

Center for Preparedness and Response (CPR)
Board of Scientific Counselors (BSC) Meeting
Monday, October 26, 2020
Webinar

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**CENTER FOR PREPAREDNESS AND RESPONSE (CPR)
BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING
MONDAY, OCTOBER 26, 2020
WEBINAR**

Roll Call, Introductions, and Review of Federal Advisory Committee Rules, Duties, and Conflict of Interest

Kimberly Lochner, ScD; Deputy Associate Director for Science, CPR and Designated Federal Official, CPR BSC

Dr. Lochner began by providing an update on the Center for Preparedness and Response (CPR) Board of Scientific Counselors (BSC) membership. CPR welcomed Dr. Kristin DeBord, who will serve as the representative for the Office of the Assistant Secretary for Preparedness and Response (ASPR). Dr. Alonzo Plough is retiring from the Board after serving four years.

Dr. Lochner reviewed the BSC responsibilities, as per its charter, and the conflict of interest waivers. All Confidential Financial Disclosure Report Update Forms were asked to be completed and returned to Dr. Lochner prior to the meeting if there were any changes made since last submitted. Members were asked to identify any conflicts of interest. No conflicts were identified.

During the meeting, a quorum must be maintained. If it is lost at any point, a break will be taken, or the meeting will be adjourned until a quorum is resumed. A roll call was conducted, and quorum was present. Dr. Lochner monitored attendance throughout the meeting to ensure quorum was upheld.

The BSC meeting is led by the BSC Chair, Dr. Suzet McKinney. Voting, if required, is conducted among the Special Government Employee Members, as well as Ex Officio Members. Only the BSC members will participate in any discussions, which will be facilitated by the BSC Chair. Other attendees will be allowed to speak during the Public Comment portion of the meeting.

All participants agreed to having their comments recorded and speakers were instructed to identify themselves before speaking to ensure an accurate record was created.

Welcome and Call to Order

Suzet McKinney, DrPH, MPH; Chair, CPR BSC

Dr. McKinney called the CPR Board of Scientific Counselors Webinar to order at 12:38 PM EST. Given that this was an abbreviated meeting, she kept her comments to a brief welcome to all attendees of the webinar before turning the meeting over to Dr. Dreyzehner for an update.

CPR Director: Update

John Dreyzehner, MD, MPH, FACOEM; Director, CPR

Dr. Dreyzehner provided an update on CPR activities. CDC is currently on its 280th day of IMS activation for the Coronavirus Disease 2019 (COVID-19) response. Since its beginning, on January 21, 2020, CDC has spent over 4 million hours of CDC staff time to address COVID-19 and has utilized a little more than 7,400 responders. For CPR, this equates to 62% of its staff (377 people) deployed to the response efforts, in addition to time spent indirectly supporting the response both in CPR and across CDC. CPR's Division of Emergency Operations (DEO) has provided diligent and dedicated staff support for all 4 million of those hours, as well as supporting more than 3,500 field deployments. Dr. Dreyzehner took a few moments to review some of the highlights from CPR's response efforts.

In addition to the COVID-19 response, DEO is supporting the Ebola and polio responses with logistics and communication support functions.

The Graduated Response Framework Steering Committee is continuing to work on minimum center capabilities for program- and center-led responses, as well as decision frameworks for escalating and deescalating between response levels. It is also determining the response support required from other CDC entities such as the Office of Safety, Security, and Asset Management, the National Institute for Occupational Safety and Health, and the Center for Surveillance, Epidemiology, and Laboratory Services.

CPR is exploring options for the Public Health Emergency Management Fellowship for cohort 13 given current travel bans and limitations due to the COVID-19 pandemic. The Fellowship alumni are currently working on COVID-19 efforts in places such as Nigeria, Japan, Mali, and Burkina Faso.

