Board of Scientific Counselors (BSC) Meeting
Office of Readiness and Response (ORR)
January 25 - 26, 2024
Hybrid (In-person/Virtual)

Contents

Thursday, January 25, 2024

Friday, January 26, 2024

BOARD OF SCIENTIFIC COUNSELORS (BSC)
OFFICE OF READINESS AND RESPONSE (ORR)
MEETING
THURSDAY, JANUARY 25, 2024
VIRTUAL/IN-PERSON

Roll Call, Welcome

Ian Williams, PhD, MS; Deputy Director, ORR; Designated Federal Official, BSC, ORR

The BSC meeting began with roll call by Dr. Williams to ensure quorum was established. Dr. Williams monitored attendance and quorum was maintained throughout the meeting.

Dr. Williams also reviewed the BSC responsibilities, as per its charter, and the conflict-of-interest waivers. Members were requested to identify any conflicts and no conflicts were identified.

Discussions were facilitated by Dr. David Lakey. If voting was required only the Special Government Employee (SGE) Members would vote.

BSC Members present:

Dr. Julie Fischer
Dr. David Fleming
Dr. David Lakey
Dr. John Martin-Lowe
Dr. Phyllis Meadows
Dr. Umair Shah
Dr. Kristin DeBord
Dr. Hilary Marston
Ms. Michele Askenazi
Dr. Benjamin Chan
Dr. Christina Egan
Dr. Emily Burke
Dr. Alexia Harrist
Mr. A.J. Schall

The meeting was called order at 9:35 AM EST.

Welcome and Introduction of the New Office of Readiness and Response (ORR)

Henry Walke, MD, MPH; Director, ORR

Dr. Walke briefed the BSC on the major highlights of the activities conducted by Office of Readiness and Response (ORR). In February 2023, CPR (Center for Preparedness and Response) transformed into the Office of Readiness and Response (ORR). The purpose of this reorganization effort was to enhance the readiness and response capacity within the U.S. Centers for Disease Control and Prevention (CDC) and ORR. The office, located under the immediate office of the CDC Director, will remain the leading entity in managing all critical readiness and response functions, both domestically and internationally.

At present, the agency is involved in numerous response efforts, both domestic and international. CDC is supporting the polio response and deploying its personnel in the field to aid in preparedness and response activities. Ongoing work is being carried out in Afghanistan and Pakistan, the two last remaining countries with wild poliovirus occurrence. Additionally, CDC is monitoring the transmission of outbreaks across various countries across the globe.

The nation is confronted with numerous respiratory viruses, including coronavirus disease 2019 (COVID-19), respiratory syncytial virus (RSV), and influenza, which present multiple public health threats. To ensure that public health systems are not overwhelmed by simultaneous responses, the CDC's National Center for Immunization and Respiratory Diseases (NCIRD) is leading these responses and coordinating support nationwide.

In July of 2023, the CDC recommended a new RSV vaccine through shared clinical decision making for adults aged 60 and above. Additionally, in August 2023, the CDC recommended RSV immunizations for all children below the age of eight months, as well as older children who are at a higher risk of severe illness caused by RSV.

The CDC is also responding to a lead and chromium poisoning outbreak linked to three brands of applesauce pouches, marketed to children. The National Center for Environmental Health (NCEH) and National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) are coordinating with the U.S. Food and Drug Administration (FDA) and supporting state and local partners. As of January 12, 2024, CDC had received reports of 354 cases from 41 different states.

Dr. Walke extended recognition and a warm welcome to the newest members of the BSC: Dr. John Martin-Lowe, Dr. Phyllis Meadows, and Dr. Umair Shah. He also took a moment to express gratitude towards Dr. David Fleming, who will be retiring from the board. Since November 2019, Dr. Fleming has served as a distinguished board member and co-chaired the newly established Health Equity Working Group (HEWG). Additionally, he holds a vital position on the Advisory Committee to the Director of CDC (ACD), which he will continue to fulfill after stepping

down from the BSC, ORR. Dr. Walke expressed his deep appreciation to Dr. Fleming for his invaluable contributions, wealth of knowledge, and exceptional expertise.

Dr. Walke initiated an opportunity for the BSC members to raise any questions or provide additional opening comments. No inquiries or remarks were put forth.

ORR Office of the Director; Update and Discussion

Policy, Planning, & Communication

Chris De la Motte Hurst; (Acting) Associate Director

Throughout the strategic planning process, ORR has ensured that its plan remains in alignment with CDC's fiscal year (FY) '24 priorities and strategic plan. The objective is to proceed under the CDC framework. Every aspect of the ORR's strategic plan, starting from the vision and mission down to the annual focus areas and action plans, is designed to enhance the agency's readiness and capabilities in detecting and responding to public health threats. ORR's strategic plan encompasses various key initiatives, including those in line with CDC's moving forward goals, objectives, and improvement areas, CDC's readiness and response priorities for which ORR takes the lead, as well as CDC's core capabilities such as state-of-the-art laboratories, prompt outbreak response at the source, and robust global capacity alongside domestic preparedness.

The FY24 strategic planning process was initiated by ORR Leadership in August 2023. They started by assessing the achievements of the previous year and then determining important overarching goals for 2024. There are four strategies for FY24:

- Strategy 1: Modernize and integrate data and systems across multidisciplinary public health entities to support data readiness and interoperability.
    - Stand up a Common Operating Platform and Picture and define and implement data readiness requirements for management of response situational awareness.
    - Build capacity to effectively leverage data during emergencies for rapid decision-making.
- Strategy 2: Advance readiness and response science to improve public health practice.
    - Mature the readiness and response science agenda to include community mitigation practices, behavioral science, and non-medical countermeasures to increase public health safety.
    - Implement readiness and response science that informs policy, guides programs, and maximizes public health impact.
- Strategy 3: Build and enhance both CDC and State, Tribal Local, and Territorial (STLT) health departments' response capability and drive collaboration among partners to enable rapid and effective response to public health emergencies.
    - Detect and characterize public health threats, enhance laboratory readiness, and maintain the highest level of biosecurity and biosafety.
    - Strengthen interagency, CDC, non-governmental organization (NGO), and STLT partnerships to advance readiness and response capabilities for all.

    - Coordinate and scale policies, systems, and funding mechanisms to support emergency response functions.
- Strategy 4: Conduct rapid and ongoing readiness and response evaluation to inform continuous improvements across detection of public health threats, readiness science, and emergency operations.
    - Implement data-driven, risk-based approaches for detection and evaluation of public health threats.
    - Develop a response readiness framework that establishes standards and evaluation criteria for CDC.

During the reauthorization process of the Pandemic and All Hazards Preparedness Act (PAHPA), the Office of Policy, Planning, and Communication (OPPC) has been closely monitoring several agency priorities that have the potential to alter ORR's authorities in responding to public health emergencies. However, due to a hold in Congress, the PAHPA's progress has been paused. The hold has also left the office awaiting clarity on the budget. OPPC monitoring the extent to which crucial provisions in PAHPA are incorporated into a potential budget deal. The events of 2023 served as a reminder of the significance of legislative affairs issues, as changes were made to the law concerning reporting requirements for theft, loss, and release of select agents, directly impacting the Agency and office operations. Therefore, it is vital for the office to maintain a vigilant watch on the proceedings in Congress.

Some important updates from Congress included a special hearing on November 30, 2023, where Dr. Mandy K. Cohen, CDC's Director, addressed the House Energy & Commerce Subcommittee on Oversight & Investigations. Additionally, leadership participated in more than 25 congressional briefings or visits throughout 2023. In 2024, ORR aims to enhance its presence strategically alongside key partners on the Hill.

In October 2023, CDC Washington initiated the Public Health Academy Event. ORR was invited to create an interactive preparedness simulation activity for staff and partners, allowing them to gain firsthand experience in public health response. This event served as an excellent platform for discussing preparedness matters in the context of the PAPHA Reauthorization. Noteworthy attendees included Dr. Cohen, Dr. Nirav D. Shah, CDC's Principal Deputy Director and Congresswoman Anna Eshoo, the original co-author of PAHPA and Ranking Member of the House Energy and Commerce Health Subcommittee.

Office of Science and Laboratory Readiness

Joanne Andreadis, PhD; Associate Director for Science

Since the reorganization of ORR, the Office of Science and Laboratory Readiness (OSLR) has experienced a significant decrease in full-time equivalent (FTE) personnel, from 18 to 7. As part of the reorganization, two programs from OSLR have been incorporated into the new Division of Readiness and Response Science (DRRS).

The primary responsibilities of the OSLR include overseeing the BSC, providing support for science administration, and promoting laboratory readiness and strategic partnerships. These functions are geared towards identifying and raising awareness about existing gaps and opportunities, setting high standards for scientific initiatives within ORR, and focusing on research that can drive actionable improvements and bring about positive changes.

The focus of OSLR extends beyond preparing for past events, it emphasizes the utilization of innovative methodologies to contemplate a wide range of potential future threat scenarios. By investing in the right areas today, the office aims to equip ORR with the necessary resources and capabilities to effectively address future threats.

The OSLR has three strategic goals:

- Goal 1: Promote scientific integrity and quality across ORR by establishing standards and ensuring adherence to suggested practices.
    - Assure ORR meets or exceeds the CDC Office of Science Strategic Science and Clearance Transformation Goals.
- Goal 2: Advance laboratory readiness to support timely surveillance, detection, and response to public health incidents involving chemical, biological, radiological/nuclear, and emerging threats.
    - Contribute to strengthening CDC and state, tribal, local, or territorial (STLT) infrastructure to ensure continuous readiness and response capabilities and capacities.
- Goal 3: Foster transformational innovation through cross-sector partnerships to advance CDC and national readiness and response capabilities.
    - Increase the implementation, translation, and dissemination of evidence-based strategies and interventions.

It is crucial to establish a dynamic and collaborative scientific ecosystem that can continuously evolve to effectively address gaps as they arise. This entails being agile and capable of adapting swiftly to changing needs and emerging challenges. OSLR is open to discussions about creating a network of experts from various disciplines and sectors, which can be leveraged for prompt problem-solving and innovation, especially during emergencies. They are also committed to setting up the necessary infrastructure that enables them to design, develop, and scale processes; prioritize scientific inquiries based on their potential impact; and foster a mindset of adaptability and innovation.

Four pillars of science and innovation have been established for ORR encompassing the essential aspects of workforce, science, operations, and systems change:

- Workforce – Prepare and sustain a safe and proficient, federal, state, and local workforce and infrastructure to lead and manage a secure, effective, timely, and coordinated public health response to priority health threats.

- Science – Decrease the time to identify causes, determine risk factors, and inform implementation of appropriate interventions for those affected by threats to the public's health.
- Operations – Improve the timeliness and accuracy of communications and situational awareness regarding threats to the public's health and at-risk populations.
- Systems change – Improve the impact of our evaluation on support if continual improvement and resilient public health preparedness and response systems.

Surveillance and Data Modernization

Katie Fullerton, MPH; Senior Advisory

The Data Modernization Initiative (DMI) is fostering progress for ORR, building upon the advancements and lessons learned during the COVID-19 pandemic. This initiative directly influences CDC's decision-making process and enhances public communication, facilitating quicker response. The investments made in data have established a solid foundation for crucial capabilities, including outbreak response, health equity, and forecasting. CDC is dedicated to increasing data accessibility and preparedness for future challenges. DMI, implemented agency-wide, involves the collaborative efforts of data, people, and policies to propel the nation forward.

There are five high-level DMI priorities.

1. Building the right foundation
2. Accelerating data into action
3. Developing a state-of-the-art workforce
4. Supporting and extending external partnerships
5. Managing change in governance

Activities are taking place throughout the Agency and within ORR to address these priorities. These efforts are happening at various levels, including federal, state, and local, and community levels. At the federal level, the focal point is the consolidation of data at CDC. To achieve this objective, ORR is primarily focused on advancing the use of a common operating platform and operating picture that facilitates efficient data sharing and supports policymaking. In collaboration with state and local entities, CDC is also working to enhance the public health workforce and establish stronger connections to ensure the availability of timely and accurate data. Furthermore, CDC is committed to promoting equitable health and delivering real-time actionable data for informed decision-making among the public.

Modernization is an ongoing process and not a one-time occurrence. The financial allocations towards DMI since FY 2020 have paved the way for CDC to initiate crucial measures in bolstering the surveillance and data infrastructure for public health in the United States. However, continued investments are necessary to enhance accessibility and interoperability throughout the public health data ecosystem, as well as expand services across CDC.

The CDC is currently assessing its systematic and comprehensive approach to ensure continuous learning and application of lessons learned. The availability of funding for data modernization ultimately impacts the extent and effectiveness of data modernization efforts and the CDC's capacity to safeguard public health. Additionally, ORR collaborates with various internal and external partners, including the data office, the Office of the Chief Information Officer, the Center for Forecasting and Analytics, and the Public Health Infrastructure Center. These joint efforts aim to advance data modernization both within the CDC and in external settings.

Division of Readiness and Response Science (DRRS): Overview

DRRS Office of the Director (OD) – Scientific Evidence and Implementation Team Overview

Lisa Barrios, ScM, DrPH; Division Director

The Division of Readiness and Response Science (DRRS) is the most recent addition to the ORR. The frequency and severity of public health crises are progressively escalating, as observed through the ongoing COVID-19 pandemic, the mpox outbreak, and the continuous activation of the Centers for Disease Control and Prevention's (CDC) Incident Management Structure (IMS) and Emergency Operations Center (EOC) over the past decade. In an endeavor to enhance the nation's preparedness and address public health risks both domestically and globally, CDC established the DRRS on October 1, 2023.

