



# CDC Advisory Committee to the Director (ACD)

*Minutes from the May 3, 2022*



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## Advisory Committee to the Director: Record of the May 3, 2022 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on May 3, 2022 via Zoom for Government and teleconference. The agenda included highlights of key issues from the CDC Director; updates from the Data and Surveillance, Laboratory, and Health Equity Workgroups (WGs); an update on the COVID-19 response; and public comments.

### Welcome and Introductions

**David Fleming, MD** (ACD Chair) welcomed everyone and recognized new member, Dr. Joshua Sharfstein. He then called the roll, which established that a quorum of ACD members was present. Quorum was maintained throughout the duration of the meeting. The ACD Membership Roster is appended to this document as Attachment #1. The following potential conflicts of interest (COIs) were disclosed:

- Dr. Adimora: Receives consulting fees and research funds from Merck and Gilead and serves on the board of the Infectious Disease Society of America (IDSA).
- Dr. Shah: Serves on the boards of STERIS and Kinsa Health.
- Dr. Sharfstein: Works with Sachs Policy Group (SPG), a New York-based advisory group for large healthcare systems on population health issues.

**Dr. Fleming** reviewed the agenda for the day and introduced Dr. Walensky, who provided an update on current issues and events at CDC.

### Director's Update

**Rochelle P. Walensky, MD, MPH** (Director, CDC) welcomed everyone, noted that the last meeting was full of insight and engagement, and expressed her excitement about another robust day of discussion with the ACD members. While they were once again meeting virtually, she said she looked forward to a time when they could meet in-person. She offered her gratitude to the members for being committed to sharing their thoughts and expertise with CDC, and welcomed Dr. Sharfstein to this important group of advisors.

As a reminder, the ACD was reestablished in recognition of how important it is to engage a group of knowledgeable experts on a broad range of topics. CDC wants and needs the ACD's input on the agency's current activities, as well as feedback on how to optimize its impact. As thought was given to how CDC could most use the ACD's help, three critical areas were identified: Equity, Data, and Laboratory Quality. The ACD previously voted to establish the Health Equity WG (HEW) and planned to vote later in the day on the establishment of a Data & Surveillance WG (DSW) and Laboratory WG (LW). In addition, there will be more questions and areas to consider in the continuation of this work moving forward.

Dr. Walensky stressed that she could not be more excited about the number of people who were interested in serving on the ACD HEW. As an indication of their collective commitment, she found it remarkable that 9 of the 15 ACD members chose to do double-duty in being part of the ACD and the HEW. She thanked Ms. Valdez Lupi and Mr. Dawes for agreeing to serve as Co-Chairs for this important WG. It was truly incredible that the notice in the *Federal Register* brought an astonishing number of applicants, given the short deadline. As a result of this notice, 109 applications were received. Each of those applicants would have been stellar additions to the WG.

The 10 people selected are engaged in the work of health equity every day in terms of working with people who have uncertain housing, those who have disabilities, youth, those who are under-served, among other areas of focus. The list is impressive and is a testimony to the recognition of the need for this conversation. She thanked the HEW members for sharing their skills, commitment, expertise, professional experience, and the passion they bring to this work. She heard great reports about the HEW's first meeting and looks forward to the months to come.

These are not the only areas that are receiving attention. The lessons learned from the COVID-19 pandemic along with the feedback Dr. Walensky has received inside and outside of the agency over the past year, have made it clear to her that it is time to take a step back and strategically position CDC to support the future of public health. As it enters a different phase of the pandemic with an eye toward future health threats, CDC is seeking advice from inside the agency on how best to transition much of their COVID-19 programmatic and scientific response activities from the centralized Incident Management (IM) structure to the agency's Centers, Institutes, and Offices (CIOs). To that end, she asked Dr. Barbara Mahon, CDC's Incident Manager, to work with senior leaders across the agency to develop a transition plan to align the COVID-19 activities with the agency's functions. This transition is expected to be made in June 2022 when Dr. Ian Williams will take over as the COVID-19 Incident Manager.