The Division of State and Local Readiness (DSLRL) is also supporting the COVID-19 response extensively. It is leveraging the Public Health Emergency Preparedness (PHEP) Program to assist with the COVID-19 vaccine campaign and coordinates closely with CDC's Immunization Services Division. The PHEP planning scenario is being shifted from anthrax readiness to the COVID-19 vaccination campaign. However, changes to the PHEP program goals have not altered the requirement for recipients to demonstrate operational readiness by June 2024 in all six domains and all fifteen capabilities for preparedness and response.

The Division of Select Agents and Toxins (DSAT) has also supported COVID-19 efforts both from a staffing standpoint and through the Import Permit process. They have been able to effectively continue their two key programs virtually, Import Permit Program and Federal Select Agent Program (FSAP). The 2019 Annual Report of FSAP was published on September 22, 2020. The findings showed that most laboratories registered with the program are compliant with the regulations. None of the relatively small number of incidents reported resulted in a risk to public or agricultural health. There have also been several improvements to the electronic

FSAP. The system provides real-time information on the location of select agents and their usage. DSAT experienced a 79% reduction in the time required for entities to resolve regulatory departures and a 99% reduction in FSAP approval times versus the former system. Further upgrades to the system are being explored.

In addition to the COVID-19 response, CPR is undertaking a strategic planning endeavor and is implementing a performance excellence framework. The goal is to provide the best decisions and information.

Dr. Dreyzehner also took a moment to introduce Dr. Nathaniel Smith as the new Deputy Director for Public Health Service and Implementation Science. Dr. Smith was formerly the Secretary of Health in Arkansas and has an extensive history dedicated to public health. Dr. Smith provided brief comments, thanking the BSC for its service and noting that these are challenging times, particularly for those in the area of preparedness. He also thanked Dr. Dreyzehner for his leadership in these efforts.

Dr. Dreyzehner informed the Board that since the last meeting in July 2020, all roles for the senior leadership team for CPR have been filled. Ms. Lovisa Romanoff is the CPR Deputy Director of Management and Operations. Dr. Chris Brown, who worked formerly for the U.S. Department of Labor's Occupational Safety and Health Administration, is now the Director of DEO. Dr. Emily Eisenberg Lobelo is CPR's Associate Director of Policy, Planning, and Evaluation. Lastly, Dr. Colin Shepard is CPR's Liaison to ASPR and is currently serving as the JCC Lead Liaison for CDC.

CPR will continue to institutionalize the lessons learned during responses, while exploring ways to utilize after action reports to improve its processes and knowledge base. COVID-19, like 9/11, has redefined and redirected preparedness efforts going forward. There is significant room for additional improvement, but the accomplishments garnered in preparedness thus far has provided public health the vault it needs to tackle the disease and reap positive outcomes in the vaccination strategies to come.

U.S. National Authority for Containment of Polio Update

Lia Haynes Smith, PhD; Director of the U.S. National Authority for Containment of Poliovirus (NAC), CPR

In 1988, a global campaign was launched to end poliovirus. At that time, 350,000 new cases were occurring each year. In 2016, there were only 37 cases occurring each year, and as of October 2020, the total number of wild poliovirus cases was 132, with the goal to achieve zero cases. As background, there are three serotypes of poliovirus. Wild poliovirus type 2 (PV2) was eradicated in 2015 and type 3 (PV3) in October 2019. In August 2020, World Health Organization's (WHO) African region was declared wild poliovirus free. Now, five of six WHO

regions have been certified as free of wild poliovirus. Wild poliovirus type 1 (PV1) transmission is still endemic in Afghanistan and Pakistan and efforts are ongoing to ensure its eradication. Poliovirus containment is also part of eradication. As long as facilities continue critical work with poliovirus, containment will be required. Any facility that plans to retain or work with the virus must enter the poliovirus containment certification process.