DRRS' mission is to develop and implement the science of readiness and response, build scientific expertise to address health disparities and community mitigation, evaluate the state of STLT readiness and response, and inform a broader framework for evaluating CDC's and partners' readiness status. An additional component of the mission is to ensure the provision of dependable, thorough, prompt, and high-quality information concerning outbreaks and all-hazard emergencies. This information is crucial as it continues to develop, change, and necessitate responses from the CDC.

The division's five priority areas are: elevate science, protect communities, decrease disparities, evaluate efforts, and leverage technology:

- Elevate Science – Elevate readiness and response science by working with inter- and intramural partners to advance relevant research, evaluation, dissemination, and implementation.
- Protect Communities – Implement behavioral science and community mitigation tactics informed by readiness and response science.
- Decrease Disparities – Decrease health disparities during public health emergencies by integrating health equity and special populations needs into all readiness and response efforts.

- Evaluate efforts: Evaluate CDC's readiness state and how CDC-wide investments enable improvement of STLT and key partner's readiness states.
- Leverage Technology – Improve data preparedness, readiness and response early warning systems, event-based surveillance, and decision-making for the Agency by advancing the common operating picture and platform.

The structure of DRRS aligns with the priority areas, and it consists of the OD and its three branches: the Community-based Solutions & Health Equity Branch (CBSHE), the Public Health Readiness & Response Evaluation Branch (PHRRE), and the Response Analytics, Decision Support, & Surveillance Branch (RADSS).

DRRS' OD has three missions.

1. Science: Promote scientific partnerships to improve whole community readiness and response science to address all-hazards emergencies and coordinate the translation of science into evidence-based practices.
2. Policy and Communications: Lead, advise, and liaise across CDC, enabling DRRS branches to meet their mission through readiness and response policy, partnerships, strategy, and communications.
3. Management and Operations: Manage, plan, and coordinate customer-focused solutions to enable DRRS' management, budget, and administrative activities.

The OD Team Structure mirrors the mission statements and consists of three teams: Scientific Evidence and Implementation, Policy & Communications, and Management & Operations. Additionally, the DRRS' OD has consolidated readiness and response science functions by incorporating the Applied Research Program and the Strategic Capacity Building and Innovation Program (SCIP) within its framework.

Extensive strategic planning has been undertaken by DRRS, even before its establishment in October. This planning involved identifying the key annual focus areas for the OD in the coming year. The focus areas are as follows:

1. Promote a cohesive DRRS mission to unify branches to meet readiness and response science goals.
2. Create and advance the science agenda to guide DRRS in building the readiness and response research base over the next 2-5 years.
3. Lead modernized and innovative approaches that enable people, processes, and technology to advance division priorities.
4. Foster collaboration with readiness and response science partners to advance research and innovation across the public health enterprise.

Dr. Barrios also provided an update to the BSC regarding the Academic Centers Program, which has now been incorporated into the Scientific Evidence and Implementation Team. Since 2008,

the CDC has been providing funding for these academic centers, which primarily focus on areas such as training and the development of an evidence base for STLT health department partners. The most recent funding appropriations for the fiscal year 2023-2024 aim to establish a network of ten regional centers for public health preparedness and response. These centers will prioritize the implementation of evidence-informed and evidence-based practices to enhance translation efforts. According to 2023 Authorization Requirements, the following guidelines have been outlined:

- *The* United States Department of Health and Human Services (HHS) *SHALL support network of 10 Centers for Public Health Preparedness and Response*
    - *Equitably distributed among US geographical regions.*
    - *May be institutions of higher education, including accredited schools of public health, or other nonprofit private entities.*
- *HHS SHALL Coordinate activities with STLT health departments and officials, health care facilities, and health care coalitions.*
- *Prioritize efforts to implement evidence-informed or evidence-based practices.*

In 2023, contracts were awarded in regions 3, 4, 6, 7, 8, 9, and 10 to support developmental work for establishing the regional centers. These contracts have enabled the establishment of regional coordinating bodies and formulation of five-year regional work plans. Additional funding was allocated to regions 8, 9, and 10 to develop work plans specifically targeting tribal, rural, and frontier communities. Similarly, regions 4, 8, and 10 received funding to support the development of data ecosystem models. Looking ahead to fiscal year 2024, of drafting a notice of funding opportunity (NOFO) to support the establishment of 10 regional centers.

Strategic Capacity Building and Innovation Program (SCIP)

Jana Austin, MPH; DRRS, OD

Ms. Austin presented an update on the approved formal recommendations by the BSC back in November 2022. The collection of recommendations and implementation are being referred to as SCIP 2.0, which aims to enhance the program with a stronger focus on modernization and innovation. These enhancements will strategically position the program to better support readiness and response capabilities while ensuring long-term sustainability. Additionally, SCIP 2.0 will create opportunities for forging new connections, fostering external collaborations, and promoting knowledge transfer into agency best practices. It will allow Centers, Institutes, and Offices (CIOs) to actively participate in preparedness efforts and maintain their engagement in emergency response. Lastly, the updated program will provide greater flexibility to address immediate threats.

The SCIP Review Working Group (SRWG), co-chaired by Drs. David Fleming and David Lakey put forth four recommendations.

- Recommendation 1- Separate the long-term and short-term elements of SCIP to disentangle, clarify, and simplify the assessment of program needs and implementation of project funding.
- Recommendation 2 - Establish a process to define, determine, monitor, and update [ORR's] long-term preparedness and response program needs, including ongoing financing needs.
- Recommendation 3 - Establish a process for a forward-looking approach to make short-term investments in enhancing capabilities for current and future preparedness needs.
- Recommendation 4 - Conduct an external assessment of SCIP's current portfolio and business model to identify improvement opportunities, and program limitations, and identify ways to streamline operations on a routine basis.

The SCIP 2.0 modernization is moving forward aggressively in addressing each of the recommendations.

The newly implemented taxonomy and funding cycle will guarantee that approved activities receive new funding for a maximum duration of three years. This will explicitly involve ORR in short-term readiness and response initiatives led by other CIOs, detaching it from long-term sustainability efforts. The COVID-19 pandemic shed light on the imperative to prioritize preparedness and response, revealing the inadequacy of SCIP funds to meet all the demands of public health preparedness and response across the Agency. Consequently, CIOs will assume greater responsibility for sustaining these efforts, while SCIP will shift its focus towards supporting innovative activities and enhancements.

The Critical Gap Mitigation category will cater to activities specifically addressing gaps in readiness and response, where SCIP serves as the primary funding source. On the other hand, the Readiness Enhancement category is dedicated to activities that build upon essential readiness, preparedness, and response capabilities. The Transformative Innovation category encompasses pioneering innovations and/or novel science-based preparedness and response capabilities.

In FY24, there are five funding opportunity areas designated for engaging in transformative innovation initiatives that offer the following:

- Actionable, early warning systems with modern and flexible methods that can support urgent responses to evolving public health threats.
- Enhanced epidemiologic tools, methods, and systems to rapidly collect, analyze, visualize, and disseminate data and information.
- Improved CDC and STLT capacity to support community mitigation measures, with a focus on disproportionately affected populations and communities.
- Increased public health laboratory throughput capacities in large-scale events for new emerging or rare pathogens.
- Tiered capabilities/capacities that can be scaled as needed to handle the extra volume of information related to an emergency response.

In the future, SCIP will increase investments in shorter-duration activities that target unique, innovative, and crosscutting needs. These activities aim to address current and future high-priority gaps in readiness and responsiveness. Proposals that are cross cutting and intended to be utilized across multiple programs will be given higher priority. This approach ensures that multiple applications, needs, STLTs, and CIO initiatives are addressed and leveraged. The focus is to generate value across a wide range of applications and needs by delivering clear, multi-threat benefits. At least two or more threats will be tackled, utilizing a threat-agnostic approach.

The SCIP six-stage lifecycle remains unchanged but has been enhanced to align with the recommendations of the BSC. Each stage has been improved to effectively address the changing landscape of public health readiness and response.

- **Stage 1** (priority setting) – SCIP included external feedback to help develop where our annual priorities will fall. Additionally, SCIP increasing our reach by including external partnership avenues for innovative technology and processes to be brought into the agency and then shared with STLTs and beyond.
- **Stage 2** (call for proposals) – SCIP set clear purposes for the funding by establishing a new taxonomy of classification and an absolute re-compete paradigm – eliminating (in a phased manner), legacy funding.
- **Stages 3 and 4 –** SCIP increased the knowledge based by including external-to-the-agency SMEs to the review panels, updated screening evaluation criteria, and truly intend to dedicate newly funded activities to game changing, unique, innovative, and cross-cutting.
- **Stage 5 –** SCIP updated our expectations of funded activities by developing Investment Agreements based on each activity vs Memorandums of Understandings that were CIOs based. These Investment Agreements will be considerably more in-depth and create a more collaborative atmosphere between ORR and the principal investigators and together challenges will be resolved if they arise.
- **Stage 6** – SCIP updated our data collection tool, which will be an on-going iterative process, refined and streamlined our data touch points and will again have external collaboration for regular interval reviews of all activities.

The SCIP 2.0 modernization has been initiated, and the FY24 Call for Proposals has been made available. The anticipated funding decisions will be disclosed in early March.

Suggestions/Comments from the BSC:

- It would be great to have the opportunity to hear about the innovative developments and advancements as these projects progress. Although we are not directly overseeing the projects, it would be valuable to understand how these innovations are transforming the services being delivered. It is crucial to demonstrate that through innovation, we can effectively drive preparedness efforts forward. This would serve as a strong case to advocate for increased focus on similar initiatives. It is important to

acknowledge that relying on traditional methods employed over the past two decades will not suffice in this rapidly changing landscape.

- We should consider the importance of ensuring adequate representation when making decisions pertaining to innovation. It is crucial to ponder whom the innovation is aimed at. Exploring these aspects further with the board will be highly beneficial.
- It might be advantageous for us to engage in proactive thinking regarding potential key events, for example, another Ebola outbreak. We should identify the crucial scientific inquiries that ought to be addressed. We should also foster strong relationships with federal partners and academia through collaboration with these newly established centers. What are the underlying questions that we could try to answer now that are going to help us be able to respond better in a variety of events?
- The challenge is a lot of responses are different; jurisdictions are different. So, we talk about a science-based or science informed practice, but in a response, it is quite difficult. How do we address that and do a better job at that implementation piece?
- Academic public health centers are essential, yet insufficient in addressing public health concerns entirely. It is imperative to emphasize the involvement of STLT departments in these discussions. Regrettably, the prevailing tendency is for academics and universities to primarily focus on the practical aspects and foster an understanding of the scientific framework, inadvertently missing out on crucial insights from STLT health departments. Therefore, there is an urgent need to integrate these entities to ensure comprehensive and effective public health measures.
- We should gain knowledge from regions within the country that consistently face emergencies but tackle them in diverse ways. Certain health organizations that have repeatedly managed emergencies and have noticeably displayed agility in terms of preparedness and responsive. They could impart some of their knowledge and provide practical demonstrations.
- We think about innovation in a very process-driven manner, but it is the workforce that is the most critical piece to innovation. We must have the training and all the other activities that will support the workforce. The biggest challenge currently is that the workforce is leaving. The workforce is tired, fatigued, and some have decided that it's time to do something else. We have had a workforce that has been under assault for many, many years, not just because of the pandemic, but well beyond the pandemic. When we are looking at innovation, we have to really be thinking about what are the lessons that we need to be learning from the very people who are actually departing the field.
- Another element to consider is preserving the principles of this collective wisdom and the history of the workforce when they have departed. The people who were there at the beginning of the pandemic who learned the innovations are no longer in the agency or their seats. How do we catapult or catalyze their wisdom, work, and expertise when preparing our nation for the future? This has to be a part of the innovation piece.
- CDC should assess whether there are lessons learned that can be explore or derive valuable knowledge from the experiences and insights of former CDC personnel, with

the intent of preserving institutional memory and facilitating continuous learning. The Agency should consider extending this practice to other entities beyond CDC as well.
- We need to have academic centers that support the jurisdictions in their region, but somehow define it in such a way that we don't have competing agendas. There should be coordination and integration.
- Invest in something that might have some longevity in its structure or components and focus less on the model itself because it is rare that a full comprehensive model will be able to be sustained. Rather think about sustained impact. Also, include a feedback loop to ensure change or impact is occurring.

Community-Based Solutions and Health Equity Branch

Sarah Lee, PhD, (Acting) Director

The CBSHE mission is to develop, advance, and implement readiness and response sciences to mitigate adverse effects for populations and settings at higher risk, improve the impact of community mitigation during public health emergencies, and advance health equity. The Branch encompasses two teams: Equity and Behavioral Sciences Team (EBST) and Community Mitigation and Special Populations Team (CMSPT). CBSHE has assembled professionals with expertise in health equity and special populations from various areas of the agency. These subject matter experts specialize in populations such as individuals facing homelessness, correctional facilities, pediatrics, and school preparedness. The objective is to detect, consolidate, and distribute evidence-based tactics that are guided by equity and behavioral sciences, both before, during, and after emergencies.

