullen added that states are relying on guidance and input from CDC to stay in the conversations regarding value-based payments.

Mr. Auerbach said that globally, CDC is encouraging insurers to work in all three components to get the most value for the money spent. Innovative preventive measures go beyond the walls of the clinical setting to reach patients, and policy at the community level where the patients live should be considered. There can be many complementary activities to change behaviors and improve health.

Ms. Rosenbaum commented that the workgroup has been strong, with excellent leadership from CDC. This work represents the best collaboration between CDC and CMS in some time. To the extent possible, CDC should prioritize Medicaid managed care. This issue is significant. Medicaid agencies are trying more innovative approaches than any other sponsor of a group plan. By definition, they have to be open to issues that CDC considers priority. As a payer, Medicaid is somewhat more elastic. Medicaid programs can invest in ways that risk-based financing may not be expected to invest. Additionally, it is important to monitor what happens as a result of the loss of premium stabilization funding. The ACA has utilized this funding for several years to ensure that insurers brave enough to serve communities with large numbers of uninsured people would not suffer losses. The funding is a permanent feature of Medicare Advantage, but it was built as a temporary feature for ACA and has been defunded. It is likely that there will be ecological pullouts in which communities that are geographically defined as the highest-risk communities will lose their insurers. This issue will be intensified by the loss of co-ops. PHHCC may need to think about the population health implications of these developments. CMS published its access rule, which was proposed in 2011. CMS is looking for global and population health measures of access. This rule will serve as another point of interaction.

Dr. Jonathan Fielding stressed that healthcare includes all of the ways to improve public health, and that public health should be vocal about the issues described by Ms. Rosenbaum. He confirmed that the 18 interventions are from the *Community Guide*. He has worked with hospitals to engage in their community benefit work. Local communities and public health should work with the IRS to hold them accountable.

Mr. Auerbach thanked the *Community Guide* and Dr. Fielding, noting that the partnership with the staff and board of the *Community Guide* has been important. They have worked together to reinforce the evidence base and to identify gaps.

Dr. Richardson was pleased to hear about the work with federal agencies and insurers. She asked if additional allies and partners on the provider side have been identified, perhaps including professional organizations focused on the six high-burden areas that could play a role in moving this work forward. The training that has been conducted for CDC could be useful to make available in some format to staff at state and local public health agencies who understand little or nothing about the current healthcare environment.

Mr. Auerbach replied that CDC is reaching out and working with large systems of care as well as with associations. For example, CDC hosted Trinity Health, which owns 90 hospitals in 20 states, for a visit to discuss where they can work together. They worked

closely with the American Academy of Pediatrics (AAP) in priority-setting. Regarding sharing the CDC training, he agreed that they were excellent and said that he would pursue the idea of sharing it more broadly. The national leaders who provided the training were able to translate their language to the public health community and make it understandable so that people could see how it related to their work.

Dr. Chu remarked that one of the difficulties associated with merging the public health and healthcare services agendas is the different parties involved. Health insurers typically say that they cannot control what doctors and hospitals do. Hospitals and doctors say that they are “prisoners of the payment stream.” This problem needs consideration. He suggested that the issue could be bridged by assessing measures of outcomes. He wondered about working with NQF and the National Committee for Quality Assurance (NCQA) to think about cross-cutting measures to support the design of a value-based purchasing program. For instance, even though people wanted to do the right thing to control HAIs, they were not a focus area until value-based purchasing and penalties for higher rates of infections came into play. Readmissions are another example of this idea. Asthma admissions and readmissions could be areas of attention for a value-based payment stream that could accelerate the slow movement. There is a great deal of turnover in membership, however.

Mr. Auerbach said that they have worked in the quality measures arena, but the effort is slow because it takes years to establish a measure, and there is a great deal of competition for measures. He sits on the Health and Wellness NQF Committee and is working on these issues. For the first time, this year CMS proposed in its measures under consideration a measure that would link hospital reimbursement to the smoking rates in the county in which the hospital operates. This measure represents the first time there is not a direct, attributable relationship between the clients served and the quality measure. There will be obstacles to the measure even beyond the vetting process, but it serves as an example of interest in pushing the envelope in many areas, including quality measures.

Global Workgroup Update and Discussion

Dr. Tom Farley (ACD Member, GWG Member) provided ACD with an overview of the previous day’s GWG meeting, which included rich discussion of the breadth and depth of CDC’s work across the globe. GWG focused in particular on four topics: GHSA, Polio legacy transition planning, Progress on Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE), and the new Child Health and Mortality Prevention Surveillance (CHAMPS) program.

