

Center for Preparedness and Response (CPR)  
Board of Scientific Counselors (BSC) Meeting  
Friday, January 24, 2020  
Roybal Campus, GCC, Building 19, Auditorium B3  
Atlanta, Georgia

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CENTER FOR PREPAREDNESS AND RESPONSE (CPR)  
BOARD OF SCIENTIFIC COUNSELORS (BSC) MEETING  
FRIDAY, JANUARY 24, 2020

**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 provided an update on the BSC membership. The board welcomed new members Drs. David Fleming and Octavio Martinez. Dr. Fleming is the Vice President of the Global Health Programs at PATH, and Dr. Martinez is the Executive Director of the Hogg Foundation for Mental Health at the University of Texas at Austin. Also new is Dr. Parham Jaber, who will serve as the Association of State and Territorial Health Officials (ASTHO) liaison representative to the BSC.

Since the last meeting, two board members' terms expired, Drs. Thomas Inglesby and Margaret Brandeau. Dr. Inglesby was the Former Chair to the BSC, and Dr. Suzet McKinney will now serve in that position.

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

A roll call was conducted, and quorum was present. Dr. Lochner monitored attendance throughout the meeting to ensure the quorum was upheld.

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

**Welcome and Call to Order**

*Suzet McKinney, DrPH, MPH; Chair, CPR BSC*

Dr. McKinney called the Center for Preparedness and Response Board of Scientific Counselors Meeting to order at 8:43 AM EST. She thanked the CPR for the opportunity to serve as chair and extended a welcome to all attendees.

**Center for Preparedness and Response Update**

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

CDC welcomes a new CPR Director, Dr. Dreyzehner, who expressed appreciation to the Board for lending advice to CPR that will improve its emergency response operations.

He also updated the BSC on the upcoming retirement of Dr. Stephen Redd, Rear Admiral, U.S. Public Health Service (retired). Dr. Redd is the Deputy Director for Public Health Service and Implementation Science and previously served as the Director for the Center of Preparedness Response.

Dr. Redd thanked the members for volunteering their service to CPR and CDC and expressed gratitude for the advice they have given over the years. He also said working with the BSC was one of the great pleasures during his time leading CPR and recommended that the board continue to provide candid feedback. After his remarks, all attendees joined in a round of applause to show appreciation to Dr. Redd.

Next, Dr. Dreyzehner gave a brief summary of his career work and provided updates on CPR recent activities. Dr. Dreyzehner grew up in Chicago, IL, where he also attended medical school. He later became an Air Force flight surgeon and trained in occupational medicine and was involved in private practice for five years. Then he took a role in a multijurisdictional county health department in Southwest Virginia, Central Appalachia and after serving in this role for ten years and becoming proficient in public health, he became the Commissioner of Health in Tennessee and served from 2011 to 2019.

Dr. Dreyzehner stated he was honored to serve in his new role at CDC with people who are passionate about the public health enterprise. He has always felt, in order to be successful in public health, emergency preparedness and response must be performed properly. The science of preparedness and response is an important and emerging area and advancing the science of preparedness and response is paramount to long term success.

Dr. Dreyzehner gave a brief update on some of CDC's response activities. CDC has two agency-wide responses, coronavirus and Ebola in the Democratic Republic of Congo (DRC), which is the second largest outbreak of Ebola virus disease. In addition, efforts to eradicate poliovirus are ongoing, and lung injury has been scaled back from an agency-wide response to a center-led response. Heightened Middle East tensions are still on the radar screen, and earthquakes in Puerto Rico have proven to be difficult. After shocks continue to occur but are becoming less intense. Roughly 170 people around the nation have been deployed to assist with these responses. Most of this work comes out of the Division of Emergency Operations (DEO).

#### **CPR Division Directors-Interval Updates**

*Rudolph Johnson, PhD; Acting Director, [Division of Emergency Operations](#) (DEO)*

The mission of the DEO is to integrate public health response and emergency management systems to provide health security at home and around the world. Quality customer service and urgent response are key to the DEO's functions. Although international responses gain the most media attention, calls regarding domestic occurrences happen daily. DEO's vision is to be the worldwide leader in public health response and emergency management integration. It works with the World Health Organization (WHO), as well as other emergency operation centers across the government, like that of the Department of Homeland Security and the U.S. Coast Guard.

CDC has multiple on-going EOC activated responses and is monitoring the Puerto Rico Earthquake events. As of Monday, January 20, 2020, CDC transitioned into an agency-wide response due to the novel coronavirus.

The DEO's preparedness activities better position the agency to successfully respond to public health emergencies. It performs functions such as:

- Conducting the Incident Manager Training and Development Program (IMTDP)
- Facilitating the Public Health Emergency Management (PHEM) Fellowship Program
- Providing in-country technical assistance
- Coordinating the Graduated Response Framework
- Managing Emergency Management Accreditation Program (EMAP) activities

DEO and the Center for Global Health are tasked with the polio response. This response has been ongoing since 2011. There are three types of wild type poliovirus. Wild poliovirus (WPV) type 2 was eradicated in September 2015 and type 3 in October 2019. Type 1 is primarily in Afghanistan and Pakistan, and there have been outbreaks of vaccine-derived polio primarily occurring in Africa. CDC is helping to address the rise in those cases in Afghanistan, Pakistan and Africa and has deployed staff to the regions. Staff are constantly monitored and given health and wellness checks.