In recent months, CBSHE has engaged in strategic planning and has pinpointed three primary annual areas of emphasis. It is important to note that these focus areas are not exhaustive but rather represent the highest priorities for CBSHE as it progresses as a branch, undertaking the implementation and execution of its work. The identified focus areas include:

1. Nurture and expand the network of population and setting-specific subject matter experts across the agency to support health equity readiness and response efforts
2. Advance CDC's readiness and response to behavioral science priorities, application, and implementation
3. Foster and maintain relationships with external partners to exchange knowledge, identify needs, and work together to address those need

Suggestions/Comments from the BSC:

- One project discussed was the implementation of a scientific methodology to examine how community groups and members can actively participate with their state and local health departments, thereby identifying the most effective ways for them to be involved in the planning and response processes. I truly value the consideration given and the

effort put into determining how we can engage individuals at the community level while strategizing for readiness and response.

- Have there been any identified cases where the CDC has displayed inequitable actions or situations? To achieve equitable outcomes, it is necessary to acknowledge instances where we have fallen short. For instance, by examining why we have been late in certain situations, we can determine if it is due to a lack of skills, conflicting priorities, or a failure to recognize the importance of prioritizing certain individuals at specific times.
- The concept of inequity sometimes gets deflated, and it can get conflated with diversity. However, they are not the same. Ensure that you have provided the opportunity for all people to have a solid response irrespective of their circumstances.
- Define health equity in the context of readiness and response so that you do not get bogged down in what you are trying to achieve.
- There is currently a strong level of trust placed in faith groups and various other community-based organizations that surpasses even the trust in public health entities. It is essential that we do not attempt to figure out everything solely within ORR and CDC today, only to later try and fit these additional groups into the planning process. Instead, we should determine how to incorporate their perspectives and efforts early on, ensuring that response activities become a much more community-driven and partner-driven process. This collaborative approach will be more effective in reaching the very groups that these trusted entities serve.
- Be sure to incorporate response plans for individuals with severe mental illness and consider coordinating with the Substance Abuse and Mental Health Services Administration (SAMHSA) on this issue.

Public Health Readiness and Response Evaluation Branch

Kanta Sircar, PhD; (Acting) Director

The mission of PHRRE is to centralize and lead readiness and response evaluation efforts across the agency, Public Health Emergency Preparedness (PHEP) Cooperative Agreement, and key partners to understand how CDC-wide and ORR investments impact and enable improvements in response readiness. The expertise of PHRRE encompasses various disciplines, including evaluation science, data analysis, and translation science. In addition, it involves the utilization of performance measurement, analytical tools, and data visualization tools. These aptitudes will be employed for both internally and externally funded programs within ORR.

The Division of State and Local Readiness (DSLR) is in charge of assessing response operations and exercises for an agency-level response. During this response, the role of the PHRRE is to provide support. The evaluation and performance management of the PHEP is a collaborative effort between DSLR and DRRS.

The PHEP Cooperative Agreement facilitates the development and enhancement of capabilities within public health departments to effectively address various public health threats. These

threats encompass infectious diseases, natural disasters, as well as biological, chemical, and nuclear-radiological events.

The PHRRE program comprises two teams, the Measurement Evaluation and Translation Team (MET) and the Data Analysis, Support, and Translation Team (DAST). Both teams possess extensive experience in cooperative agreements, specifically in the development of performance measurements, data analysis, and logic models, with a particular focus on the PHEP Cooperative Agreement. The MET team specializes in evaluation and translation science, while the DAST team excels in data management, visualizations, and statistical analysis. These functions were transferred to DRRS from DSLR. PHRRE is well-positioned to provide expertise not only in evaluation for PHEP Cooperative Agreements but also for other cooperative agreements, programs, and initiatives.

For FY24, PHRRE will focus on the following key annual focus areas:

1. Develop and implement a framework to evaluate readiness and response capacity for CDC based upon ORR priorities and the STLT/PHEP readiness and response evaluation framework.
2. Develop tools and processes to enable continuous evaluation and improvement in CDC's readiness and response capacity and investments made by ORR into activities conducted by STLTs, NGOs, and other key partners.
3. Assess CDC investments conducted by STLTs, NGOs, and other key partners to understand how this impacts public health readiness and response.

Response Analytics, Decision Support, and Surveillance Branch

Stephen Soroka, MPH; (Acting) Branch Chief

The mission of the Response Analytics, Decision Support, and Surveillance Branch (RADSS) is to advance situational awareness and response data science efforts to provide reliable, comprehensive, timely, high-quality information on public health threats and emergencies as they are identified, evolve, and require CDC responses. RADSS is structured to integrate various interconnected functions that revolve around scientific approaches to responses. Its primary emphasis lies in establishing a robust data management infrastructure, facilitating data analytics, and enhancing situational awareness.

The program activities and functions of the branch are derived from various divisions within the Agency. The DEO's Situation Awareness Team offers valuable support in public health emergency planning and response efforts by disseminating information to leaders and responders, enabling them to make informed decisions based on scientific evidence. The CDC's Global Disease Detection Operations Center (GDDOC) serves as a centralized unit for monitoring global outbreaks and hazards, ensuring prompt surveillance and response. Additionally, the branch incorporates enterprise platforms such as the Data Collation and Integration for Public Health Event Response (DCIPHER) and HHS Protect from NCEZID, which

facilitate collaborative and highly interoperable environments on routine public health surveillance and response events for use by CDC and their partners. These platforms efficiently collate data, streamline data operations, and empower key decision-makers with actionable insights. The platforms presently function as the central common operating platform for CDC.

The functions within RADSS have been divided into three teams. The first team, known as the Public Health Intelligence (PHI), is tasked with collecting, validating, and distributing information regarding both domestic and international public health risks as they occur and progress through event-based surveillance. The PHI team enhances CDC's readiness to swiftly identify, track, and address sudden public health emergencies.

The role of the Response Data Analytics and Visualization Team (RDAV) is to ensure that the necessary data is readily available and comprehensible for CDC responses. This involves translating, analyzing, interpreting, and disseminating relevant data, including visualization and field reports. RDAV's role also includes offering technical assistance and expertise to efficiently establish and execute response data services for CDC CIOs and both domestic and international partners. This support leverages CDC's extensive knowledge in various areas, such as epidemiology, public health informatics, data analytics, and geospatial science.

Lastly, the Infrastructure and Services Team (IST) is responsible for delivering the necessary infrastructure for managing and upkeeping CDC's common operating platform. Additionally, they offer training in response data science and platform usage, maintain response knowledge management, ensure adherence to response data standards and processes during response events, as well as manage essential data sources and interoperability with other CDC and partner systems to ensure reliable and timely data availability.

To support the mission and expertise accumulated within RADSS, the branch will initially focus on the following key areas:

1. Advance CDC’s Common Operating Platform and Picture to improve readiness and data-informed suggestions and decisions
2. Accelerate interoperability of RADSS' data tools, systems, and analyses
3. Coordinate and enable improvements to CDC’s data readiness landscape across CDC and with CDC partners

Suggestions/Comments from the BSC:

- It is important for STLT partners within the state to possess a thorough understanding and familiarity with the data being collected and analyzed. This collaborative approach is significant not only at the federal level but also at the state and local levels, ensuring unified comprehension and alignment among all stakeholders.

Division of Regulatory Science and Compliance (DRSC): Overview

Samuel S. Edwin, PhD; Director

The Division of Regulatory Science and Compliance (DRSC) consists of three principal programs: the Federal Select Agent Program (FSAP), the CDC Import Permit Program (IPP), and the U.S. National Authority for Containment of Poliovirus (NAC). FSAP and IPP are federal regulatory programs, wherein FSAP oversees the possession, utilization, or transfer of biological agents or toxins that may pose a significant threat to public health and safety. IPP governs the importation of infectious biological agents, infectious substances, and vectors capable of causing communicable diseases in humans. NAC aims to effectively implement and supervise the global poliovirus containment plan in the U.S., thereby minimizing the possibility of poliovirus release.

The Division of Select Agents and Toxins (DSAT) underwent a reorganization on October 1, 2023, which led to its transformation into the DRSC. This reorganization was prompted by evolving needs and structural requirements. Consequently, two teams, Management and Operations, and Policy and Communications were established under the OD, along with four branches: FSAP Operations Branch, IPP Operations Branch, Biosafety, Science, Training, and Expertise Branch (new), and Innovation and Information Technology Branch (new). Some minor changes were made to the existing branches and teams, and the NAC was also incorporated into the new division under the OD. It is important to note that despite the name change, the regulatory authority remains unchanged. One of our primary areas of focus is to enhance cross-training opportunities to foster professional growth among staff and enhance the division's capabilities.

In 2023, the FSAP completed two decades of operation, since its inception following the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002. Regulations were introduced during the year 2003. The FSAP is a collaborative initiative between the CDC and the Animal and Plant Health Inspection Service, bolstering safety and security standards in laboratories across the country. Consequently, the FSAP has positively impacted and enhanced the overall work environment in these facilities nationwide.

Dr. Edwin highlighted some of the program metrics of the FSAP. Since 2003, there have been:

- No confirmed thefts of a select agent or toxin from a registered entity
- No deaths among laboratory workers
- No reported cases of illness or death in the general public due to work with select agents and toxins in regulated laboratories
- No animal or plant disease outbreaks due to work with these agents in regulated laboratories

DRSC hosts the Responsible Official (RO) webinar series that covers various topics of interest from the community of laboratories that it oversees. There are normally six webinars per year and all topics are pertinent to the containment labs. Below are a few of the topics covered in the series for 2023.

- BSL-3/ABSL-3 Verification Process and Requirements
- BSL-4/ABSL-4 Laboratory Verification Policy
- SARS-CoV/SARS-CoV-2 Chimeric Viruses Guidance Overview
- Animal and Plant Health Inspection Service (APHIS)/CDC Forms 3 and 4
- RO/ARO Roles and Responsibilities
- Drills and Exercises
- eFSAP Information System User Discussion
- History and Evolution of the U.S. Federal Select Agent Program

The rise in biosafety and biosecurity measures has led to significant legislative action in Congress. According to the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, which was issued on December 29, 2022, the CDC is obligated to inform Congress about any instances of theft, loss, or release of select agents and toxins at federal laboratory facilities. An initial notification must be provided within 72 hours of the incident being reported, followed by updates within 14 days if necessary. The DRSC is fulfilling its obligation to submit these reports, along with voluntary cooperation received from their U.S. Department of Agriculture (USDA) colleagues.

The 8th annual report for the FSAP was released by DRSC in November 2023. This report offers a detailed overview of the program's regulatory activities and examines the regulatory functions performed by the program. It also assesses compliance with the select agent regulations in laboratories nationwide throughout 2022. Additionally, the report emphasizes FSAP's continuous efforts to collaborate with the regulated community in order to improve regulatory compliance. Notable figures and statistics from the FSAP 2022 Annual Report include the following:

- 234 registered entities
- 197 inspections conducted
- 8,516 active individual security risk assessments
    - Denied access for 16 individuals.
- 0 releases resulted in illness, death, or transmission among workers or to the outside of a laboratory into the surrounding environment or community (out of 170 reports)

The publication of the 2022 FSAP Inspection Report took place in July 2023. This report is an annual evaluation of the timeliness data related to inspection reports. Its objective is to provide laboratories with feedback on their performance in meeting the program's goals. In 2022, all 198 final inspection reports were sent to entities within the desired timeframe of 30 business days.

Dr. Edwin briefly highlighted certain statistics on the Import Permit Program. This program concerns non-select agents that enter the United States and are primarily utilized for purposes such as the development of medical countermeasures, enhancement of diagnostics, training, education, and research. Out of the total 3,000 permits reviewed, 2,794 permits were issued. Among these, 429 permits were associated with SARS-CoV-2. Additionally, a total of 217 inspections were conducted, focusing on risk-based assessments to ensure the presence of adequate biosafety measures.

The NAC has received the HHS Secretary's Award for Distinguished Service for the implementation of policies that operationalize the containment process for the U.S. The NAC has reduced the number of facilities retaining wild poliovirus type 1 from 44 to 22 (50% reduction).

Dr. Edwin provided an overview of the challenges and opportunities faced by divisions. DRSC presently employs a list-based oversight system with 68 agents. Notably, there are certain areas of concern, particularly the 15 agents listed in the dual-use research of concern (DURC) category. The current experimental definitions for DURC are excessively wide-ranging in relation to the existing regulatory framework. Federal regulations do not cover entities engaged in high-risk research involving serious or lethal disease agents (non-select agents) resulting in increased virulence or transmissibility. As the field of synthetic biology progresses, the conventional taxonomy boundaries will become more ambiguous, making it increasingly challenging to apply a traditional list-based approach in this domain.

The division is seeking assistance from the BSC to provide insights on two questions.

1. Is a list-based regulatory approach obsolete?
2. Should risk-based regulatory oversight be pursued with enhanced focus on those facilities with high risk?

Division of State and Local Readiness (DSLR): Update

Christine Kosmos, RN, BSN, MS; Director

The Division of State and Local Readiness (DSLR) collaborates with health departments in STLT jurisdictions across the United States to enhance and maintain their readiness and capabilities. These efforts have been in progress since the events of 9/11, and DSLR actively engages with its recipients to foster, enhance, and uphold their preparedness and response capacities.

