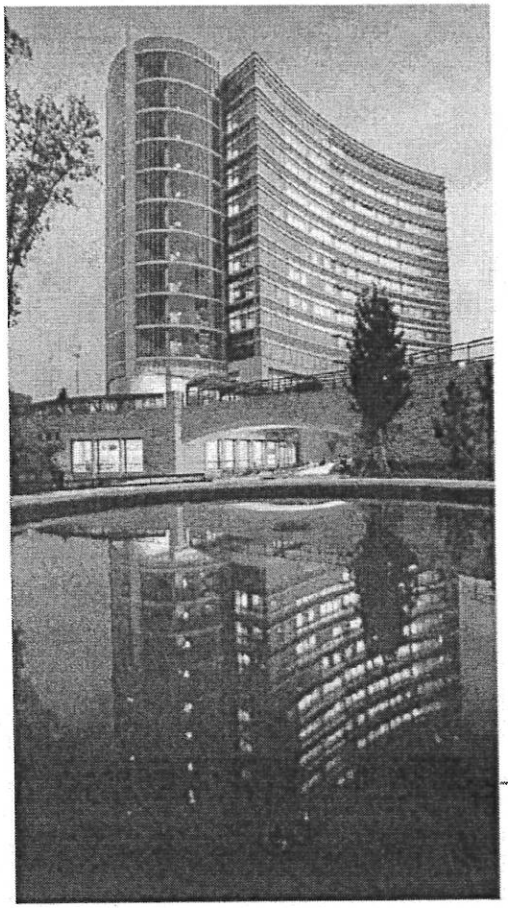

Minutes from the April 23, 2015

CDC Advisory Committee to the Director

Release Date
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- ❑ Socialize these efforts. The most effective advocates for these resources are people within countries. Engage MOHs and political leaders to define and own the importance of these capabilities and the costs of maintaining them.

Discussion Points

Dr. Frieden pointed out that the Ebola response and GHS initiative have provided opportunities for CDC to forge new relationships with other parts of the US government. The area remains challenging, however, and he hoped that the GWG could provide advice on it in the future.

Dr. Greenberg commented that new members of the ACD would receive a manual of policies and procedures of the committee, including a list of all the workgroups and who serves on which. It is expected that each ACD member will serve on one or two workgroups or subcommittees. Much of ACD's work is accomplished in these small groups.

CDC Progress on Laboratory Safety Improvements

Dr. Leslie Dauphin (Interim Lead, Laboratory Safety) provided ACD with updates on CDC's progress in responding to the recommendations from the ACD, as well as progress on additional laboratory safety improvements that were initiated as part of CDC's internal review. CDC's laboratory staff are dedicated to safety. This work is important to the agency and its staff. The process will be continuous, and CDC will continue to seek opportunities where they are appropriate.

In July 2014, in response to laboratory incidents, CDC imposed a moratorium on the transfer of biological material out of biosafety level (BSL)-3 and BSL-4 laboratories until processes were reviewed and improved. The moratorium provided an opportunity for the agency to review all of its laboratory practices and policies and to identify opportunities for improvement. The process included a review of all laboratory practices in all of CDC's BSL-3 and BSL-4 laboratories. An internal Laboratory Safety Improvement Workgroup (LSIW) was created, comprised of experts in laboratory safety, policy, and other areas from across the agency. The group additionally met with stakeholders within the agency to ask for recommendations regarding how to improve procedures.

The review showed that CDC laboratories have solid practices in place and provided an opportunity to share and harmonize practices across laboratories. There were areas for improvement, however. One of the instituted changes was the implementation of checklists for critical steps in protocols for inactivation of pathogens. Procedures were also applied for contamination control, segregation of materials, and additional safeguards, such as camera systems in high-containment laboratories. The camera systems were initially not well-received, but they are a viable alternative to having two people in a laboratory. The systems are working well. They are used to record critical steps of procedures. The supervisor can review the steps to ensure that they were performed correctly and approve the transfer of materials. The moratorium for 52 of the BSL-3 and BSL-4 laboratories was resolved in October 2014.

In September 2014, CDC completed a "Clean Sweep" of all of its facilities on all of its campuses. This process included a review of over 1000 rooms to identify biological select agents and toxins in non-secure places.

In January 2015, disinfection procedures were standardized across CDC's infectious diseases laboratories, and procedures for custodianship of specimens were enhanced in February 2015. March 2015 saw the rollout of a new electronic specimen inventory management system. The initial rollout was to CDC's infectious disease laboratories at the Atlanta campus, and rollouts to

additional facilities will occur soon. More than 200 staff have been trained on this system. CDC also completed a self-initiated biological specimens inventory, which exceeded the requirements of the Clean Sweep. The inventory comprised a box-by-box and vial-by-vial inventory of more than 7 million samples in long-term storage. On April 1, 2015, CDC updated the Select Agent Incident Response Plan to include specific, standardized decontamination procedures in the event of a release.