In addition to assessing the pandemic response specifically, Dr. Walensky also asked Jim Macrae, a senior and longtime leader from the Health Resources and Services Administration (HRSA), and senior CDC leaders Debra Houry, Robin Bailey, and Sherri Berger to hold confidential one-on-one interviews with CDC employees and other key stakeholders inside and outside of the agency to gather feedback on the agency's processes, systems, and structure and to solicit suggestions for strategic change. More information will be provided about the recommendations and CDC's actions during future ACD meetings when time will be devoted to dive into the questions that arose through this effort. This is the work that will position CDC strategically for its future and to advance the agency's future goals.

Along with these efforts, CDC recently updated its Strategic Plan to reflect where the agency is in this moment of the pandemic and public health, and to emphasize the agency-wide commitment to health equity and workplace and workforce diversity and inclusion. The 2022-2027, CDC's Strategic Plan advances science and health equity and affirms the agency's commitment to one unified vision—equitably protecting health, safety, and security. The plan continues to leverage 5 core capabilities of the agency, reflecting the commitment to equity and diversity and identifying where investments have been made through the COVID-19 pandemic. These core capabilities are: 1) building and maintaining a diverse public health workforce, 2) developing and deploying world class data and analytics, 3) maintaining state-of-the-art laboratories, 4) responding to domestic and international outbreaks at their source, and 5) strengthening global capacity and domestic preparedness.

Strengthening and modernizing these core capabilities provides an opportunity to leverage the capacity the agency has built with critical investments in support of the COVID-19 response and positions CDC for a successful future. Those investments include developing a COVID-19 vaccine implementation structure, expanding laboratory capacity to support genomic sequencing, enhancing CDC's Data Modernization Initiative (DMI), and strengthening workforce capacity within CDC and through response-related funding to health departments. CDC has made enormous strides in diversifying its workforce with the selection of Robin Bailey as

the agency's Chief Operating Officer (COO), Leslie Dauphin as the Director of the Center for Surveillance, Epidemiology, and Laboratory Services (CELS), Leandro Mena as the Director of the Division of STD Prevention, and José Romero as the Director of the National Center for Immunization and Respiratory Diseases (NCIRD).

Dr. Walensky reminded everyone that she mentioned the new Center for Forecasting and Outbreak Analytics (CFA) during the previous ACD meeting. She had the opportunity on April 19<sup>th</sup> to visit at the White House for the official launch of this new center. CFA will bring together the next generation public health data, expert disease modelers, public health emergency responders, and communication experts to help ensure that they never again face a public health emergency unprepared. Like the creation of the ACD, creation of the CFA has been one of Dr. Walensky's top priorities since becoming the CDC Director in January 2021. The CFA will be available for analyses at every stage of a health threat. Early on, this center will assess an outbreak and its potential to reach epidemic status. Later, the CFA will be able to compare the expected impact of different interventions and help jurisdictions to decide whether and where they need to direct their resources. The CFA will provide data on the epidemic and when an outbreak might be over. In this way, the CFA will help reduce the potential for social and economic disfunction from health threats.

The CFA already has been proving its value. During the pre-launch phase, the CFA helped anticipate the timing and impact of the impending Omicron surge. Shortly after the variant's arrival in the United States (US), the CFA partnered with the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) and CDC's already robust modeling data analytics team. CDC was able to alert public health leaders and their partners, providing advance notice of the timing and magnitude of the surge and the severity of the disease—allowing them to plan. This is just the beginning. Through the CFA, CDC will develop a program to provide insight about disease events for the public and work closely with partners across the federal government to fortify preparedness activities. Consistent with ongoing efforts at CDC, this new center has the potential to improve and save even more lives in ways that can only be imagined at this time. Dr. Walensky looks forward to watching the CFA grow, along with CDC's DMI that will strengthen the data sources available and make sure the pipes are in place to feed those data to CFA.

In closing, Dr. Walensky emphasized that it is an exciting time for CDC and that she is glad to be a part of it and have the ACD as part of it as well. She again thanked each member for their willingness to participate on this committee. Over the next few years, she looks forward to them coming to know one another very well.

## Discussion Summary

Dr. Adimora inquired as to whether there is a need for additional resources for the CFA, especially in the era of funding for COVID-19 being questionable.