The GHSA was created to accelerate country implementation of the International Health Regulations (IHR) core competencies, including detection, reporting, and responding to infectious disease outbreaks. The Ebola experience illustrated that countries are not prepared to do this. Funding comes from CDC and other federal agencies to assess countries’ abilities to address infectious disease threats, as well as other countries. The assessments support the creation of plans to address where countries are weak. There are 17 countries in Phase I, with 13 more countries coming on line.

Issues raised by GWG included the coordination of GHSA work by CDC, DoD, and the United States Agency for International Development (USAID). The US government efforts are currently coordinated by the National Security Council (NSC), but NSC will not continue in that function in the future. Maintaining coordination going forward is

important not only at the US government level, but also at the country level where coordination also needs to take place with national governments, WHO, and other entities. In addition as a means for detecting outbreaks, GWG also discussed the importance of GHSA as an opportunity to improve local response capacity.

Polio is at a historic moment, as the world is on the cusp of polio eradication. There have been only 51 polio cases in two countries thus far in 2015. CDC deserves credit for thinking ahead about what to do with the polio infrastructure, which is funded at high levels and incorporates highly trained and highly effective workers who have been successful. Some maintenance work will need to be done, such as virus surveillance, biocontainment, and vaccine stockpiles, but the infrastructure can also be used in other areas, such as immunization, outbreak response, and biocontainment. There is a risk of losing capacity when the funding levels decrease, and there are opportunities to transition the capacity into the public health infrastructure in countries.

GWG commended CDC for contemplating how to transition the incredible resource of the polio infrastructure. The polio infrastructure was instrumental in the Ebola response in Nigeria, for instance. This example, and others like it, supports the case for legacy planning and transition.

CDC led field-testing of a new Ebola vaccine in the middle of the Ebola crisis. The STRIVE vaccine trial is ongoing under difficult circumstances in Sierra Leone. Over 8000 people have been enrolled in the trial, and over 6000 people have been vaccinated to date. The vaccine seems promising, but the timing of the trial with the controlling of the Ebola epidemic is such that its efficacy cannot be measured. STRIVE demonstrated that a field trial can be conducted under extraordinarily difficult circumstances in the midst of an emergency.

GWG discussed the degree to which CDC should support research in crisis situations in the future. The group generally supported this research. More tools need to be available in such situations, and conducting research is reasonable. There was discussion regarding the degree to which the protocols and mechanisms for creating the trial could be presented as a template that could be implemented quickly in the event of another major epidemic that requires similar research.

CHAMPS is a new system funded by BGMF. The program will capture detailed infectious disease etiologic information about mortality in children under the age of five, initially from six sites with plans for expansion. GWG discussed how to use the system not just for etiologies, but also as a broader surveillance effort that collects data about the context of child mortality that could be used for local prevention efforts. This approach could garner more local buy-in and support prevention in a broader sense. A death, whether with or without an infection, takes place within a social context. A great deal of understanding about prevention can come from understanding that context.

GWG discussed a number of cross-cutting issues as well. The group recognized the value of a single-pathogen focus, as illustrated in polio eradication and TB control efforts. However, while a great deal of funding comes with a single-pathogen focus or a narrow focus, there is a need to build public health infrastructure in under-resourced countries where CDC works. Thought should be given how to use funding not just for a single pathogen, but also for strengthening the public health infrastructure. The issue is difficult, but it arose throughout the meeting.

Additionally, GWG raised the importance of local community participation. This work should benefit local people, who should perceive it as a benefit and have a role in shaping it.

Discussion Points

Dr. Rebecca Martin (Acting Director, Center for Global Health (CGH), CDC) said that within GHSA, CDC's non-governmental organization (NGO) and community partners agree with the importance of the community's role in implementing new efforts and treatments to communities and in strengthening systems. Sustainability is important at the country level, and GWG discussed CDC's work with WB and other sectors in specific countries in macroeconomics and other relevant areas. Sustainability is also important at the US government level and the GHSA structure in the future. Regarding transitioning the polio legacy funds, the window of opportunity is now to plan for the future while there is still work to be done in polio, but there are opportunities to show how the funds are used beyond polio in immunization or in strengthening public health infrastructure. CDC has a unique role in emergency response and in research. CDC links with partners to move these areas forward and to prepare materials and opportunities in advance to respond to emergencies and conduct needed research.

Dr. Fleming commented that GWG is a strong workgroup, with ACD member representation and membership from other US government agencies, philanthropies, and a cadre of international experts. He asked for a motion to approve the minutes from the April 2015 GWG meeting.

