CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC Advisory Committee to the Director (ACD)

Minutes from the November 14, 2023 Meeting

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Advisory Committee to the Director: Record of the November 14, 2023 Meeting

The Centers for Disease Control and Prevention (CDC) convened a hybrid meeting of its Advisory Committee to the Director (ACD) on November 14, 2023 in-person and via Zoom for Government and teleconference. The agenda included Agency Priorities and Updates from CDC Director Mandy Cohen; CDC Updates on recommendation actions from the Data and Surveillance Workgroup (DSW), Health Equity Workgroup (HEW), and Laboratory Workgroup (LW); reports and updates from the HEW, DSW, and LW; and presentations on Supporting Healthy Families and the COVID-19 Rescission.

Welcome and Roll Call

David Fleming, MD (ACD Chair) called the meeting to order and welcomed the ACD members, CDC leadership and staff, guests, and attendees joining virtually. He then called the roll, which established that a quorum of ACD members was present. Quorum was maintained throughout the meeting. The ACD Membership Roster is appended to this document as Attachment #1. The following potential conflicts of interest (COIs) were disclosed:

- Dr. Joshua Sharfstein: Began a 10% Intergovernmental Personnel Act (IPA) with the National Institutes of Health (NIH) to work on Hepatitis C (Hep C) and is recused from issues related to Hep C on the ACD.
- Dr. Nirav Shah: Director at STERIS.

Dr. Fleming noted that the ACD was somewhat smaller since the last meeting, given that Drs. Goldman and Albert had rotated off. He emphasized that they had been great additions to the ACD in terms of the primary committee itself and Dr. Goldman in the DSW and Dr. Albert in the HEW. Dr. Fleming stressed that while it was a sad parting time, he wanted to express gratitude on behalf of the ACD and the CDC to both parting members for their wisdom and dedication to this group and its cause. Drs. Goldman and Albert are examples of the kinds of leadership the committee is able to include to serve the ACD. CDC and Department of Health and Human Services (HHS) have been working hard to officially bring on additional outstanding committee members. With that, Dr. Fleming reviewed the agenda for the day.

CDC Update: Laboratory Workgroup Recommendations

Victoria Olson, PhD (Deputy Director, Office of Laboratory Science and Safety, CDC) and Reynolds (Ren) Salerno, PhD (Acting Director Center of Laboratory Systems and Response, CDC provided updates about how CDC has been progressing on implementing some of the LW recommendations. The LW report was published in February 2023 and included some excellent recommendations. CDC has been working actively to implement many of these and reported activities relative to the following recommendations during this meeting:

- 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 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.
- Incorporate redundancy into the national responsibility for test development.

As a reminder, the CDC Moving Forward Initiative was designed to improve management, reduce bureaucracy, and strengthen CDC emergency readiness and response. As part of the effort, some important enterprise-wide functions were elevated into reporting directly to the Immediate Office of the Director (IOD), including the Office of Laboratory Science and Safety (OLSS). The Director of the OLSS is the Associate Director for Laboratory Science and Safety (ADLSS), Dr. James Pirkle. The ADLSS is the single point of laboratory accountability for numerous regulations and policies and is part of the IOD. In addition, CDC is creating the Center for Laboratory Systems and Response (CLSR), which will report to the ADLSS. The CLSR will be providing cross-cutting laboratory operations and systems support, collaborating with clinical and public health laboratory systems and federal partners to fulfill the ultimate goal of supporting scientifically advanced, response ready, and efficient laboratory response to diagnostic testing for infectious disease outbreaks, epidemics, and pandemics.

In terms of how CDC has been fostering the culture of laboratory quality, significant progress has been made on a few elements that help support quality management for the laboratory. The Quality Manual for Microbiological Laboratories (QMML) has been completed. This document describes quality standards for the wide portfolio of activities in which CDC laboratories are engaged (e.g., clinical diagnostics, surveillance, and research) in order to meet or exceed regulatory requirements. The draft was completed at the end of 2022 and has gone through extensive reviews for improvement, which were based on review and feedback from Center laboratory leadership, the CDC laboratory community, and many Laboratory Directors from the Association of Public Health Laboratories (APHL). Implementation of the QMML has begun and is ongoing to foster continual improvement in laboratory quality.

CDC also is dedicated to providing an Electronic Quality Management System (eQMS) that can be used throughout the agency. This eQMS was designed to be flexible, easy to use, and facilitate CDC laboratory quality activities. Some of the quality indicators that this system will track include document management; personnel training and qualifications; equipment and instrument maintenance; non-conforming events, root cause analyses, and risk analyses; corrective and preventive actions; personnel competency assessments; and proficiency testing. The first 2 modules, document management and personnel training and qualifications, already have been launched to the pilot laboratories. CDC is actively seeking to configure the other modules in order to deploy them as soon as possible.

With respect to the LW recommendation to ensure that CDC tests receive an external review before deployment, the agency has the Infectious Disease Test Review Board (IDTRB). The IDTRB was stood up in March 2022 with a mission to: 1) review and approve all modified and new tests that will be shared outside of CDC; and 2) ensure external review of test validation by subject matter experts (SMEs). This additional review that is somewhat external to the program ensures that all of the validation criteria have been met, that tests truly are fit for purpose, and that the procedures are clear to someone who is not too close to the process. The quality process to be completed within the Center includes documented test method validation, review, and approval within the Center prior to submission to the IDTRB. Concept and pre-development include review and approval by Centers, Institutes, and Offices (CIO) leadership. Test method design includes review and approval by CIO Branch and Division leadership, and test method validation includes review by 2 SMEs external to the program and the CIO Associate Director for Laboratory Science (ADLS).

Once these steps in the process have been accomplished, submission is made to the IDTRB for formal review. The submission form includes necessary test validation documentation and CIO approvals. The IDTRB engages further with 2 more SMEs from a pool of volunteers who are experts in various test methodologies, who submit justified recommendations to the IDTRB. The IDTRB reviews the recommendations, and the Administrator communicates the results to the Principal Investigator (PI). If the test is not approved, the Administrator aids in the requested remediation prior to resubmission. Board approval is provided with clear language on how each test should be used. The impact of this process is that verification and review ensures that tests are high-quality

and suitable for their intended purpose prior to externalization by Board SMEs and members. In addition, it encourages continuous quality improvement while providing quality assurance to ensure reliable test results. This has been stood up and is performing quite well.

One of the most significant recommendations the LW made in its February 2023 report was for the creation of a new laboratory center at CDC, which was established and was officially approved in June 2023. Administratively, the CLSR came into existence as of October 1, 2023. CDC is now in the process of standing up and staffing the Center, as well as ensuring that it has adequate resources to complete all of the great work that it is anticipated to do. As noted earlier, the CLSR Director reports directly to the ADLSS who is the most senior laboratory scientist at the agency, which is an extremely important role. The Center currently includes only 1 Division, the Division of Laboratory Systems (DSL). However, there is a commitment to incorporate the Division of Core Laboratory Services and Response (DCLSR) in Fiscal Year (FY) 2024. These 2 Divisions reflect what CDC is trying to do with this Center, as well as how innovative this Center is for the agency.

The DLS has existed for some time, but its role and responsibility is to engage the external clinical laboratory community. It has the responsibility of managing the cooperative agreement that the agency holds with the APHL and ensuring that CDC has a productive relationship with all of the Public Health Laboratories (PHLs) throughout the country. In addition, it is CDC's connection in the CLIA Program, which is the regulatory program for clinical laboratory medicine across the US. In that role, the DLS is responsible for engaging, supporting, and working with all clinical laboratories across the country (e.g., commercial, hospital, or physician laboratories) to ensure the quality of that work. While the DSL is highly externally engaged, the DCLSR is an internal cross-cutting laboratory support organization for CDC laboratories. Neither of these divisions has a single pathogen, disease, or program for which they are responsible. The program laboratories that focus on specific pathogens or diseases are not a part of this CLSR intentionally. The CLSR is designed to be cross-cutting and supportive of all of CDC's programs whether they are internally operating laboratories or externally engaging the clinical laboratory community. The hope is that jointly, the CLSR and these 2 cross-cutting divisions will represent a new capacity at CDC focused on laboratory systems and response.

Some significant changes were made to the DSL and the DCLSR during the past Summer. Hopefully, these changes will demonstrate the commitment that CDC is making to improving the way the agency thinks of laboratory preparedness and response, externally and internally. A new branch was created in the DLS called the National Laboratory Response System Branch (NLRSB), which did not exist previously. The most important change in that branch is that the Laboratory Response Network for Biological Threats (LRN-B) was moved from the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) into the DLS NLRSB, given that this branch also has had the responsibility for engaging the commercial laboratory sector. For instance, the LRN-B was primarily responsible for transitioning the CDC orthopoxvirus test to the 5 commercial laboratories during the Mpox response. The LRN-B also has been the principal architect around improving laboratory data exchange external to agency. In addition, the Enterprise Laboratory Information Management System (ELIMS) Team was moved into the NLRSB. ELIMS is the data system that all of CDC's infectious disease laboratories use, as well as the system that is used to transmit test results from CDC to PHLs. The intent was to marry the internal electronic management system with the work being done externally with PHLs and clinical laboratories, ideally to ensure over time that data transmission is holistic and works more smoothly than in the past. It is important to emphasize that CDC recognizes the criticality of laboratory data exchange with laboratory preparedness and response. All of that essential programmatic work is being placed in one Center as opposed to being spread across many Centers and having a variety of leadership.

The DCLSR that is scheduled to move from NCEZID into the CLSR in FY 2024 also has created a new branch called the Preparedness, Response, and Outbreak Support Branch (PROSB), which essentially is the mirror image of the LRN-B. This branch is now entirely focused on internal CDC support to CDC laboratories for preparedness and response. The PROSB hopefully has created a CLIA surge laboratory testing facility within this branch that will be available to support CLIA testing during any public health response, which did not exist before COVID-19. Overtime, the hope is to build within this branch a more standardized process across the agency for new test development and test deployment from CDC out to public health or clinical laboratories as necessary. This is standardizing the way laboratory preparedness and response is thought of from within CDC so that there is less reliance on individual SME laboratories to handle all response functions.

Another initiative that CDC undertook over the Summer and Fall that recognize many of the comments and recommendations from the LW is the *Request for Information (RFI): Public-Private Partnerships to Support Test Development and Production*. This RFI specifically asked the private sector to tell CDC how they could better support surge laboratory testing during public health responses. CDC was able to surge to the private sector during COVID-19 and Mpox, but both of those transitions from PHLs to private sector clinical laboratories was ad hoc and there was not a well-honed system or process within CDC to help manage that transition. Therefore, the agency asked the private sector what they would need theoretically, if the resources could be identified, to contract with the private sector in advance so that the transition from PHL testing to private sector clinical laboratory testing during public health emergencies could be executed more quickly and smoothly. A total of 9 responses were received, including 8 from commercial laboratories and 1 from a large government contractor. A lot of great information was included in these responses, which is now being processed.

A second RFI focused on test production and modification. CDC clearly needs help from the private sector to be able to quickly and with high quality develop new tests, especially if encountering outbreaks of disease that is unfamiliar or for which there is not a readily available test. Historically, CDC has relied on an SME laboratory to be responsible entirely for that test production. The agency wants to diversify that capability and be able to engage appropriately with the private sector for help in new test production and, perhaps more importantly, test modification. This was the case during the Mpox outbreak during which CDC needed to rely on commercial laboratories to modify a relatively simple CDC test so that it could be used in a high throughput commercial laboratory setting following approval and authorization by the Food and Drug Administration (FDA). CDC was able to do this only because 5 commercial laboratories offered to do the work for the agency for free, but they do not want to count on that in the future or spend the time during an emergency to do that kind of work.

Not only did the LW make a recommendation, but also many publications over the last 6 to 9 months have called for someone in the government to define in writing the National Laboratory Response System; how it works; the roles and responsibilities of all of the players in this complex system that spans hospitals, commercial laboratories, physician office laboratories, urgent care centers, nursing homes, and public health laboratories of various capacities and sizes; and how they all work together. Everyone needs to understand this in advance of an emergency rather than figuring it out “on the fly.” CDC intends to work diligently over the next 12 months to do exactly that. The agency awarded a contract to Gryphon Scientific with the goals to: 1) gather and review information from the clinical laboratory survey, after action reports, and internal and external SMEs; 2) create a roadmap for partnering with private sector laboratories and other partners to meet needs during a Public Health Event; and 3) explore mechanisms for formal agreements with partners through Memorandums of Understanding (MOUs) or contracts. The hope is to develop and publish a report within the next year.

In conclusion, the hope is that the CLSR will be able to achieve its goals to: 1) provide cross-cutting laboratory operation and systems support for CDC's infectious disease laboratories, including standardization of test development and deployment as well as support for laboratory animal studies; 2) work across CDC, federal partners, and the national laboratory system to ensure scientifically advanced, timely, and efficient laboratory response and diagnostic testing for infectious disease outbreaks, epidemics, and pandemics; and 3) strengthen the agency's public health responses by placing the Laboratory Response Network (LRN) under new leadership, coordinating diagnostic and testing capabilities of the public and commercial sectors, consolidating CDC's laboratory data exchange and laboratory response programs, and providing additional support to internal CDC laboratories during Public Health Emergencies (PHEs).

Discussion Summary

Dr. Shah said he was very excited by this work and emphasized that the fact that the word "response" was part of the title was a clear message to everyone. He requested more information about how the CLSR partnerships are shaping up with the new Office of Public Health Data, Surveillance, and Technology (OPHDST) and the Center for Forecasting and Outbreak Analytics (CFA).

Dr. Salerno said that they recognize how important the roles of the OPHDST and CFA are in preparedness and response. The relationship between the CLSR and the OPHDST is much more mature than it is with the CFA, given that the old DLS has been working with the OPHDST and the Data Modernization Initiative (DMI) program for years. The Electronic Test Orders and Results (ETOR) work and the Laboratory Data Exchange (LDX) strategy have been central to much of the work of the DLS for years. As a result, they have been actively engaged with the OPHDST throughout and the relationship is quite strong. The CFA is still in the process of being stood up. While the CLSR has had many meetings with the CFA's leadership, the relationship is not as strong because the CLSR is not working with them in the same way that they are actively working with the DMI organization.