There are two paths for certification. The first path is for poliovirus essential facilities (PEFs) that plan to work short term with poliovirus materials. They will apply for certificate participation, which is the first step in the certification process. This signals the facilities intent to work with poliovirus post eradication. The U.S. NAC recommends specific containment conditions for ongoing work with PV2 infectious materials effective now and during the transition period as facilities work under the certification process. By the end of the transition period, April 2022, these PEFs must either destroy their poliovirus materials or transfer the materials to another PEF. The facilities that cease work under the certification process are not expected to work towards containment measures outlined in the Global Action Plan (GAPIII). Currently, eight of the twelve PV2 U.S. PEFs will follow this path.

The second path for certification includes a smaller number of PEFs who retain poliovirus materials for long-term work. As these facilities transition into laboratories designed for higher containment, the facilities will work under the certification process and are expected to implement the risk mitigation strategies. They will also prepare for an audit and work towards implementation of all the GAPIII containment elements to obtain either an Interim Certificate of Containment (ICC) and/or a Certificate of Containment (CC). The remaining four of the twelve PV2 PEFs will follow this long-term path.

The NAC continues to follow a collaborative approach to containment implementation. This has improved facility engagement and informed the products and policies developed. It also assists in increasing understanding among the facilities the importance of PV containment. Globally, the U.S. has the largest number of certifications endorsed by the Global Certification Commission, the global oversight body for PV containment. The NAC also continues to implement its risk mitigation strategies to help facilities improve their biosafety and security practices. The COVID-19 pandemic has led to delays in the PEFs' abilities to complete necessary research and impacted the auditors' abilities to conduct site visits; however, the NAC has identified ways to continue engagement of recently reported PV2 facilities.

Dr. Haynes Smith then reviewed the policy development process and the policies that have been developed in tandem with the Poliovirus Containment Working Group (PCWG), which includes members of the former Biological Agent Containment Working Group. When the NAC creates new policies, the policies are reviewed by the PCWG. Updates are made to the policy based on the PCWG's recommendations. The finalized policy is presented by the working group's co-chairs to the BSC for review and endorsement. The policy is then sent to the PEFs for review, and is again, updated based on the feedback received. All feedback is shared with the PCWG. The final policy undergoes the CDC clearance process and is published. For transparency and awareness, the NAC shares the published policies with WHO.

All NAC policies are reviewed annually, and revisions are made to strengthen the policies if needed. Revisions are also reviewed by the PCWG, who will determine if revisions are substantial and alter the intent or interpretation of the policy. If revisions are not substantial, the PCWG will approve the revisions and the policy will continue through the review process. If the revisions are significant, the policy would be presented again to the BSC for review, endorsement, and a new vote before continuing through the review process. Thus far, eight policies have been developed that interpret GAPIII requirements and are as follows:

- NAC Policy: Storage Outside of Containment
- NAC Policy: Physical Security
- NAC Policy: Record of Access
- NAC Policy: Inventory
- NAC Policy: Transfer
- NAC Policy: Personnel Reliability
- NAC Policy: Personal Protective Equipment and Hand Hygiene Practices
- NAC Policy: Biorisk Management and Risk Assessment

All finalized policies currently apply to PEFs that will pursue the long-term path of the ICC and/or a CC.

The presentation was turned over to Drs. Catherine Slemple and Dawn Wooley to review the current risk mitigation strategies for poliovirus containment and the recent policy changes, as well as present three new policies to the BSC for discussion and deliberation. The current Risk Management Strategies (RMS) document contains roughly 41 strategies over three categories: biosafety, security, and emergency response. Because these strategies were developed for PV2 and did not include in vivo work, there was a need to examine this area more closely.

Below is a summary of the strategies and their subgrouping category.

- Biosafety strategies (36)
 - Dedicated or separate PV2 materials from other areas (4)
 - Primary containment (3)
 - Personal protective equipment (PPE) (8)
- Security strategies (3)
 - Control access to laboratories
 - Control access to freezer

- Emergency response strategies (2)
 - Plan for release of PV2
 - Incident reporting

The updates to these strategies came as a part of the annual review of all NAC documents, including feedback received from the PEFs. The PCWG and the NAC would like to incorporate this new information into the strategies so that they are more practical and applicable to ongoing and future work in the facilities. Moreover, eradication of PV3 has occurred; therefore, the policies needed to be expanded to incorporate mitigation efforts for PV3, which will ensure stronger biosafety and response efforts. Below are the highlights of changes made to the RMS.