Dr. Walensky indicated that CFA has early start-up funding from the American Rescue Plan (ARP). The DMI efforts and the longitudinal plan for CFA will be essential. The data will have to flow fluidly to the CFA because the efforts will only be as good as the data they have. There will be a need for attention to both data and longitudinally available personnel to staff the CFA and be able to work collaboratively and innovate within it. She is very interested in maintaining not only the funding that they have but also in growing it. The team in place now is small and mighty, but efforts are currently underway to expand that team. Durability is going to be

essential in terms of the ability to predict, prepare, innovate, and explore. Sustainability of funding will be essentially for achieving durability.

Dr. Morita congratulated Dr. Walensky for all that she has accomplished, even in the midst of the pandemic. In terms of data authorities, she wondered whether there were hurdles that had to be overcome in trying to do the forecasting for the Omicron variant. Some of the challenges that have been experienced by governmental public health in the past have been related to the authority of public health to access data.

Dr. Walensky appreciated the question because one of the key challenges she has observed during her 15-month tenure is that people often expect to see data from CDC that the agency does not have the authority to report on or collect. With the DMI efforts, they should be able to connect the pipes where all of the data fits well. However, if there is no standardization of those data, those data will not be forthcoming even if the pipes connect. The previous day she was in a conversation regarding whether, after the public health emergency ends, CDC will have the capacity to report all of the data people are expecting from them. She has heard from some jurisdictions that they are not interested in reporting to CDC. Authority will be a key issue among the stumbling blocks in terms of data modernization efforts and the CFA, but the agency is actively working on this.

Dr. Fleming suggested that perhaps the DSW could provide advice on this as well.

Dr. Sharfstein recalled that when he was Health Commissioner of Baltimore, a researcher figured out an equation to predict heat-related deaths. When the researcher reported to them days that would be very hot, they would open cooling centers, issue press releases, et cetera. They were known for this at the local level, and it was based on receiving good forecasting. He wondered how Dr. Walensky envisions the great CFA resource working with states and localities to strengthen how they pivot to translate information to their population.

Dr. Walensky emphasized that while the CFA was stood up in the time of a pandemic, this resource is intended to be for both infectious and non-infectious forecasting. The CFA also is intended to be innovative with regard to how the agency works with industry, partners, and academia. There have been a lot of models throughout the pandemic at the national level, but the national average does not necessarily help local public health partners. Therefore, they want to ensure that the CFA models are applicable at the local level by having an interface to assist local public health departments.

Dr. Martinez noted the opportunity to think about effective communication particularly in terms of setting up the CFA. He believed CDC should consider how the CFA's formation relates to how trust has become an important factor over the last 2.5 years of the pandemic. CDC must be trusted, so he wondered what Dr. Walensky's thoughts were about how standing up the CFA plays into the overall image of the CDC.

Dr. Walensky agreed that communication is key and noted that there has been extensive discussion about who the audiences are for the CFA. One of the goals is to work with CDC's Communication's Team to ascertain and articulate the audiences (e.g., public health departments, schools, parents, et cetera), given that communication strategies will differ depending upon the audience. This is true of CDC's day-to-day work as well in terms of communicating with various audiences.

Dr. Taylor thanked Dr. Walensky for her passion and all she does. She concurred with the importance of communication and getting CDC back to being the trusted voice. The CFA, as a source of data directed to multiple target audiences, could contribute a great deal to the effort to restore the trust in good science and get people to understand that science is a part of their lives.

Mr. Dawes expressed gratitude to Dr. Walensky for prioritizing health equity as one of three important issues moving forward. It dovetails into the CFA as well. Working with groups across the country in terms of data literacy, it has been clear that this has not been prioritized. Without a working knowledge of data to drive decision-making, he believes that the movement for health equity is hindered. From his standpoint, they have come up against issues with data sovereignty with Native American communities and the lack of engagement early on with communities disproportionately impacted by COVID-19 and other comorbidities. He inquired as to how disproportionately affected communities are a part of the CFA and have been helping to drive the agenda moving forward in the process.