Motion

It was moved and seconded to approve the minutes from the April 2015 Global Work Group meeting of the ACD. The motion carried unanimously with no abstentions.

State, Tribal, Local and Territorial Subcommittee Update and Discussion

Dr. Mullen (ACD member, STLT Subcommittee Chair) presented an update from the STLT Subcommittee and its four Think Tanks and presented recommendations for the ACD's consideration and approval. The STLT subcommittee has convened four Think Tanks to address and provide feedback on different issues that have surfaced. This mechanism has been an important way to corral the interests of the major beneficiaries of CDC funding and the implementers of public health work.

The Social Determinants of Health (SDOH) Think Tank is focusing its work on changing the narrative in public health to include SDOH. It has focused its work on strategies that CDC can use to: raise awareness about SDOH as they relate to health outcomes, inform practice, inform policy, increase the ability to assess trends, and contribute to the SDOH evidence base. OSTLTS, the Office of the Associate Director for Policy (ODAP), and the Office of Minority Health and Health Equity (OMHHE) have contributed to the convergence of SDOH work across CDC and are working to infuse CDC with SDOH principles. Note that this group works to coordinate its efforts with the ACD Health Disparities Subcommittee (HDS). Their work is also consistent with the thinking in ASTHO and NACCHO.

- The SDOH website, which is a “one-stop shop” for accessing CDC-CDC-supported SDOH resources. The website [Social Determinants of Health: Know What Affects Health](#) grew out of recommendations adopted by the ACD and is consistent with the deliberations of HDS. It provides tools to access non-health data, tools and guidance for moving data into action, CDC programs that incorporate SDOH, such as PICH and the Childhood Lead Poisoning Prevention Program, as well as policy options that can impact SDOH. It is hoped that this website can help users answer the frequent questions as: What can you do about SDOH? How do you measure and value them? How do you integrate it into the rest of public health work?
- The SDOH Think Tank continues to consider appropriate recommendations for the STLT Subcommittee to bring to the ACD. Criteria will include: a need to focus on what public health agencies do; whether it fits within what CDC can do; whether it is practical; how it links to existing CDC efforts; and the potential impact of the recommendations on health outcomes.

The **Public Health Finance Think Tank** grew out of STLT Subcommittee conversations regarding the Prevention Block Grant which was moved from NCCDPHP to OSTLTS. The group has focused on how these grants might support foundational capabilities in public health. There was acknowledgement that there is more work ahead to track the impact of the monies and to improve business practices, including accountability. It was noted that foundational public health capabilities are addressed through PHAB, local health entities, and state health agencies which are places where OSTLTS may better focus its efforts.

Foundational public health capabilities are addressed through PHAB, local health entities, and state health agencies. OSTLTS may better focus its efforts.

The STLT Subcommittee discussed whether Public Health Finance Think Tank should be sunsetted, and determined that it should not. Having a consistent body that is readily convened provides an opportunity to discuss issues in a nimble and effective way and to provide feedback quickly.

Through the STLT Subcommittee, the ACD has adopted recommendations from the **Public Health Surveillance Think Tank** in the past. The Public Health Surveillance Think Tank recognized progress on how mortality data are reported through the National Center for Health Statistics (NCHS), the transformation of notifiable disease reporting, and electronic reporting of laboratory data. The Public Health Surveillance Think Tank generated the following recommendations for consideration:

- *By mid-2016, CDC should convene appropriate partners* to develop recommendations for:*
 - *A national strategy for electronic case reporting (eCR)*
 - *Identifying the resources to prospectively support the required eCR and related infrastructure. Resources include financial, workforce and technical capacities.*

** Examples of partners: Federal partners (e.g., the Office of the National Coordinator for Health Information Technology (ONC), CMS, DoD, the Health Resources and Services Administration (HRSA)), State and local*

health departments, electronic health record (EHR) vendors, healthcare organizations and allied associations (e.g., the Council of State and Territorial Epidemiologists (CSTE), the Joint Public Health Informatics Taskforce (JPHIT), ASTHO, NACCHO, the Association of Public Health Laboratories (APHL))

Dr. Chesley Richards (Director, Office of Public Health Scientific Services (OPHSS), CDC) thanked the Public Health Surveillance Think Tank and STLT Subcommittee for their help in moving forward issues that are important for surveillance. CDC is at a “watershed moment” in terms of making progress in mortality and notifiable disease reporting and syndromic surveillance, improving the timeliness and quality of data received by CDC and reducing the burden on CDC partners.