The DRC Ebola response has been ongoing since 2018. The cases are restricted to the Congo. There have been 3,392 total cases and 2,235 deaths reported. CDC provides in-country data analysis, health communications, epidemiology, surveillance, infection prevention and control, community engagement, vaccine activities, border health, and emergency management. What continues to be a challenge is the deployment of staff due to security concerns and community resistance. Support has been provided to the surrounding countries to reinforce their response capabilities.

The lung injury response was led by centers at CDC that traditionally were not involved in emergency responses. In a short period of time, the DEO trained these centers and provided infrastructure and general staff associated with the Incident Management System. This allowed for stronger communication and the ability to combine the science with observations that were occurring. As of January 7, 2020, 2,602 hospitalized EVALI cases or deaths have been reported to CDC from all 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands). Fifty-seven deaths have been confirmed in 27 states and the District of Columbia. CDC and FDA recommend that people should not use THC-containing e-cigarette or vaping, products, particularly from informal sources like friends, family, or in-person or online sellers. In addition, Vitamin E acetate should not be added to e-cigarette or vaping products. Furthermore, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.

Dr. Johnson provided an overview of the Graduated Response Framework, which was initially presented to the Board in April 2019. The framework is comprised of three response levels: agency-wide, center-led, and program-led. The framework also involves customer engagement and the ways the DEO becomes involved in discussing issues, uncovering the needs, and translating information that will lead to a more focused response. A more in-depth presentation on the Framework was provided later in the agenda.

*Mark Hemphill, MS; Deputy Director, [Division of Selection Agents and Toxins \(DSAT\)](#)*

DSAT regulates all entities that possess, use, or transfer biological agents or toxins that have the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant products. The United States Department of Agriculture (USDA) has similar regulation responsibilities related to agriculture. There are a series of zoonotic agents dually regulated between DSAT and the USDA. As result, the agencies have coordinated their regulation efforts and have evolved into a single

program called the Federal Select Agent Program (FSAP) (42 CFR part 73, 9 CFR part 121, 7 CFR part 331).

DSAT also oversees one section out of the U.S. Public Health Service Foreign Quarantine Regulations. The CDC Import Permit Program (IPP) (42 CFR § 71.54) regulates the importation of infectious biological agents, infectious substances, and vectors that can cause disease in humans. The primary purpose of the regulation is to ensure recipients of agents coming into the United States known to be of infectious biological concern, primarily laboratories, have safety measures in place that will allow them to securely work and contain the biological material before it is received.

Mr. Hemphill highlighted recent activities that have occurred in DSAT since the last CPR BSC meeting. The [2018 FSAP Inspection Report Processing Annual Summary](#) was released in October 2019. The 2019 Annual Report of the Federal Select Agent Program will be released in 2020.

The data revealed that almost all inspection reports (93%) were sent to entities within FSAP's goal of 30 business days, emphasizing the program's continuous commitment to providing timely feedback. FSAP issued 194 final inspection reports in 2018 with 93% overall (181/194) issued within the 30-business day target. Among the reports distributed by CDC/DSAT, 95% achieved this goal. APHIS/AgSAS also adopted the 30-business day target, and amid their reports issued, 84% met the goal. The data for 2019 is being compiled and the figures received so far show greater improvement compared to the results of 2018.

DSAT has sought ways to better serve the regulated community. One of those innovations is the [FSAP Inspection Checklist App: Federal Select Agent Program Laboratory Examination Tool \(FSAP-LET\)](#). The downloadable mobile application assists in performing internal laboratory inspections. It contains a series of checklists that are the same as the ones utilized by DSAT inspectors. This helps with local annual oversight and assessments. The tool has received great feedback from the regulated community.

DSAT also sponsors several outreach efforts to ensure the regulated community is aware of policies. April 4, 2019, FSAP held a webinar regarding the updated policy statement on entity annual internal inspections required by the select agent regulations. In February, May, and September 2019, DSAT hosted webinars to provide training on recent updates to eFSAP. The division continues to support the American Biological Safety Association (ABSA) independent forum to encourage routine peer-to-peer sharing of information and best practices.

On an annual basis, DSAT and the USDA host a week-long training session for the Responsible Official (RO). The training assists with implementing duties and requirements under the regulation and increasing understanding of the regulatory requirements. Last year, a little over half of the regulated community (130 total attendees) attended.

The Import Permit Program hosted a public webcast on December 4, 2019 that addressed import permit regulations for infectious substances. Other federal regulators, who have similar oversight, also presented to their community of interest on the federal requirements for importing infectious substances into the United States. Other participating federal partners included the U.S. Customs and Border Protection, Department of Transportation, and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. The webcast received 1,774 viewers.