The division has morphed several times over the 20-plus years that it has been in existence, and it is changing again. The change is based on the lessons learned from the coronavirus disease (COVID-19) as well as other responses that it has been working on over the past four years, the listening sessions DSLR has held with state and local partners as well as federal partner entities. The division has learned from its partner agencies what DSLR needs to undertake to provide valuable service to state and local partners, and that feedback from the state and local partners

has also been incorporated into DSLR's strategic process thereby informing the division's work as it moves forward.

DSLR's future vision, not only enhances the conventional 15 PHEP capabilities that the division has previously aided STLT health departments in achieving but also incorporates a more intentional emphasis on preparedness for immediate response. This involves ensuring that states and local authorities can put response plans into action effectively and develop exceptional response operations.

DSLR has implemented the Public Health Response Readiness Framework intending to enhance STLT response operations in 10 crucial areas and transform them into highly efficient responders. Additionally, the division has used the additional PHEP funding it has received over the years to increase PHEP support for local health departments, including those in rural and frontier regions, to enhance their preparedness. Furthermore, the division ensures that state and local health departments are prepared for large-scale responses that necessitate the dispensing, administration, and delivery of medical countermeasures. Another important focus is to provide comprehensive technical assistance to STLT jurisdictions through consultation, guidance, and quick access to CDC subject matter experts. Lastly, DSLR is committed to strengthening the STLT workforce by assigning CDC staff to public health departments, thereby expanding the footprint of CDC field staff across the U.S. and its territories.

The existence of 15 preparedness and response capabilities can be seen as the preparations made before a race, whereas the Response Readiness Framework offers guidance and next steps during the race, leading to implementation. This framework has been developed through collaboration with DSLR partners and honed over the past few years. It now serves as the standard for excellence in response operations. The framework adopts a collaborative approach to readiness, actively involving stakeholders in supporting jurisdictional partners. It utilizes the expertise of ORR, CDC subject matter experts and national partners.

The framework was constructed through a strategic evaluation of DSLR that included the following activities.

- Leveraged "Next Generation of PHEP" strategic planning to inform new program design
- Designed Response Readiness Framework to define excellence in response operations and response capabilities
    - Stood up 10 Response Readiness Framework work groups, producing 30 work plans
- Established new PHEP evaluation strategy –with a focus on response readiness
- Developing new, improved PHEP Notice of Funding Opportunity or NOFO
    - Participating in the HHS NOFO 100 pilot
- Updating the PHE exercise framework to focus on NOFO strategies and activities
    - Chemical, biological, radiological, nuclear, explosives (CBRNE) readiness
    - Large-scale MCM readiness
- Building new IT system –Ready CAMP – based on a platform used by other CDC programs

- Reorganized DSLR to better support Response Readiness Framework priorities and activities
- Expanded approach to technical assistance
- Established a new branch focused on response and supporting STLT jurisdictions
    - Health department liaison officers are now permanent DSLR staff
- Renewed focus on grants management, reduction of recipient burden, administrative preparedness excellence, and innovation
- Transitioned most of the existing evaluation branch to the new ORR Division of Readiness and Response Science to support the new ORR strategic direction and CDC Moving Forward initiative
- Continued field staff expansion, adding new Preparedness Field Assignees and Career Epidemiology Field Officers

A new PHEP NOFO for 2024 has been released. DSLR has outlined the key factors for the success of this NOFO, encompassing the integration of the Response Readiness Framework and the implementation of a simpler evaluation strategy. To enhance efficiency, the NOFO will be more streamlined, utilizing a modified HHS template that aims to reduce administrative burden. Lastly, the requirements will be explicitly defined to ensure clarity.

Division of Emergency Operations (DEO): Update

Mark Frank, MPH; Deputy Director

The Division of Emergency Operations (DEO) leads and manages CDC's Emergency Management Program. This program facilitates and ensures CDC’s preparedness, readiness, and response capabilities toward public health threats. The EMP relies on three core areas, people, place, and processes. People refer to the workforce that not only supports the daily operations within CDC’s Emergency Operations Center (EOC) but also the subject matter experts from across the Agency who lead and support CDC’s response efforts. Place has evolved beyond the conventional EOC and expanded to encompass virtual platforms that are used during emergency responses. Lastly, processes cover emergency response plans and standard operating procedures that guide CDC’s emergency response operations.

There have been some structural changes resulting from the reorganization of DEO.

- The Plans, Training, and Exercise and Evaluation Branch has been renamed as the Plans, Exercise, and Evaluation (PXE) Branch. PXE's mission now lies in the development of plans, execution of exercises, and evaluation of CDC’s response capabilities, both during training exercises and real-world responses.
- The Logistics Support Branch has officially been renamed as the Resource Support Branch (RSB). This change aligns with the branch's primary mission of providing for a broad range of support capabilities during emergency responses. RSB has also absorbed some of the functions from the Global Rapid Response Team (GRRT) that were previously in CDC’s Global Health Center.

- DEO has established an Emergency Management Training and Capacity Development Branch (EMTCDB) This branch now includes the Training Team from the previous Plans, Training, and Exercise and Evaluation Branch, and it also has absorbed the Global Emergency Management Capacity & Development Team. This branch is responsible for supporting training endeavors at CDC and collaborating with global partners to develop emergency management programs with Ministries of Health and National Public Health Institutes. DEO has established the Emerging Threats and Response Coordination Team within the Office of the Director. This team was originally located in the National Center for Emerging and Zoonotic Diseases within the Division of Preparedness and Emerging Infections. That team engages with federal and international partners to prepare for and respond to suspect or confirmed intentional threats or incidents, involving biological, chemical, or radiological agents.

As part of the reorganization, other functions have moved from DEO to other offices within the CDC. The Emergency Risk Communications Branch (ERCB) was relocated to the CDC Office of Communication and was renamed the Office of Emergency Risk Communication (OERC). DEO's Situational Awareness team was moved to a branch in ORR's new Division of Readiness and Response Science (DRRS).

DEO is working on two major initiatives that will enhance and improve CDC's response capabilities. The first initiative is called CDCReady, which is a new, cloud-based IT platform that consolidates a variety of IT systems and applications to better enhance emergency operational capabilities and response analytics capacity. CDCReady modernizes EOC-related functions and addresses the needs of responders who support CDC's emergency response activities.

DEO's second initiative, CDCReady Responder is an agency-wide response staffing and training program that will enroll most, if not all, CDC staff into one or more cadres that align with their knowledge, skillsets, and experience. CDCReady Responder is changing how the agency identifies and prepares staff to respond ahead of public health emergencies. Ultimately, it will build a diverse workforce of qualified and trained responders who can rapidly establish and sustain response activities when emergencies occur.

DEO asked for the BSC's assistance in answering the following questions:

- The updates we provided today focus on the strategic preparedness efforts DEO is leading for CDC and, as such, will contribute to our all-hazards readiness posture. Are there particular threat areas that an all-hazards approach may not fully prepare us for, which DEO should consider when building CDCReady functionality, enrolling and preparing staff through CDCReady Responder, or shaping our other initiatives?
- Thinking about skills and expertise needed to support public health responses at all levels and across multiple partners, what future areas might the BSC suggest helping CDCReady Responders be most prepared to support jurisdictions and other partners when emergencies occur?

As a result of limited time, BSC members will directly respond to the divisions regarding any queries raised at the conclusion of their presentations.

Private-Public Partnerships: Presentation and Discussion

Joanne Andreadis, PhD; Associate Director for Science

The significance of public-private partnerships was emphasized during this session. One area that demonstrated the importance of such partnerships was laboratory response activities during COVID-19. The pandemic, with its rapid and extensive spread, truly highlighted the critical role of these partnerships to enhance public health services, improve accessibility, and establish multiple layers of risk management to eliminate vulnerabilities when dealing with complex and uncertain response activities. Dr. Andreadis provided introductions for the session speakers.

PPPs for Surge Testing, Test Development, and Test Modification

Reynolds M. Salerno, PhD; Acting Director, Center for Laboratory Systems and Response

In February 2023, the ACD Laboratory Workgroup released a report that conducted a thorough assessment of the CDC's laboratory operations, taking into account the insights gained from the pandemic and mpox responses. The report encompassed ten suggestions put forth by the workgroup. However, for the purpose of this session, Dr. Salerno emphasized a select few.

- Establishment of senior leader for laboratories, reporting to the CDC Director, with major responsibility and authority for laboratories at the agency.
- Cultivate and foster a culture of laboratory quality through the adoption of a comprehensive clinical laboratory quality management system across the agency.
- Involve external experts in its review and deployment process for clinical tests for pathogens with pandemic potential.
- Consolidate key laboratory support functions into a new Center, focus on clinical laboratory quality, laboratory safety, workforce training, readiness and response, and manufacturing.
- Create and exercise plans for developing tests for novel public health challenges.
- The CDC should incorporate redundancy into the national responsibility for test development.

As part of the Moving Forward Initiative (2021) led by Dr. Walensky, the Center for Laboratory Systems and Response (CLSR) was established and placed within the Office of Lab Science and Safety at the CDC. This marked a significant milestone as it is the first dedicated center within the agency solely focused on laboratory activities. The primary objective of the CLSR is to enhance and streamline laboratory diagnostics, while improving the framework for laboratory readiness and response. The center was officially activated on October 1, 2023. Currently, it consists of the Division of Laboratory Systems, which is responsible for engaging with the public and clinical laboratory community, as well as aiding in the development of laboratory system capacity. In the upcoming fiscal year, FY24, the Division of Core Laboratory Services and

Response will also be transitioned to CLSR. The present location of this division is NCEZID, supporting the operations of all CDC laboratories. The integration of these two divisions under the CLSR will strengthen readiness and response throughout CDC and will foster collaboration with clinical and commercial laboratory partners. The following priorities have been outlined for CLSR.

- High-quality laboratory science at CDC
- Reliable laboratory diagnostics for outbreaks and harmful exposures
- Extensive engagement with public and private-sector partners

Several activities are occurring at CDC to advance laboratory quality. One is to revise CDC's plan to develop and deploy emergency diagnostic tests. In 2023. CDC published its first comprehensive Quality Manual for Microbiological Laboratories, which established a rigorous test validation process for CLIA laboratories at CDC. CLSR now has responsibility for the Enterprise Laboratory Information Management System. This system handles specimen management and test result reporting for all CDC ID laboratories. Also established was a new comprehensive electronic quality management system, which will track standard quality indicators in all CDC laboratories. Lastly, the new Infectious Disease Test Review Board independently evaluates all new ID tests before distribution outside of CDC.

The Laboratory Response Network (LRN) represents the foundation of CDC's laboratory preparedness and response initiatives. Established in 1999, this network is dedicated to swiftly addressing biological and chemical dangers through laboratory analysis, enabling crucial determinations concerning public health and safety. Consisting of 120 laboratories nationwide, this network has proven to be an invaluable resource for both CDC and public health.

CLSR is working with the LRN to improve public health readiness and response. The center is working with specific advanced LRN laboratories for a supplemental review of new CDC tests. They are also collaborating with the LRN to support new test development, validation, and modification of existing CDC tests. Dr. Salerno presented LRN’s priority assay development projects for FY24, which include the following:

- Update emergency use authorizations (EUAs) for two pathogens.
- Submit to FDA for 510(k) and de Novo clearance for several assays.
- Position susceptibility tests and lower-priority assays in Pre-EUA status.
- Remove those LRN assays for which large-scale public health testing is most likely not needed and rely on CDC programs for diagnostic testing capacity.

Following the Zika outbreak, the CDC acknowledged the necessity of enhanced cooperation with the commercial laboratory industry. To foster greater partnerships in the laboratory domain, the CDC established a memorandum of understanding (MOU) on surge diagnostic testing during public health crises. In 2023, the CDC modified and upgraded the MOU, and regular monthly meetings are conducted between the CDC and its partners to emphasize the

importance of bolstering relationships and streamlining processes for handling public health emergencies. The partners in this MOU are ACLA, AdvaMed, AMP, APHL, Office of the Assistant Secretary for Preparedness and Response (ASPR), College of American Pathologists, COLA, Council of State and Territorial Epidemiologists (CSTE), NILA, and the FDA. New partners are consistently incorporated regularly.

A call has been made by numerous scholars, experts, and esteemed publications to improve the definition and functioning of the laboratory system in the event of a major public health crisis. In response, Gryphon Scientific was granted a one-year contract on September 18, 2023, to collaborate with the CDC and other departments within the agency, as well as the laboratory community, to clearly articulate the roles and responsibilities within the laboratory system during an emergency response. The project encompasses three main objectives. Firstly, it involves gathering and analyzing information from the clinical laboratory survey, after-action reports, and internal and external subject matter experts to develop a comprehensive preparedness roadmap. Secondly, the focus is on creating a roadmap that establishes partnerships with private-sector laboratories and other relevant entities to meet the requirements during a public health emergency effectively. Lastly, the project aims to explore mechanisms for formal agreements with partners, such as MOUs or contracts.

CLSR has also released two requests for information (RFI). The first is for public-private partnerships to support surge testing and was published on October 10, 2023. The purpose of the RFI was to ascertain the level of interest of private sector laboratories to inform and establish pre-event collaborations. The objective was to understand the type of support, costs, and resources needed to provide test development support and surge diagnostic testing before and during a public health emergency and determine the best methods to execute these arrangements.