- Added wild PV3 and vaccine derived PV3 infectious material following the October 2019 declaration of eradication
- Added mitigation strategies for in vivo work
- Implemented biosafety in microbiological and biomedical laboratories, biosafety level 2, and animal biosafety level 2 standards
- Added requirement to notify state and local agencies of possession of PV materials

Several examples were provided of the proposed changes to the RMS, and they are as follow:

- Biorisk management
 - In vitro and in vivo work must be reviewed by facilities Institutional Biosafety Committee or Institutional Animal Care and Use Committee
 - Conduct risk assessments to identify in vitro and in vivo procedures where inactivated material could be used
- Inventory
 - Records must document characteristics (e.g. serotype, strain, date of collection, disposition) associated with each sample
 - Develop procedures to investigate missing, lost or stolen PV infectious materials identified as the priority areas
 - All inventory investigations must be documented and, if the material cannot be found or person (s) were exposed, the PEF must notify the U.S. NAC
- Biosafety
 - All in vitro and in vivo work must be performed in primary containment devices [e.g. biosafety cabinet (BSC)]

- Containment casing (e.g. open cages placed in inward flow, HEPA-filtered ventilated enclosures) for small animal housing and transport
- Negative airflow cabinets with HEPA-filtered exhaust must be used for equipment that generate aerosols but cannot be placed in a biological safety cabinet
- Double gloves for all procedures
- Security
 - Control access to keys, combinations, etc.
 - Record access of all facilities personnel and visitors
- Decontamination and water disposal
 - Coordinate decontamination and waste disposal procedures with state and local health departments, environmental companies, and comply with federal, state and local regulations
- Emergency response procedures
 - Develop and coordinate procedures with first responders
 - Perform drills and exercises periodically (e.g. annually)
 - Incident reporting procedures must include contacting the U.S. NAC and all appropriate federal, state, and local agencies

The floor was then open for discussion among the BSC members. Dr. Vish Vishwanath asked if risk communication would fall under the risk mitigation strategy. Dr. Slempp said not much discussion has occurred at this point, but it should be part of the emergency response and preparedness piece. It would also pair with some of the work occurring with local agencies. Dr. Haynes Smith said the document, for now, is for the PEFs while they are in a transition process to prepare for GAPIII containment. She agreed that communication would be part of their emergency response preparation, but it has not been explicitly outlined in the RMD. Dr. Slempp encouraged Dr. Haynes Smith to consider adding communications and ask the PEFs to think through how they would do community dialogue as a part of their plan. Dr. Haynes Smith said there is a polio simulation exercise that will be occurring with the PEFs in the beginning of 2021, where this topic will be added to their discussions.

Dr. Brent Pawlecki noted one of the lessons learned in the COVID-19 response related to communications was the lack of consideration of human resource policies related to worker's compensation, absence management, and other incidents that would occur more so for the employees involved, as well as the community. He asked that it also be considered in the planning discussions. Dr. Slempp said it could also be added into the exercise planning for next year.

With no further discussion, Dr. McKinney asked for a motion to approve the recommendations of the PCWG for the modification to the RMS. Dr. David Fleming made the motion, which was seconded by Dr. Jennifer Horney. The BSC voted unanimously to accept the modifications as prescribed.

Dr. Slemp briefly updated the BSC on the upcoming review of three additional policies: inventory, transfer, and (secure) policy. These are not substantial changes. Discussions are ongoing. They will be disseminated to the committee one last time for final comments before returning the final report to the NAC on October 30, 2020. If no further major changes are made, PCWG would propose that the changes be shared with the PEFs for their comments rather than waiting six months for the BSC to review the minor changes before garnering the PEFs feedback. If the PEFs make no significant changes, then the policies would move to the CDC approval process. An overview of the three policies and their changes were included in the BSC read-ahead material. Any changes made by the PEFs will also be made available to the BSC. Policies to be reviewed next include inactivation, PIM guidance, and shared use of the PEFs.