The Electronic FSAP (eFSAP) Information System is an electronic record system that enables users to register, amend registration, and submit requests for approval to transfer select agents within the United States. Updates to eFSAP within the last year included the following:

- User-interface enhancements across all aspects of eFSAP
- Completion of all APHIS/CDC Form 1 amendment types
- APHIS/CDC Form 1 Section 4 and 7B data export
- APHIS/CDC Form 1 work objective versioning
- Notification enhancements, flagging, and archiving
- Inspection module refinements and additional features
- Printing of APHIS/CDC Forms 2-4
- File archiving
- Super administrator role for entities
- Simple Principal Investigator (PI) replacement
- FBI/BRAG (CJIS) integration

There are a number of new features coming to eFSAP in early 2020. The Entity Administrative Center enables ROs and alternate responsible officials (ARO) to view all entity personnel with access to eFSAP as well as the person's user role. It also gives ROs and AROs the ability to change user roles as needed or temporarily restrict access. The Entity Principal Investigator (PI) User Role enables limited eFSAP access to entity principal investigators. The PIs will be able to review, modify, and save, but not submit, APHIS/CDC Form 1 Section 7A/C amendments on which they are listed as a PI. They will also be able to review and modify information for their strains and serotypes in APHIS/CDC Form 1 Section 7B. Lastly, the System-Generated Registration Certificate allows entities the ability to view, download, and print their official certificate of registration directly from the eFSAP landing page.

Lastly, DSAT has developed a strategic plan that is publicly available on the website. The division is actively engaged in establishing metrics and measures associated with the goals and objectives in the plan. Those will be shared with the public and will showcase how well DSAT is implementing the strategic plan.

*Christine Kosmos, RN, BSN, MS, Director, [Division of State and Local Readiness](#)*

DSLRL's mission is to assure response-ready state, local, tribal and territorial (SLTT) public health agencies. This is a long-term goal. Response ready means state and locals are capable of successfully responding to any public health event or emergency that threatens the health and safety of the community.

The division has worked and collaborated with its state and local partners over the years to design and develop an evaluation strategy for state and local operational readiness. Operational emergency readiness boils down to two central questions: What is the level of readiness within state and local public health and how have improvements been made over the level of readiness in the last 17 years?

The Operational Readiness Review (ORR) Expansion Initiative expanded ORR to cover all 15 public health emergency preparedness and response capabilities. It creates one tool to assess the PHEP recipient's planning and operational strengths, areas of improvement, and technical assistance needs across all capabilities. It also accurately measures program standards across jurisdictions and provides meaningful

data to demonstrate program impact. Lastly, it gives an accurate picture of public health preparedness to respond across the nation.

In order to ensure ORR, DSLR employs four strategies:

- Administer the Public Health Emergency Preparedness (PHEP) Program
- Enhance state local and territorial (SLT) workforce capacity through strategic placement of field staff
- Assess national operational readiness across all 15 public health preparedness and response capabilities
- Support threat-specific readiness for select threats including anthrax, pandemic influenza, and others

With regard to MCM, a goal and target were set for the state and local partners. By the end of 2022, communities and recipients must demonstrate operational readiness for a large-scale MCM response in the following six domains.

- Receipt, Stage, Store (RSS) Warehousing
- Distribution Planning
- Transportation
- Security
- Dispensing Planning
- Point of Dispensing (POD) Staffing for Anthrax Scenario

This is demonstrated by participation in the operational readiness review, which is a requirement of the grant. They also have to demonstrate readiness through exercises or real-world events. This is an evaluation of planning and execution. In addition, they must show yearly progress towards meeting their deliverables and address their gaps.

The snapshot tool below, called the eye, illustrates the data of jurisdictions evaluated during this particular time period. It helps identify, at a glance, level of readiness from red, yellow, to green. For this time period, 2017-2018, Chicago was the only city achieving green in all areas.





Figure 1. The Eye Snapshot Tool: Illustrates jurisdictions' readiness levels among the six domains.

During a large-scale response, DSLR wants all districts to be capable of standing up an emergency operation center and incident command structure. By and large, state and locals have made significant progress in this area. For example, 95% of jurisdictions have readily identified six vital incident command positions and 71% of jurisdictions have promptly pinpointed first responders and critical infrastructure staff. Another 29% of jurisdictions are working to find essential first responders.

In the case of POD protocols, 48% of POD protocols meet CDC standard. However, there are still some unmet needs such as insufficient staffing to meet long-term mission requirements for POD staffing and protocols for data reporting to federal entities.

POD security is another area where DSLR has identified security standards and 57% of jurisdictions have met those. Again, there are areas of improvement such as:

- Evacuation procedures
- Exterior security
- Interior security
- Scalability
- Security management plan
- Security breach procedures

Seventy-six percent of jurisdictions are meeting CDC requirements for identifying sufficient warehousing sites. When DSLR took a deeper dive into the medical warehouse component, the area limiting readiness was cold chain and cold chain management.

For staffing, 67% of jurisdictions had sufficient warehousing staffing plans. The gaps for staffing include:

- Distribution lead, primary and backup
- Logistics, primary and backup
- Receiving site lead, primary and backup
- Security coordinator, primary and backup
- Current DEA registrant

Roughly 76% of jurisdictions have sufficient transportation security plans. The areas for improvement are:

- Crossing jurisdictional lines
- Crossing government sovereignty
- Intermediary stops (to the RSS, regional distribution site, local distribution)

The majority of gaps are found in the area of exercises. This is due to the new exercise requirements. DSLR recognizes that they must give their state and local partners better guidance on ways to meet the requirements. Approximately 67% of jurisdictions had sufficient evidence of engagement with vulnerable population stakeholders. For staff assembly and notification, 81% of jurisdictions met the criteria. In light of the findings, DSLR is developing technical assistance strategies to make improvements. They meet with the jurisdictions on a quarterly basis. Every jurisdiction has a technical assistance plan after their evaluation. DSLR meets with them routinely to develop plans for improvement where needed.