Dr. Walensky agreed that this has to be a key part of the effort. From a workforce standpoint, CDC's workforce has to be as diverse as the communities it serves. If the public health workforce involves people from and working in those communities, they will understand their data. There is no intention for anyone to lose data sovereignty. The whole point is to work together collecting the data synergistically so that CDC can feed information back to local communities. If data arrive at CDC sequentially, there are further delays. CDC would rather work collaboratively with local health departments to understand their data with them and to collect data in a standard manner such that it can be cross compared with other health departments to forecast at the local level. Weighted averages do not have local relevance in terms of their policies.

In terms of CDC transitioning from a full agency-wide mobilization for COVID-19 to a more measured response, Dr. Fleming requested a snapshot of what that looks like for the agency. He could not imagine the difficulties of people doing this for 2 years. He appreciated the efforts to return to normalcy with an opportunity for some rest, and for getting back to other issues that the agency has to work on.

Dr. Walensky stressed that while COVID-19 has been at the forefront of what people are hearing about, in the last year there have been 63 foodborne outbreaks that CDC had to address. It also is the case that over 2000 CDC staff have been involved in the response at any given time throughout the pandemic. The COVID-19 activities will be more streamlined such that people will be working on programs and COVID-19. The agency needs to have less than 2000 people on detail focused solely on COVID-19 and to move some of the COVID-19 activities to a natural home in programs, because the activities do need to continue but without 20% of the agency on detail.

Ms. Valdes Lupi asked how the organizational review might be different from previous assessments and what the action steps might be that are anticipated to follow. She noted that a lot of state and local health departments are now taking stock of the last couple of years and revisiting organizational capacity.

Dr. Walensky indicated that the agency is partaking in three activities simultaneously. The first regards how to move many of the response activities to programs. The second pertains to the findings of the many listening sessions that Jim Macrae is convening related to lessons learned from the pandemic about implementing new guidance. CDC has never been involved in a pandemic that required such swift action with such evolving science. Consideration is being given to the lessons learned in terms of things that went well, things that could have gone better, and ways to streamline other guidance across the agency. It is not lost on her that there has not been an agency review in a while in terms of CDC's systems, structures, and processes. They have hired about 10% new FTE. There is a new sector for the CFA, that needs to find a home. They are thinking about where some of the activities should live, how to integrate these structures into the CIOs, and if there is more to learn. She is trying to keep an open mind, given that they have not had time over the last 15 months to digest some of these activities and that the listening sessions are ongoing. There certainly have been enough external magnifying glasses, critiques, and discussions that she feels like they should do an internally facing assessment as well.

## Data & Surveillance Workgroup Update / Terms of Reference (TOR)

**Dan Jernigan, MD, MPH** (Deputy Director, Public Health Science and Surveillance, CDC) emphasized that the task at hand is a big one that touches on multiple parts of public health, and that he looks forward to hearing from the ACD members about how CDC can have the greatest impact by improving its surveillance and data systems to have faster and better data for actionable intelligence for decision-making at all levels of public health. As a reminder of the DMI priorities and to underpin the day's conversations, CDC published its first Data Modernization Initiative Strategic Implementation Plan.<sup>1</sup> This comprehensive new approach is framed around 5 critical priorities for work across CDC and across the agency's state, territorial, local, and Tribal (STLT) partners. Those 5 areas are to: 1) build the right foundation; 2) accelerate data into action; 3) develop a state-of-the-art workforce; 4) support and extend partnerships; and 5) manage change and governance.

The first priority of building the right foundation means building the pipes that Dr. Walensky mentioned from health care and other sources of data into a place where it can land. For that, CDC is implementing a cloud-based infrastructure within the agency and supporting states through cooperative agreements and other funding to initiate that cloud-based infrastructure as well. Once in place, sharable approaches to data analysis and utilization tools will be developed that can be utilized across various programs in order to move toward breaking down existing programmatic silos.