Dr. Sharfstein expressed appreciation for all of the work that has been done at CDC and the incredible collaboration that the WG has with everyone at CDC. It is great to see this moving forward and that it is well-aligned with how the WG combined many views. To follow up on some minor points in the report, reflecting on the COVID-19 tests, the emergency response structure did not have all of the laboratories that were part of making that test under it. He wondered whether the design of the Incident Command (IC) had been addressed such that this challenge could be resolved by having the IC oversee not only the core laboratories, but also other particular laboratories so that there is a coherent management structure in a crisis. One of the other recommendations was to consolidate laboratories at the division level or, if not possible, the branch level.

Dr. Olson emphasized that they enjoyed working with the LW and that it was a great exchange of wonderful ideas and that they valued all of the input the LW provided. CDC is actively working toward consolidating laboratories at the branch level, with Dr. Houry making sure that this effort continues moving forward.

Dr. Salerno added that from his perspective, the CLSR needs to be stood up and recognized as adding true value to CDC and the overall public health system. He trusts that once this is done, the community and culture within CDC, especially that thinks about how the agency organizes itself during public health responses, will recognize that the CLSR should be at the forefront of laboratory operations and thinking for every response. His vision is that the CLSR would have a permanent place within the CDC's graduated response structure such that every response of any significant size or shape would have to include the leadership from the CLSR, and that it would be incumbent on and the responsibility of this new Center to ensure that CDC is taking an agency systems approach to laboratory response and not placing all of the responsibilities on an individual SME laboratory, but is bringing to bear all of the agency's expertise on test development, test distribution, laboratory data exchange, et cetera. It will take some time for the CLSR to establish that reputation and be given that responsibility.

Dr. Sharfstein emphasized to CDC that while they could stand up a great center with a lot of expertise, but in the moment, it is really important that somebody is empowered over all of the laboratories so there is not a situation in which the laboratories are "pointing a finger" at each other. Issues can occur between the laboratories in an emergency.

Dr. Morita commended the LW and CDC for the work that has been done. It is clear that the agency took the recommendations to heart and is responding thoughtfully and carefully to them. It is impressive that work is being done on the fundamentals that are necessary and valuable. She inquired as to whether the team feels that that they have the adequate resources to stand up the CLSR in a way that is most impactful, and wondered whether they were working in a systematic and slow manner because they want to be careful or because they lack resources. She could see a place within its future Terms of Reference (TOR) for the DSW to work closely with the CLSR moving forward, given the incredible need for collaborative effort across the various CIOs and with respect to the great opportunity related to data exchange.

Dr. Salerno said he was very proud of the agency for moving forward with creating a new center in a challenging fiscal environment. Unlike the CFA, there is no Congressional mandate or Congressional line item specifically for creating and sustaining the CLSR. From that perspective, he would argue that it took a lot of leadership for the agency to declare publicly that this new Center would be created without the assurances of a Congressional line item. This does not happen very often at CDC and there has never been a laboratory-specific center in the agency's history. That said, there is a fiscal reality. There is no choice but to stand up the CLSR in a deliberate and admittedly gradual fashion, using existing resources that the agency is willing to redirect to help establish this Center. It is incumbent upon those who are responsible for the CLSR to help demonstrate its value and build its reputation both internally and externally, trusting that the resources will increase over time. That speaks to the earlier question about the CLSR's responsibilities, which will evolve over time as well. While there currently are just 3 employees in the CLSR, they are actively recruiting as fast as they can. However, they do not have the resources to hire hundreds of people into this Center at this point. He does not think that is necessary in the short-term in order for the CLSR to succeed, and that over time they can build the Center and its reputation over time—internally and externally. The elevation of the CLSR's relationship with the broad clinical laboratory community will be important and could result in support from outside of CDC for this Center. That also will help the CLSR grow and as it grows and its reputation improves internally and externally, he trusts that its responsibilities in future responses also will grow commensurately.

Mr. Dawes pointed out that one struggle in this country when there are disease outbreaks (e.g., epidemics, pandemics) is realizing an equitable response. He asked how the CLSR has been or will be engaged with the Office of Health Equity (OHE) to ensure that equitable responses can be realized in the future.

Dr. Salerno acknowledged that he had been in his position for about a week and had not yet personally engaged the OHE, but among the first 10 positions on the CLSR organization chart for which he currently has funding to fill is a Senior Health Equity Coordinator. As far as he is concerned, this is an absolutely essential function for the CLSR to have health equity front and center for the work the Center does and hopes to be able to demonstrate more work in that area in the future.

Dr. Martinez appreciated the point about the complexity of public-private partnerships. With that in mind in terms of this new approach and Center, he requested an update on interoperability with all laboratories and a timeframe for improvement of data exchange, which will be critical for the next PHE.

Dr. Salerno responded that tremendous strides were made during the pandemic in terms of electronic laboratory reporting (ELR). There was very little ELR of public health data prior to the pandemic. During the pandemic, the overwhelming majority of laboratory test results were reported electronically to jurisdictions and

from jurisdictions into CDC and the federal government. That was a huge leap forward for laboratory reporting. While he knew Dr. Martinez was asking a much broader question about interoperability, CDC is working actively on moving from 1-way reporting from the laboratories that are performing the tests to the public health department and on to CDC to a more fluid 2-way ELR system through which tests results and orders are transmitted electronically from one facility to another and back—especially when those orders and results cross the public-healthcare boundary. While there is a lot of work to be done, a lot of progress has been made. On the laboratory front, the CLSR is working with the OPHDST and is supporting the concept of specific intermediaries, including the APHL Information Management System (AIMS) and the Report Stream CDC intermediary that will allow any laboratory that is performing public health tests to send their tests results into the intermediaries. The intermediaries will standardize the data and elements associated with the data and automatically distribute the results to any and all entities (e.g., jurisdictions, federal government, CDC) that need the data instantly. The intermediaries also will enable the de-identification of the data so that jurisdictions receive identified and the government and CDC would receive only de-identified data. That process historically has been complicated, time-consuming, and slowed down the response. If CDC can persuade the broad laboratory system and community to engage with and use the intermediary concept, laboratory data exchange would be improved significantly. This would not only be beneficial during public health response, but also would improve healthcare and the interoperability between public health laboratories and laboratories in the healthcare system. This will take a long time, a lot of work, and a lot of resources, but there is a good strategy for doing this.

Dr. Medows expressed warm appreciation for the presentation, significant progress to date, the new organization structure, and the responsiveness to the input from the LW and stakeholders.

Dr. Houry expressed appreciation for the recommendations that are generated by the ACD WGs. She emphasized that to be very clear, they had zero additional dollars for funding this effort. Given the COVID recissions, there were some 1-time funds that were able to be used for some of these activities. However, that is now gone and they are doing what they can with existing or decreasing resources. She is very proud of this group and all of CDC's laboratory scientists. Change is not easy. She participated in 19 listening sessions with laboratory scientists and administrators across the agency regarding a lot of the recommendations and the structure. Her vision was division level, but people have to be brought along without forcing things on them. The branch level turned out to be the way to move forward for now and even that has caused a lot of angst, consternation, and phone calls. There is now a Standard Operating Procedure (SOP) for how the agency implements responses overall with graduated levels, so they are in a much better place—in part thanks to the WG and scientists and leaders at CDC.

Dr. Fleming expressed gratitude to Drs. Olson and Salerno for presenting an update, stressing that there is a lot of interest and that it is gratifying to see the progress that is being made.

Laboratory Workgroup Report

Jill Taylor, PhD (LW Co-Chair) noted that working with CDC and its scientists has been a pleasure. They have been open, honest, and responsive, which has made the LW's job much easier. During this presentation, the WG put forth 2 TORs for a vote.

Term of Reference Vote #1: Public-Private Partnerships

Issue: CDC laboratories need to use the best laboratory science advances to protect public health—advances that often originate in academia, small companies, or major instrument manufacturers. These advances include new instrument platforms, new diagnostic tests, and new laboratory diagnostic technologies. At the same time, CDC should be promoting testing that can be readily performed on commonly available instrument platforms and using diagnostic technologies that are readily available to private and public health partner laboratories.

Questions: How can CDC ensure that it stays at the forefront of laboratory technology and laboratory science advances that benefit public health? At the same time, what could CDC do better to promote testing on commonly available instrument platforms and to better use diagnostic technologies that are readily available to private and public health partner laboratories?

The LW met virtually on September 15, 2023 during which LW members heard from 2 external guests: Dr. Bruce Tromberg, National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institutes of Health (NIH), and leader of the Rapid Acceleration of Diagnostics (RADx®) Program; and Mr. Rodney Wallace, Director of the Biomedical Advanced Research and Development Authority (BARDA) Detection, Diagnostics and Devices Infrastructure (DDDI) Division. The LW also heard from 2 CDC SMEs: Dr. Ren Salerno, Acting Director, CDC CLSR; and Dr. Duncan MacCannell, Director, CDC Office of Advanced Molecular Detection (AMD). Regarding the challenges identified in terms of enhancing public-private partnerships at CDC, CDC's formal engagement practices are complex, lengthy, and time-consuming. There also are inadequate resources to support continuing scientific advancement at CDC. In addition, there are cultural norms that must be addressed with respect to balancing investing in scientific advances with avoiding the perception that the government is favoring one company or technology over another. These are realities that have to be taken into account. The WG's conclusion was that the CDC does not take full advantage of the scientific expertise and technological advances available outside of the government, and that there are examples of other federal agencies that do engage in a more flexible and approachable way with academia and private industry (e.g., NIH, BARDA, and Department of Energy).

It is important to make clear that CDC already is working with public-private partnerships, which have advanced the agency's mission. Some examples include:

- An MOU with clinical partners for surge testing.
- The SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) genomics consortium collaboration that includes scientists from clinical and public health laboratories, academic institutions, and the private sector
- An MOU with commercial laboratories during the Mpox outbreak that was done without resources
- The Pathogen Genomics Centers of Excellence (PGCoE) network, which involves collaborations between US public health agencies and academic institutions
- A CDC collaboration with RADx® and an industry partner who are currently collaborating on hepatitis C virus (HCV) elimination

In terms of laboratory preparedness during PHEs, the COVID-19 pandemic clearly indicated that all laboratory sectors played an essential role in providing diagnostic or surveillance testing, and that no one sector acting alone could support the unprecedented needs. There is a critical need to develop, formalize, and exercise the concept of a national laboratory system in which all partners understand their roles and responsibilities, and act in a coordinated fashion during biological emergencies. CDC, as the country's premier laboratory, should take the lead in organizing the health-related federal agencies and all sectors of the laboratory and diagnostics manufacturing industries to develop a role-based plan for managing the next biological emergency. The first step in developing that plan must be to make building and maintaining external relationships of prime importance to CDC.

The LW proposed the following Action Steps related to public-private partnerships, which they brought forth to ACD for a vote:

1. CDC should explore the feasibility of developing formal partnerships with other federal scientific agencies to take advantage of their pre-existing relationships with private industry.
2. CDC should make working with the private sector an accepted approach to ensuring that CDC stays at the forefront of laboratory technology.
3. CDC should consider making testing for rare or esoteric diseases available in non-CDC public health laboratories and large academic reference laboratories.
4. CDC should take the leadership role in convening representatives of all laboratory sectors in the US, as well as leadership from federal agencies with a health and preparedness role. The task of this group would be to develop and exercise a living plan for coordinating the functions of the agencies and laboratory sectors during biological emergencies.
5. CDC should consider always including external subject matter experts (SMEs) in the laboratory sciences as members on relevant CDC Advisory Committees and Boards of Scientific Counselors.

Discussion Summary Vote #1

Dr. Sharfstein pointed that while the LW appreciated the RFI process that can be used for bigger questions, they thought that there should be more nimble mechanisms for engagement that still have ground rules and structure but do not require the RFI process.

Dr. Morita wondered whether the recommendations should be directed toward particular parts of CDC, such as the CLSR, which could result in the ability to garner more resources.

Dr. Fleming noted that the fact that the ACD would be making these recommendations to the CDC Director makes clear that from a resource perspective, it would be necessary to look across the agency.

Vote #1: Public-Private Partnerships

A motion was made and seconded for the ACD to adopt the LW Report and 5 Actions Steps pertaining to public-private partnerships as ACD recommendations. The ACD voted unanimously to adopt the LW Report and 5 Actions Steps as ACD recommendations to move forward to CDC and HHS, with no dissentions or abstentions.

Term of Reference Vote #2: Recruit/Retain Outstanding Laboratory Scientists

Issue: Excellent laboratory scientists are essential for high-quality, advanced laboratory testing, laboratory research and clinical laboratory testing. The market for such scientists is highly competitive with the private sector offering compensation that is extremely difficult for CDC to match.

Question: How can CDC better recruit and retain outstanding laboratory scientists to ensure high-quality, advanced laboratory testing at CDC?

Regarding the topic of recruiting and retaining laboratory scientists, the LW met virtually on October 24, 2023 during which they had a very frank discussion with CDC staff, including: Tara Henning, PhD, who leads the Laboratory Leadership Service (LLS) Fellowship Program; Kelly Mathis, Supervisory Strategic Business Partner, Office of Human Resources (OHR); Jason Washington, Strategic Business Partner, OHR; Victoria Olson, PhD, Deputy Director, OLSS; and Wendi Kuhnert, PhD, Deputy Director for Laboratory Readiness and Response, NCEZID. To summarize the LW's findings, the administrative processes in place at CDC to recruit scientific staff are complex, rendering it challenging and sometimes impossible, to find and attract technically qualified personnel. Even when technically qualified personnel are identified, the ability to recruit the most capable personnel is often not administratively supported. The result is a shortage of talented and qualified scientists to direct and staff laboratories performing diagnostic testing, as well as those responsible for national

preparedness and response functions during biological and environmental emergencies. Similar limitations were identified with respect to scientists working in and leading CDC's research laboratories. The CDC's administrative challenges in recruiting and retaining highly qualified scientific staff result in a national vulnerability that puts public health and safety at risk.