DSLR is using data to not only move the needle at the state and local level but also to better understand what needs to be done as a program and a discipline in order to position itself to assist state and local partners with advancing their readiness.

#### **BSC Comments to CPR Divisions:**

- CDC should be applauded for its response to the coronavirus. That said, there seems to be a lag in information, where it feels like the media is more on top of real time information than some of the information received from CDC.
- The National Academies had a roundtable in Northern California due the fires and one of the issues brought up was regarding first responders, particularly the firefighters. Their culture is that of a bravado and macho mentality; therefore, they are not using the respirators while in the field. As a result, there has been an increase in lung issues in first responders. There needs to be some thought in determining ways to overcome some of the cultural issues that can embed themselves and be detrimental.
- With regard to technical assistance, infuse the learning community concept. At the Hogg Foundation, when working with communities, grantees work with other grantees to create a learning community. They are learning from one another and not always having to receiving it from those higher up, in DSLR's case CDC, or the federal government.
- Build an infrastructure that will enable state and local experts to be able meet with and network with their colleagues or peers to learn from one another and advance their programs.
- An integrative preparedness science is important. Something is missing around understanding how to perform the transdisciplinary science. It would be interesting to talk about how to do a

formal assessment of pulling the sciences together to advance the applied science of preparedness. The Hogg Foundation would like to work with CDC along those lines.

- Dr. Slemp asked all the division leaders to think of one or two areas the BSC could work collaboratively with them on to advance the system.

Before moving to break, Dr. Dreyzehner provided an update from the morning's telebriefing regarding the 2019 novel coronavirus response. A Level 3 travel advisory has been issued for Wuhan, China. Level 3 relates to nonessential travel. There is a second case of 2019 novel coronavirus in Chicago, IL. The Illinois Department of Health is reporting the patient is a 60-year old woman, who is in stable condition. All contacts are currently well and are being interviewed. A CDC team was deployed to assist. Nationally, there are currently 63 patients under investigation from 22 states. Screening will continue at five airports: Hartsfield–Jackson Atlanta International, Chicago–O'Hare, San Francisco International, Los Angeles International, and New York–Kennedy International. Up to date information can be found at [www.cdc.gov/wuhan](http://www.cdc.gov/wuhan).

### **Graduated Response Framework: Progress Update**

*Rudolph Johnson, PhD; Acting Director, Division of Emergency Operations*

*Debra Lubar, PhD; Deputy Director for Management and Operations, National Center for Emerging and Zoonotic Infectious Diseases*

CDC has developed a new way to talk about emergency responses. Emergency operations has changed drastically since 2001. Emergency response and emergency management has been integrated into almost all the centers across CDC. DEO decided to examine the capacities across the agency, the ways DEO were supporting the centers, and the ways the agency operations have matured. These concepts needed to be captured in a new framework. This effort started in the National Center for Immunization and Respiratory Disease, who has very advanced emergency response capabilities around pandemics. During the CPR leadership transition, those ideas were introduced to and adopted by CPR.

The previous framework described responses as levels 1, 2, and 3, with level 1 requiring the greatest response efforts. The goal of the new Graduated Response Framework was to establish joint ownership of a new CDC framework that supports all levels of agency response. The new framework:

- Reflects increases in the capacity of some CIOs;
- Better captures and communicates all the agency's response efforts;
- Defines the levels of response;
- Aligns DEO and CIO capabilities, responsibilities, and expectations; and,
- Clarifies internal capacities that CIOs need to have.

Below is an illustration of the levels in the Graduated Response Framework.