In terms of the second priority, Dr. Walensky mentioned all of the activities underway within the CFA. The agency is looking to the CFA to help advance the innovation for predictive analytics, scenario modeling, and other efforts for forecasting. It is in that space that the agency is supporting standards development work with the Office of the National Coordinator for Health Information Technology (ONC) with HHS in order to leverage the electronic health record (EHR) environment to ensure that public health is a part of that ecosystem. The standards development activities will take some time, but they must be started now.

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<sup>1</sup> <https://www.cdc.gov/surveillance/pdfs/FINAL-DMI-Implementation-Strategic-Plan-12-22-21.pdf>

With regard to the fifth priority pertaining to managing change and governance, it is well-recognized that what CDC is trying to do and what is needed within STLT health departments is to think differently about surveillance and how data are received and shared, and to understand that this is a change management issue that requires a lot of understanding about where people are, where they need to be, and how to get there.

CDC's commitment to data modernization includes commitment to investments in data systems, strategies and capabilities, policy levers, and multi-sector partnerships that are in place through the DMI Consortium and other mechanisms the agency is using as well. The DMI strategy is changing collaboration and innovation across CDC and across STLT partners. This includes an agency-wide commitment to setting and achieving specific objectives and key results. The biggest difference in the current DMI is the community around this effort toward shared success. Many have been part of the dialogue, listening sessions, and multiple recommendations that have been provided to CDC or have been published that support DMI and a shared vision for what public health can be. CDC is listening and incorporating those recommendations. Listening to partners in the wider conversation will ensure that the DMI is responsive, flexible, and attuned to the needs of public health and the nation.

It is important to understand how CDC's funding and structure have impacted its modernization efforts thus far. In terms of implementing DMI, one of CDC's biggest strengths has shown itself to also be one of its biggest challenges. CDC is comprised of many centers, each with different areas of expertise. This way of working has allowed the agency to go deep in the science, which is a benefit. Science and surveillance are engrained in every part of the agency. A survey conducted a few years ago found that about one quarter of CDC staff conduct surveillance-related activities and nearly half of CDC's health scientists work in surveillance-related units. This underscores the importance of CDC scientists in the surveillance enterprise. The challenge lies in the fact that each center often has its own disease-specific funding streams, which over time has resulted in more than 100 different surveillance systems tracking thousands of diseases and conditions. This type of categorical funding can result in silos and a lack of connection across various parts of the agency. That translates into heavy burdens for CDC's data providers at the state and local levels who often must report to multiple systems in multiple ways. This way of working has become the status quo across all of public health. These silos exist at every level.

CDC is known for and trusted largely because of its expertise in tracking health threats through its surveillance systems and in sharing these data and discoveries to inform decision-making. At the same time, CDC maintains more than 100 surveillance systems for different uses. This creates a reporting burden, duplication, and can create discrepancies among the data elements and the need to use multiple information technology (IT) systems. When surveillance estimates were evaluated as part of CDC's surveillance strategy, it was identified that the agency's active surveillance systems cover broad ranges of topics that fall into 4 categories:

- Infectious Diseases (~50%)
- Non-Infectious Health Conditions (~23%)
- Both Infectious Disease and Non-Infectious Diseases and Conditions (~2%)
- Risk Factors and Exposures (~17%)

Creating an additional challenge is that the world of data continues to proliferate and change rapidly in the midst of a data revolution. This data revolution creates opportunities to advance public health in ways that were hard to imagine a generation ago. It also brings increased complexity to CDC's work. For instance, data informing the COVID-19 response originated from traditional and non-traditional healthcare settings, community and municipal organizations, private sector, and many different EHR systems. These data came from big systems and small and electronic and paper formats. The central challenge for CDC and for public health at large was to turn the vast amount of data delivered at different times, through different channels and intermediaries, and of different quality and completeness into useful and actionable information. An enterprise view of the world of data can offer insight into this information that is timely, accessible, content-rich, and cost-effective. The major question CDC is answering through DMI regards how the agency can harness its strength, the deep expertise built up over decades, while overcoming the challenges in order to truly operate as one CDC and as one public health community along with the agency's STLT partners.