The LW proposed the following Action Steps related to recruiting and retaining outstanding laboratory scientists, which they brought forth to ACD for a vote:

1. CDC Executive Leadership should urgently request a review of federal recruitment policies and procedures and a report on policy changes that can be made to address this issue. The LW understands that some changes may require Congressional action but believes progress can be made short of such reforms as well.
2. CDC should strongly consider capitalizing on the success of the Laboratory Leadership Service (LLS) program to design an additional year that could prepare LLS Fellows to sit for the Board Exams to qualify them as Clinical Laboratory Directors.
3. CDC should enhance retention of scientists by developing a career path that will support laboratory scientists advancing in their careers while remaining in the laboratory doing critical work for the American people.
4. The Office of Human Resources at CDC should contact Human Resources offices at other federal agencies that require scientific and technical staff to become informed about their scientific hiring practices and policies.

Discussion Summary Vote #2: Recruit/Retain Outstanding Laboratory Scientists

Dr. Taylor emphasized that the LW did not wish to be critical of the OHR because they are doing their job in terms of assuring that all of their practices are equitable and appropriate, but more flexibility is needed in hiring practices to be able to attract and retain qualified scientists at CDC.

Dr. Fleming stressed that the LW has done a lot of great work. This particular topic caught his eye as far as pointing out the realities of some of the relatively straightforward steps that in theory CDC could take, given that it is a government bureaucracy work to bring in the required talent.

Dr. Martinez asked whether the LW looked internally to determine whether leadership skills development is being provided. Often, this does not occur in bureaucracies or large organizations. Even academia has a tendency to promote based on one's history rather than helping someone move to the next step to be successful in a leadership position, which may differ from what brought one to the attention of getting the leadership positions.

Dr. Taylor responded that the LW did not get into that level of granularity. The focus was primarily on getting people in the door with the right qualifications.

Dr. Sharfstein added that while Dr. Matinez's point was very good, the challenges now are that the people who are engaged in hiring for laboratory positions are frustrated even in getting applications in from people who they know are applying to get to the interview stage.

Ms. Valdes Lupi asked whether in the conversations among the WG members or with CDC colleagues there was discussion about similar challenges that are occurring within some of the larger health departments that have laboratories, and the potential for taking an enterprise systems approach in terms of recruitment into the field and opportunities for laboratorians at the state-level to move into CDC and vice versa. She also wondered whether there are any mechanisms available for IPAs or to have similarly trained individuals in the private industry or academia placed within CDC.

Dr. Taylor indicated that there are more details in the LW report regarding specific mechanisms, such as 2-way fellowships such that academic or private industry can work at CDC and vice versa. There also are specific recommendations about making sure that all recruitments go outside. Some recruitment is aimed at existing employees rather than the full field. The shortage nationwide is absolutely true and there definitely is a gap in the short-term. There has been a huge exodus of public health and laboratory scientists following the pandemic. All mechanisms available must be used to get people interested in science and laboratory careers and raise the profile of the value of such careers among young graduates.

Vote #2: Recruit/Retain Outstanding Laboratory Scientists

A motion was made and seconded for the ACD to adopt the LW Report and 4 Actions Steps pertaining to recruiting and retaining outstanding laboratory scientists as ACD recommendations. The ACD voted unanimously to adopt the LW Report and 4 Actions Steps as ACD recommendations to move forward to CDC and HHS, with no dissentions or abstentions.

Sunsetting the Laboratory WG

The LW Chairs expressed their gratitude and appreciation to the members of the LW; the ACD Designated Federal Officer (DFOs), Dr. Auerbach and Dr. Houry, and LW DFO Lauren Hoffmann; and the external SMEs and CDC experts and all those with whom the LW met for their openness and willingness to discuss challenges and find solutions. The LW had great conversations, learned a lot, and expressed their hope that they have been helpful to CDC and can continue the conversations.

Discussion Summary Vote #3: Sunsetting the Laboratory WG

Dr. Fleming thanked the incredible LW, noting that he had the opportunity to attend a couple of the LW's meetings where he had the opportunity to observe the LW's work and CDC support in action, which were quite amazing. Another attribute of the LW are its Co-Chairs, the "Dynamic Duo" of Drs. Taylor and Sharfstein. He emphasized that just because the LW's TORs have been completed does not mean that the work is done. The ACD will rely on the LW to ensure that the ACD continues to hear updates from CDC on implementation of its recommendations and identifies emerging laboratory issues as they arise in the future.

Vote #3: Sunsetting the LW

The ACD acknowledged and expressed appreciation for the significant contributions of the LW in advancing CDC's public health laboratories. After careful evaluation of the LG's achievements, the successful completion of its goals, and the valuable insights gained during its tenure, the ACD made a motion to sunset the LW. The motion was seconded and the ACD voted unanimously, with no dissentions or abstentions, to sunset the LW.

Supporting Healthy Families

Charlene Wong, MD (CDC Senior Advisor for Health Strategy) reported that Dr. Cohen's 3 priority areas include: 1) identifying and responding rapidly to health threats, which includes CDC's work on the Fall/Winter respiratory season; 2) improving mental health and combatting overdoses; and 3) supporting young families—the focus of this presentation. Within these focus areas, they have been discussing how to meet CDC's mission to protect health and how this requires working as a team. With that in mind, the frame that is being used is "Protecting health as a team sport." The collaborative approach has been prioritized because the goal is to accelerate impact on these important areas by bringing teams in public health alongside health care, social supports, public and private sectors, and other teammates. Working as a team means building relationships and identifying aligned priorities with partners; identifying shared goals in order to share accountability with federal, state, and local partners; tactically moving in this way by developing a set of collaborative initiatives to model how CDC and public health do this work; and coming together to tell the story of the successes and impact that have been

built together, which is another critical component to protecting health as a team sport. The 3 focus areas are complex and tricky to navigate. For instance, mental health and maternal health are not moving in the right direction. These require teamwork in public health, healthcare, social support, and community ecosystems to move in the right direction.

CDC is moving to action and tactics through a set of collaborative initiatives in existing CDC programs, policies, or data activities that can accelerate impact on major public health issues by leaning into results-based partnerships and increased partner engagement. A lot of this work was begun by talking with the agency's colleagues at the federal level to ascertain where together they could showcase the joint leadership of federal government agencies through aligned priorities for which measurable impact could be demonstrated within the next 9 to 12 months. Dr. Wong noted that all of the examples of collaborative initiatives she would share have been proposed, narrowed, and refined by CDC's CIOs with cross-agency input. These all build upon the many established partnered public health activities that have been ongoing at CDC for a long time.

These collaborative initiatives and the approach of protecting health as a team sport are aligned with multiple improvement areas identified through Moving Forward. An obvious element of Moving Forward is the section called "Results-Based Partnerships." The goal of this section is "To increase collaboration with partners to solve major health problems, CDC is promoting results-based partnerships agencywide by increasing partner engagement through new management systems and communication and providing more avenues to receive partner feedback." Some of the collaborative initiatives are implementing several partnership best practices, including aligning on strategic priorities, building a collaborative tactical work plan, and stating measures of shared accountability. Specific to the priority area of Supporting Young Families, CDC is breaking down siloes and prioritizing upstream prevention so that children and families have what they need to thrive. Dr. Wong shared 3 examples to illustrate this type of work: "Learn the Signs. Act Early" for child development, improving care for postpartum mothers, and expanding implementation of positive childhood experiences and strategies. For each of the 3 examples, she described the collaborative initiative and why it is important in this moment and highlighted the shared accountability piece.

In terms of the "Learn the Signs. Act Early." tool, a concerning rise has been seen since COVID in the number of children who are missing developmental milestones. Certainly, this is feeding into the youth mental health crisis and many other issues occurring among children currently. "Learn the Signs. Act Early." is a fabulous online-based CDC tool that anyone can use to help them identify developmental issues earlier. It is known that the earlier issues are identified and the sooner children are linked to support, the better the outcomes. To meet this moment in which more young children are missing milestones, CDC is working with partners to supercharge dissemination and use of this free, ready-to-go, evidence-based tool. For instance, CDC is working with the Health Resources & Services Administration (HRSA) to train up staff in Federally Qualified Health Centers (FQHCs); the Administration for Children and Families (ACF) because they want to help CDC get this tool into the hands of more early care and education providers where there has been huge turnover during the pandemic; and the US Department of Agriculture (USDA) and local nutritional partners through Women, Infants, and Children (WIC) programs that are interacting with families. Some of the metrics that have been identified to promote results-based partnerships are: 1) increase the number of "Learn the Signs" App users by 25% to at least 2.2 million by October 2024 (baseline from 1.8 million in September 2023); and 2) at least 50% of the 151 Early Childhood Development-funded FQHCs report using "Learn the Signs" training and materials by August 2024.

In another example of supporting young families that overlaps with the mental health focus area, CDC is excited to be co-leading work on expanding the implementation of positive childhood experiences strategies that often is referred to as preventing adverse childhood experiences (ACEs). The more ACEs children experience, the more likely it is that they will have poor health outcomes. A wonderful product[1] CDC has that addresses ACEs is titled, "Adverse Childhood Experiences Prevention: Resource for Action." This collaborative initiative is all about partnership in order to bring more of the strategies that are known to work that are in this resource to life with CDC's partners for more children and families. For this project, CDC is working with the ACF, the American Academy of Pediatrics (AAP), and the Office of the Surgeon General (OSG) to prioritize the approaches included in this product to focus on strategies that promote social connectedness for children and families, such as parenting strategies. They are leveraging existing networks, such as grantees who are thought to be best-suited to cross-share information. There also is an opportunity to leverage some measures, such as positive childhood experience and social connectedness. The metrics for this strategy are to increase downloads of the CDC's "ACES Prevention: Resource for Action" by 10% by October 2024. Additional metrics to be developed with partners.

Regarding the final example of some of the work to improve care for post-partum women, this is a top priority with multiple partners within HHS and beyond. The post-partum period has been identified as a critical opportunity in particular for working with states and local jurisdictions. Along with partners from the Centers for Medicare and Medicaid Services (CMS), the American College of Obstetricians and Gynecologists (ACOG), the Office of the Assistant Secretary for Health (OASH), and the Indian Health Service (IHS), CDC has focused on hypertension as a major cause of maternal morbidity and mortality. IHS and Tribal partners are listed because this work is leading with equity, given that rates of hypertension and related disorders in pregnancy are much higher in Tribal populations. With a "Hypertension in Pregnancy QI Change Package" anticipated to be launched in May 2024, input is being sought from IHS and Tribal partners to learn what will be useful to them in thinking about supporting American Indian/Alaskan Native (AI/AN) pregnant people in their journey, particularly as it relates to hypertension. Working with CMS will help understand the payment structures and mechanisms to support more of this type of work. The metrics for this strategy are a 20% increase in the percentage of people with hypertension disorders in pregnancy receiving effective treatment (e.g., self-measured blood pressure monitoring, medication, lifestyle changes) in 200+ participating practices by December 2024.

In conclusion, Dr. Wong emphasized that these are just 3 examples of collaborative initiatives in this space that cover topics such as childhood immunization and school-based supports for youth behavioral health. This work is part of CDC's commitment to promoting results-based partnerships, being part of an integrated system that protects the public's health, and building partnerships as a core capability at CDC. Moving into the discussion, Dr. Wing expressed her hope that the ACD had seen in these examples that these initiatives are about inspiring action and bringing more public health data and best practices to life in more states and local communities. She invited ACD's thoughts on: 1) how CDC can work most efficiently and effectively with healthcare systems, payers, and other community-based partners who, in many cases, will be the arm that will be bring these efforts to light; and 2) how the agency can evaluate these efforts or generate evidence on how to bring more of these types of collaborative efforts to implementation (e.g., implementation science).

Discussion Summary

Dr. Morita emphasized that the concept of CDC partnering with other federal agencies is an area in which there is a lot of opportunity that has been unrealized in the past. It is clear in this work that there is a focus on marginalized populations that is demonstrated by the partnerships with FQHCs and WIC. Regarding accountability and tracking, the metrics identified do not necessarily get into tracking the uptake of the various interventions by marginalized populations. From a health equity perspective, those are the groups who need the most support. The way to ensure that those groups are getting what they need is by tracking the data by population.

[1] https://www.cdc.gov/violenceprevention/pdf/ACEs-Prevention-Resource_508.pdf

Dr. Wong indicated that certainly this could be done for some of the collaborative initiatives in which those data are more readily accessible, but can be one of the challenges for many of these types of initiatives. Use is being tracked for "Learn the Signs. Act Early." While all of the suggestions proposed across CIOs led with equity, the measurement component can be trickier for some strategies. Consideration is being given to how other datasets can be leveraged as a proxy for uptake, such as Medicaid claims data to assess sociodemographic information in terms of hypertension. Some of these are very much targeted toward addressing the inequities and disparities that are known to exist.

Dr. Martinez pointed out that with ACEs it is easy to think about focusing on the parents of the children, but given the trends that have happened, especially with the opioid crisis, a greater number of grandparents are raising their grandchildren. Given that, it is important to ensure that these resources also are addressing all individuals who are raising children. This is particularly relevant for rural America. It is important that marketing of the resources takes these nuances into consideration in order to reach these types of families. He agreed that post-partum care is a super important timeframe in terms of child development but wondered whether any thought has been given to pre-conception. Going upstream as much as possible is important given the ecosystem that exists prior to conception that then results in how a child is to be raised and the factors that are going to impact them, especially in terms of ACEs.

Dr. Wong indicated that there has been discussion about taking a multigenerational approach to supporting young families, particularly given that households with even broader multigenerational structures are often in historically marginalized populations. CDC can think even more deeply about opportunities to engage other partners to ensure that these populations are reached.

Dr. Wong responded that part of the reason the post-partum period came up was because one of the discussions in terms of policy levers has been thinking about the opportunities available to them. For instance, 37 states have now extended post-partum Medicaid coverage to 12 months. Just giving that coverage extension is not going to actually bring the benefits to the women who most need it. Post-partum was a nice use case to address the whole spectrum from maternal care to primary care, which would then lead into inter-pregnancy spacing and pre-conception and potentially a healthier next pregnancy. Thinking about pre-conception is certainly important. Everything is about getting very far upstream.

Related to the recommendations that the HEW developed, Ms. Valdes Lupi asked whether Dr. Wong could say more about how equity is embedded in the 3 agency-wide priorities and what thought has been given to community engagement and partnering with communities in terms of developing all of the work that follows and the measures. In terms of partnerships with other agencies, she suggested leveraging existing Community Advisory Boards (CABs) and others.