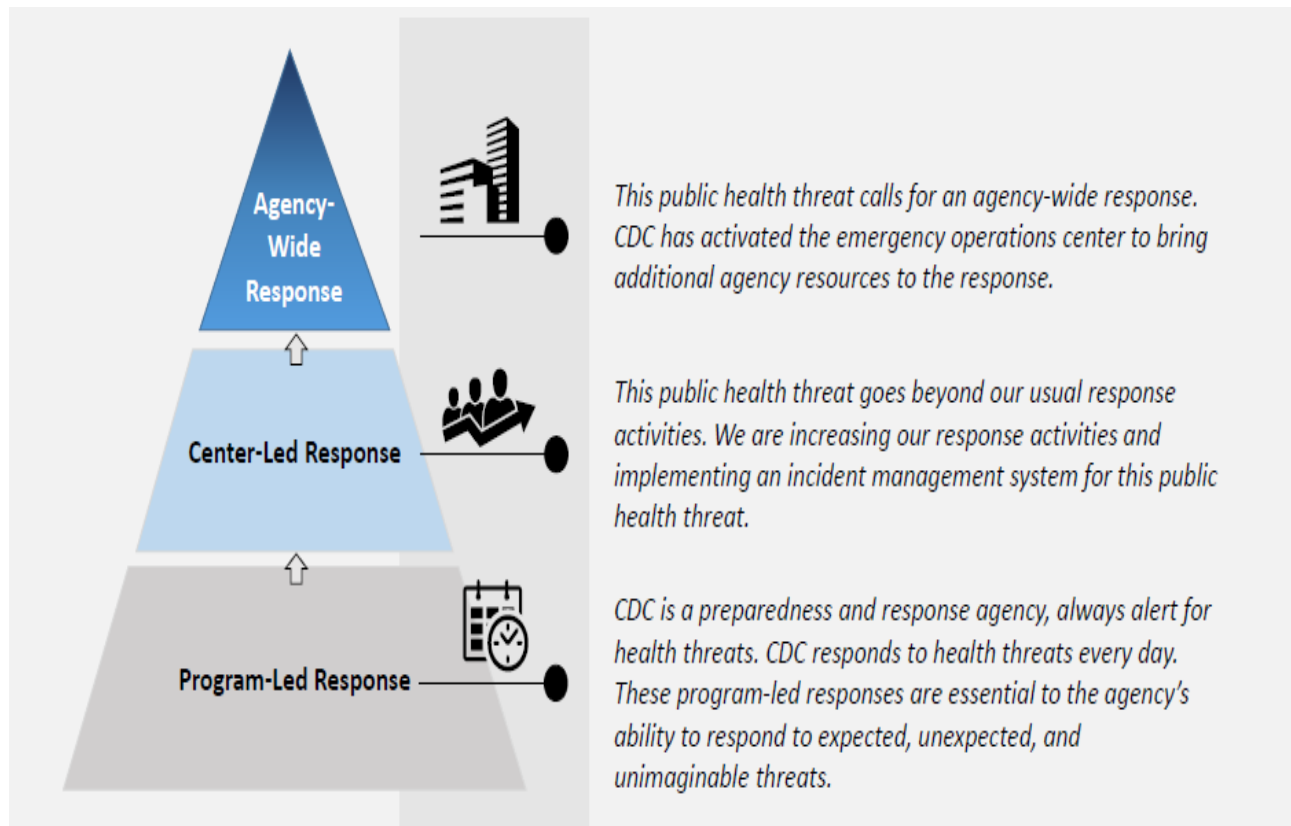


Figure 2. Graduated Response Framework

Program-Led Responses are the typical, day-to-day events, outbreaks, or emergencies that can be handled at the program level. It can also be managed by a division or a branch. Examples of Program-Led Responses are food borne outbreaks, hepatitis outbreaks, and seasonal influenza. The Center-Led Response is a new concept. Since some centers have developed capacities of their own, they are able to respond to an emergency without the DEO's participation. Lastly, the Agency-Wide Response is an Emergency Operations Center (EOC) level response; however, it does not have to be conducted at the EOC.

There are different elements that determine when transition needs to occur between the levels. The response elements include:

- Public health impact
- Coordination needs
- Staffing and other resource needs
- Media and policymaker interest

The operational measures define the assistance provided to the response leaders at the different levels. They include:

- Reporting and approval chains
- IMS stand up

- Access to agency-wide resources
  - DEO engagement (not all or nothing)
  - Emergency business processes
  - Staffing strategies

Program-Led Responses are for expected or limited public health events. Division or program-led routine responses are managed by program processes and coordination, similar to management of a disease cluster or outbreak. This will probably not look much different than daily business. Over time, more clarity will be developed regarding the support the programs receive when they are in this posture, as well as a better description of the activities that occur. The message that would be communicated in such a response would be something similar to this statement:

*“CDC is a preparedness and response agency, always alert for health threats. CDC responds to health threats every day. These program-led responses are essential to the agency’s ability to respond to expected, unexpected, and unimaginable threats.”*

The Center-Led Response occurs during a domestic or international incident or event with the potential to create significant concern or impact. One or more CIOs establish an Incident Management System for a response. This response occurs when the capacity needed exceeds the program-level ability to coordinate. There is a necessity to define this level and create expectations of DEO and the business services offices at CDC. They will help support the agency’s ability to operate more effectively and efficiently in this space; the advantage is not creating a new operating structure but using the center structure and management for the responses. The communication statement would look like the following:

*“CDC has instituted an incident management system for this public health threat.”*

The Agency-Wide Response is very similar to the previous EOC definitions. This is a domestic or international incident or event that has the potential to cause a significant concern or impact. The event or incident requires a unified and enhanced agency-wide response to be conducted in the Emergency Operations Center or CDC facilities outfitted with similar capabilities. Agency-wide responses can be scaled to meet escalating or de-escalating conditions or needs. Examples of these types of responses would Ebola (2014) or H1N1 (2009). The key messages seen in those times would be similar to the following:

*“CDC has activated the emergency operations center/an agency-wide incident management system for this public health response.”*

The Escalated Agency-wide Response is just above the Agency-Wide and is used when public health emergencies may require additional measures. As part of an Agency-Wide Response, additional response elements may indicate the need for additional operational measures. An example of a key message for these instances would be as follows:

*“CDC has activated the emergency operations center/an agency-wide incident management system for this public health response.”*

The Graduated Response Framework allows CDC to communicate using common nomenclature and common points of reference. Customer engagement is the key component.

The next step in the process will involve the Steering Committee, which will meet for the first time on Thursday, January 30, 2020. The objectives of the Steering Committee are to meet with all representatives from across the centers, institutes, and offices, explain the expectations for participation, and identify key focal areas that people are finding concerning.

The speakers ended their presentations with some questions for the BSC:

- Is the new messaging for each response level clear? Does it resonate?
- Do you have any recommendations regarding the direction of the Steering Committee and Workgroups?
- What considerations/recommendations do you have for measuring improvements to response operations over time?