LSIW conducted 13 staff engagement sessions on laboratory safety-related topics. The responses were compiled into a report that informed the internal group's recommendations to Dr. Frieden regarding improving laboratory safety. Additionally, a Laboratory Consultation Program was piloted in two laboratories. This program is designed to be a peer-to-peer consultation rather than a regulatory review.

ACD's recommendations to CDC regarding laboratory safety are aligned with the results of the internal review. The recommendations are divided into seven categories:

Leadership:

- ❑ Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC.
- ❑ Create a position for a biomedical scientist in the Director's office to lead this (*laboratory safety programs*) effort.

Governance:

- ❑ Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees with ultimate authority at the level of the Office of the Director.

Risk Assessments:

- ❑ Broaden the scope of the Institutional Biosafety Committee (IBC) to include work with pathogenic microorganisms and biological toxins or establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.
- ❑ Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.

Laboratory Safety Training:

- ❑ Establish a standardized lab safety training curriculum across CDC with standardized methods for competency skills mapping and refresher training.
- ❑ Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and the Environment, Safety, and Health Compliance Office (ESHCO) or other central lab safety entity.
- ❑ Responsibilities and facilities for lab safety training should be in-house.

Culture of Safety/Incident Reporting:

- ❑ Efforts to establish a culture of *responsible science and accountability* are of critical importance. This culture of responsible science will require prompt and accurate reporting of incidents or breaches in standard protocol without fear of reprimand or punishment.

- ❑ Reporting is important for facilitating the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned from these activities should be shared with the community.
- ❑ In this culture of safety response, ensure that scientists operating safe laboratories are recognized for their work.

Biosafety and Occupational Medicine:

- ❑ Raise the stature of ESCHO in the CDC organization by staffing it with scientists with professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance.
- ❑ Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized ESHCO committee.
- ❑ Expand the scope and capabilities of the Occupational Medicine Program to facilitate a more robust and active effort in monitoring employee health and in responding to laboratory incidents.

Progress Reporting and Laboratory Accreditation:

- ❑ CDC should track and report on its progress in establishing programmatic elements and processes recommended in this report in some formal way.
- ❑ CDC laboratories should go through an external review and accreditation process for all labs.

Regarding leadership, CDC believes that the laboratory is the "backbone" of public health. The agency identified funding to implement improvements in laboratory safety. A budget increase is requested to continue to improve safety and build capacity. Further, the new position of Associate Director for Laboratory Science and Safety (ADLSS) was established. This person will report directly to the CDC Director. Interviews of candidates are underway.

To address the recommendations pertaining to governance, CDC established a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in BSL-3 and BSL-4 laboratories. Oversight and support for this group will reside in the new Office of the ADLSS. Its goal will be to harmonize practices across the agency and will include representation from centers that have laboratory programs or have impact on laboratory programs.

The new Laboratory Safety Review Board is one way that CDC is addressing the recommendations regarding risk assessments. The board has convened and is reviewing laboratory procedures. The board has established set criteria so that each procedure meets certain requirements. The evaluation process showed that the laboratory staff had not been trained on how to perform risk assessments. A new Biological Risk Assessment Course was established to teach staff how to identify and mitigate risks in the laboratory. The feedback from the course was promising, and based on the evaluation of the first course, a new course was recently taught and data from that evaluation are being compiled. At the same time, a new policy is being developed to require the use of risk assessments for experimental work.

In the area of laboratory safety training, CDC is working to establish a standardized, competency-based, core safety training curriculum across the agency. Public health laboratory competencies were recently released and provide a framework for these efforts. Competencies have been identified and documented for standard, core laboratory safety training. A group created to address curriculum issues has evaluated 23 CDC safety training courses to map competencies and identify gaps. The group has developed a prioritized list of courses for a

standardized safety training curriculum based on needs and is developing learning objectives for priority courses. Additionally, the Laboratory Leadership Service (LLS), a new laboratory fellowship at CDC, has been established and will begin in July 2015. Plans are moving forward for development of a laboratory safety training curriculum.

In order to promote a culture of safety and incident reporting, CDC has implemented new and enhanced procedures for prompt reporting of laboratory incidents. The Laboratory Safety Helpdesk will allow for rapid reporting of incidents. Transparency and sharing lessons learned are important. Findings and recommendations related to CDC's laboratory-related incidents are shared on the internal and external CDC websites. CDC continues to engage with staff and with external partners. A new program known as "Laboratory Safety Champion" recognizes staff who promote laboratory safety and best practices. Staff are also recognized through a listserv to CDC's laboratory community.