Dr. Wong indicated that she came with Dr. Cohen from North Carolina where everyone leads with equity, so the 3 focus areas certainly were identified leading with equity. It is known that there are immense disparities in all 3 of these areas. The work of "Protecting Health as a Team Sport" is about bringing strategies to action that will help start addressing those disparities. A good example of community engagement is related to the Fall/Winter respiratory season and the new RSV immunization product to protect infants. Given that AI/AN babies have a rate of hospitalization due to RSV that is 4 to 10 times higher, there is a unique recommendation for the for nirsevimab infant immunization. This is one of the collaborations on which CDC has been working with AAP, CMS, Tribal partners, and others. A listening session process is being kicked off that will begin after the respiratory season with listening sessions to ascertain what worked, what did not work, what questions were raised by the community, what misinformation there was, et cetera. This will allow for unrushed time to align on what the messaging should be for the next seasons and what resources need to be developed together so that by summer, support and communications will be ready to be launched for the next season. They will have

sociodemographic data for immunization rates by regions and sociodemographic groups as part of the data modernization work to get even more granular data. Dr. Liburd is part of the work to develop these and ensure that all of the CIOs are aware of CABs and other community groups.

Mr. Dawes said he was delighted with the 3 priority areas, the holistic approach that is being taken, and the intent to look at the whole ecosystem. One thing that struck him was that mistrust is rampant among various groups, such as people with disabilities, racial and ethnic minoritized groups, and so forth. He did not see any organizations that have the trust of some of these communities, such as the National Association for the Advancement of Colored People (NAACP) and others who have been in the trenches advancing health equity. He asked for a sense of how CDC intends to include groups that represent these groups.

Dr. Wong responded that certainly more of that is built in currently in the AI/AN work. Certainly, some of the partnerships are about leveraging each other's networks. For example, in the work around ACEs the lists are local, community-based groups that do have that trust. All of the work with national partners she discussed is getting effectuated at the state and local levels working through grantees in many cases that do have trusted relationships. She will take this question back to the team for additional information as they think about implementation support and being intentional in ensuring that they are engaging the right groups.

Dr. Taylor pointed out that 2 pieces of information that have arisen recently are the decrease in childhood vaccinations and the massive increase in homeschooling, which are likely to become public health crises very soon. In terms of engaging with communities, it is important to include these issues in the conversations to understand whether people are objective to the vaccine or the mandate.

Dr. Wong indicated that one of the collaborative initiatives she did not highlight focuses on catch-up of routine vaccination for children. In terms of homeschooling, the number of exemptions that just came out is alarming. CDC has a wonderful campaign that is at the center of this collaborative initiative called "Let's Rise." This initiative is about partnerships with healthcare providers (HCP), education, and others. Somewhat adjacent to the question is that in thinking about schools and the many challenges there, another CDC initiative focuses on school-based behavioral health supports. It is known that children feeling connected at school is a protective factor and is likely to keep them in school. In addition, the Division of Adolecent and School Health (DASH) has been newly merged with the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), which can be leveraged as an opportunity to assess the strategic priority as it relates to supporting physical and behavioral health in children in schools.

Dr. Sharfstein expressed appreciation for how in this set of initiatives they recognize that it is not only about what CDC does directly, but also that CDC can focus on a goal and bring in people around it. Having Dr. Wong and Director Cohen around these demonstrates the authority that CDC can have, even for things not under its direct control, as a coordinating and leadership force in achieving public health outcomes. He asked whether thought had been given to the structure that is needed for successful intervention so that it can be replicated across other issues and perhaps eventually across the agency so that it can be adopted for other programs.

Dr. Wong emphasized that thought is definitely being given to what sustainable structures are needed. Particularly because this is so aligned with Moving Forward and results-based partnerships, they are leveraging work that has been ongoing. For instance, in thinking about the results and shared accountability elements, they align the way measuring and reporting are being done with the Performance Management Framework that is being put in to place as part of the work of Moving Forward. A major part of all of this is building and sustaining relationships, following up with the action needed, and making sure that they are coordinated across CDC in reaching out to CMS and asking them to do different things or pay for different things with CDC. For instance, an infrastructure piece that is being built as part of Moving Forward is a consumer online tool to track which

partners they are working with, who is working with them, and so forth. They also are working with teams in the Office of Policy, Performance, and Evaluation (OPPE) to think about how to document the process so that it is more "plug and play" across different types of topic areas.

Dr. Morita stressed that the challenge with immunization is an area in which the concept of partnering with community is going to be essential. It is important to take advantage of the lessons learned from COVID in terms of the power and impact of trusted partners at the national, state, and local levels in order to decrease health inequities and disparities. It is critical not to lose these opportunities, particularly with community partnerships.

Dr. Fleming emphasized that one issue that has been identified is that there is fragmentation and siloing at the federal level. At the frontline level in delivering services, there also is fragmentation and siloing across all of the various interventions for the same mom and child who need to benefit multiply across all of these. He wondered whether any thought had been given to what CDC and the federal government might do to help integrate thinking about the range of these interventions so that frontline community-based organizations (CBOs), community health workers (CHWs), and providers can more quickly identify and assure across all of these interventions that the ones that are most important are the ones that are actually getting delivered.

Dr. Wong responded that in healthcare and other sectors, things follow the money. CDC has been working closely with CMS to think about the payment structures that are needed to bring public and healthcare closer together to support services. Given that there are limited intervention resources, it is important to match the limited and right intervention resources in the right places and for the right people. One of the collaborative initiatives she did not highlight is in the mental health, overdose, and Overdose Data to Action (OD2A) space. CDC is working with the Substance Abuse and Mental Health Services Administration (SAMHSA) to convey that CDC is helping to support incredible public health data and best practices related to overdose in the OD2A program, with dollars going to state and local jurisdictions. SAMHSA does the same thing in terms of funding state and local jurisdictions for treatments of naloxone and medication-assisted treatment (MAT). In some cases, it has happened organically that the "dots have been connected" at the state or local level to bring those limited resources together to the best places. CDC is working with SAMHSA to determine what CDC and SAMHSA can do together in terms of collaborative technical assistances (TA) with state and local grantees so that it is not just hoping that something happens organically at the local level.

COVID-19 Recission

Sherri Berger, MSPH (Senior Counselor, CDC) presented a summary focused on the Fiscal Responsibility Act (FRA) of 2023: Impact on COVID-19 Supplemental Funding for CDC, which drives the COVID-19 recission. The FRA resulted in a rescission, or returning, of COVID-19 supplemental funding from CDC. These were not funds that already had been obligated. If funds already had been allocated to a state or local public health department or other partner but had not yet been spent, those dollars were not rescinded. These were funds that had approved spend plans but were not yet obligated by the agency. All of the funds had been planned but had not yet been obligated. For instance, there might have been a multi-year grant program that had been awarded the first 3 years but the second 2 years had not been awarded. Those were the kinds of dollars that were rescinded. Another thing this bill did that had nothing to do with COVID was put spending caps in place for the for the Federal Appropriations process for FY 2024 and 2025. The bill capped discretionary funding levels for FY 2024 and FY 2025, which will impact CDC's base budget through the annual appropriations process.

CDC received COVID-19 supplemental dollars from 2 sources. The first was about $27 billion for which Congress specified use. $600 million was deposited into the Infectious Disease Rapid Response Reserve Fund (IDRRRF). CDC had obligated more than 91%, not including funds deposited into IDRRRF, at the time the bill was signed. Close to $1.3 billion was rescinded. The second source was from the $55 billion that was allocated to HHS that was intended to be allotted to CDC for public health workforce or testing and mitigation, of which CDC had

obligated more than 96% at the time the bill was signed. Close to $1.7 billion was rescinded. This included all remaining public health workforce dollars. HHS retained some testing and mitigation funds.

Over the multiple COVID supplementals since 2020, CDC was to receive $27 billion directly to be allocated as follows:

- Coronavirus Preparedness and Response Supplemental Appropriations Act = $2.2 billion
- Coronavirus, Aid, Relief and Economic Security Act = $4.312 billion
- Paycheck Protection Program and Health Care Enhancement Act = $1 billion
- Coronavirus Response and Relief Supplemental Appropriations Act = $8.54 billion
- American Rescue Plan Act of 2021 = $11.52 billion

Over the multiple COVID supplementals since 2020, CDC was to receive $55 billion via HHS to be allocated as follows:

- American Rescue Plan Act of 2021, Workforce = $6.06 billion
- American Rescue Plan Act of 2021, Testing & Mitigation = $16.9 billion
- Paycheck Protection Program and Health Care Enhancement Act = $10.25 billion
- Coronavirus Response and Relief Supplemental Appropriations Act = $21.36 billion

The largest impact to COVID-19 Supplemental Funding provided to CDC included rescinding of balances of certain line items to be returned to the US Treasury. The first category was vaccine distribution and related activities (e.g., safety monitoring, effectiveness studies, collection and sharing of vaccine data, support to NGOs and CBOs to increase vaccination rates, et cetera) of $850+ million. The second category was for vaccine confidence of $102 million. The third was global health activities of approximately $300 million. The good news was that some key priorities such as data modernization and genomic sequencing were not impacted, given that so much of those funds had been obligated or were in a pipeline, or Congress recognized that these funds always were intended to be multi-year funds for building infrastructure.

Most remaining funds are intended for specific activities (e.g., data modernization, genomic sequencing, wastewater surveillance, et cetera). CDC is working to obligate the remaining funds. Where feasible, the agency is actively working to continue its commitment to the work. Examples of programs that were scaled back or ended early included the following:

- Immunization Information Systems ($163M)
- Partnering for Vaccine Equity program ($150M)
- Vaccine Confidence ($102M)
- Global Vaccine Readiness and Technical Assistance ($62.5M)
- Enhanced Pan-Respiratory Surveillance ($102.5M)
- Global Public Health Data Innovation ($46.9M)
- Disease Intervention Specialists ($473.3M)
- Laboratory Data Exchange ($240.8M)
- Public Health AmeriCorps ($118.3M)

In terms of other FRA impacts beyond COVID-19, though the numbers are subject to change, the bill also capped discretionary funding levels for FY 2024 and FY 2025, which likely will impact CDC's base budget through the annual appropriations process. The House's FY24 mark for CDC was not great, though the Senate was better. CDC is currently operating under a Continuing Resolution (CR), which may be extended a few more times before there is finally a negotiation between the House and Senate, but they are very far off in terms of the bill in which CDC sits (Labor-HHS-Education). In June, the allocation released for the House and Senate was a Senate cap for

Labor-HHS-Education of $195.2 billion and a House cap for Labor-HHS-Education of $147.1 billion. The House allocation was $48.1 billion lower than the Senate and the Senate was almost $12 billion below FY 2023 levels. The House LHHS Sub-committee subsequently revised the planned budget cap, it is now $23 billion lower. • The Senate mark was $9.142 billion, including $7.712 billion in budget authority, $1.186 billion in the Prevention Fund, and $244.330 million in transfers from PHS Evaluation funds. In total, this is roughly $40 million below the FY 2023 Enacted. CDC's bill is typically one of the most controversial and it appears that they are going to try to take some of the easier bills off of the table and resolve those sooner. CDC's probably will be closer to the end of the batch.

Discussion Summary

Dr. Fleming observed that COVID-19 resulted in a fair amount of resources being allocated to CDC and state and local health departments. As a result, it was possible to do new things. Sometimes in a budget cutting environment, it is last in-first out when dollars go away. Arguably, many interventions implemented during COVID, such as health equity, may represent priorities going forward. He asked whether there was anything CDC and/or the ACD could do to enable the perspective of determining what is most important to keep rather than last in-first out.

Dr. Sharfstein observed that one challenge is that there is an issue of the moment like COVID, funding comes in for that, and then it suddenly goes away. He wondered if Ms. Berger had any perspective on how those mini-surges of funding could be used to build overall capacity or if it was a "fool's errand" to think of it that way.

Ms. Berger said she probably would ask the jurisdictions because at the end of the day, that is where the bulk of the resources are going. Inside CDC, infrastructure investments are needed. It is not completely a "fool's errand" and there is an opportunity for investments, such as moving to the Cloud. There are 1-time infrastructure investments that perhaps take 3 years to achieve, so it is not completely outside the realm of possibility. However, memories are short. It is sad to see programs such as Public Health AmeriCorps go away when she thought this was the future of the public health workforce pipeline. There is and always has been a gap in understanding what public health is, and there is not the same level of advocacy that exists in other parts of the government. There is so much competition within public health about what is most important rather than the idea of focusing on the infrastructure and the capacity to build data and a workforce that would benefit everybody. While champions are needed, it has been years since the agency has had some champions on The Hill.

Ms. Valdes Lupi said it struck her that vaccine distribution and confidence comprises the bulk of the funds that will be returned at almost $1 billion. There have been conversations about whether it is "Public Health" or the "Public's Health." This relates to earlier discussions about vaccine uptake generally decreasing for pediatric vaccines and the challenge for CDC and the field pertaining to rebuilding trust of the public. She wondered how to mitigate the impacts of having to return this large amount of funds, particularly with regard to what will be even more barriers in terms of the work that CDC and public health departments in collaboration with communities.

Dr. Fleming expressed gratitude to Ms. Berger for her service to the CDC and emphasized that she would be missed.

Agency Priorities and Updates

Mandy K. Cohen, MD, MPH (CDC Director) discussed agency priorities and updates to the ACD during her first presentation to this advisory committee. She thanked the ACD for the opportunity to speak and to get to know them during this meeting. She expressed gratitude for the incredibly important work that has shaped the work that CDC is doing in terms of laboratories, data, and equity. She thanked Dr. Houry for being her teacher since

coming to CDC, who has helped her navigate and learn quickly. She stressed that when the ACD is chatting with Dr. Houry, almost immediately Dr. Houry has a conversation with Dr. Cohen. She welcomed Andi Lipstein Fristedt as the new Deputy Director for Policy, Communications, and Legislative Affairs. This is a new position that is emblematic of some of the work the agency is doing to leverage work across CDC and invest in some core functions that can make CDC stronger. She also recognized other leaders in attendance and noted that they would be celebrating Ms. Berger the next day for her 28 years of service. CDC would not be where it is without Ms. Berger's leadership and tenacity.