The second RFI is for public-private partnerships to support test development and production. This RFI was published on October 31, 2023, and its purpose was to ascertain the level of interest of private-sector test developers to inform and establish pre-event collaborations. The objective was to understand the type of support, cost, and resources needed to enhance diagnostic test production capacity before and during a public health emergency. So far there have been 21 responses received from the laboratories and companies. Those responses are being collated and will be used to develop a request for proposal (RFP) for the private sector. However, there is currently no funding available at this time for this endeavor, but CLSR is estimating how much funding it needs to engage the private sector laboratories as well as reagent manufacturers.

1. CLSR is looking for feedback and suggestions from the BSC regarding three questions.
2. Do you have any specific feedback on the initiatives discussed in this presentation?
3. What else can we do to improve public-private partnerships to benefit readiness and response?
4. What suggestions do you have for CDC to get the funding we need to formally engage public and private-sector partners on readiness and response initiatives?

Pharmacy Public Private Partnerships for Public Health Preparedness and Response

Joe Miller, MBA, PhD; Increasing Community Access to Testing (ICATT) Program Lead, Associate Director of Laboratory Science, Division of Core Laboratory Services and Response

The objective of the Increasing Community Access to Testing (ICATT) Program is to provide fair access to healthcare services to marginalized communities in times of outbreaks. This objective is achieved through collaborations with pharmacies. The ICATT program encompasses four specific subgoals or activities.

1. Equitable COVID-19 diagnostic testing for increased-risk communities, with a focus on medical necessity and uninsured people.
2. Surge testing in state and local jurisdictions in times of high testing need.
3. Testing for unaccompanied minors at the southern border.
4. Providing management oversight for pharmacy-based vaccinations.

The ICATT team is presently based in the ORR and comprises of 11 full-time employees (FTEs). Its structure encompasses five teams, namely Pharmacy, Data, Quality, Contracts, and Operations. The ICATT program extensively relies on data for its operations, necessitating substantial data management and analysis. At present, each team member is on a one-year assignment, with an anticipated reduction in the number of FTEs as the workflow diminishes.

The ICATT operates approximately 10,000 active testing sites across all 49 states (North Dakota), including Washington, D.C., and Puerto Rico. Each week, these sites complete anywhere from 5,000 to 10,000 tests. To prioritize the distribution of resources, the sites are selected based on social vulnerability, urbanicity, and accessibility to testing. The sites mainly consist of pharmacies and clinics. Through contractual agreements, ICATT can offer a range of testing options, including antigen, NAATi Laboratory, COVID/Flu multiplex, and over-the-counter testing. ICATT also collaborates with the ASPR and FEMA to provide surge testing, although it is not expected to be necessary. On the Southern Border, there are eight testing sites dedicated to supporting unaccompanied children entering the United States. Additionally, 24,000 sites are participating in the Bridge Access Program, administering vaccines.

The ICATT program, which was previously located in the Office of the Assistant Secretary for Health (OASH) and then ASPR, has had multiple contracts. Since its establishment in CDC, the program has engaged in competitive contracting and has partnered with providers such as Walgreens, CVS, Rite Aid, Quest, and eTrueNorth. CVS and Walgreens are major contributors to the ICATT's testing and vaccination services, with a significant presence at various testing sites. These network programs offer both laboratory-based and point-of-care testing capabilities. While CVS primarily focuses on antigen testing, Walgreens specializes in NAAT point-of-care testing for COVID. The role of eTrueNorth is to facilitate communication and collaboration between the program and independent laboratories.

The ICATT data system, built on Palantir technology, serves multiple government partners across diverse domains. It facilitates surveillance, and research initiatives, acquiring insights into the current COVID scenario, assessing vaccine efficacy, and monitoring COVID variants.

ICATT has established partnerships with numerous federal agencies due to its extensive data resources. However, the program faces challenges in allocating sufficient time for analyzing all the available data and forming additional partnerships to enhance the dissemination of information regarding testing and vaccine responses. Nevertheless, efforts are being made to prioritize and expand these activities in the future.

In a simplified manner, Dr. Miller explained the ICATT's warm base principle. This approach entails minimizing service scale to the bare minimum necessary while still ensuring the presence of essential testing capabilities, data systems, and prompt responsiveness to public health crises. The warm base revolves around three fundamental components. Firstly, establishing a foundational level of federally supported testing. Secondly, sustaining the capacity to generate surveillance data that bears epidemiological importance. And finally, constructing a mechanism that facilitates swift escalation to counteract future threats.

The current program is in the process of assessing its course of action considering preparedness and response. It is deliberating whether to focus on supporting testing, acquiring data, or maintaining data systems. The availability of funding until May 2025 will greatly influence the program's capabilities. The BSC has been asked by ICATT to aid in addressing the following inquiries:

- Where does the program best fit within the agency?
- How should the ICATT program scale (including funding) after the current contracts expire on May 31, 2025?
- Does a warm base strategy make sense for ICATT?
- Between responses, what preparedness activities should ICATT pursue?
- What should be the Scope for ICATT?
    - Testing, vaccinations, distribution of therapeutics, telemedicine, etc.?
    - Should ICATT continue to support the uninsured?
    - Include resources for other pathogens?
- How can ICATT leverage partnerships with other federal, state, and local governments?

Suggestions/Comments from the BSC:

- The fact remains that the resources are simply not there or scarce. While I am a strong proponent of dual use, it is unrealistic to assume that personnel and technologies can seamlessly function when abruptly deployed during emergencies. Continuous utilization and maintenance are essential. Whether implementing smaller or larger surges, that aspect needs thorough consideration.

- In terms of scaling the ICATT program, I believe that those of us who have an equity lens perspective would strongly support it. We might even consider expanding the program to include the underinsured and prioritize those who have historically been overlooked. Additionally, it is worth mentioning the significant utilization of the program by tribal communities. These communities have played a remarkable role in addressing the challenges posed by the pandemic, not only for their populations but also for the surrounding communities. Whether it is through the Indian Health Service (IHS) or other means, it is important not to overlook their contributions.
- One of the major obstacles we face is determining how to motivate the private sector to actively contribute to resolving the issue, rather than hastily joining in during times of crisis without a coherent approach. Unfortunately, I do not have a definitive solution for this. However, as you mentioned, perhaps one idea would be to establish strong relationships and present the rationale for collaboration, which can help convey the shared benefits of working together toward a common good.
- During the H1N1 outbreak, Texas successfully implemented an efficient approach by collaborating with a private company to assign barcodes to the strategic national stockpile. Subsequently, this stockpile was securely housed in one of their warehouses and promptly dispatched to pharmacies throughout the state. Any individuals who fell ill were able to conveniently visit their local pharmacy, just as they would for any other medical condition, and obtain the necessary medication directly from there. This was a better alternative to delivering large pots of money or medications.
- The focus has primarily been on COVID-19 at a national level, with resources allocated, but it is crucial to acknowledge the importance of being able to swiftly expand testing and vaccination efforts within local communities or states, especially for individuals who are uninsured or have limited insurance coverage during outbreaks such as measles, hepatitis A, or even influenza. I am unsure of the degree to which states and localities currently possess the ability to carry out such measures or have established the necessary local connections, knowledge, and resources as those of CDC. So, a case could be made that this holds significance not only for COVID or future major national issues but also as a regular occurrence on a community level. It applies to any outbreak that might necessitate community-wide testing or vaccination, for which pharmacies may well play a crucial role. However, presently, there is a lack of capacity to efficiently expand such services.
- The pharmacies can play a significant role in assisting with the identification and outreach of populations who are uninsured, underinsured, or hard to reach. By informing individuals about the availability of pharmacy-based resources, even those without adequate insurance coverage can access these resources. Pharmacists can then determine whether there is an insurance company to bill or explore alternative funding options. Therefore, it is not necessary to specifically identify these individuals, but rather establish accessible locations where they can receive immunization or testing services.
- Unfortunately, in the urban core, CVS and other similar pharmacies are either nonexistent or their presence is not sufficient to make a substantial impact. I would like

to emphasize the importance of considering larger establishments that can offer this service on a wider scale.

- There exist numerous models, beyond the realm of public health, through which the uninsured and underinsured can be reached. By collaborating with small businesses and the food industry, a significant portion of these populations can be effectively targeted. Consider these anchor partners as potential avenues for engagement.
- What this did is reveal that there is a definite gap in the structure of services to the most disadvantaged to marginalized populations in society. So. how do we take that and the lessons learned to really rethink our model of delivery? I think you have an opportunity to inform the larger system of health delivery in this country. And I hope you take it beyond the walls of CDC.
- I would be very interested in an economic analysis of what this meant to those partners. I know I can't walk in a CVS and just walk out with one thing, even if I am just pick up a prescription. I am going to buy something. I think they benefited from being a partner in this and not only from $50 million or so that was provided through this agency. I think they had an economic return. And I think capturing that for the business community would be really important.
- Public expectation and demand has changed. It is not just about how government is doing things. It is what the public now expects we will deliver. And I think that is an important part of your equation.
- I think we need to rethink pods a little bit and when we would use them as they currently exist. The whole model of combining vaccination, testing and treatment seems very powerful in one place, in a very distributed way across many different communities. That is something that we have to think about as part of our arsenal.
- Consider integrating telehealth with the pharmacy network as part of our everyday healthcare. Instead of a traditional visit, patients could visit their pharmacy, where they could have a blood draw, and the samples would be sent out for testing. Simultaneously, patients could engage in a telehealth visit, during which healthcare professionals would have access to the test results and provide necessary guidance based on the data. This approach holds potential in shaping the future model of healthcare by contributing to the development of a sustainable pharmacy network. Moreover, in times of crisis or emergency, the pharmacy network can serve as a reliable foundation for growth, scalability, and expansion.
- There has been lot of the discussions around binary test results. So, was it COVID? Yes or no? And if the answer is yes, there are a host of solutions. But if it is no, the public has no idea what it is. So, what do they do? What if they further test for flu and RSV and the results are still negative? I think this gets back to laboratory science to continue to accentuate the focus on even better laboratory detection systems that are not just binary with yes or no answers but also really give the public a better understanding of their condition.

Public Comment

No public comments were made.

Closing Remarks

David Lakey, MD; Chair, BSC, ORR

Before adjourning, Dr. Walke opened the floor for closing comments, thoughts, and reactions.

- Update on the train derailment response.
- Include a presentation on the CDC DMI strategies and how they all fit together.
- Priority action progress.

Adjourn

With no further business to be covered, the meeting was adjourned at 4:14 PM EST.

BOARD OF SCIENTIFIC COUNSELORS (BSC)
OFFICE OF READINESS AND RESPONSE (ORR)
MEETING
FRIDAY, JANUARY 26, 2024
VIRTUAL/IN-PERSON

Roll Call, Welcome

Ian Williams, PhD, MS; Deputy Director, ORR; Designated Federal Official, BSC, ORR

The BSC meeting began with roll call by Dr. Williams to ensure quorum was established. Dr. Williams monitored attendance and quorum was maintained throughout the meeting.

Dr. Williams also reviewed the BSC responsibilities, as per its charter, and the conflict-of-interest waivers. Members were requested to identify any conflicts and no conflicts were identified.

Discussions would be facilitated by Dr. Williams. If voting was required only the Special Government Employee (SGE) Members and Ex Officio Members would vote.

BSC Members present:

Dr. David Lakey
Dr. Julie Fischer
Dr. John Lowe
Dr. Phyllis Meadows
Dr. Umair Shaw
Dr. Kristin DeBord
Dr. Hilary Marston
Ms. Michele Askenazi
Dr. Benjamin Chan
Dr. Christina Egan
Dr. Alexia Harrist
Dr. Emily Burke

The meeting was called to order at 9:02 AM EST before proceeding to the first presentation.

Polio Containment Workgroup (PCWG) Updates/Voting

Lia Haynes Smith, PhD; NAC Director

Dr. Haynes Smith provided a concise overview of the efforts carried out by the U.S. National Authority for Containment of Poliovirus (NAC) to combat and confine the virus. The three poliovirus types, namely 1 (PV1 or WPV1), 2 (PV2), and 3 (PV3) were addressed in the presentation. PV2 was successfully eliminated in September 2015, followed by the eradication of PV3 in October 2019. Presently, PV1 remains the sole active poliovirus in circulation.

The Polio Eradication Campaign was initiated in 1988 to curb the rampant spread of the disease. During that period, the annual count of polio cases exceeded 350,000. However, considerable progress has been made, with the number reduced to a mere 120 cases per year by 2020. Presently, PV1 remains prevalent in only two countries, namely Afghanistan and Pakistan, while it has successfully been eliminated in five out of the six regions recognized by the World Health Organization (WHO). Nevertheless, despite the noteworthy decline in PV1 cases, there persist challenges concerning the circulation of vaccine-derived poliovirus (cVDPV) of types 1 and 2.

The Global Polio Eradication Initiative (GPEI) is a partnership between WHO, CDC, United Nations International Children's Emergency Fund (UNICEF), Bill and Melinda Gates Foundation, Rotary, and GPEI. This collaborative group devised a new eradication strategy to address the dual emergency of WPV1 and cVDPV outbreaks. A recent review was conducted on their efforts by an independent monitoring board, which determined that progress is off track for meeting the goal of WPV1 eradication and the cVDPV goal will be missed. However, despite delays to the timeline, the numbers are closing in on zero, and the timeline has been adjusted based on the delays by the Global Certification Commission. The eradication of the WPV1 milestone is set for 2026 and cVDPV for 2028. These milestone delays directly impact poliovirus containment efforts.