The recommendation to raise the stature of ESCHO within CDC has led to consideration of permanent organizational changes after the ADLSS is named. In the meantime, new standard position descriptions have been created for occupational health scientists and quality scientists. Further, a representative from each of the laboratory centers has been named to a group that meets monthly to share concerns about laboratory safety and to discuss harmonizing safety practices across the agency.

CDC provides regular updates to its internal and external advisory groups and the public, remaining transparent regarding procedures. CDC is planning a pilot program for external accreditation. Five laboratories at CDC are participating in the program to attain external accreditation to International Organization for Standardization (ISO) standards. The process includes stakeholder engagement and is moving forward.

The next steps include continuing to address the ACD recommendations. The External Laboratory Safety Workgroup (ELSW) has been invited to a second site visit.

Discussion Points

Dr. Berns commented that he, Dr. Kanabrocki, and the rest of the ELSW has been gratified by CDC's response to the recommendations and by all of the progress that has occurred. He observed that CDC might experience more issues in this area than other agencies because CDC works with more of the really tough agents, frequently without initially knowing what they are working with. Secondly, work at CDC is done under great pressure to produce fast answers. In that situation, the temptation to engage in practices that are less than ideal can become overwhelming. He said he hoped that the agency was considering how to apply priorities so that the people doing the work understand that it is more important to do things right, even when they must be done expeditiously.

Dr. Goldman commented on the issue of custodianship and what happens to people's samples when they leave a facility. Sometimes reagents and other samples end up in boxes and no one knows what they are. She would appreciate hearing more about how to manage this challenge, as it would be helpful to other government agencies and institutions.

External Laboratory Safety Workgroup Update

Dr. Joseph Kanabrocki (External Laboratory Safety Workgroup Chair) explained that the charge to the ELSW was to evaluate safety programs in HHS laboratories, beginning with CDC. The group has since visited NIH and will visit FDA. The review of NIH included a review of the

implementation and execution of their biosafety and biosecurity protocols, and to propose suggestions for improvement.

ELSW includes biosafety professionals, physicians, microbiologists, investigators, and public health scientists. They have met via teleconference and in person at CDC and NIH. ELSW presented its observations regarding laboratory safety at CDC to the ACD in January 2015, and the ACD adopted the suggestions.

To begin the review at NIH, ELSW received a comprehensive set of documents, including safety protocols, governance structures, reporting structures, chains of command for reporting, performance evaluation, and other policies and mechanisms. ELSW made observations and suggestions in several areas. In other areas, the program is very strong and did not need further suggestions.

The NIH Intramural Division of Occupational Health and Safety (DOHS) Program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies. The program is well-established and steady, and this consistency contributes to its recognition as the sole source for safety guidance at the NIH. The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined by the ELSW. Safety awareness is viewed as an expectation, and this philosophy is exemplified via the involvement of senior NIH leadership in the safety infrastructure. Additionally, when financial resources are needed for unanticipated challenges in the realm of safety, the resources are identified and provided. An example of this approach is that the discovery of the smallpox vial led to the hiring of additional staff to exhaustively inventory every freezer, refrigerator, and cold room on the NIH campus during the biosafety stand-down.

Governance structures at NIH are supportive in maintaining a culture of shared responsibility and accountability across the Institutes. An electronic database system has been established and is a useful tool to communicate with regard to issues of research safety and compliance. The scope of protocols reviewed by the IBC includes recombinant microorganisms as well as work involving non-recombinant pathogenic microorganisms (Risk Group 2, 3 and 4); however, the IBC spends most of its time reviewing non-recombinant groups 3 and 4 pathogens, while the risk 2 group is delegated to the Institutional Biosafety Officer. The officer is very well-qualified, but the workload is large for one individual, so the ELSW suggested providing additional resources for this review.

IBC protocols are kept current by submission of amendments via an electronic protocol submission and approval system, but there is no expiration date or term limit on that protocol. Assigning an expiration date for each protocol not to exceed five years would promote safety. The ELSW suggested that scientists who serve on the IBC and other safety committees at NIH should be acknowledged for their service.

Risk assessment of research proposals are performed in a collaborative effort that involves the Principal Investigator, the IBC, the Biosafety Officer, and other DOHS staff. The responsibility is shared and not conducted only at the bench level or the program level. This approach is important. Because the IBC considers all rDNA protocols, but review of protocols involving non-recombinant RG 2 pathogens are delegated to the Biosafety Officer for review, it is not clear that the protocol-driven risk assessment process is a full risk assessment. The ELSW suggested that the IBC should be involved in the review of those projects at some level. The ELSW further suggested augmenting the risk assessment process to build in questions to continually ask Principal Investigators whether and how they have considered ways to approach

an experiment in ways that would further mitigate risks. ELSW also suggested that DOHS consider amending the risk assessment questions that are asked regarding Dual Use Research of Concern (DURC). The committee hoped that the potential impact of a release from containment would be considered.