Reflecting on her almost 5 months as CDC Director, Dr. Cohen recognized the incredible breadth and depth of the immense amount of work CDC has underway. The mission that guides the agency in terms of protecting the health of this country and the work is incredible in terms of what that entails. She sees talent all over the agency doing this incredible work. CDC also has incredible teammates outside the agency. One reason her calendar has been so punishing is that she has visited many states and localities already, most of which have talked about getting ready or now being ready for the Winter respiratory virus season and the importance of vaccines. She is trying to make sure she is meeting with and hearing from folks across the US, because she believes in valuing relationships and showing up in person, which helps to know and see folks differently. Many great things are happening throughout the country. She also took her first internationally trip to Brazil where she was able to see the power of global relationships and the importance of CDC's global work shine through. While there, she had the opportunity to tour vaccine manufacturing facilities and to talk about the $2 billion investment Brazil is going to make in their laboratory capacity. CDC can share lessons learned with them and vice versa as they make those investments.

Dr. Cohen emphasized how proud she is to see the CDC come out of a historic pandemic, learn some hard and important lessons, and embed them into the work. Moving Forward was the right track and right start for the organization and she thinks the reorganization is going to make CDC a stronger and more effective agency. Moving Forward is about more than moving boxes on the organization chart. It also is about embedding lessons learned, rapid communication of scientific information, and working as one team. Those efforts are still underway, and she sees every day how CDC is investing in those core capabilities to make the agency stronger. These are unprecedented times in terms of increasing health threats now and on the horizon. These also are unprecedented times of scientific innovation and breakthroughs. There have never been the kinds of tools that are available right now to address health threats in terms of vaccines, treatments, detection platforms, diagnostic capabilities, artificial intelligence (AI) breakthroughs, et cetera. She expressed her hope that the ACD sees CDC as being more transparent in its efforts with regard to the timeliness and accessibility of communications and in how they are bringing together data. For instance, COVID does not live separately from influenza and RSV. Rapid communication is begin disseminated about all 3 to provide guidance about changes to these viruses, early variants that look worrisome, et cetera.

The team also is focusing on operational excellence. This means that not only does the agency provide recommendations for vaccines, but also holds itself accountable for getting folks vaccinated by breaking down all types of barriers (e.g., education, distance, cost, et cetera) to ensure that vaccines are accessible as possible. The team stood up the enormous Bridge Program in record time, which is now operating with success across the country to give folks access to no-cost vaccines with pharmacy partners. The VFA program that Ms. Berger spoke of has been in the CDC's budget and is something Dr. Cohen has been speaking about to members of Congress, which is one way the agency is extending what the Bridge Program is doing. Another element of operational excellence is building relationships. She was heartened to see the partnership of work for the Fall/Winter respiratory season. For instance, when the new nirsevimab RSV infant immunization came on the market, there was no billing code for pediatricians to be paid for administering nirsevimab. CDC worked with the American Medical Association (AMA), AAP, CMS, and others to get a code and for CMS to adopt it. In addition, there was a code to include counseling as well to explain what nirsevimab is. This intersection between operational

excellence, the scientific recommendation, and the partnership component was outstanding work. While the focus on operational excellence has been great, there is more work to do.

As Dr. Cohen thinks about CDC moving into the future, she has focused on 3 areas as mentioned earlier: 1) identifying and responding to health threats; 2) improving mental health and combatting overdoses; and 3) supporting young families. She emphasized that she could use the ACD's help within these 3 areas of focus. A pressing issue right now is that more people need to be vaccinated. CDC could use all voices to articulate good information to combat the misinformation that is circulating in order to break through a lot of noise. In addition, there is a lot going on in the world. In addition to folks just being busy, there also is vaccine fatigue and mistrust. Input also is needed on working together to further the work that CDC is doing in terms of data best practices and collaborations. She and Dr. Houry have been talking about a potential working group for the ACD to consider. She began her first All-Staff meeting with the concept of building trust, which is foundational. She wondered if there is a working group about building trust that focuses on communication and partner engagement, which the ACD could help CDC think about in the context of the 3 areas of focus or broader. The HEW very much highlighted for CDC the importance of partnerships with community organizations. She wondered about the ways in which CDC could be a better partner to community organizations in terms of ensuring that there is equity in all policies. Perhaps a working group could focus on trust-building, communications, misinformation, vaccine fatigue, and partner engagement and furthering equity work with community organizations. This would be a newer space in which CDC could build some more muscle for the organization.

Discussion Summary

Dr. Fleming shared that he lives on Bainbridge Island in Washington where there is lousy cell service, and they are one of the few households there that still has a dedicated landline to use when cell phone service is out. In July 2023, his landline rang. Because they primarily receive robocalls on this line asking for money, they ignored the call. About an hour and a half later, his wife stepped into his office to let him know that the new Director of CDC called the landline and said she just wanted to say "hi" and that if he had an opportunity to call her back. He called and had a great conversation with Dr. Cohen to get to know each other a little and for him to hear about some of her priorities. She also reached out to other members of the ACD to do the same. Speaking on behalf of all of the ACD members, they had come away impressed with Dr. Cohen's smarts, passion, and priority that she gives to people and relationships.

Dr. Sharfstein recognized that one of the many things Dr. Cohen brings to this job is tremendous experience in the healthcare sector in addition to her tremendous experience in the public health sector. With respect to trust, key partners and opportunities for public health are physicians and medical systems. Despite an enormous amount of evidence, many emergency departments (EDs) do not offer effective opioid disorder treatment for people who are at incredibly high risk despite the fact that this offers an enormous decline in mortality. While there are randomized controlled trials (RCTs) and recommendations from every relevant organization, there is still an enormous amount of stigma. Therefore, EDs do not implement the recommendations. CDC historically has stayed on one side of the line for medicine, but he wondered how Dr. Cohen is thinking about that.

Dr. Cohen emphasized that CDC has very much been talking about protecting health as being a team sport and that public health and health delivery systems must be brought closer together to be on one team. For her, the start of knitting that together begins with data exchange and must get down to the programmatic level. There are a couple of threads there. First is the data work that the agency is doing to knit folks together. There must be partnerships across the federal government because CDC does not own every lever. A lot of time has been spent in thinking about how to work together with CMS, some of which pertains to data and some of which pertains to payment. One reason there is not engagement in terms of substance use disorder (SUD) has to do with thinking about how the Medicaid 1115 Waiver is being used. As best practices and data emerge, an effort has to be made

to make sure that each agency can use its tools in coordination with other agencies. In CDC's Winter virus respiratory work, most of the communication efforts are focused on providers because the data repeatedly show that they are the most trusted. The most important reason people did not get vaccinated is because their doctor did not bring it up, so they assumed it was not important. As the ACD considers working groups, perhaps there is something specific on working to bring healthcare and public health even closer together.

Dr. Morita was glad to hear that Dr. Cohen is a strong advocate and proponent of the VFA program, which is a critical infrastructure component that would be incredibly valuable for the country in peacetimes as well as in pandemics. She loves the concept of building trust and focusing on communication and partner engagement. There was discussion in an earlier session about the critical role community organizations played during the pandemic in terms of building trust within some of the more marginalized communities in the country. There are great models for this. CDC did some wonderful work with adult vaccination efforts by funding community organizations to get into more local grassroots efforts, as well as making sure that state and local jurisdictions could use their federal resources to support community groups on the ground. She strongly supported the idea of the working group Dr. Cohen envisioned.

Dr. Shah asked Dr. Cohen to elaborate on her thoughts about how she sees CDC partnerships evolving over time with the private sector, which the FDA and other agencies have done very well. This seems like an unlimited opportunity area with all of the new AI and other technologies.

Dr. Cohen indicated that they have been talking about this actively as a team. She thinks there are incredible opportunities to partner with the private sector in strategic ways, particularly with regard to new diagnostics in the global space where folks want to do new and incredible things and want to use some of the emerging AI tools to help think about how to identify threat signals from within the background noise. While this has not been as top of mind, the pandemic highlighted how important it is and they are working to think about this more deeply. An example of where this worked well was in the laboratory space during Mpox in terms of partnering with commercial laboratories. Some of the lessons learned from COVID were applied to the Mpox response. When she has spoken to colleagues at Quest and LabCorp, they noted having already seen a difference in terms of engaging in ongoing conversations, sharing best practices and information, and being able to turn those partnerships on again for Mpox. This likely will be embedded into CDC's work going forward, and this also can be done in terms of treatment, AI, and data. The agency is partnering a lot with the private sector on data innovations. She did this in North Carolina and believes it is necessary. There are times when the government innovates and she is proud of that, and there are times when the private sector innovates. Both have to be leveraged.

Dr. Martinez observed that this country is at an inflection point in terms of structural racism and the impact at a systemic level. That includes the CDC. In 2021, CDC declared racism to be a public heath threat. Things have changed so much in just the past 3 years in terms of pushback. For instance, Texas passed an anti-DEI bill. CDC made a commitment to make investments in DEI within its organization and he wondered how Dr. Cohen envisioned this effort moving forward given the environment in terms of continuing to address structural racism as a public health threat.

Reflecting on some of the lessons learned from her work in this space in North Carolina, Dr. Cohen indicated that they focused on thinking about how to give everyone the opportunity for health no matter which zip code they are born into or live in. That was a very unifying theme in North Carolina, which is a relatively purple state. She worked for a Democratic Governor but had a Republican supermajority. When she first joined, health was unifying for them. People wanted to be healthy, and they wanted their families and communities to be healthy. They all had different visions of what levers to pull to get there, but they could agree that health was fundamental and necessary for economic success, so they started there. While this did not mean that they fixed

all of the problems in North Carolina overnight, she is proud that they are going to expand Medicaid in a bipartisan way for the first time in 7 years. The point is to think about unifying places that they can work on together that bring them closer to health opportunities for anyone no matter what zip code, which is Dr. Cohen's North Star of the work. Then there is the work on transparency, operational excellence, and relationships. The structural pieces pertain to operational excellence. There are barriers that keep public health from being the most effective possible. One of the things the team has talked about, with which the ACD could help them, regards how to work more with community organizations. One reason this is hard is because structurally, the way the CDC allocates money is challenging for the agency and for the community organizations with which they want to work. While there are ways to get past that, they have to do the operational work to find the way to improvements. That is only one of many examples. CDC leads with equity in such a fundamental way, it makes Dr. Cohen very proud to be part of the team. There is work to do and she thinks CDC needs to continue to be a leader, including how data are collected and reported. CDC still collects race and ethnicity in many ways across its programs. This could be standardized in order to make things easier for the agency's partners. Equity in all policies is the best approach.

In terms of contracting, Dr. Martinez wondered whether it would be possible to have a small percentage of 3% to 5% built into contracts to address structural racisms and social determinants of health (SDOH).

Dr. Cohen said these are the kinds of questions to bring to the surface in order to determine the right ways to do this. Community organizations will have to work through a process of being evaluated and sharing data, because that is the currency with which CDC works. Consideration could be given to how to work with partners to help CBOs be better at tracking their work and feeding data into these systems. In North Carolina they partnered with philanthropy to help CBOs to be able to do that work. Not only did it further the work, but also it was community and economic development work. That was very powerful. CDC is looking for those types of partnership opportunities. While she did not want to prescribe the solution, she thought it was something a working group definitely could dive into.

Ms. Valdes Lupi expressed deep appreciation for the insights Dr. Cohen brings regarding the importance of communication, transparency, operational excellence, and relationships. Those are the building blocks that those in philanthropy describe as in terms of trust-based philanthropy and accountability to communities. Those perspectives will be important, particularly in thinking about how to operationalize the fantastic work of the HEW with the leadership and counsel of Dr. Liburd and her team. In terms of the metaphor of a "team sport," they are on the bench waiting to be sent out on the ice. It seems like this is an inflection point, particularly in this work. She is looking forward in the upcoming months to hearing the same types of robust updates that they heard from the LW in terms of how CDC is operationalizing changing organizational structure, redesigning practices, and taking an enterprises approach being reflected in the work of the HEW.

Dr. Fleming pointed out that there are many audiences around which it is important to build trust in public health, including trust within the public health system, CBOs, individuals, and leadership. He asked Dr. Cohen what her thoughts are on prioritizing and where she is feeling the need is most important to start.

Dr. Cohen said that was a tough one because it is not possible to choose just one. If she were to prioritize the 2 most important, 1 is to make sure that they are getting timely comments and solutions for real people—for Americans who are trying to keep themselves and their families healthy. They want to do the right things, but they need help sifting through all of the noise and they need something that is going to work for them in their reality. That is an audience she wants to prioritize and for whom she wants to bring the best of science, evidence, and data and also make it practical. That means not only different messages and timeliness, but also different mechanisms of communication must be used. Thought must be given to where folks are getting their information. That may be through TikTok rather than the *New York Times* or the *New England Journal of*

Medicine (NEJM). They are trying to use more videos instead of written materials, trying more podcasts, and she is on Instagram. Second is the provider community (e.g., public health practitioners, doctors, nurses, pharmacists). They are team members of Team Public Health. In order for a team to function well, they have to know what play is being called. In addition to communicating the most simple, timely, accurate information to the American public and the more detailed information to both. CDC is doing both and needs to continue to do so. Then there are the deep practitioners, the scientific community, that the agency absolutely needs to be more coordinated with. The agency can focus communications for the American public, the provider community, and the science community simultaneously. There is a science to communicating that includes scientific evidence on behavior change and interventions that should be brought into this conversation.

Dr. Sharfstein pointed out that trust is not only about the audience, but also involves who to trust. The obvious answer is trust in CDC, but thinking about that more broadly also might be useful. It is trust in public health overall. CDC could play an important role in sharing information about strategies and supporting local, state, tribal, and territorial (STLT) health departments as they are communicating. The more trust there is in STLT health departments, the more trust there will be for CDC and vice versa. A specific example to make this more concrete is that one of the complaints during the pandemic was that a lot of local and state health officials were frustrated that they were learning about major activities at the FDA after they happened. People were asking about what it meant for them personally and local health officials were unprepared. That is not good for trust. If it is a team sport and local health officials need to be trusted, CDC has to be part of their voice and think about their needs, which is mutually reinforcing within public health.