**BSC comments:**

- The response levels are clear and resonate. It would be extremely helpful to insert historic responses from the past to be used as examples. This will help the public conceptualize each level better.
- The description makes it seem that in agency-wide responses you are standing back, but it is just the opposite because all the centers and programs have been working consistently up until that point. Consider making that point a stronger part of the message.
- Hopefully, the work groups will minimize some of the frictions that were discussed in the April 2019 BSC meeting around moving up the levels in the triangle. It was stated that people may hesitate to ask for help with basic, functional pieces, even if they are short resources, if they know it will pull staff out of a response. The work groups could determine what can eliminate those frictions. On the other end of the spectrum, they can determine ways to avoid activating resources that are not ultimately utilized.
- A suggestion would be to convene focus groups of policy stakeholders to see if this resonates with them or what it will take to ensure they understand the three levels and the triggers required to move to the next mechanism. If you do not control your messaging, someone else will.
- There are individuals that are always added after the response has started, like the behavioral and mental health professionals, yet, they add the most pervasive and long-lasting health impact in many of the responses. There should be some measure of how quickly those individuals are being engaged and added to a response.
- It is unclear when and how the decision is made to move to another phase in a response, and in particular, deactivating the response. The longer a response goes, sometimes the more entrenched people become in their response mode. This trigger should therefore be thought out well in advance.
- Encourage the work groups to look to international partners and examine the ways they manage complex disasters and emergencies. Countries such as Israel have embraced preparedness from a systems perspective countrywide. There are lessons and expertise that can be garnered, and it will give the work group members an opportunity to step outside of CDC and become familiar with other complex systems and organizations managing responses.

- Take responses from prior years and walk the work group through them in a case study fashion. This will help them understand the response progression from program level to a center level and then an agency level.
- There is confusion in the details of an agency response and an escalated agency response. They seem to be pretty much the same. Some clarification is needed.

## **US National Authority for Containment of Poliovirus Update**

*Lia Haynes Smith, PhD; Director and National Poliovirus Containment Coordinator*

Dr. Haynes-Smith provided a general overview of poliovirus, eradication and containment.

In 2015, the WHO Assembly endorsed the Global Action Plan III (GAPIII) for poliovirus containment. There was a recognition that, as you move closer to eradication, the likelihood of poliovirus containment breach consequences increases. This can cause a reintroduction of poliovirus from a facility into a community, which would be catastrophic, and could cause the re-establishment of paralytic disease. The goal of global containment is to reduce the risk of poliovirus release from a facility to as close to zero as possible

In 2014, WHO published the GAPIII for poliovirus containment. It defines a strategy to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and cessation of oral polio vaccine use. GAPIII stipulates 16 technical requirements for containment. Facilities, who want to retain poliovirus post eradication, must comply with these requirements. Currently, PV2 and WPV3 may only be handled in certified poliovirus-essential facilities (PEFs).

One of the requirements with GAPIII is that any country that wants to retain poliovirus must designate a national authority for containment. In January 2018, the Assistant Secretary for Health and Human Services designated the polio containment activity, known as the U.S. NAC, to be housed at CDC owing to its expertise in poliovirus eradication and laboratory containment. The NAC is appropriately situated in CPR so that it may leverage some of the infrastructure set forth in DSAT. Currently, there is no regulation that compels U.S. facilities to adopt WHO GAP III containment measures nor to empower the NAC to do its work. The NAC relies on laboratories and facilities to willingly adopt and comply to not only the GAPIII requirements but also policies the NAC has created. This is a collaborative approach to containment.

The NAC has two primary functions. One is to maintain a national inventory of infectious and potentially infectious materials. Potentially infectious materials may be respiratory, stool, or environmental samples that were collected in a place and time when WPV was circulating or a polio vaccine was in use. As part of the national survey, the NAC is responsible for identifying all U.S. facilities that may have these materials and to maintain an inventory of those locations, which is reported annually to WHO.

The NAC is also responsible for implementing the application and audit process to become a PEF in the United States. WHO has outlined a certification scheme for these facilities. It starts with an introduction, which is called a Certificate of Participation. This is an indicator to WHO and the NAC that the facility is committed to starting and engaging in the certification process. Part of the responsibilities in this realm require the NAC to ensure that the facilities have an understanding of containment needs and the GAPIII requirements. Where needed, the NAC also develops policies that interpret WHO GAP III

elements for U.S. circumstances. In addition, it seeks WHO endorsement for PEF applications and conducts audits to assess implementation of GAP III containment elements.

To date, the U.S. NAC has launched a website, created a way for NAC and PEFS to exchange documents, and implemented the third iteration of the National Poliovirus Survey. There are ten facilities in the U.S. that plan to become PEFs. Sixty percent of them expect to complete their work by April 2021 or earlier. The remaining plan to retain samples longer-term. All the facilities have to enter into the certification process, which begins with submitting an application for certificate of participation. Applications are submitted to the Global Certification Commission (GCC), which is an oversight body for WHO. To date five certificates of participation have been endorsed by the GCC. This is a notable accomplishment because it is the largest number of certificates held by any country endorsed by the GCC.