The emerging opportunities in Electronic Case Reporting (eCR) will help health departments receive data from the clinical sector more efficiently, more effectively, and with greater value. It is a critical time not only to work with public health, but also to work formally with EHR vendors, the clinical sector, healthcare payors, and other partners. With Meaningful Use 3 including eCR as a measure in 2018, the investments that CDC has already made, and the progress in local jurisdictions, EHR vendors have indicated readiness to work together. A “Blue Ribbon Panel” (as suggested by this recommendation) may lead to important recommendations for moving forward.

The Public Health Associate Program (PHAP) Think Tank has focused on sustainability and quality of the program. PHAP has been extremely valuable for health departments, as it provides a well-trained and well-educated workforce for the future. The declining public health workforce is a concern at the state and local levels, and there are also strains on community-based organizations (CBOs). PHAP received early assessments of the quality of the program. Of the respondents to the 2013 survey, 93% had very positive feedback regarding the effectiveness and value of the program, 83% stated that the training that they received in the program was valuable in the position that they took after the training was completed, and 57% of the cohort continued to work in a public health agency.

Sustaining a program like this one requires funding that is not always readily apparent. The PHAP Think Tank strongly endorses PHAP and recommends it be sustained in the future as an integral part of workforce development and training at CDC. The STLT Subcommittee thus proposed the following recommendations for consideration by the ACD:

- *CDC should make the PHAP an ongoing and permanent part of the CDC’s workforce training portfolio.*
- *By the fall of 2016, CDC should develop recommendations for ensuring high quality, early career/entry level public health fellowships (e.g., PHAP) and shorter trainings (e.g., Trainings in Place) needed for STLT public health in the future. The recommendations should:*
 - *Draw on existing workforce needs assessments by existing CDC fellowship programs, partners, others;*
 - *Anticipate the numbers and types of staff needed at entry levels to meet future workforce needs; and*
 - *Identify resources required to address these needs and maintain high quality fellowships/trainings.*

Discussion Points

Dr. Richardson asked whether the eCR recommendation included suggestions or recommendations regarding the data elements that would be included in eCR, or if it was a high-level statement.

- Dr. Richards answered that the recommendation focuses on the specific exercise of conducting a notifiable disease and reportable condition report from an EHR, not about all data elements in an EHR or about all data elements collected for public health purposes. This specific case reporting is called out in Meaningful Use for 2018. The data elements, the composition of notifiable diseases, and how much has to be in the EHR versus how much is collected in other ways will be part of the discussion.

Motion

It was moved and seconded that ACD adopt the STLT Subcommittee recommendation regarding eCR reporting (as previously stated). The motion carried unanimously with no abstentions.

Motion

It was moved and seconded that ACD adopt the STLT Subcommittee recommendations regarding PHAP and workforce development. The motion carried unanimously with no abstentions.

Health Disparities Subcommittee Update and Discussion

Dr. Lynne Richardson (ACD member, HDS Chair) provided an update on the “CDC ACD HDS Recommendations for Achieving Health Equity.” The Subcommittee is active and talented, including experts from a spectrum of disparities, populations, and sectors. A great deal of work is going on across CDC in health equity. A number of Center directors have presented to HDS, and members have been struck by the commitment and scope of the agency’s work in health equity. There are so many competing demands on CDC’s time, it is important to keep health equity in the forefront.

In April 2014, HDS presented recommendations to the ACD, which were approved. They were designed to advise CDC regarding staying engaged and moving progress toward health equity. The subcommittee has tracked progress on the recommendations, which were to:

1. Develop a CDC framework for action to achieve health equity
2. Identify and monitor indicators of health equity
3. Align universal interventions that promote better public health, with more targeted, culturally tailored interventions in communities at highest risk to reduce health disparities and achieve health equity
4. Support the rigorous evaluation of both universal and targeted interventions and, where indicated, the use of culturally appropriate evaluation strategies, to establish best practice approaches to reduce health disparities and achieve health equity

5. Build community capacity to implement, evaluate, and sustain programs and policies that promote health equity, especially in communities at highest risk
6. Support training and professional development of the public health workforce to address health equity

Progress has been observed on several of these recommendations. Recommendation 1, regarding developing a framework for action, included a number of components:

- Measurement of health equity
- Essential elements of health equity programs
- Policy levers to support health equity
- Infrastructure needed by the agency to optimize its efforts in health equity

Several activities at CDC support this recommendation. The 4th annual State of Health Equity at CDC Forum held on October 14, 2015 was titled *The Power of Policy: Working Across Sectors to Get to Equity*. Each of the forums has been focused on the components of the Framework for Action. The fifth and final planned forum will focus on the issue of infrastructure. OMHHE has convened partners from across the agency to create a robust framework for action. Additionally, in collaboration with ASTHO, a special supplement of the *Journal of Public Health Management and Practice (JPHMP)* on health equity will be published in December 2015. The issue outlines the components of the framework for action and is an exciting development.