Dr. Cohen emphasized that particularly in "peacetime" outside of an emergency, they have to make space to make sure they are getting feedback and not surprising anyone. That is one of the reasons that Andi Lipstein Fristedt's role as the new Deputy Director for Policy, Communications, and Legislative Affairs. CDC needed to change and mature its processes of getting feedback and hearing from others. This is still a work in progress, but she expressed her hope that people were starting to see this in the guidelines. As someone who has led during a crisis, sometimes one learns something and has to say it the same day. The agency is trying to embed the lessons learned from having to move fast during a crisis.

Mr. Dawes expressed his excitement about CDC's focus on equity in all policies. Pivoting to the extension of the workforce, he asked Dr. Cohen to speak about her priorities to bolster the public health workforce in light of the attrition rate due to early retirements, burnout, and so forth.

Dr. Cohen acknowledged that the workforce is a big topic. Thinking about the core capabilities that the ACD was talking about when she first came in, there are 5 core capabilities that CDC needs to have and fund across all of its efforts: laboratory, data, response, global, and workforce. Those are the 5 that she generally has in her brain when she thinks about ways in which they need to make sure the agency has that foundation to do its work. The workforce is challenging, particularly the public health workforce, because it takes time to train people. Everyone is feeling workforce challenges. Certainly, health delivery systems are in terms of nursing. CDC has long recognized that they need to train folks, which is demonstrated by the Epidemic Intelligence Service (EIS) and the Public Health Associate Program (PHAP) programs. There are ways in which CDC has asked Congress for some additional authority to be able to retain those trainees and convert them more quickly to full-time employees. This is one of the asks that CDC has been working on regarding its Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization work. Beyond CDC, this also relates to working with schools of public health to ensure that they are finding ways to give folks exposure to working in the field, the government, and academic to make sure that they are building skillsets so that people can more easily make the transition from academic to practice. She was hearing Dr. Frieden's voice in her head because he is an incredible advocate for making sure the public health workforce is strong, well-trained, and has field expertise. One program that she was super excited about that was built during the pandemic was working with AmeriCorps to build a Public

Health AmeriCorps, which builds on the tenants of CHWs and using people in communities to do the public health work that is needed.

Dr. Martinez asked Dr. Cohen to discuss her strategy for addressing the silo effect inertia that continues to plague all sectors (e.g., academic, federal government, private sector).

Dr. Cohen said this was her favorite thing to talk about. She gets very excited about having organizations work together as one team. Thinking back on her work in North Carolina and what she left behind was an organization that worked together as one unit. That was health and human services in terms of bringing together early childhood education, with the Medicaid Program, with public health in service of opportunities for health for all no matter what zip code. That is how her brain operates and there are a couple of ways to do that. First is calling out an area of focus to get everyone moving in the same direction as a team, such as focusing on the Fall/Winter respiratory season. Every leader across CDC has been doing work on the Fall/Winter virus season no matter where they work. They did not have to be in respiratory viruses. For instance, pregnant moms are very much affected by what is occurring with respiratory viruses. Since it is not possible to light the world on fire all at once, you pick areas of focus and drive them forward. Second, data are super critical to knitting together siloed organizations in terms of sharing data across different areas of focus such as the human immunodeficiency virus (HIV) and hepatitis C worlds. Of course, both of those are impacted by HIV, tuberculosis (TB), substance abuse, and mental health. Skill-building and training also are important. She is excited that the Policy and Programs Team is actually doing training on partnerships and skill-building, and they have an area of focus for folks to effectuate that training. They presented awards the previous week and invited Adam Grant to speak because he specializes in organizational psychology, skill-building, working collaboratively as teams, et cetera. He gave a great presentation.

Dr. Taylor said she did not think public health was at an inflection point yet, but is getting closer to the whole public health field changing to move from the siloed laboratory with hard walls to point-of-care (POC), non-traditional sites such as the home. Pretty soon people will have a toaster-size box in their kitchens in which they will put a capsule in to find out what their children have and determine whether to send them to school. A lot of thought will have to be given to this. It has to be cheap, effective, rapid, sensitive, et cetera. In terms of training, public health workers are going to be mom and dad at home, a nurse, or other persons working at non-traditional sites. In addition to education, thought must be given to data, personal privacy, and consensus on what data are to be collected (e.g., zip code, gender, positive) and submitted to the health department. Thought must be given to population health in terms of personal health. People tend to think public health pertains to someone else—not them. The thinking needs to be changed completely, which is both exciting and challenging.

Dr. Cohen said that she is excited for the future and agreed that there is a lot to think through and anticipate. Some of the foundational work that CDC is doing now puts the agency on the road to the future because it addresses the question of audience. Personal health feeds into population health, but there are definitely muscles to build. Data capture is important and is one of the ways to start to knit this together. A lesson that must be learned in public health is parsimony on data. She heard 3 data points: zip code, gender, positive or negative on the test. Most of CDC's scientists will want a few more data points, but they have to get to a streamlined method for getting an initial signal to noise.

Dr. Fleming expressed appreciation for Dr. Cohen's attendance and engagement in discussion with the ACD. They heard a lot of good input on suggestions for the WGs, which they will deliberate and bring back an update. In the context of relationship building, they look forward to the opportunity to create those relationships in more informal settings. He asked Dr. Cohen to say a few words about anything she would most value in terms of the relationship she builds with the ACD and how they can most help her.

Dr. Cohen expressed gratitude for the great job the ACD is doing. She asked that the ACD help run ahead of CDC. She loved the conversation they were having in relation to Dr. Taylor's suggestion to paint the future in 10 years in terms of thinking about what needs to be done now to get ready for that future to ensure that CDC and public health are ready and prepared. Foundationally, if they do not get at trust-building, that future worries her. There is foundational trust that no matter how good the workforce is, they will not be successful. The ACD can help the CDC look out into the future to identify what needs to be anticipated now. The agency is going through a lot of exciting and wonderful changes now, but they need to make sure they are going through the right changes and not just "skating to the where the puck is," but where it is going. That would be her parting ask. She emphasized what a great conversation it had been in terms of opening her mind to a number of issues.

Dr. Fleming stressed that the ACD looks forward to working with and helping Dr. Cohen with her very tough and important job.

CDC Update: Health Equity Workgroup Recommendations

Leandris Liburd, PhD, MPH, MA (Acting Director, Office of Health Equity, CDC) thanked the HEW for their leadership and contributions over the past year in laying out action items that, when fully implemented, can enhance and accelerate CDC's efforts to achieve healthy equity across its broad portfolio of public health science and programs. The HEW brought together diverse standpoints and lived experiences to strengthen and challenge CDC's ways of knowing and how they engage with the public in promoting and protecting the nation's health. CDC will work hard to move forward the wisdom of the HEW. Through 3 Task Areas, the HEW submitted Action Items to the ACD that were adopted as recommendations by the ACD and subsequently acknowledged by the Secretary of HHS. The OHE has been tasked with leading the implementation of the recommendations in close collaboration with the national CIOs of CDC. Building upon CORE,[2] CDC's health equity science and intervention strategy, the recommendation center communities and population groups disproportionately impacted by public health threats. The recommendations also focus on drivers of largely preventable health disparities and inequities, and systems changes that ultimately transform how the agency does its work for more equitable protection of the health, safety, and security of the US. Dr. Liburd briefly reviewed CORE; shared the recommendations; described some of what is currently being done to incorporate the recommendations into CDC's science, programs, and policies; and discussed the work that remains.

Launched in 2021, CORE is the first agency-wide health equity strategy. The mobilization of the national CIOs that make up the CDC around this strategy has been impressive. CORE strives to move beyond naming differences through markers such as race to identifying and addressing changeable drivers such as contextual factors that impact population health outcomes. CDC's CORE Framework weaves health equity into the fabric of all that the agency does. CDC's CORE commitment to health equity stands on 4 key pillars. The "C" is for "Cultivate comprehensive health equity science." In this context, CDC embeds health equity principles in the design, implementation, and evaluation of its research, data, surveillance, and intervention strategies. The "O" is to "Optimize interventions." Within regard to pillar, CDC uses scientific, innovative, and data-driven strategies that address environmental, place-based, occupational, policy, and systemic factors that impact health outcomes and address drivers of health disparities. The "R" is to "Reinforce and expand robust partnerships." In terms of this pillar, CDC seeks out and strengthens sustainable multi-level, multi-sectoral, and community partnerships to advance health equity. The "E" is to enhance capacity and workplace diversity, inclusion, and engagement. Toward that end, CDC is building internal capacity to cultivate a multi-disciplinary workforce and more inclusive climates, policies, and practices for broader public health impact. The national CIOs submit progress updates to a dashboard and agency-wide reports are compiled by the CORE Leadership Team annually. The ACD recommendations provide a blueprint that can inform how CDC does its work, illuminate gaps in the pursuit of health equity, and challenge the agency to greater innovation.

[2] https://www.cdc.gov/healthequity/core/

Consistent with the recommendation for Task Area #1 *to enable and assure the meaningful involvement of communities in agency decision-making and the development of health equity policies, program implementation, and evaluation*, CDC recognizes that community engagement is the cornerstone of good public health practice. There are many CDC programs that have meaningful community leadership and engagement in their implementation, such as the Racial and Ethnic Approaches to Community Health (REACH) Program, the Partnering for Vaccine Equity (P4VE) program, and community-based approaches to reducing sexually transmitted diseases (STDs) to name a few. Since 1999, CDC has supported the REACH program, which focuses on physical activity and other chronic disease prevention activities. 2024 will mark the 25th anniversary of REACH, which is the longest running racial and ethnic disparities initiative at CDC. REACH continues to be a strong, community-focused program in over 40 areas across the country. Much of its success has been due to its commitment to community leadership, coalition building, and the engagement of a trusted network of community leaders. The OHE recently released "Health Equity Intervention and Action Principles"[3] that is a set of 7 evidence- and practice-based principles designed to support the development, scaling, and implementation of interventions while also fostering systems and processes that promote health equity. To ensure that racial and ethnic communities are prepared for the 2023-2024 respiratory virus season, the OHE reached out to CBOs and national minority-serving institutions (MSIs) to put respiratory virus season prevention messages in the hands of community leaders. The OHE also is collaborating with CDC's Public Health Infrastructure Center and state and local Offices of Minority Health and Health Equity (OMHHE) to improve and increase community engagement among STLT departments of public health.

In terms of the recommendations for Task Area #2 *to align and restructure, as necessary, CDC policies, resource allocation, and program practices to maximize the ability for staff and partners to address health inequities in their day-to-day work*, numerous statutes, regulations, and other federal directives guide and inform CDC's operational policies, resource allocations, and program practices. That notwithstanding, through CORE, the OHE convenes health equity SMEs from across programs to identify health equity guidance that could be incorporated into CDC's non-research Notice of Funding Opportunity (NOFO) template. These changes to the NOFO template will cue NOFO writers to address health equity in the design of the NOFO and after published for competition, will cue applicants to address health equity in the framing of their programmatic response. The OHE is providing training to NOFO writers to build comfort, capacity, and consistency with effectively integrating the health equity considerations. Where there are opportunities for wider distribution of announcements of NOFOs, the OHE can work with the Office of Financial Resources (OFR) to identify those venues that will reach more eligible applicants.

With respect to the recommendations for Task Area #3 *to immediately initiate a coordinated, agency-wide approach to develop and integrate strategies to influence the effects of drivers of health equity across the entire range of its public health programming*, the OHE has worked closely with the Office of Science to develop health equity science principles. Among domains of excellence for science, the OHE ensured the inclusion of a health equity domain that provides criteria for appropriately addressing health equity in the development of scientific manuscripts and other related products. They are still socializing these principles in the health equity domain across CDC. Through the DMI, the OPHDST is working on data platforms to put health equity drivers at the fingertips of CDC scientists, which will be followed by the development of tools to assist CDC scientists and evaluators, communities, and public health programs in optimizing their use. Much of this work is still in progress, but the necessity of understanding and addressing drivers of health disparities and health inequities using data and other public health strategies is a priority for CDC.

[3] https://www.cdc.gov/healthequity/whatis/healthequityinaction/topics/he-intervention-action-principles.html

As a result of the health equity recommendations from the ACD, CDC has a blueprint from which to chart additional efforts that will accelerate movement toward achieving health equity. CDC recognizes that health equity must be at the core of developing any intervention; innovative solutions, including AI; and policy or programming for populations affected by health disparities, including the authentic representation and inclusion of community members and CBOs. Looking ahead, CDC is committed to transforming its public health research, surveillance, and implementation science through innovation and collaboration. CORE allows CDC to learn more about the drivers of disparities and the impact of social determinants on health outcomes. It allows the agency to expand the body of evidence of what interventions will reduce the inequities that affect health and invite partners from multiple sectors who can collaborate to implement solutions. The recommendations reiterate that CDC must be intentional about pursuing and securing community engagement. In addition, the agency must integrate health equity considerations in funding to address drivers of health inequities. CDC also must recruit and retain a workforce that represents diversity in academic disciplines and lived experience, and that is prepared to go to work. This will reduce and ultimately eliminate health disparities while ensuring that all people have the opportunity to attain the best health possible.

Discussion Summary

Dr. Fleming asked Dr. Liburd to share what keeps her up at night. While recognizing that this is a great report and CDC is moving forward, there certainly must be challenges.

Dr. Liburd said that in all candor, one thing that keeps her up at night is the lack of understanding of the societal benefits of pursuing and attaining health equity. This has resulted in counter-narratives that seek to slow and, she would argue, halt the progress and movement of this work. Another thing that keeps her up at night regards momentum in terms of how to continue to pursue this work. Everything that she described requires a level of sustainability.

Dr. Shah asked what the most helpful thing would be that the ACD could do to help advance this work.

Dr. Liburd responded that she would say not backing down on the investments in and commitment to health equity. She does not know how forceful the forces will be in terms of pushback against this work. The ACD members could use their voices within their respective organizations to support whatever commitments those organizations are making to health equity. The breadth of health equity is wide enough that they could “put a stake in the ground” on any the related components, such as structural racism, elimination of disparities in the delivery of healthcare, the failure to adequately engage communities in the work of public health, the failure to use culturally responsive approaches to the work, and being sensitive to and confronting how inequities are being perpetuated and being thoughtful about how to counter that.

Dr. Hardeman said she was thinking about what it would look like to operationalize agency-wide leadership in health equity. There are a couple of approaches, such as thinking about how to create a deeper bench of folks who understand an issue and ensuring that every single CDC leader is well-versed in and understands health equity.