The NAC also conducted site visits to assess the current containment conditions and gap assessments to locate areas of improvement. Part of the engagement efforts require the NAC to have additional seminars and webinars. It is a part of the Global Polio Eradication Initiative. Member partners include the United Nations Children's Fund (UNICEF), CDC, WHO, Rotary International, Gavi, and the Bill and Melinda Gates Foundation; webinars are offered through the collaborative partnership. Lastly, the NAC is developing policies that will help implement the specific aspects of poliovirus containment. In the past two years, it has developed a model for establishing a NAC. The model has been recognized globally. In addition, the NAC is providing guidance to others regarding its work.

#### **Biological Agent Containment Working Group (BACWG) Update**

*Suzet McKinney, DrPH, MPH; BACWG Co-Chair, Chair, CPR BSC*

*Cathy Slemper, MD, MPH; BACWG and CPR BSC*

The BACWG was assembled to provide input to the BSC/CPR regarding biological select agents, importation of infectious materials, and containment of polioviruses. It was first convened in May 2017. The workgroup includes BSC members as well as other experts. It is co-chaired by BSC members Dr. Suzet McKinney and Dr. Dawn Wooley. Co-leads from CDC, the Directors of DSAT and the NAC, also assist the working group.

The BACWG provided an update on the development of a U.S. NAC policy on Biorisk Management and Risk Assessment and on their work assessing U.S. Government approaches to oversight and governance of biologic agents with the potential to spread beyond human control.

The Biorisk Management and Risk Assessment Policy is a key part of WHO GAP III requirements. The BACWG provided input on the policy and presented it to the CPR BSC for their advice and guidance.

The Biorisk Management System/Risk Assessment Policy is a critical piece. All PEFs must implement a biorisk management system and conduct site-specific risk assessments (GAP III elements 1 and 2). The labs were reviewed by the NAC and Sandia National Laboratories, who identified gaps. The policy provides requirements and recommendations to improve PEF risk management systems and consistency across facilities of risk assessments. It also outlines the biorisk management system and risk assessment requirements and recommendations.

It instructs the institutions to establish an independent biorisk management committee and to implement quality management system principles and practices. It also directs the facilities to create



clear communication channels and communication plan, particularly around near misses and other events, and to ensure robust training and personnel competency programs. The policy aligns very closely with the GAPIII requirements.

Dr. McKinney then provided an update on the BACWG's findings on USG approaches to oversight and governance of biological agents with potential to spread beyond human control. The BACWG reviewed existing USG oversight and governance mechanisms and guidance documents related to biological agents of concern. Moving beyond the review, a number of experts, government officials and non-government scientists met with the BACWG to provide presentations based on their expertise and experience related to these issues.

BACWG input on the topic was directed toward actions that the US Government should take with respect to the following areas: feasibility to create uncontrollable biological agents; state of current United States policies, guidelines, and regulations; and future of oversight and incentives for responsible conduct. The BACWG observations and input led to much discussion from the Board as well as CDC subject matter experts.

Examples of BACWG input and observations included:

Regarding the feasibility to create uncontrollable biological agents, existing harmless agents capable of autonomous spread could be altered to inflict harm through either deliberate or accidental engineering. Moreover, advances in biotechnology have made it increasingly feasible for researchers to engineer biological agents with the potential to spread beyond human control.

Regarding the state of current U.S. policies, guidelines, and regulations, the BACWG observed that there are significant gaps in the USG's policies regarding potential risks from novel agents with potential to spread beyond human control, and the USG lacks a standard policy that is adopted by all departments and agencies. Furthermore, international coordination and communication is needed regarding national governance approaches for proposed research that has the potential to produce an agent with the capacity to spread beyond human control.

Regarding future of oversight and incentives for responsible conduct, local Institutional Biosafety Committees may not have the expertise to assess the potential of a pathogen to spread beyond human control. In addition, as technology allows for smaller, more autonomous groups to do increasingly complex biological research and engineering, the risk grows that a small group, who may not have the restraints, values, and norms of the mainstream scientific community, might undertake dangerous activities carelessly or for destructive purposes.

### **BSC Comments**

- For the US NAC, the goal should be to create a supportive environment for the staff, and it should not be punitive. It is about quality improvement and support that is needed to develop the staff in an environment, where they feel comfortable coming forward and being honest about issues that are affecting them and should be brought to the attention of their immediate supervisor and director of a unit.

- For the US NAC, there is a concern about privately funded sources as well as a rogue player and how they can be monitored early on and closely. There might be value in looking to other agencies in the government that might be able to identify clandestine operations.
- The framing of the input on biological agents that could spread widely should be directed to actions that CDC could take.
- Need to discuss the intent of the workgroup's input and lay out conceptually the important issues, make clearer the intended audience and where accountability lies. Also, were there disagreements or differing opinions among the workgroup and how were those captured.
- This is the start of a dialogue on this issue of biological agents that can spread beyond human control, CDC is trying to look forward around threats and emergencies and be preventive.

### **Public Comment Period**

No comments from the public.

### **Meeting Recap, Action Items & Future Agenda Topics**

BSC members engaged in a discussion around future topic areas and action items. Below are their suggestions.

Dr. McKinney would like the board members to think of areas or issues that require a deeper dive. Are there other areas that warrant discussion by the BSC? During the Graduated Response Framework (GRF) presentation, a member suggested examining case studies to assist with framing the GRF and moving it forward in CDC. This is an area she would like to revisit at a future meeting. Another idea to considered are ways to make an economic case for PHEP funding. How can the impact of PHEP funding on the public health enterprise be best communicated? She also wanted to discuss the efforts being undertaken to better partner and align the scientific community with the practice community.