Public Comment Period

No public comments made.

Meeting Adjourn

With no further comments, Dr. McKinney adjourned the meeting at 1:28 PM EST.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of October 26, 2020 meeting of the Center for Preparedness and Response (CPR) BSC are accurate and complete.

1/14/21

Date

/Redacted/

Suzet McKinney, DrPH, MPH
Chair, Board of Scientific Counselors, CPR

APPENDIX A: CPR BSC MEMBERSHIP ROSTER

DESIGNATED FEDERAL OFFICIAL

Kimberly Lochner, ScD
Deputy Associate Director for Science,
CPR Centers for Disease Control and Prevention
Atlanta, Georgia

CHAIR

Suzet McKinney, PhD, MPH
CEO/Executive Director
Illinois Medical District Commission
Chicago, Illinois

MEMBERS

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Vice President Global Health Programs
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Seattle, Washington

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STAR Health Sciences Complex,
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Brent Pawlecki, MD
Chief Health Officer
The Goodyear Tire & Rubber Company
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Vice President for Research and Evaluation and Chief Science Officer
Robert Wood Johnson Foundation
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Kathleen Tierney, PhD
Emerita Director
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Dawn Patricia Wooley, PhD
Associate Professor
Department of Neuroscience, Cell Biology, and Physiology
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Dayton, Ohio

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Director, Strategy Division
Office of the Assistant Secretary for Preparedness and Response
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RADM Denise M. Hinton
Chief Scientist, Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats
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Paula Bryant, PhD
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and Translational Research
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National Institute of Allergy and Infectious Diseases
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LIAISON REPRESENTATIVES

Christina Egan, PhD, CBSP
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Chief, Biodefense Laboratory, Wadsworth Center
New York State Department of Health
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Parham Jaberj, MD
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APPENDIX B: CPR BSC Webinar Meeting Attendance Roster
October 26, 2020

NAME	AFFILIATION	PRESENCE
Suzet McKinney	Chair and SGE	Via Zoom
Octavio Martinez	SGE	Via Zoom
Alonzo Plough	SGE	Via Zoom
Jennifer Horney	SGE	Via Zoom
Brent Pawlecki	SGE	Via Zoom
Catherine Slemp	SGE	Via Zoom
Kathleen Tierney	SGE	Via Zoom
Vish Viswanath	SGE	Via Zoom
Dawn Wooley	SGE	Via Zoom
David Fleming	SGE	Via Zoom
Paula Bryant	Ex Officio	Via Zoom
Kristin DeBord	Ex Officio	Via Zoom
Denise Hinton	Ex Officio	Via Zoom
Michele Askenazi	Liaison	Via Zoom
Benjamin Chan	Liaison	Via Zoom
Parham Jaber	Liaison	Via Zoom
Christina Egan	Liaison	Via Zoom
Laura Magana	Liaison	Via Zoom
Jamie Ritchey	Liaison	Via Zoom
A.J. Schall	Liaison	Via Zoom

APPENDIX C: ACRONYMS

BSC	Board of Scientific Counselors
CPR	Center for Preparedness and Response (CDC)
DEO	Division of Emergency Operations (CDC)
DSAT	Division of Select Agents and Toxins (CDC)
DSLRL	Division of State and Local Readiness (CDC)
FSAP	Federal Select Agent Program
GAP III	Global Action Plan III
PCWG	Poliovirus Containment Working Group
PEF	Poliovirus-essential facilities
PHEP	Public Health Emergency Preparedness
PV1	Wild poliovirus type 1
PV2	Wild poliovirus type 2
PV3	Wild poliovirus type 3
RMS	Risk Management Strategies
US NAC	US National Authority for containment
WPV	Wild poliovirus
WHO	World Health Organization