In 2018 the member states of the WHO passed unanimously a resolution that prioritized global poliovirus containment. This resolution urged international commitment to expedite the full implementation of containment requirements as described in WHO's Global Action Plan (GAP). GAP is the containment standard and it is described in four pillars:

- Identify facilities in every country that might have poliovirus material.
- Destroy any unneeded material.
- Facilities that feel like they have scientifically valuable material should transfer those materials to facilities that have been certified by WHO to contain the material.
- Complete the certification process to become a designated poliovirus essential facility (PEF), if material needs to be retained for an extended period of time.

Any country that has a facility that would like to retain poliovirus materials long-term must designate a national authority for containment. Twenty-two countries have PEFs. Of the 22 countries, they are hosting roughly 69 PEFs. The U.S. has the largest number of PEFs.

The NAC was formed in 2017 within the Office of Public Health Preparedness and Response (OPHPR) with the aim of containing poliovirus. In 2018, the Acting Assistant Secretary of HHS officially designated the poliovirus containment activity as the U.S. National Authority for Containment of Poliovirus. Its primary responsibility is to ensure the risk of poliovirus release in U.S. facilities is minimized. Since its establishment, the NAC has achieved the following accomplishments:

- Identified over 16,700 laboratories to participate in its national survey, which identifies facilities that may have poliovirus materials.
- Encouraged destruction of over 230,000 vials of poliovirus material.
- Transferred over 1300 vials or containers of poliovirus material to PEFs.
- Audited more than 85 facilities.
- Reduced the number of facilities retaining PV2 and PV3 materials down from 32 to now less than five.
- Created 13 guidance and policy documents in conjunction with the Polio Containment Work Group (PCWG) that have been endorsed by the BSC.
- Responded and participated in three polio outbreak simulated exercises.

There are over 18 facilities that currently hold WPV1 material. While this indicates a decrease in the number of facilities with WPV1 (by over 50%), it is still a cause for concern for the NAC. The primary objective of global initiatives is to expedite containment measures, thus it is crucial to motivate these facilities to undergo containment certification before WPV1 eradication is achieved.

The NAC released its first publication, which was accepted, and it described the establishment of the U.S. NAC and its activities to implement containment in the United States.

The GAP was first published by WHO in 2014 and is the containment standard that defines the strategies to minimize poliovirus-associated risk after type-specific eradication of wild viruses or cessation of oral polio vaccine. It is now on its fourth edition after revisions added in 2022. It contains 14 technical element/requirement categories for containment. Only long-term PEFs may handle PV2, WPV3, and VDPV3 infectious materials post-eradication and must follow the requirements established in GAPIV. Official finalization of the document is expected to occur soon. Below are the 14 elements for GAPIV containment:

1. Biorisk management system
2. Risk assessment
3. Worker Health Program
4. Competence & Training

5. Good microbiological Practices
6. Clothing & Personal protective equipment (PPE)
7. Security
8. Facility Physical Requirements
9. Equipment & Maintenance
10. Inventory
11. Waste management, decontamination
12. Transport Procedures
13. Emergency response
14. Accident/incident investigation

The updated version of the GAPIV standard brings forth distinct challenges for both the NAC and U.S. PEFs. One notable challenge is Element 1, which focuses on biorisk management and encompasses approximately half of the GAPIV standard requirements. This particular element is a novel concept (i.e., biorisk management) for U.S. facilities, which may pose difficulties when it comes to implementation. As an illustration, certain facilities might need to establish a dedicated biorisk management committee, with well-defined roles and responsibilities spanning across all levels, from top management to the staff executing the tasks. Additionally, there must be a well-defined process in place to gather conclusive data that showcases continual improvement. These metrics, timelines, and qualifications must also apply to the facility's suppliers and vendors.

One additional obstacle is Element 2, which involves conducting thorough risk assessments using established methodologies such as failure mode and effective analysis (FMEA). These risk assessments are necessary throughout the program and its various components. Elements 4 and 5, which encompass competency and good microbiological techniques, also present challenges. While training has always been a crucial aspect of high containment programs, GAPIV now mandates that PEFs establish competency standards for every individual involved. This will undoubtedly require efficient coordination and meticulous documentation for all personnel. Lastly, Element 8 focuses on facility requirements, including heating and cooling systems as well as exit showers. The specifications outlined in this element are more encompassing compared to the requirements set by the Environmental Sciences Laboratory (ESL4).

David Lakey, MD; PCWG Co-Chair and BSC, ORR

Dr. Lakey began by describing the policy-making document review procedure at CDC. When crafting a new policy, the NAC collaborates with the PCWG for evaluation and suggestions. These evaluations and suggestions are then relayed to CDC's subject matter experts. Subsequently, the PCWG reviews the proposed changes, which are subsequently presented to the BSC for their assessments and suggestions. Once the BSC completes their review, the policy documents undergo evaluation by PEFs to gather their feedback and comments. Taking into account the received suggestions, the NAC makes necessary updates to the policies before submitting them to CDC for clearance and distribution. Ultimately, the finalized policy

documents are publicly shared on the NAC website, as well as with the PEFs and WHO. Only if there were any substantial changes will the policy documents be first reexamined with the PCWG before going back to the BSC for reapproval and then continuing to move through the remaining steps of the cycle to gain CDC clearance and distribution.

The PCWG membership has undergone significant changes since presenting to the BSC in November 2022. As of now, there are two newly appointed co-chairs and two additional members-at-large. One of the co-chairs holds the position of Professor of Sociology and Emergency Response, while the other serves as the Vice Chancellor for Health Affairs and Chief Medical Officer for the University of Texas System.

The expertise within the membership encompasses various areas, including two professors specializing in biorisk communication. Additionally, it has a federal government security advisor and a federal government polio project reviewer/manager, representing the states of Colorado, Washington, DC, Illinois, Ohio, Pennsylvania, and Texas.

The NAC has successfully finalized and released the Interim Potentially Infectious Material (PIM) Guidance for Laboratories and Non-Laboratories on its official website in May 2023. Additionally, they have established a Policies page on the NAC Website, with its launch scheduled for March 2024. These aforementioned documents specifically pertain to GAPIII, which marks the third edition of the Global Action Plan. Currently, the process has commenced to update all 11 NAC policies in accordance with the new GAPIV requirements. These updated policies will also be made available on the NAC website once the revisions have been completed. Notably, the three policies, namely Risk Mitigation Strategies for Work with PV Infectious Materials, Storage Outside of Containment, and Personal Protective Equipment and Hand Hygiene, have already been successfully updated in alignment with GAPIV. The BSC has reviewed and approved earlier versions of each of these documents.

In spring 2024, the NAC and PCWG are scheduled to make updates to four additional policies to comply with GAPIV requirements. These policies include Inventory, Transfer, Shared Use (Non-PV Work in PEF), and Biorisk Management and Risk Assessment. On Wednesday, January 24, 2024, the groups convened to review the Inventory policy, and the Transfer Policy will be discussed during their February 2024 meeting. Furthermore, during the same meeting on January 24, 2024, the PCWG provided feedback to the NAC on science projects, emergency response plans, and facility outreach. They also received a comprehensive global eradication update from the CDC Center for Global Health (CGH) Leadership.

During the session, Dr. Lakey presented three policies that will undergo voting. BSC members were provided with earlier editions of these policies as pre-reading material for this meeting. The Risk Mitigation Strategies Policy, which was initially released in October 2018, entails the establishment of poliovirus-specific containment standards. These standards incorporate various elements such as PPE, decontamination procedures, waste disposal protocols, security measures, and immunization requirements. The aim of this policy is to enhance biosafety level 2 (BSL2) practices to meet the more stringent containment standards of GAPIV. Many WPV1

PEFs currently work at biosafety BSL2 and have no previous experience with high containment. This policy applies to WPV type 1 PEFs applying for or possessing a Certificate of Participation (CP). and will prepare PEFs for the GAPIV high containment requirements. Revisions were made as follows:

- GAPIV definitions
- Removes WPV/VDPV types 2 and 3, OPV type 2 infectious materials
    - Only Interim Certificate of Containment (ICC)/Certificate of Containment (CC) PEFs can possess these materials
- Adds:
    - Gryphon Scientific PPE suggestions
    - 12-hour notification deadline to submit U.S. NAC Incident Reporting Form and notify agencies
    - CDC EOC as point of contact for reporting incidents to NAC
    - Annual drills/exercises to test PEF plans

The Storage Outside of Containment Policy was published in September 2019. Its purpose is to address the issue of some U.S. PEFs lacking the necessary space or resources to store poliovirus materials within the designated poliovirus containment perimeter. This was not covered by GAPIII, which mandated that all storage be within containment and dedicated solely to polio, without allowing for shared space or storage units. The policy encompasses various aspects related to the storage of materials, including PPE, security, transportation, waste disposal, and decontamination requirements. It applies to both ICC and CC PEFs, and it requires adherence to the GAPIV definitions and requirements. Adjustments have been made to the policy in the following areas:

- Wild/vaccine-derived type 1 infectious material
- cVDPV as an example of VDPV material
- 12-hour notification deadline to submit U.S. NAC Incident Reporting Form and notify agencies
- CDC EOC as a point of contact for reporting incidents to NAC
- Report PV IM and PIM inventory changes, destruction, and transfers to NAC

Lastly, the PPE and Hand Hygiene Policy was published in September 2019 and was originally written to ensure worker protection in place of exit showers. It applied to ICC and CC PEFs and also required adjustments to meet the GAPIV definitions and requirements. Changes to the policy were as listed as follows:

- Wild/vaccine-derived type 1 infectious material
- Project-specific risk assessment requirement and guidance for PEF to identify all PPE needs
- Develop written procedures on PPE usage, selection, and maintenance
- PPE requirements in emergency response procedures
- Minimum PPE:

- Coveralls, double gloves, face coverings, dedicated shoes
- Change out of street clothes

Before voting on the policies, the floor was open to the BSC for discussion, comments, and suggestions. Below are the recommendations and edits made by the BSC.

- On the in vitro policy, for number one, the policy needs to be added to the title. And for number two, on page 13, where you are referencing biosafety, it mentioned these two strategies for decontamination and that these two need to be used. It just was not clear from the drafting in the paragraph what "these two" were. [It was noted in the meeting that this was referencing sodium hypochlorite or autoclaving and will be corrected for clarity.]
- We must make every effort to support our global partners, particularly WHO, in spreading awareness about the significance of immunizations and safeguarding the safety and well-being of health workers who have unfortunately faced strain and aggression while striving to eliminate this completely eradicable disease. It is essential to recognize that the absence of global security affects us all, even within our borders.
- According to policy 5.8 on emergency response, the activation of the emergency response system involves various entities such as national, state, local, and community partners from emergency management, fire law enforcement, EMS, and health departments. However, I noticed that the policy fails to mention communication efforts directed toward the public, in addition to the involved partners. I am uncertain if this aspect should be emphasized more explicitly in such policies. Nonetheless, in my experience with emergency response policies related to infectious diseases or other hazards, there has always been a significant focus on public involvement and reliance on various partners. Including these considerations would be appropriate. [It was noted that the policy will be revisited to ensure that it aligns with the other policies regarding emergency responses and communication protocols to the public.]
- Be sure to include social media platforms.
- Dr. Shah referred to an article written in the Journal of Infection. It was published in September 2022. He suggested that the BSC review some of the concerns stated in the journal.
- There is a place where one tiny piece of guidance on handwashing references a risk assessment and unpublished risk assessment from Gryphon Scientific in the context of the text. Everything else is referenced in the references as a whole at the end, and it stands out very strangely because it's based on general guidance overall is predicated on a piece of unpublished study. It could bring unnecessary attention to itself. [It was noted that the NAC will revisit the PPE Policy and review this reference.]

The motion was called for each of the policies.

- Risk mitigation strategies – motion made by Dr. Shah and seconded by Dr. Fischer
- Storage Outside of Containment – motion made by Dr. Shah and seconded by Dr. Fischer
- PPE and Hand Hygiene- motion made by Dr. Shah and Seconded by Dr. Fisher

The BSC unanimously approved all of the policies to move forward and they will include the edits made by the board.

Dr. Haynes Smith provided concluding remarks on the upcoming tasks for the NAC. Despite accomplishing notable advancements, a considerable amount of work still lies ahead. The projected timeframe for the WHO eradication continues to be 2026; however, there exist obstacles that could potentially postpone both the endgame and NAC timelines. There are currently WPV2/3 PEFs applying for ICC and WPV1 PEFs applying for a CP. The anticipated timeline for WPV1 to progress to the subsequent phase is by the end of 2025. The identification and management of PIM in the United States are currently under development, presenting a considerable challenge.

Health Equity Workgroup (HEWG) Updates

Devaki Kumarhia PhD; HEWG Designated Federal Officer, ORR

Dr. Kumarhia, in collaboration with Ms. Brianna Barnes, leads the HEWG and shared an update on the group's endeavors. The formation of HEWG occurred in 2023, aiming to collect vital data and evaluate approaches to aid the BSC in devising insights and suggestions for an effective health equity agenda focusing on readiness and response. A comprehensive set of objectives and tasks have been devised by the group, aiming to be accomplished within the first year since its inception.