Dr. Liburd indicated that through the CDC Moving Forward effort, there are 3 priority actions that came out of the OHE. One is the articulation of a health equity strategic framework that elaborates CORE, which has been drafted, and training of staff around that. Another is that over the last 2 years, more people have been hired into the agency with the title of Health Equity Lead, Senior Advisor for Health Equity, or Associate Director for Health Equity who have the specific responsibility of health equity and who tend to be fairly senior at the division or center level. The OHE will be working more closely with them and is currently meeting with them twice a year. A survey was conducted to ask how the OHE could be more helpful and the OHE will be working with the staff in these positions at that level to support them within their respective CIOs and sharing with them

strategies, standards, et cetera. There have been numerous internal activities. For instance, there is a Diversity and Inclusion Executive Steering Committee. While this committee was recently renamed, it is an organization of center-level leaders. Everyone who serves on the committee has to be at a GS-15 level or higher. That is a forum through which to disseminate these messages. There is now an annual CORE Forum that brings together the entire agency. The next one is scheduled for April 2024.

Dr. Martinez asked whether, from a budget and resource standpoint, the OHE has adequate resources to implement the strategy and vision she laid out.

Dr. Liburd explained that the OHE's primary resources are human resources and SMEs within the office. They are currently optimizing those resources. Another opportunity this year was that through the Executive Governance Board, all of the national CIOs were asked to speak to how they are allocating resources around the priorities of the agency—one of which is health equity. While those resources are in the CIOs and not the OHE, they have many commitments to use a specific amount of money to address health equity within their programs. There is still time ahead to see how all of that ultimately shakes out.

Dr. Fleming emphasized that one of the ACD's goals will be to ultimately make it so that Dr. Liburd is getting a good night's sleep instead of laying away at night.

Health Equity Workgroup

Daniel Dawes, JD and Monica Valdes Lupi, JD, MPH (HEW Co-Chairs) reminded everyone that the HEW's purpose was to: 1) provide input to ACD on the scope and implementation of CDC's CORE strategy, influencing internal work and that of STLT public health agencies, constituents, and partners; 2) prepare reports with findings, observations, and outcomes to enhance the CORE strategy; 3) suggest innovative and promising health equity practices; and 4) suggest ways to embed anti-racist policies and practices in public health programs. As Dr. Liburd discussed, to manage its charge, the HEW created 3 task areas/groups that are outlined in the following table (not in prioritized order) along with their ACD lead and members:

TASK AREA #1	**TASK AREA #2**	**TASK AREA #3**
Enable and assure the meaningful involvement of communities in agency decision-making, the development of health equity policies, program implementation, and evaluation	Align, and restructure as necessary, CDC policies, resource allocation, and program practices so as to maximize the ability for staff and partners to address health inequities in their day-to-day work	In concert with communities, take immediate and decisive action to expand, embed, and integrate approaches to measure and influence drivers of health equity across all public health programs
ACD Lead: Daniel Dawes	**ACD Lead:** Monica Valdes Lupi	**ACD Lead**: David Fleming
Members	**Members**	**Members**
David Brown	Nafissa Cisse Egbuonye	Ada Adimora
Delmonte Jefferson	Octavio Martinez	Michelle Albert
Maria Lemus	Rhonda Medows	Philip Alberti
Bonnie Swenor	Julie Morita	Cary Fremin
Bobby Watts	Mysheika Roberts	Rachel Hardeman
	Paula Tran	

In terms of accomplishments, the HEW established 8 recommendations to support CDC in advancing health equity. The ACD adopted Task Area #3 in February 2023 and Task Areas #1 and #2 in May 2023. The full set of recommendations has been acknowledged by HHS. In terms of next steps, CDC will consider the HEW's Action Steps and the resulting 8 ACD recommendations for implementation and will continue to provide progress updates.

Agency-wide leadership and commitment are going to be very important. The HEW is grateful that Dr. Liburd has been the steady hand in leading the equity work over many years and that is now everyone's work throughout the agency. The emphasis on engaging and investing in communities is critical, particularly those black and brown communities that bear the disproportionate burden of health inequities. The HEW appreciated the earlier conversations with Dr. Cohen and her teammates about health equity in all policies and health equity across the 2 focus areas and the way the agency is approaching the work ahead. In terms of strategic foresight and innovation, the HEW members look forward to being able to continue to support CDC and learn more about innovations, best practices, and approaches to operationalizing the work that has started in recognizing that racism is a public health crisis that will take an agency-wide approach. Ongoing updates on how the recommendations are being operationalized will be greatly appreciated. Recognizing that the HEW has met its charge, it is now time to consider sunsetting the WG.

Discussion Summary

Dr. Medows objected to sunsetting the HEW because updates need to be given regarding their Action Steps.

Dr. Fleming assured her that despite sunsetting the HEW, the ACD would continue to receive updates from CDC on their progress in addressing the HEW's proposed action steps. He emphasized that just because the TORs were completed did not mean that anyone at CDC or on the ACD thought the work was finished. Health equity is one of the most critical and difficult challenges facing public health in this country today. While this is a great set of initial recommendations, it is imperative to remain vigilant. The ACD looks forward to hearing reports from CDC on implementation and hear about, identify, and work to solve the range of health equity issues that are going to continue to emerge and will need to be acted upon by this committee and across CDC.

Given the importance of the OHE in the operationalization of the recommendations, it was suggested that a vote be taken to include an OHE update as a standing agenda item during each ACD meeting.

Vote #1: Sunsetting the HEW

The ACD acknowledged and appreciated the significant contributions of the HEW in advancing health equity initiatives. After careful evaluation of the WG's proposed Action Steps that were later approved by the ACD in the form of 8 recommendations and subsequently acknowledged by the HHS, the ACD thereby made a motion to sunset the HEW, which was seconded. The ACD voted unanimously to sunset the HEW, with no dissentions or abstentions.

Vote #2: Health Equity as a Standing Agenda Item

A motion was made and seconded for the ACD to include health equity as a standing agenda item that includes an update from the OHE. The ACD voted unanimously to include health equity as a standing agenda item that includes an update from the OHE.

CDC Update: Data and Surveillance Workgroup Recommendations

Jen Layden, MD, PhD (Director, Office of Public Health Data, Surveillance, and Technology, CDC) provided an update on CDC's responses to the DSW's recommendations. During the course of the work by the DSW, significant progress has been made on several recommendations. The first set of recommendations that came out of the ACD generally included topics on data policy and data standards. Specifically, the recommendations were: 1) CDC should develop a proactive, streamlined approach for data use agreements (DUAs) with STLT partners; 2) define a "minimal data necessary" concept, at least for some core data sources; and 3) move toward public health system standards and ultimately certification. Dr. Layden provided an update on the progress that has been made in each of these areas. "Core Data" includes the core data sources that were referenced in the initial set of ACD recommendations. It is important to acknowledge that this is not the scope or totality of the

data sources that CDC uses but are the ones that are often leveraged, particularly in times of responses and in day-to-day public health activities.

Regarding DUAs, the ACD recommended:

- *A proactive approach to DUAs to prepare for future responses*
- *A streamlined creation and negotiation process*
- *Consistent language across CDC DUAs on protecting individual privacy*
- *For CDC's DUA to address other concerns like the use and re-release of data, consistent with laws applicable to each party*

A lot of great work has been done in this space. There is a 3-pronged approach with a goal to create a consistent, agency-wide approach for the core data sources for which there would be a set of common core elements or terms and an opportunity for data sources specific to the addenda and to address where there may be variations due to STLT laws or requirements. The goal is to make this more efficient and transparent in the sharing in relationships that CDC has with its state partners. Significant work has been done to draft the new DUA approach. In terms of the components, it has a set of common, non-variable terms that apply to the core data sources. These are terms that are related to established federal law requirements (e.g., security, privacy) and important procedures (e.g., notification to jurisdictions ahead of release or publication). There also would be an opportunity for an addenda to the common terms that can be used for specific data sources. There also would be a place in the addenda to address specific jurisdictional terms (e.g., requirements or limitations to data sharing in STLT law) and procedures (e.g., data standards). To operationalize this approach, a shared policy governance would be established within the OPHDST. This will allow for accountability and streamlined engagement (e.g., where to direct questions) across the agency and with STLT partners.

Regarding the timeline, there has been tremendous progress to draft the "Core DUA" internally working with each program that is responsible for the core data sources, the OGC, and other partners across the agency. They have started to socialize this with partners. The goal is to transition all of the DUA for Core Data to OPHDST by December 2023 for management and execution. They recognize that in the next couple of months, especially when socializing this with STLT partners, that there will be some feedback that will need to be incorporated into the final DUA. Beginning in January, there will be a process to negotiate the terms of the Common Provisions and Addenda and strengthen internal policy governance. As they continue to do this, they will want to ensure that they are evaluating for efficiency and to ensure that it is meeting the needs of data access and data governance.

The key benefits and impacts anticipated are that this will strengthen data exchange relationships with STLTs, increase trust and transparency, support future technological innovations, maintain necessary jurisdictional flexibility, reduce the burden on STLTs and CDC to negotiate and monitor individual DUAs, and improves engagement and accountability.

Regarding Minimal Data, the ACD recommended:

- *Establishing base standards for minimal data necessary for public health activities for the 6 core data sources*
- *Leveraging Health IT data standards when possible, to promote efficient data sharing and exchange*
- *Harmonizing data standards to reduce duplication*
- *Ensuring data availability for situational awareness*

The relative importance of these recommendations is due to some of the challenges that were apparent during recent responses, such as Mpox when hundreds of variables were requested on initial case report forms. These recommendations became part of CDC's *Public Health Data Strategy* goals and milestones. CDC felt this was

critical work and wanted to ensure that they are accounting for it in the prioritization of the agency's data strategy efforts. This is listed as one of the milestones with a particular focus for the minimal data on case and laboratory data based. Similarly, they have made a lot of progress on Case Data Situational Awareness. While it seems like it should be straightforward to define basic core elements, there was a need and importance in getting a lot of input across CDC programs, efforts that are underway with the agency's STLT partners working with CSTE, and factoring all of those things into developing minimal line-level data elements that they would define as minimal data necessary.

This effort started soon after the recommendations came out beginning with Generic V2, which is the way that states send case data to CDC for case data for 127 notifiable diseases for 50 to 60 elements. Working with programs and others, these were cross-referenced with other data elements that may be of importance to define. They are now working with jurisdictional partners to validate that list. The next step would focus on how to align those data elements with health IT standards and ensure that the systems that everyone is using in public health align how they capture those data as well. A similar process has been underway for the laboratory data, which is also going well. With case and laboratory well underway, the next focus will be to define the minimal data necessary for hospitalization data and healthcare capacity. Currently, the data are received at CDC through multiple data systems. Quite a few elements are received, which places a significant burden on that data senders. The effort to define what CDC needs for these data in times of baseline and in times of emergency is underway, with significant involvement and participation across the agency.

The key benefits and impacts anticipated are that this effort will provide clarity for CDC leaders and scientists about what data they have, where they are, and how to access them; will allow CDC programs more time for data analysis and application, and less on the mechanics of collecting the data; and potentially will lead to a more collaborative data atmosphere across the public health ecosystem, which will enable faster cooperation in emergencies and all public health action—rather than a siloed data approach.

Regarding Public Health Certification, the ACD Recommended:

- *Establishing public health standards and certification*
- *Ensuring that public health data systems and technologies develop and maintain core capabilities*
- *Ensuring that public health data systems and technologies can integrate standardized data from healthcare organizations*

At the same time that the ACD made this recommendation, a complementary set of recommendations came out of the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology for Economic and Clinical Health (HITECH) committee about establishing some standards for some systems. They are now moving forward with getting close to the Final Rule for the first release and are now moving forward with the Notice of Rulemaking Process (NRP) for the next set of standards that would apply to public health system certification. CDC's ONC partners have been a very collaborative and important part of this approach. What CDC is looking at internally is to understand the scope of what this applies to and how they would support, from a resource standpoint and implementation standpoint, a movement toward the standards and ultimately certification of the core public health systems. CDC is working closely with its ONC partners because of their legislative authority space, as well as experience in system certification. CDC wants to understand and map out what this would look at across CDC and STLTs and determine how they can incentivize and support movement toward adoption of these certification standards.

One of the things that CDC was able to fund this past year was the establishment of implementation centers. While these are still being stood up and have not been finalized yet, the Public Health Infrastructure Grant (PHIG) program allows CDC to establish implementation centers that potentially will serve as a regional hub to support jurisdictions in adopting these standards and system requirements. The agency views this as a main

source and mechanism by which they would support STLT partners in the pathway toward a more standardized interoperable data system. Internal to the agency, CDC needs to go through its governance system to ensure that there is awareness of what the path will look like and will bake into that governance process what that system standards are so that they can review new investments with the right context.

In May 2023, the ACD made a second set of recommendations focused on the workforce that included 3 priority areas to address epidemiology, public health data science and informatics, and information technology, which were to:

- *Assess workforce needs to support the DMI, including identifying the range of skills needed, the size of the workforce gap, and a prioritized roadmap to meet short and medium-term needs*
- *Assemble a cohesive workforce training strategy aligned with identified needs and work with the private sector and academia partners to build programs that enable upskilling, recruitment, and retention*
- *Issue guidance on the use of dedicated data infrastructure funds including how funds may be used to support the epidemiology, public health data science, and IT workforce*

They are working to identify where this responsibility lives and are working closely with their Human Resource (HR) counterparts across the agency; their Public Health Infrastructure Center partners, because they have had a role in workforce training; and their Office of the Chief Information Officer (OCIO) colleagues in identifying the pathway to mapping out what the workforce needs are and how to support training in the short- and long-term.

To provide some background on the new terms of reference, as CDC continues down this modernization path, there has been tremendous progress in the exchange of data. One of the challenges that they are experiencing is the identification of constrained resources. There are never going to be enough resources to do everything that they want to do. The agency has an ecosystem that is siloed, inefficient, and has a lot of redundancies. CDC has hundreds of data systems that often collect the same data elements. There have been good strides, given that the initial number was 600 data systems and now there are several hundred. However, the agency is often pinging partners for the same data. As they continue to modernize, health care partners and other data senders say they want to support the public health use cases and recognize the importance and value of this, but the want to know how CDC is making this more efficient for senders in terms of reducing the burden and doing this in a more streamlined and coordinated way. CDC recognizes that as they continue down this path, that it is an important approach and mindset they need to take. They know there will be challenges to rationalizing and streamlining the number of systems as well as the way that they pull and exchange data from the various partners.