Recommendation 2, on establishing indicators for health equity, recognizes the importance of measurement. The STLT Subcommittee Think Tank on SDOH and HDS are cross-pollinating on this issue. A small workgroup of HDS has been reviewing CDC's efforts on indicators throughout the agency, focusing on the Healthy People (HP) 2020 framework for SDOH. The last HDS meeting included a report on an example of an indicator that could be developed to help monitor disparities. This work holds a great deal of promise and is already integrated into public health and the CDC framework.

Recommendation 3, regarding the need to align targeted and universal interventions, has achieved progress in a number of ways across CDC. HDS was pleased to see progress on the language in all CDC Funding Opportunity Announcements (FOAs). New optional language has been crafted to allow grantees to pull funds from different sources and sectors and combine them with CDC funds. HDS hopes that all CDC centers will incorporate this language. Another important issue that should be imbedded into programmatic work is the question of adapting and including individuals with limited English proficiency. The appropriate language groups are different in different communities, but the issue is often not considered when programs are rolled out.

The 6th recommendation focuses on training. HDS also supports the PHAP program and feels that it should not only be sustained, but also should be expanded. PHAP is a success story by any measure. It addresses issues of diversity of the public health workforce as well as its competence. OMHHE provided specific training on health equity to the PHAP trainees last year. The program has been successful in recruiting a highly diverse group of qualified individuals. OMHHE is working across CDC to imbed health equity into a range of professional development and ongoing training opportunities.

On behalf of HDS, Dr. Richardson urged CDC to keep health equity prominent, as it is central to the mission of public health to pay attention to those who are at greatest risk and to help them maximize their health.

Discussion Points

Dr. Mullen commented that employment and hiring practices carry with them issues of implicit bias in terms of obtaining a first job without having experience. PHAP addresses many of these issues. Workforce is declining in the entire health enterprise, and the workforce is not as diverse as it needs to be. On top of the quality that PHAP brings, it also brings societal benefit.

Regarding a framework for routinely monitoring health equity, Dr. Farley asked about efforts to monitor the social and economic factors which drive health disparities, such as income inequality or graduation rates by race. Public health tends to shy away from these social factors and focus instead on health outcomes. Perhaps public health should track and share social and economic indicators.

Dr. Richardson said that some of the HP 2020 indicators on SDOH move in this direction by accessing non-health data sources that might be useful in tracking what happens in communities. This work is challenging, as certain levels of data sources are recommended in this regard, and some non-health sources may be more exploratory or developmental. Many people at CDC are considering these questions.

Mr. Auerbach said that the SDOH website is almost ready to be shared. It represents an effort to highlight where there has been geocoding of information and to provide ready access to information when it already exists. There has been unevenness throughout CDC regarding how people use data and whether they were aware it existed. The website will guide internal and external people toward the state-of-the-art and best practices.

Dr. Richardson added that the website will help identify gaps and where stable data sources need to be created.

Dr. Fielding agreed with Dr. Farley's observation, having observed pushback from HHS during the development of HP 2020 on addressing social indicators. This work took time to complete. Enormous progress has been made in this area, but public health needs to look broadly and become accustomed to using indicators from other sectors, such as square feet per capita for parkland in a community, housing indices, transportation and time of commuting, and economic and educational issues.

Suggestions for Future ACD Agenda Items

Dr. Fleming invited ACD members to share their reactions to the day's meeting, advice to CDC, and ideas for future agenda items.

Dr. Goldman hoped that the SDOH issue could be considered in light of environmental health. She volunteered to help with that effort. Many environmental determinants are social, and vice versa. CDC may be able to advance its work in this area.

Dr. Iton thought the meeting had been informative. Public health should be aware of new and interesting data from Dr. Nadarajan "Raj" Chetty and his colleagues at Harvard

University, who are studying geographic economic mobility. The ability to correlate that robust data set, which can track families and individuals over a period of approximately 12 years, with life expectancy could be instructive in linking health equity and larger equity more firmly in the minds of the public.

Dr. Mullen said she learned a great deal from the meeting, and expressed her hope that there would be another meeting before too much time passed.

Dr. Farley agreed that the meeting was great.

Dr. Richardson concurred and added that she valued the ability to have in-person ACD meetings. The conversations are different and better among ACD during in-person meetings, and the involvement of senior CDC staff is appreciated.

Dr. Berns echoed praise for the meeting and pointed out the overlap between the issues of concern for ELSW and the SAP. He expressed his hope that CDC would take a holistic view of them, because they represent the same problem.