During the summer of 2023, the co-leads had a meeting with the co-chairs at that time, Drs. David Fleming and Marisa Levine. They leveraged Dr. Fleming's position as the Chair of the ACD to identify overlapping tasks and goals per the CDC's terms of reference and the ACD's Health Equity Group's suggestions to the Director. Dr. Kumarhia emphasized that the ACD's work merely informs the HEWG, and the HEWG's work is not intended to replicate the ACD's efforts. To ensure efficient project management, it was suggested that workgroup members rotate to handle specific activities or tasks outlined in the terms of references, adopting a scrum-style approach and creating deliverables in segments. Subsequently, in early Fall 2023, Dr. Levine stepped down from both the BSC and HEWG. As a result, Dr. Kumarhia and Ms. Barnes are presently in the process of recruiting more members and additional co-chairs.

HEWG has successfully procured contract support to conduct a literature search to establish measures and metrics for health equity in the readiness and response domain. The contract support has already furnished the workgroup with preliminary metric suggestions, derived from the literature review. Currently, the primary focus of the workgroup is to arrange the inaugural full HEWG meeting, involving all existing members. Once the workgroup has examined and

deliberated on the initial metrics, they will subsequently be shared with the BSC. During the first meeting, the workgroup will determine the subsequent steps to be taken for their agenda.

A suggested approach for membership has been put forth by Dr. Fleming during the preliminary discussions. This strategy entails a focused selection of members based on the specific goal, activity, or task at hand. To ensure continuity, there will be static members, while the group will gradually expand as more foundational materials and suggestions are produced. Presently, the co-chairs of the group comprise Drs. David Fleming, Paul Halverson, and Phyllis Meadows. Additionally, Dr. John Martin-Lowe is currently serving as a member of the HEWG. Tentatively, a meeting is scheduled for the second week of February 2024 to review the materials generated by contract support.

Dr. Kumarhia outlined the methodology employed by the contract support team to conduct the literature review. The team first identified key terms, parameters, and data sources relevant to the subject of health equity during public health emergencies. A comprehensive search was then carried out on PubMed and the CDC's website. The results obtained were meticulously evaluated for their relevancy and categorized as either "High," "Medium," "Low," or "Not Relevant" based on pre-defined criteria. Subsequently, articles deemed of "high" relevance were thoroughly reviewed, and summaries were prepared. These publications were further categorized based on the type of public health emergency, health equity topics, metrics, and social determinants of health taking into consideration demographic and/or socioeconomic variables.

Based on the guiding analytical inquiries for the literature review, the paper succinctly outlined the various aspects of health equity, metrics, and/or Social Determinants of Health in public health emergencies. It also emphasized their distribution across demographic and socioeconomic factors.

After the presentation, the BSC provided the HEWG with their comments and suggestions.

Suggestions/Comments from the BSC:

- I believe it is crucial to consider various organizations that represent professionals in the field. These include ASTHO, the National Association of County and City Health Officials (NACCHO), CSTE, and APHL, as well as the national academies that have focused heavily on health equity as they have responded to emergencies. These organizations should be approached for two reasons. Firstly, to seek their assistance because they have a wealth of knowledge to offer, and secondly, to obtain their assessment of the potential gaps in ORR's work. This piece may require the assembly of a small board of scientific counselor-like group in addition to the small workgroup so that we can engage partners and community members regarding emergency responses and determine ways to build back trust with the community.
- It is crucial to acknowledge the significance of community involvement during this equity process. Several communities have unfortunately experienced adverse

consequences and exclusion from decision-making. The work you all contribute is instrumental in addressing these issues and identifying additional measures that the BSC can use in its thinking of how to bridge these gaps.

- It would be beneficial to conduct a thorough assessment of the various activities taking place within the government landscape to expand your knowledge and involvement.
- The issue lies in the concept that the disparities observed during this process surpassed the scope of the situation. There were certain underlying structural and functional factors within the healthcare system, including the public health sector, that have endured and continue to pose challenges. By solely focusing on addressing inequities during a crisis, we fail to seize the chance to examine the broader array of challenges that persist daily.

Dr. Shah volunteered to work with the HEWG.

Strategic Discussion

David Lakey, MD; Chair, BSC, ORR

Dr. Lakey facilitated a strategic discussion with the BSC and CDC leadership to gather further insights, remarks, and suggestions stemming from the presentations delivered throughout the two-day gathering. Below is an overview of the comments and suggestions that were provided.

- I am impressed by the vast number of exceptionally talented fellow board members who possess a diverse set of skills and expertise. I believe it is crucial for us to engage in a conversation focused on enhancing our effectiveness, usefulness, and impact. While we appreciate the information shared about various programs, policies, and general discussions, it is essential that we explore concrete ways to truly make a difference and lend meaningful assistance to ORR in our capacity as the board of scientific counselors.
- I have concerns about potentially overwhelming the board with excessive tasks and achieving nothing substantial. It would be better to narrow down our scope and utilize the working groups to clearly outline our goals for this year. In doing so, we can then attract additional talented individuals to join the working groups and make meaningful progress.
- I believe the HEWG's work holds immense significance. A crucial aspect, however, lies in ensuring that specific deliverables are established to prevent repetitive discussions over time. It is important to identify measurable actions that signify progress in achieving the goals.
- We collaborate with multiple centers to establish a prompt response to any potential harm that may affect the American people. This includes various situations such as natural disasters, deliberate threats, biological threats, or naturally occurring events. Hence, there may arise an opportunity, similar to our approach in the laboratory sector, where we successfully incorporated another center and enhanced its functionality. This center could be financed through our SCIP programs and plays a vital role in maintaining laboratory preparedness, and showcasing the activities we undertake.

Additionally, we should also consider making decisions on prioritizing investment in CDC's responsibilities. There are possibilities to engage with our National Center for Environmental Health and initiate a discussion regarding these particular risks. Therefore, we need to evaluate our approach to funding, both internally and in collaboration with state and local entities, with respect to heat-related health concerns. We must determine the most effective allocation of our limited intramural funding, as well as the funds provided through the SCIP program, in relation to Laboratory Response Network for Chemical Threats (LRN-C), rad nuke, and Heat and Health. It is crucial to identify the specific areas where we can focus our efforts and make meaningful progress.

- I believe this BSC readiness and response plan encompasses multiple aspects within the CDC, providing opportunities for us to delve into various areas. We could also include workforce preparedness at the federal level, as well as readiness and response at the state and local levels. Additionally, we can focus on data analysis and address any requirements for the year 2024, based on the board's interests. In my opinion, ensuring health equity is a crucial matter, and it is important that we have appropriately planned for it, show progress in this area, and actively engage the board and the working group to make advancements. Exploring one or two other relevant topics could prove beneficial for our agenda in 2024.
- I have an interest in the field of translation and its implications for practitioners and partners, specifically with community members and communities. Establishing trust involves not only being transparent but also providing suitable platforms and means to accomplish it.
- I would like to reopen the discussion regarding the establishment of implementation centers. The pandemic has emphasized the urgency of improving our collective coordination and implementation of scientific knowledge, particularly in responding to crises like a pandemic. However, I have reservations about relying solely on collaborations with universities for implementation purposes.

  My intention is not to cast a negative light on our academic colleagues. Instead, I believe it is important to consider certain realities and explore alternative approaches or opportunities. It seems that most universities are not actively engaged in the implementation of public health responses. I am concerned that without strong collaboration between universities and state and local public health agencies, we will witness a further division between the realms of science and public health organizations.

  This divide became apparent during the pandemic, where scientific knowledge and best practices were often not effectively implemented by the public health organizations responsible for their execution. Implementation involves not only the scientific aspect but also takes into account policy considerations, local contextual factors, political dynamics, and the differences between state, local, territory, and tribal public health agencies. Considering the incorporation of specific local factors, policies, and political

dynamics, it is uncertain whether universities possess the necessary expertise to provide insights on implementation-related matters.

- It would greatly benefit ORR if the board could assist us in identifying effective ways to establish meaningful connections. This will allow us to ensure seamless coordination among all our programs, such as the science agenda, inter-divisional work, engagement with states and locals, SCIP fund utilization, and successful implementation. Consequently, this collaborative approach will result in a more streamlined and concerted effort across ORR.
- Implementation science is something that maybe we also need to focus on because as it was previously stated, things aren't readily transferable from one locality to another. Part of that is also determining the needs and existing resources.
- In light of yesterday's discussion, what resonated with me is the realization that numerous programs will generate an extensive volume of data. Consequently, my main focus lies in contemplating the effective sharing, communication, and intentional integration of this data into a comprehensive strategic action plan. One of the things that this group could do through BSC activities is think with all of our colleagues here about what that strategic plan looks like for using the data in a staged, sequential, and incremental manner. This way the data is being generated, absorbed, and used at the same time to guide and prioritize the next activities.
- The need to determine the critical partners is one of the strategic threads that kept surfacing for me throughout all of the presentations.
- How we were provided with this information was truly remarkable, although it remained isolated in my thoughts. Therefore, as we progress, it would be beneficial to consider viewing these different individuals as a cohesive system, as that's where I struggled to establish the connections. I acknowledged the potential opportunities, but I wasn't constantly certain about the systematic approach in response to the office's duties.
- During this discussion and throughout the past day and a half, two major themes have emerged: reorganization and communications. These two aspects must intersect because individuals outside our organization may lack clarity on the purpose and activities of ORR. Therefore, I propose conducting a roadshow across the federal government, alongside our partners. This endeavor would aim to explain the reasons behind the reorganization, clarify ORR's role, and also shed light on what to anticipate in terms of our involvement with respiratory diseases, and more.
- In the course of agency-led responses, it is crucial to swiftly develop and publish a science agenda. This agenda must not only be created and shared but also continuously updated and evaluated. Currently, internal guidance exists that outlines the process and assigns responsibilities for accomplishing this; however, the assistance of this board could play a valuable role in supporting the immediate development and implementation of the science agenda.
- I believe it would be beneficial to enhance our response by initially establishing a clear definition of what it entails to be effective public health responders. Subsequently, we should focus on developing the necessary skills and expertise to meet these standards.

The next step is to determine to what capacity and how to sustain it. I believe the key consideration lies in thoroughly determining the desired level of capacity and capability to be developed not only within state and local public health sectors, but on a national scale.

- We need to adopt a strategic approach when examining the future prospects of LRN, encompassing the realms of both biology and chemistry. We should evaluate the strategic direction that the LRN should undertake and contemplate the objectives it ought to pursue. There was talk of inclusion of untraditional partners like large laboratories, which is wonderful. But I think we really need to focus in on the actual LRN structure and in the state and local jurisdictions.
- To ensure smooth operations even in unforeseen circumstances, it is imperative to incorporate interoperability, flexibility, and adaptability within our systems. This will equip us to effectively handle unexpected situations.
- I believe the board has a crucial responsibility to hold us accountable and ensure that we do not limit ourselves to conducting PCR tests solely for specific threats in the laboratory. As we discuss various topics in detail, the board should play a role in overseeing our efforts to incorporate flexibility and adaptability across all aspects, including EPI labs and surveillance. This approach is not limited to the laboratory field alone but must be applied comprehensively to all areas.
- I believe we often overlook the deficiencies and gaps present in the capacity and capabilities of a strong public health system. It is essential for this board to consider and address the areas that are lacking. Additionally, we need to find effective ways to bring to policymakers' attention the tasks and initiatives that remain undone due to limited resources or budget constraints, particularly in terms of preparedness and response.
- When considering a response, it is essential to take into account the role of water. I know that that work may come under a separate division specifically dedicated to environmental matters. However, it is my belief that a holistic view on response cannot be achieved without acknowledging the wide range of threats present in our surroundings. And this is not topically; I think inter-organizational will be important.
- Perhaps it would be beneficial to adopt a more comprehensive global perspective in order to identify the key threats. This approach will assist us in refining the priorities for ORR and assist in identifying existing gaps.
- I believe the primary challenge faced by this group lies in adopting a strategic approach and maintaining a strong focus on tangible objectives that can propel us forward. It is crucial for us to exercise caution in order to avoid dispersing our efforts too widely or becoming too immersed in tactical details.

Public Comments

No public comments were made.

Closing Remarks

David Lakey, MD; Chair, BSC, ORR

ORR Leadership is interested in ensuring that the board uses an appropriate science agenda developed by the scientists. Dr. Lakey felt that if the BSC can contribute to the strategic discussions, it would be beneficial.

In order to prepare for any kind of event, be it familiar or unfamiliar, it is essential to enhance the data sources systems. This is a crucial aspect that demands immediate attention and progress. As mentioned previously, and acknowledged by all, it is imperative to have a skilled, knowledgeable, and experienced workforce to successfully execute these tasks. It is crucial to continually explore innovative solutions and adapt to changing circumstances. This underscores the significance of developing flexible response mechanisms and maintaining robust critical infrastructure going forward.

Additionally, it would be fruitful for both the board members and the CDC to consider what specific and significant questions a time-limited work group could focus on, in order to make substantial progress. This could serve as a valuable next step for discussion. Dr. Lakey said the BSC and ORR should also consider the format for the upcoming meeting.

Henry Walke, MD, MPH; Director, ORR

Dr. Lakey was thanked by Dr. Walke, who also expressed gratitude to everyone in attendance and for the board's participation and lively discussion.

Adjourn

With no further business to be covered, the meeting was adjourned at 11:41 AM EST.