Data and Surveillance Workgroup

Julie Morita, MD and Nirav R. Shah, MD, MPH (Co-Chairs) recognized that it was clear from Dr. Layden's update that a lot has been accomplished, especially related to the first set of recommendations. CDC definitely took those to heart and moved forward to aggressively address many of the issues. The second set from May 2023 did not actually receive approval until September 2023. Because of that, that work has not progressed as much. However, the DSW is confident that CDC will make progress with those as well. Related to transitioning from the prior to the new TORs, the discussion about the budget earlier in the day made very clear why the challenges and priorities have changed. New TORs were drafted because the existing TOR document does not address the current challenges faced by the OPHDST. The new TOR document will align the DSW's objectives with the CDC's current priorities and needs of the office. The DSW's new TORs will address the following challenges:

1. **Fragmented Data Ecosystem:** The CDC currently employs multiple data reporting systems, each designed for specific purposes and programs. This fragmentation leads to inefficiencies in data collection, processing, and analysis, as well as increased administrative overhead.

2. **Data Silos and Redundancies:** Different reporting systems often operate in isolation, creating data silos that inhibit seamless information sharing across departments and programs. Redundant data entry and storage occur due to overlapping functionalities, resulting in wasted resources.

3. **Inconsistent Data Quality and Health IT Standards:** With various reporting systems in place, maintaining consistent data quality and adhering to standardized data collection protocols becomes challenging. Inconsistencies in data quality can impede accurate trend analysis and hinder the CDC's ability to respond effectively to emerging health threats.

4. **Resource Allocation and Sustainability:** The operation and maintenance of multiple reporting systems require significant financial and human resources and is not a sustainable model.

5. **Delayed Response to Public Health Emergencies:** The fragmented data reporting landscape may lead to delayed responses during public health emergencies, as critical information might not be readily available or easily accessible.

6. **Integration Challenges with External Partners:** Collaborating with external stakeholders, such as state health departments or international organizations, becomes more complex when disparate reporting systems are involved. Integration difficulties may lead to delays in sharing crucial health information.

7. **High Burden:** There are redundant reporting expectations, often for the same or similar data, on partners, including healthcare and jurisdictional partners. This places a high burden on critical partners, with sometimes limited return value.

Rather than sunsetting, the plan is for the DSW to move forward on addressing CDC Data Reporting Systems. The questions to address the key issues in the new TORs are:

1. How can the CDC implement a process to comprehensively assess data reporting systems, aiming to enhance sustainability, alleviate partner burdens, and minimize potential redundancies?

2. How can this process effectively streamline the evaluation of technical, system, and procedural aspects within CDC's data reporting systems, while establishing clear criteria for identifying and eliminating redundancies?

Based on Dr. Layden’s update on the prior work, the DSW has taken on hard challenges and CDC stepped up to the challenges. The work going forward is going to be difficult moving forward. There will be datasets that the agency has collected for 20 or 30 years and the DSW is going to have to say “no” because there must be parsimony in order to lower the burden and cost.

Discussion Summary

Dr. Taylor shared that the APHL and the CSTE are looking at a minimum dataset specifically for getting a test approved by a laboratory in an emergency. There is consensus between the APHL laboratory directors and epidemiologists. They are now socializing this somewhat broader. CDC is aware of this. At a certain point, they will want to socialize this more broadly with the CDC to ensure that they are on the same page. She sees this as a subset of the minimum dataset that CDC is considering, because it is specifically to avoid the Mpox situation in which physicians needed to get permission to test.

Dr. Layden said she would be happy to see this when APHL and the Council of State and Territorial Epidemiologists (CSTE) are ready.

Dr. Fleming appreciated in the TORs the notion of alleviating partner burdens in thinking about this. One of the burdens working at the state and local levels is the burden of inflexible financing, such that funding streams for a specific disease or reporting condition oftentimes are limited to activities around that. This may not be surmountable given Congressional language, but he encouraged the DSW to consider whether partner burden could be alleviated by increasing the flexibility that health departments and others have in using funds so that they can use it in the most efficient ways as opposed to necessarily continuing to have to abide by the categorical approaches. He thought that was implicit in these TORs.

Vote: DSW's Updated TORs

A motion was made and seconded for the ACD to adopt the proposed new TORs for the DSW. The ACD voted unanimously to adopt the proposed new TORs for the DSW, with no dissentions or abstentions.

Closing Remarks / Adjourn

David Fleming, MD (ACD Chair) expressed gratitude to everyone and emphasized what a great meeting this had been. The ACD benefitted from the tremendous CDC presentations, and it was a pleasure for everyone to get to meet the new CDC Director. He thought everyone was gratified with the work that has been accomplished across the 3 WGs, the differences they have made in CDC, and CDC's responsiveness in reporting back to the ACD on how they have and will continue to adopt the ACD's recommendations. He acknowledged the departure of Bridget Richards, who the ACD has been relying on as its core support over the past several years. Ms. Richards has accepted a new job within CDC's NCEZID. He stressed that they appreciated all of the work that she did and that they would miss her. He acknowledged all of the support that the ACD receives across the WGs from CDC. It really does feel like a partnership and the ACD appreciates the work that CDC puts into this in order to make this process successful. The next ACD meeting will be in February 2024.

Debra Houry, MD (DFO) expressed her appreciation for everyone's time throughout the year in attending scheduled ACD meetings, as well as engaging in the significant amount of work that is done between meetings. The WGs have completed a tremendous amount of work and CDC has made tremendous progress in operationalizing the recommendations. She emphasized that when the WGs and ACD make suggestions and share ideas, CDC hears those and will always do their best to be responsive. It was nice to have the opportunity to spend time with the members at dinner to engage with everyone in an informal setting, which gave her the opportunity to get to know each of them individually and as a collective. She invited members to reach out to her at any time. She assured everyone that she and Dr. Fleming would think through what the newly proposed WG would look like and would bring that back to the ACD for further input. In closing, she expressed appreciation to Dr. Fleming for always being their steadfast leader. Dr. Fleming thanked Dr. Houry for taking on the role of DFO for the ACD, particularly given all of her other "duties as assigned" and providing huge leadership to the committee and within CDC through the ACD.

With no further business posed or questions/comments raised, the meeting was officially adjourned at 2:48 PM ET.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the November 14, 2023 meeting of the Advisory Committee to the Director, CDC are accurate and complete.

01.09.2024

_____

Date

David Fleming

_____

David Fleming, MD
Chair, Advisory Committee to the Director
Centers for Disease Control and Prevention

Attachment #1: ACD Membership

CHAIR
David W. Fleming, MD
Clinical Associate Professor
University of Washington School of Public Health
Seattle, Washington
Term: 10-01-2021 – 06-30-2023

DESIGNATED FEDERAL OFFICER
Debra Houry, MD, MPH
Acting Principal Deputy Director
Deputy Director for Program and Science
Chief Medical Officer
Centers for Disease Control and Prevention

MEMBERS
Adaora Alise Adimora, MD, MPH
Professor of Medicine and Epidemiology
Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, North Carolina
Term: 09-27-2021 – 06-30-2025

Daniel E. Dawes, JD
Senior Vice President, Global Health
Executive Director, Global Health Equity Institute
Founding Dean, School of Global Public Health
Meharry Medical College
Nashville, TN
Term: 09-28-2021 – 06-30-2024

Rachel R. Hardeman, PhD, MPH
Blue Cross Endowed Professor of Health and Racial Equity
Founding Director
Center for Antiracism Research for Health Equity
Division of Health Policy and Management
University of Minnesota School of Public Health
Minneapolis, Minnesota
Term: 09-28-2021 – 06-30-2025

Octavio N. Martinez, Jr., MD, MPH, MBA, FAPA
Executive Director
Hogg Foundation for Mental Health
Senior Associate Vice President, Division of Diversity and Community Engagement
Clinical Professor, Steve Hicks School of Social Work
Professor of Psychiatry, Dell Medical School
The University of Texas at Austin
Austin, Texas
Term: 09-28-2021 – 06-30-2025

Rhonda M. Medows, MD
President
Providence Population Health
Renton, Washington
Term: 09-27-2021 – 06-30-2024

Julie Morita, MD
Executive Vice President
Robert Wood Johnson Foundation (RWJF)
Princeton, New Jersey
Term: 09-29-2021 – 06-30-2024

Nirav R. Shah, MD, MPH
Chief Medical Officer
Sharecare
Palo Alto, California
Term: 09-27-2021 – 06-30-2025

Joshua M. Sharfstein, MD
Vice Dean for Public Health Practice and Community Engagement
Johns Hopkins Bloomberg School of Public Health
Baltimore, Maryland
Term: March 30, 2022 – June 30, 2023.

Jill Taylor, PhD
Senior Advisor for Scientific Affairs
Association of Public Health Laboratories (APHL)
Silver Spring, Maryland
Term: 09-28-2021 – 06-30-2023

Monica Valdes Lupi, JD, MPH
Managing Director for the Health Program
The Kresge Foundation
Troy, Michigan
Term: 09-27-2021 – 06-30-2024

Attachment #2: Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ACD	Advisory Committee to the Director
ACEs	Adverse Childhood Experiences
ACOG	American College of Obstetricians and Gynecologists
ADLS	Associate Director for Laboratory Science
ADLSS	Associate Director for Laboratory Science and Safety
AI/AN	American Indian/Alaskan Native
AIMS	APHL Information Management System
AMD	Office of Advanced Molecular Detection
APHL	Association of Public Health Laboratories
BARDA	Biomedical Advanced Research and Development Authority
CABs	Community Advisory Boards
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CFA	Center for Forecasting and Outbreak Analytics
CHW	Community Health Workers
CIOs	Centers, Institutes, and Offices
CLIA	Clinical Laboratory Improvement Amendments of 1988
CLSR	Center for Laboratory Systems and Response
CMS	Centers for Medicare and Medicaid Services
COI	Conflict of Interest
CORE	Cultivate, Optimize, Reinforce, Enhance
CSTE	Council of State and Territorial Epidemiologists
DASH	Division of Adolecent and School Health
DCLSR	Division of Core Laboratory Services and Response
DDDI	Detection, Diagnostics and Devices Infrastructure
DFO	Designated Federal Officer
DMI	Data Modernization Initiative
DSW	Data & Surveillance Workgroup
DUA	Data Use Agreement
ED	Emergency Department
EIS	Epidemic Intelligence Service
ELR	Electronic Laboratory Reporting
ELIMS	Enterprise Laboratory Information Management System
eQMS	Electronic Quality Management System
ETOR	Electronic Test Orders and Results
ET	Eastern Time
FDA	Food & Drug Administration
FRA	Fiscal Responsibility Act
FQHC	Federally Qualified Health Center
FY	Fiscal Year
HCP	Health Care Personnel
HCW	Health Care Worker

Acronym	Expansion
HCV	Hepatitis C Virus
HEW	Health Equity Workgroup
HHS	(United States Department of) Health and Human Services
HITECH	Health Information Technology for Economic and Clinical Health
HIV	Human Immunodeficiency Virus
HR	Human Resource
HRSA	Health Resources & Services Administration
IC	Incident Command
IDRRRF	Infectious Disease Rapid Response Reserve Fund
IDTRB	Infectious Disease Test Review Board
IHS	Indian Health Service
IOD	Immediate Office of the Director
LDX	Laboratory Data Exchange
LLS	Laboratory Leadership Service
LRN	Laboratory Response Network
LRN-B	Laboratory Response Network for Biological Threats
MAT	Medication-Assisted Treatment
MSI	Minority-Serving Institution
LW	Laboratory Workgroup
MOU	Memorandum Of Understanding
NAACP	National Association for the Advancement of Colored People
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NEJM	*New England Journal of Medicine*
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIH	National Institutes of Health
NLRSB	National Laboratory Response System Branch
NOFO	Notice of Funding Opportunity
NRP	Notice of Rulemaking Process
OASH	Office of the Assistant Secretary for Health
OCIO	Office of the Chief Information Officer
OD2A	Overdose Data to Action
ONC	Office of the National Coordinator for Health Information Technology
OPHDST	Office of Public Health Data, Surveillance, and Technology
OFR	Office of Financial Resources
OHE	Office of Health Equity
OHR	Office of Human Resources
OLSS	Office of Laboratory Science and Safety
OMB	Office of Management and Budget
OMHHE	Office of Minority Health and Health Equity
ONC	Office of the National Coordinator for Health Information Technology
OPHDST	Office of Public Health Data, Surveillance, and Technology
OSG	Office of the Surgeon General
P4VE	Partnering for Vaccine Equity
PGCoE	Pathogen Genomics Centers of Excellence
PHAP	Public Health Associate Program
PHE	Public Health Emergency

Acronym	Expansion
PHIG	Public Health Infrastructure Grant
PHLs	Public Health Laboratories
PI	Principal Investigator
POC	Point-of-Care
PROSB	Preparedness, Response, and Outbreak Support Branch
P4VE	Partnering for Vaccine Equity
QMML	Quality Manual for Microbiological Laboratories
RADx®	Rapid Acceleration of Diagnostics
REACH	Racial and Ethnic Approaches to Community Health
RFI	Request for Information
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SPHERES	Sequencing for Public Health Emergency Response, Epidemiology and Surveillance
STD	Sexually Transmitted Disease
STLT	State, Tribal, Local, and Territorial
SUD	Substance Use Disorder
TA	Technical Assistance
TB	Tuberculosis
TOR	Terms of Reference
US	United States
USDA	US Department of Agriculture
WG	Workgroup
WIC	Women, Infants, and Children

Attachment #3: Workgroup Minutes

Workgroup	Date	Minutes
Lab	10.23.2023	10-23-23-LW-Minutes_Final.pdf (cdc.gov)
Data and Surveillance	06.16.2023	June-16-2023-DSW-Minutes_Final_Signed-1.pdf (cdc.gov)
	08.14.2023	August-14-2023-DSW-Minutes_final_signed-1.pdf (cdc.gov)