- Highlight best practices around things that most people would not know are happening in their communities. The information garnered can be disseminated to a much larger group.
- Determine ways to fuel the academic workforce pipeline around science and preparedness. There has been significant growth in that area. CDC tried some efforts that were not quite successful and there was curriculum created that was never released. There needs to be more data driven information regarding this area rather than an anecdotal perspective of what is happening in that space.
- Review the broad category of topics that have been placed in the vulnerable populations space. There is exciting work occurring in health equity and there is more work occurring in that regard related to preparedness and response and the need for more methodologies that involve deep community engagement and knowledge when developing preparedness plans.
- Take a deeper dive into implementation science. What are the barriers? What elements advance the uptake of best practices? What makes communities understand the need for those initiatives? How do you create a culture that utilizes and values that science?
- Take a closer look at data and artificial intelligence to understand how artificial intelligence will play a role in the future of public health.
- Hear the successes and challenges that are being experienced in the programs as changes have occurred over time. What are the barriers internally and externally? Liaison members can contribute to the conversation also to inform the board of how their agencies interact with CDC at various levels in the emergency response process.

- Have a better framework for the topics presented to the BSC. With Dr. Dreyzehner being in his current leadership position, as he takes the next few months to evaluate the needs of the programs, he can take note of any gaps or areas he feels should be presented to the BSC for advice and guidance. The topics of the BSC can be driven from those newly identified challenges.
- Cyber risk does not impact health directly but all of the things that happen as a result do, so if critical systems go down, the healthcare infrastructure is put at risk. Would love to see more discussions focused around that area in the future. What are the threats? What are the risks? If it is not known, can CDC perform an assessment of cyber risk and have the information presented to the board?

### **Meeting Adjourn**

Dr. Dreyzehner thanked Drs. Lochner and Andreadis for their work in organizing the meeting, as well as helping him to better understand the role of the BSC. He also applauded Dr. McKinney on her performance as the new chair. He also expressed gratitude to all the members, ex officio, and liaisons of the BSC for bringing their expertise to the table to inform the work of CPR.

With no further comments, Dr. McKinney adjourned the meeting at 2:56PM EST.

CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the January 24, 2020 meeting of the Center for Preparedness and Response (CPR) BSC are accurate and complete.

4/13/2020  
Date

/S/  
Suzet McKinney, Dr. P.H., M.P.H.  
Chair, Board of Scientific Counselors, CPR

APPENDIX A:

CPR BSC Meeting Attendance Roster  
Atlanta, GA – January 24, 2020

<b>NAME</b>	<b>AFFILIATION</b>	<b>PRESENCE</b>
<b>Suzet McKinney</b>	Chair and SGE	In Person
<b>Octavio Martinez</b>	SGE	In Person
<b>Alonzo Plough</b>	SGE	In Person
<b>Jennifer Horney</b>	SGE	In Person
<b>Brent Pawlecki</b>	SGE	In Person
<b>Catherine Slempp</b>	SGE	In Person
<b>David Fleming</b>	SGE	In Person
<b>Dan Dodgen (ASPR)</b>	Ex Officio	In Person
<b>Parham Jaberri</b>	Liaison	In Person
<b>Michele Askenazi (NACCHO)</b>	Liaison	In Person
<b>Benjamin Chan (CSTE)</b>	Liaison	In Person
<b>Christina Egan (APHL)</b>	Liaison	Via Phone
<b>Laura Magana</b>	Liaison	Via Phone

## APPENDIX B: 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, Dr.P.H., M.P.H.  
CEO/Executive Director  
Illinois Medical District Commission  
Chicago, Illinois

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## APPENDIX C: ACRONYMS

ABSA	American Biological Safety Association
APHL	Association of Public Health Laboratories
ASPPH	Association of Schools and Programs of Public Health
ASPR	Assistant Secretary for Preparedness and Response (HHS)
ASTHO	Association of State and Territorial Health Officers
BACWG	Biologic Agent Containment Working Group
BSC	Board of Scientific Counselors
CIO	Centers Institute and Offices
CPR	Center for Preparedness and Response (CDC)
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CDC	Centers for Disease Control and Prevention
CSTE	Council of State and Territorial Epidemiologists
DEO	Division of Emergency Operations (CDC)
DSAT	Division of Select Agents and Toxins (CDC)
DSLRL	Division of State and Local Readiness (CDC)
DSNS	Division of Strategic National Stockpile (CDC)
EMAP	Emergency Management Accreditation Program
EOC	Emergency Operations Center
ExO	Ex Officio
FACA	Federal Advisory Committee Act
FSAP	Federal Select Agent Program
GAP III	Global Action Plan III
MCM	Medical Counter Measures
PEF	Poliovirus-essential facilities
PHEM	Public Health Emergency Management Fellowship Program
PHEP	Public Health Emergency Preparedness
HHS	US Department of Health and Human Services
IMTDP	Incident Manager Training and Development Program
SLTT	State, Local, Tribal and Territorial
SBI	Strategic Business Initiative Unit (CDC)
SME	Subject Matter Expert
USDA	United States Department of Agriculture
USG	US Government
US NAC	US National Authority for containment
WPV	Wild poliovirus
WHO	World Health Organization