DOHS is recognized across the NIH as the central authority in support and promotion of laboratory and research safety programs at the NIH. The division demonstrates an appropriate balance between regulatory compliance and facilitation of research activities. The office has strong leadership and staff are professional, competent, and dedicated. Under the DOHS, safety programs are consistent, respected and standardized across NIH. The workforce is stable, home grown, responsive, and supportive. Communications from the division are frequent and promote strong relationships. ELSW suggested that NIH consider developing a "Culture of Safety" survey tool similar to that developed by the CDC in an effort to accurately gauge areas for improvement in laboratory and research safety programs currently and over time.

Laboratory safety training is offered centrally through the DOHS via a variety of methods. All persons who work at or visit the NIH campus are trained. NIH Campus identification cards, and thus access to the NIH campus, are provided only upon completion of training. At the NIH, verification of competency for hands-on laboratory activities is currently limited to containment laboratories (BSL-3 and BSL-4). ELSW suggested expanding competency beyond those levels.

The NIH Intramural Occupational Medicine Program is a very strong, comprehensive occupational medicine program that serves as a model occupational health program for any biomedical research entity. Collaboration with other DOHS staff is clear.

Regarding systems and facilities, ELSW observed that the design of several of the BSL-2 laboratories were not optimal in providing separation of laboratory/research materials from desk and personal space assigned to investigators. The workgroup suggested considering that DOHS staff be involved in the design and remodeling of laboratories.

Regarding incident reporting, NIH staff conveys comfort in reporting of incidents with no fear of reprisals. This observation was consistently observed in interviews with staff at all levels of the NIH. An example of this comfort is the immediate reporting when the smallpox vial was discovered.

Staffing is a challenge for NIH, which employs a large number of contract employees. A robust on-boarding process includes training. Regarding internal communication mechanisms, laboratory managers may have experience in their own institute but may not have opportunities to meet with their counterparts at other institutes. There is an opportunity for a forum to share lessons learned and best practices.

The ELSW visit to the FDA in May 2015 will be followed by another visit to the CDC in the late summer or fall of 2015.

Discussion Points

Dr. Berns noted that the visit to NIH was interesting and rewarding. The set of observations and advice is upbeat, but the NIH is not perfect. Like any large research enterprise, NIH has made biosafety and biosecurity a priority for some time.

Dr. Greenberg asked whether the ELSW follow-up responsibilities will include evaluating how well CDC has addressed the recommendations that it made. A report from ELSW on this front to the ACD would be welcomed.

Dr. Kanabrocki replied that the group is interested in exploring CDC's response more deeply.

Dr. Berns said that NIH is acting on the suggestions and observations.

Dr. Kanabrocki added that ELSW has been impressed with the activities of the internal group at CDC. The ELSW focused on risk assessment and the role of the IBC, as well as training of bench staff. He advised that the protocol review activities of the internal committee be linked to the risk assessment and training activities of the IBC.

Dr. Frieden thanked Drs. Berns and Kanabrocki and the ELSW.

Motion

Dr. Richardson moved to approve the recommendations of the ELSW. Dr. Mullen seconded the motion. The motion passed unanimously with no abstentions.

Motion

Dr. Richardson moved to approve the minutes of the ELSW conference calls. Dr. Mullen seconded the motion. The motion passed unanimously with no abstentions.

Public Health – Health Care Collaboration Workgroup Update

Dr. Georges Benjamin (Public Health – Health Care Collaboration Workgroup co-chair) provided a recap of the Public Health – Health Care Collaboration (PHHCC) Workgroup recommendations that were approved by ACD.

The approved recommendations were:

- Support a more coordinated health system that links clinical care with public health.
- Fully leverage ACA requirements for non-profit hospitals and community health improvement.
- Promote a short set of performance measures to improve quality and delivery of preventive services across health systems.
- Develop guiding principles to support active engagement between public health and health systems.

The recommendations relate to bringing the public health and healthcare delivery communities closer in a variety of ways. The healthcare community includes providers, payers, and all those involved in the health enterprise in the US.

Mr. John Auerbach, Associate Director for Policy, CDC, addressed the ACD regarding progress on the recommendations.

The first area of progress is the development of a website for community health improvement (CHI). The purpose of the CHI Online Navigator is to provide hospitals and other community