Dr. Fielding was tempted to say that the meeting was great, but he was once told that there is not such thing as a great meeting. It is a question of what happens afterward. He said he looked forward to what comes next.

Dr. Kanabrocki said that the meeting was thought-provoking in many areas. As the direct involvement of ELSW dwindles, he said he hoped to hear continued progress regarding laboratory safety and the SAP. He agreed with Dr. Berns that the issues are interrelated and must be linked, as one focuses on safety and the other on security.

Dr. Frieden added that the SAP is primarily external and regulatory, while the laboratory safety issues are internal to CDC's intramural research. There are adjacencies, however, and CDC is considering how to coordinate staffing. He said he looked forward to continued input on these issues.

Public Comments

At 2:43 p.m., Dr. Fleming noted that no one had signed up to provide public comment. He opened the phone line for any public comment. Hearing none, he proceeded with the agenda.

Closing Comments / Meeting Adjourned

Dr. Fleming thanked ACD and CDC for the meeting and expressed his appreciation for the opportunity to chair it. In order to maximize the value of the time that ACD has in its meetings, there will be a continued effort for the presentations to include specific questions regarding the issues that are the most important for CDC to receive advice on from ACD. He reminded everyone that in November 2016, there would be an election to bring a change in the Presidential Administration. If ACD can provide any advice or input in making that transition, they will.

Dr. Frieden said he looked forward to following up on the great advice provided by ACD during the meeting. An underlying theme through many of the discussions was the concept of risk: risk that is inevitable in global health; risk that is inevitable in infectious

diseases; the risk/benefit ratios about which CDC should be more blunt, such as the risks of opiates as pain relievers or the risks of antibiotics for treatments of illnesses that may not be the result of an infection; the risks of research; and the risks of accepting donations from different entities. The two sides of the risk/benefit equation are to do everything possible to minimize risk understanding that it is a “slippery slope” to zero risk, when there are unrealistic expectations regarding the elimination of risk, and to consider benefits carefully. If the benefits do not have a likelihood of outweighing the risks after the risks are minimized, the experiment should not be performed, the antibiotic or opiate should not be prescribed, and/or the donation should not be accepted.

Another theme of the day was the importance of community-wide action in AMR, PDO, and other areas. Coordinated action across multiple sectors on focused, accountable, effective, measurable interventions will yield results that should be communicated in an open and transparent manner. If the results are successful, the action can be defended, extended, and scaled up.

He acknowledged the enormous productivity of the ACD subgroups, which has resulted in substantial input, change, and improvement in the way that CDC operates. He thanked ACD for their work on the overall committee and the smaller groups, and he encouraged them to continue to provide advice on what the agency can do differently and better.

Dr. Fleming officially adjourned the meeting at 2:48 p.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the October 29, 2015, meeting of the Advisory Committee to the Director, CDC are accurate and complete.

Date

David Fleming, MD
Chair, Advisory Committee to the
Director, CDC

Attachment #1: Meeting Attendance

ACD Members Present

Chair: David W. Fleming, MD, Vice President, Public Health Impact, PATH

Kenneth I. Berns, MD, PhD, Distinguished Professor Emeritus, Molecular Genetics and Microbiology, College of Medicine, University of Florida

Benjamin K. Chu, MD, MPH, MCAP, Group President, Southern California and Hawaii; Regional President, Southern California; Kaiser Foundation Health Plan, Inc. and Hospitals

Thomas A. Farley, MD, MPH, Chief Executive Officer, Public Good Projects

Jonathan E. Fielding, MD, MPH, MBA, Distinguished Professor of Health Policy and Management and Pediatrics, Fielding School of Public Health and David Geffen School of Medicine, University of California, Los Angeles

Lynn R. Goldman, MD, MS, MPH, Dean, Milken Institute School of Public Health, The George Washington University (via telephone bridge)

Anthony B. Iton, MD, JD, MPH, Senior Vice President, Healthy Communities, The California Endowment (via video-teleconference)

Joseph Kanabrocki, PhD, CBSP, Associate Vice President for Research Safety and Professor of Microbiology, The University of Chicago

Jewel M. Mullen, MD, MPH, MPA, Commissioner and State Health Officer, Connecticut Department of Public Health

Lynne D. Richardson, MD, FACEP, Professor and Vice Chair of Emergency Medicine; Professor of Health Evidence and Policy Population, Mount Sinai School of Medicine, Icahn School of Medicine at Mount Sinai