CERTIFICATION

I hereby certify that to the best of my knowledge the foregoing minutes of January 25-26, 2024, hybrid meeting of the Board of Scientific Counselors, Office of Readiness and Response are accurate and complete.

4/15/2024
Date

_____/S/_____
David Lakey, MD
Chair, BSC, ORR

APPENDIX A: BSC ORR Membership Roster

DESIGNATED FEDERAL OFFICIAL

Ian Williams, PhD, MS
Deputy Director
Office of Readiness and Response (ORR)
Centers for Disease Control and Prevention
Atlanta, Georgia

CHAIR

David Leroy Lakey, MD
Vice Chancellor of Health Affairs and Chief Medical Officer
The University of Texas System
Austin, Texas
Term: 5/13/2021 – 9/30/2024

MEMBERS

Julie Fischer, PhD
Senior Technical Advisor for Global Health
CRDF Global
Arlington, Virginia
Term: 6/10/2022 – 9/30/2025

David Fleming, MD
Clinical Associate Professor
University of Washington School of Public Health
Bainbridge, Washington
Term: 11/7/2019 – 9/30/2023

Paul Halverson, DrPH
Founding Dean, Professor of Policy and Management
Richard M. Fairbanks School of Public Health
Indiana University
Indianapolis, Indiana
Term: 6/8/2022 – 9/30/2025

Phyllis Meadows, PhD, MSN, RN
Senior Fellow, Health Programming
The Kresge Foundation
Troy, Michigan
Term: 8/7/2023 – 9/30/2023

Kathleen Tierney, PhD
Professor Emerita, Sociology, University of Colorado Boulder
Fellow, Institute of Behavioral Science
Faculty, Institute of Behavioral Science
University of Colorado Boulder
Boulder, Colorado
Term: 6/13/2022 – 9/30/2025

Shah, Umair, MD, MPH
Secretary of Health
Washington State Department of Health
Olympia, Washington
Term: 8/7/2023 – 9/30/2026

EX OFFICIO MEMBERS

Paula Bryant, PhD
National Institutes of Health (NIH)
Director, Office of Biodefense, Research Resources, and Translational Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Rockville, Maryland

Kristin L DeBord, PhD
Assistant Secretary for Preparedness and Response
Director, Strategy Division
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Washington, District of Columbia

Hilary Marston, MD, MPH
Food and Drug Administration
Chief Medical Officer
Office of Clinical Policy and Programs
Silver Spring, Maryland

LIAISON REPRESENTATIVES

Michele Askenazi, MPH, CHES
National Association of County and City Health Officials (NACCHO)
Director of Emergency Preparedness, Response, and Communicable Disease Surveillance
Tri-County Health Department
Greenwood Village, Colorado

Benjamin P. Chan, MD, MPH
Council of State and Territorial Epidemiologist (CSTE)
State Epidemiologist
New Hampshire Department of Health and Human Services
Division of Public Health Services
Concord, New Hampshire

Christina Egan, PhD, CBSP
Association of Public Health Laboratories (APHL)
Chief, Biodefense Laboratory, Wadsworth Center
New York State Department of Health
Albany, New York

Alexia Harrist MD, PhD
Association of State and Territorial Health Officials (ASTHO)
State Epidemiologist and State Health Officer
Wyoming Department of Health
Cheyenne, Wyoming

Laura Magana, PhD
Association of Schools and Programs of Public Health (ASPPH)
President and CEO
Washington, District of Columbia

A.J. Schall, Jr., BS
National Emergency Management Association
Director, Delaware Emergency Management Agency
Department of Safety & Homeland Security
Smyrna, Delaware

APPENDIX B: Attendee List

SGE Board Members

Julie Fischer
David Fleming
David Lakey
John-Martin Lowe
Phyllis Meadows
Umair Shah

Ex-Officio Board Members

Kristin DeBord
Hilary Marston

Liaison Board Members

Michele Askenazi
Emily Burke
Benjamin Chan
Christina Egan
Alexia Harrist
AJ Schall

CDC Representatives

Oluwatomiloba Ademokun
Susan Adkins
Sherry Adrianos
Cresandra Anderson
Noelle Anderson
John Anderton
Joanne Andreadis
Jana Austin
Rachel Avchen
Shimere Ballou
Briana Barnes
Lorenzo Barr
Lisa Barrios
Amir Bayatpoor
Kanwar Bedi
Clinetta Bellamy
Doug Bialecki
Betty Billie
Mo Blaylock
Sandra Boyd
Daniel Brencic
Sharyn Brown
Sherrie Bruce
Lonnie Bryant
Jay Butler
Michelle Calio
Andrew Carter
Kris Carter
Lisa Caucci
Tai-Ho Chen
Kevin Clarke
LaTonya Clay
Giselle Climpson
Rachel Clinton
Kira Coggeshall
Taylor Coleman
Megan Collins
Rachel Cook
Pam Cox
Charmen Crawford
Thomas Cremer
Walter Randolph Daley
Krutarth Dave
Lisa Davis
Chris De La Motte Hurst
Kristin Delea
Kelly Dickinson
Kijafa Dickinson
James Diggs
Stephanie Dopson
Dee Dee Downie
Teresa Duff
Audria Dunson
Thomas Dykes
Olivia Edemba
Samuel Edwin
Melissa Erkens
Nicole Estes
Amanda Evanson
Federico Feldstein
Jie Feng
Daniela Franco-Montoya
Mark Frank
Katie Fullerton
Sundak Ganesan
AL Garcia
Robert Garcia
Shaw Gargis
Theresa Gayles
Brittany Gentry
Shelbi Gholson
Maleeka Glover
Andrew Godoshian
Zev Goldberg
Brant Goode
Kerestin Goodman
Mark Green
Rebecca Gurvich
Kortney Gustin
LaShonda Hall
Harold Hardrick
Roger Harlan
Danny Harley
Allison Harrington
Amanda Harris
Cameron Hartwill
Raena Osizwe Harwell
Lia Haynes Smith
Katy Henderson
George Hickson
Janine Hines
Mary Hoelscher
Stacey Hoffman
Kilsun Kay Hogue
Jeannie Hong
Miriam Hoppe
Alex Horne
Christopher Horton
Amber House
Bill Howard
George Huntzicker
Otto Ike
Chuck IT Manager

Terry Jackson
Monique Jester Williams
Jennifer Johnson
LaBrina Jones
Terrance Jones
Enitra Jones Sprouse
Jaime Jones-Wormley
Brandi Jordan
Namita Joshi
Robynne Jungerman
Erin Kennedy
Katende Kinene
Russell King-Jones
Barbara Kitchens
Christine Kosmos
Devaki Kumarhia
Alan Lam
Rodriques Lambert
Charles Lane
Gregory Lanman
Nastassia Laster
Modinat Lawal
Sarah Lee
Kimberly Leeks
Mary Leinhos
Elizabeth Lemasters
Rosa Lira
Lindy Liu
Kimberly Lockwood
Jennifer MacFarquhar
Becky Maholland
Hugh Mainzer
Kawi Maliutha
mark mandelbaum
Lauren Manning
Khatia Martinez
Katia Matias
Matthew Mauldin
Eva McLanahan
Amanda McWhorter
Carlos Mercado
Shauna Mettee Zarecki
Joe Miller
Leigh Anne Miller
Gwendolyn Morris
Allie Morse
Kalimah Muhammad
Harry Newsome
Kate Noelte
Kristen Nordlund
Fahmi Omar
Lunda Onesias
Christy Ottendorfer
Dometa Ouisley
Lawrence Papier
Linde Parcels
Nicki Pesik
Taran Pierce
Carrie Pierce
Kara Pilote
Avaree Pink-Lewin
Catherine Piper
Richard Pitts
Rachel Power
Joanna Prasher
Nyki Preacely
Katie Pugh
Shoukat Qari
Ada Quinones-Hernandez
Victoria Ramirez
Muhammmad Ramzan
Meredith Reagan
Chris Reinold
Laura Ross
Shawnbria Rsy
Laird Ruth
Ren Salerno
Paramjit Sandhu
Magon Saunders
Jarad Schiffer
Vickie Scott
Alexandria Sedlak Gonzalez
Borocquell Shaheed
Bryan Shelby
Kenny Sigler
Kanta Sircar
Theresa Smith
Ernest Smith
Gregory Smith
Zachary Smith
Robin Soler
Steven Soroka
Shannon Souvinette
Chaunte Stampley
Suganthi Suppiah
Neal Sutherland
Todd Talbert
Bryan Taylor
Stacy Thorne
Tiandra Thornton
Doug Thoroughman
Linda Tierney
Samantha Tostenson
Stephanie Tran
Silvia Trigoso
Henry Walke
Desiree Walker
Lawanda Washington
Quiana Washington
Allison Watson
Michael Wellman
Keira Wickliffe Berger
Sarah Wiley
Ian Williams
Vronique Wilson
Nicole Young
Yon Yu
Ling Zhou

Public Attendees

Andrew Adams
Christina Barbour
Mitchell Berge
Alanna Brown
Nick Cox
Rocelyn de Leon-Minch
Sydney Donati-Leach
Gindy Feeser
Grace Golden

Janet Hamilton
Robert Hood-Cree
Sam Jarvis
Michelle King
Janet Lamb
Marcelle Layton
Tangela Love
Belinda Ngongo
Lisa Peterson
Melissa Powell
Amaya Ramos
Kaajal Singh
Rita Stinnett
Mike Stobbe
Alexander Tin
Nicole Zimmerman

APPENDIX C: Acronyms

ACD	Advisory Committee to the Director
APHIS	Animal and Plant Health Inspection Service
ASPR	Office of the Assistant Secretary for Preparedness and Response
BSC	Board of Scientific Counselors
CBSHE	Community-based Solutions & Health Equity Branch
CC	Certificate of Containment
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health
CIO	Chief Information Officer
CLSR	Center for Laboratory Systems and Response
CMSPT	Community Mitigation and Special Populations Team
COVID	Coronavirus Disease
COVID-19	Coronavirus Disease 2019
CP	Certificate of Participation
CPR	Center for Preparedness and Response
CSTE	Council of State and Territorial Epidemiologists
DAST	Data Analysis, Support, and Translation Team
DCIPHER	Data Collation and Integration for Public Health Event Responses
DEO	Division of Emergency Operations
DMI	Data Modernization Initiative
DRSC	Division of Regulatory Science and Compliance
DRRS	Division of Readiness and Response Science
DSAT	Division of Select Agents and Toxins
DSLR	Division of State and Local Readiness
DURC	Dual-Use Research of Concern
EBST	Equity and Behavioral Sciences Team
EMTCDB	Emergency Management Training and Capacity Development Branch
EOC	Emergency Operation Center
ERCB	Emergency Risk Communications Branch
EUA	Emergency Use Authorization
FEMA	Federal Emergency Management Agency
FDA	U.S. Food and Drug Administration
FMEA	Failure Mode and Effective Analysis
FSAP	Federal Select Agent Program
FTE	Full Time Equivalent, Full Time Employee
FY	Fiscal Year
GAP	Global Action Plan
GAPIII	Global Action Plan IV third edition
GAPIII	Global Action Plan IV fourth edition
GDDOC	Global Disease Detection Operations Center
GPEI	Global Polio Eradication Initiative
GRRT	Global Rapid Response Team

ICATT	Increasing Community Access to Testing
HEWG	Health Equity Workgroup
HHS	United States Department of Health and Human Services
ICC	Interim Certificate of Containment
IMS	Incident Management Structure
IPP	Import Permit Program
LRN	Laboratory Response Network
LRN-C	Laboratory Response Network for Chemical Threats
MET	Measurement Evaluation and Translation Team
MOU	Memorandum of Understanding
Mpox	Monkeypox
NAC	U.S. National Authority for Containment of Poliovirus
NACCHO	National Association of County and City Health Officials
NCEH	National Center for Environmental Health
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCIRD	National Center for Immunization and Respiratory Diseases
NOFO	Notice of Funding Opportunity
OASH	Office of the Assistant Secretary for Health
OD	Office of the Director, Office of Development
OERC	Office of Emergency Risk Communication
OPHPR	Office of Public Health Preparedness and Response
OPPC	Office of Policy, Planning, and Communication
ORR	Office of Readiness and Response
OSLR	Office of Science and Laboratory Readiness
PAHPA	Pandemic and All Hazards Preparedness Act
PCWG	Polio Containment Work Group
PHEP	Public Health Emergency Preparedness
PHI	Public Health Intelligence Team
PHRRE	Public Health Readiness & Response Evaluation Branch
PIM	Potentially Infectious Material
PPE	Personal Protective Equipment
(W)PV1	(Wild) Poliovirus 1
PV2	Poliovirus 2
PV3	Poliovirus 3
PXE	Plans, Exercise, and Evaluation Branch
RADSS	Response Analytics, Decision Support, & Surveillance Branch
RDAV	Response Data Analytics and Visualization Team
RFI	Request for Information
RFP	Request for Proposal
RO	Responsible Official
RSB	Resource Support Branch
RSV	Respiratory Syncytial Virus
SAMHSA	Substance Abuse and Mental Health Services Administration

SCIP	Strategic Capacity Building and Innovation Program
SGE	Special Government Employee
SRWG	SCIP Review Working Group
STLT	State, Tribal, Local, or Territorial
UNICEF	United Nations International Children's Emergency Fund
USDA	U.S. Department of Agriculture
cVDPV	Circulating Vaccine-Derived Poliovirus
WHO	World Health Organization