Sara Rosenbaum, JD, Harold and Jane Hirsh Professor, Milken Institute School of Public Health, The George Washington University, Department of Health Policy and Management

CDC Participants

Thomas R. Frieden, MD, MPH, Director, Centers for Disease Control and Prevention

Anne Schuchat, MD (RADM, USPHS), Principal Deputy Director

John M. Auerbach, MBA, Associate Director for Policy

Ursula E. Bauer, PhD, MPH, Director, National Center for Chronic Disease Prevention and Health Promotion, CDC

Beth P. Bell, MD, MPH, Director, National Center for Emerging and Zoonotic Infectious Diseases

Sherri A. Berger, MSPH, Chief Operating Officer

Coleen A. Boyle, PhD, MSHyg, Director, National Center for Birth Defects and Developmental Disabilities

Denise Cardo, MD, Director, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases

Hazel Dean, ScD, Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Heather Duncan, BS, MPH, Director, Public Health Associates Program Office

Mary E. Hall, MPH, Associate Director for Science, Office of Minority Health and Health Equity and Alternate Designated Federal Officer, Health Disparities Subcommittee

Stacey Hoffman, MPH, Office of the Chief of Staff, Office of the Director

Debra Houry, MD, MPH, Director, National Center for Injury Prevention and Control

Michael F. Iademarco, MD, MPH (CAPT, USPHS), Director, Center for Surveillance, Epidemiology and Laboratory Services, OPHSS

Iroquo Igbinosa, MD, Office of the Chief of Staff, Office of the Director

Robin M. Ikeda, MD, MPH (RADM, USPHS), CDC Deputy Director, Office of Non-communicable Diseases, Injury and Environmental Health; Director for Noncommunicable Diseases, Injury and Environmental Health

Harold W. Jaffe, MD, MA, Associate Director for Science, Office of the Director

Erica Jimencz, MSW, MPH, Office of the Chief of Staff, Office of the Director

Rima Khabbaz, MD, CDC Deputy Director for Infectious Diseases, and Director, Office of Infectious Diseases; Acting Director, National Center for Immunization and Respiratory Diseases

Seth Kroop, MPA, Office of Public Health Preparedness and Response

Judy Lipshutz, MPH, Office of State, Tribal, Local and Territorial Support

Katherine Lyon Daniel, PhD, Associate Director for Communication, Office of the Director

Erin Malone, Deloitte Consulting, Office of Health System Collaboration, Office of the Associate Director for Policy, Office of the Director

Rebecca Martin, MD, Acting Director, Center for Global Health; Acting Designated Federal Officer, Global Work Group

Judith (Judy) A. Monroe, MD, FAAFP, CDC Deputy Director, State, Tribal, Local and Territorial Support; Director of the Office for State, Tribal, Local, and Territorial Support, and Designated Federal Officer, STLT Subcommittee

Steve Monroe, PhD, Associate Director for Laboratory Science and Safety

Dena S. Morris, MPP, Director, CDC Washington Office

Rebecca L. (Becky) Payne, MPH, Deputy Chief of Staff; Designated Federal Officer, Ethical Considerations for Public Private Partnerships Workgroup

Stephen C. Redd, MD (RADM, USPHS), Director, Office of Public Health Preparedness and Response

Chesley Richards, MD, MPH, FACP, CDC Deputy Director for Public Health Scientific Services and Director, Office of Public Health Scientific Services

Victoria Jeisy Scott, PhD, Influenza Division, National Center for Immunization and Respiratory Diseases

Laura Seeff, MD, Director, Office of Health Systems Collaboration, Office of the Associate Director of Policy; Designated Federal Officer, Public Health – Health Care Collaboration Workgroup

Stuart Shapira, MD, MPH, National Center for Birth Defects and Developmental Disabilities

Christa Singleton, BS, MD, MPH, Division of State and Local Readiness, Office of Public Health Preparedness and Response

Nicole Smith, PhD, MPP, MPH, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Jocelyn Wheaton, MPH, Office of the Associate Director for Policy, Office of the Director

Sarah Wiley, MPH, Senior Advisor, Office of Infectious Diseases; Designated Federal Officer, Laboratory Safety Workgroup

Enjoli Willis, BS, MPH, Office of the Chief of Staff, Office of the Director

Michelle Wilson, MSW, Office of Appropriations, Office of Financial Resources, Office of the Chief Operating Officer

Carmen Villar, MSW, Chief of Staff, and Designated Federal Officer, Advisory Committee to the Director

CDC Foundation

Douglas Nelson, Chair, CDC Foundation Board (via telephone)

Charlie Stokes, President and CEO

Betty Wolf, Vice President for Advancement

General Public

Kendra Cox, BA, MA, Writer/Editor, Cambridge Communications, Training, and Assessments (CCTA)

Attachment #2: Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ABSA	American Biological Safety Association
ACA	(Patient Protection and) Affordable Care Act
ACD	Advisory Committee to the Director
ADLSS	Associate Director for Laboratory Science and Safety
AHA	American Hospital Association
AMR	Antimicrobial Resistance
APHL	Association of Public Health Laboratories
AR	Antibiotic Resistance
ASTHO	Association of State and Territorial Health Officials
AUR	Antibiotic Use and Resistance
BCBSA	Blue Cross/Blue Shield Association
BMGF	Bill and Melinda Gates Foundation
BSC	Board of Scientific Counselors
BSL	Biosafety Level
CAP	College of American Pathologists
CARB	Combating Antibiotic-Resistant Bacteria
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health
CHAMPS	Child Health and Mortality Prevention Surveillance
CHCHS	Center for Health Care Strategies
CHNA	Community Health Needs Assessment
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
COI	Conflict of Interest
CRE	Carbapenem-resistant <i>Enterobacteriaceae</i>
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CSTE	Council of State and Territorial Epidemiologists
CTG	Community Transformation Grant
DFO	Designated Federal Officer
DHDSP	Division of Heart Disease and Stroke Prevention
DHQP	Division of Healthcare Quality Promotion
DoD	(United States) Department of Defense
DPP	Diabetes Prevention Program
DURC	Dual Use Research of Concern
eCR	Electronic Case Reporting
EHR	Electronic Health Record
EIP	Emerging Infections Program
EIS	Epidemic Intelligence Service
ELSW	External Laboratory Safety Workgroup
ESHCO	Environment, Safety, and Health Compliance Office
FBI	Federal Bureau of Investigation
FDA	(United States) Food and Drug Administration
FOA	Funding Opportunity Announcement

Acronym	Expansion
FTE	Full-Time Employee
FY	Fiscal Year
GHS	Global Health Security
GHSA	Global Health Security Agenda
GRRT	Global Rapid Response Team
GWG	Global Work Group
HAI	Healthcare-Associated Infection
HDS	Health Disparities Subcommittee
HHS	(United States Department of) Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HP	Healthy People
HRSA	Health Resources and Services Administration
IBB	Institutional Biosecurity Board
IBC	Institutional Biosafety Committee
ICU	Intensive Care Unit
IHR	International Health Regulations
IRS	Internal Revenue Service
ISO	International Organization for Standardization
IT	Information Technology
JPHIT	Joint Public Health Informatics Taskforce
LARC	Long-Acting Reversible Contraception
LIMS	Laboratory Information Management System
LLS	Laboratory Leadership Service
LSRB	Laboratory Safety Review Board
MAT	Medication-Assisted Treatment
MDR	Multidrug Resistant
MERS	Middle East Respiratory Syndrome
NACCHO	National Association of County and City Health Officials
NAMD	National Association of Medicaid Directors
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHS	National Center for Health Statistics
NCIPC	National Center for Injury Prevention and Control
NCQA	National Committee for Quality Assurance
NGO	Non-Governmental Organization
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NQF	National Quality Forum
NSC	National Security Council
NVDRS	National Violent Death Reporting System
OADLSS	Office of the Associate Director for Laboratory Science and Safety
OADS	Office of the Associate Director for Science
ODAP	Office of the Associate Director for Policy
OIG	Office of the Inspector General
OMHHE	Office of Minority Health and Health Equity
ONC	Office of the National Coordinator for Health Information Technology
OPHPR	Office of Public Health Preparedness and Response

Acronym	Expansion
OPHSS	Office of Public Health Scientific Services
OSHA	Occupational Safety and Health Administration
OSTLTS	Office of State, Local, Territorial and Tribal Support
PCAST	President's Council of Advisors on Science and Technology
PDO	Prescription Drug Overdose
PHAB	Public Health Accreditation Board
PHAP	Public Health Associate Program
PHHCC	Public Health – Health Care Collaboration (Workgroup)
PI	Principal Investigator
PICH	Partnerships to Improve Community Health
PPE	Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
SARS	Severe Acute Respiratory Syndrome
SDOH	Social Determinants of Health
SIM	State Innovation Modes
STLT	State, Local, Tribal, and Territorial (Subcommittee)
STRIVE	Sierra Leone Trial to Introduce a Vaccine Against Ebola
TB	Tuberculosis
USAID	United States Agency for International Development
UV	Ultraviolet
VPP	Voluntary Protection Program
WB	World Bank
WHO	World Health Organization