The DSW is being established to provide work products to the ACD regarding agency-wide activities related to the scope and implementation of CDC's DMI strategy. The ACD was provided with a document of the Terms of Reference (TOR) for the DSW. Through the DSW, the agency will be able to consider its existing challenges from a more holistic perspective to find solutions. Under its primary charge to provide input to the ACD regarding potential solutions to issues and questions, the DSW will help to: 1) identify innovative, equitable, and promising modernization practices and approaches; 2) align with the principal pillars of DMI; 3) advance modern, harmonized data policies and practices; and 4) develop advice and recommendations to support the effective execution of DMI across the agency.

Keeping equity as the focus, the DSW will be comprised of a balanced group of subject matter experts (SMEs) in public health science and practice, policy development, health system implementation, and surveillance and informatics. Members will be included from jurisdictional government agencies, non-governmental organizations, academic, and the private sector. These experts will work with the ACD to develop advice and recommendations to CDC to support the effective execution of CDC's DMI strategy across the agency, ultimately playing a key role in the agency's work with public health, healthcare, academic, and private sector partners. There are 6 main focus issues (Authorities, Data Exchange, Forecasting & Analytics, Workforce, Breaking Down Siloes, Assuring Sustainability) and related questions that the DSW will be asked to consider.

With respect to Issue #1: Authorities, CDC does not have broad and direct authority to require jurisdictions or other entities to report data. CDC and STLT public health agencies depend on and are bound by laws, regulations, and policies that determine the content, form, and manner of the data they collect, report, and use. The variation in these laws, regulations, and policies across jurisdictions and levels of public health may create impediments to data sharing and exchange and limit efforts to gather data at the regional or national level on critical elements, such as social determinants of health (SDOH), often depending upon interpretation.

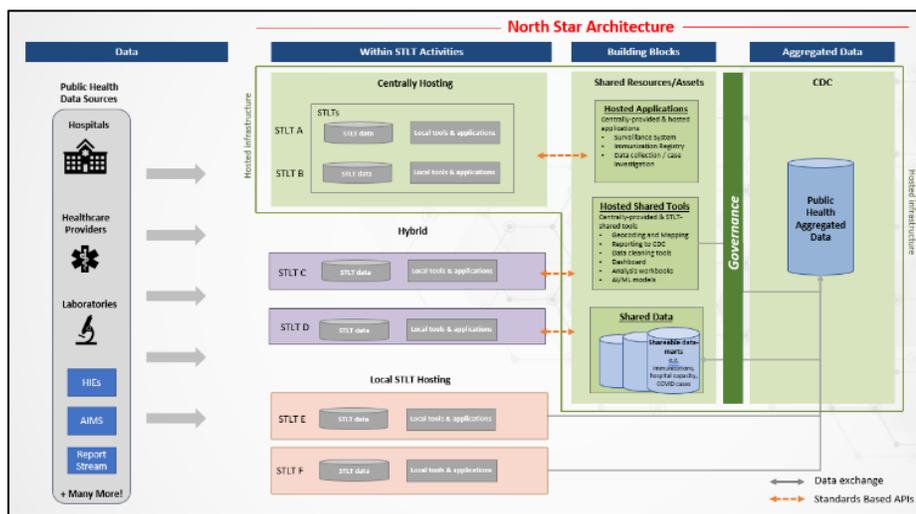
CDC is in a very different place than before the pandemic. To monitor disease burden, data were collected through electronic laboratory reports (813 million COVID-19 tests), case-based disease surveillance (79 million case reports), emergency department (ED) visits (7.4 million COVID-19 encounters), immunization records (551 million vaccinations administered), virus genomics data (2.1 million published sequences), healthcare data (140 TB of clinical and administrative data), and hospitalization data (4.6 million total admissions). These data offer an

incredible national picture of what is occurring, a lot of which was made possible through emergency orders. When the pandemic public health emergency has ended, those authorities may end as well.

Regarding Issue #1: Authorities, the question for the DSW is:

- How can CDC support common approaches to data sharing and access for public health data, particularly through supporting policy and system approaches, consistent with applicable laws and regulations, to build trusted networks for data exchange and address vulnerabilities created by variation across sectors and levels of public health?

In terms of Issue #1: Data Exchange, exchanging data has been a very burdensome and time-consuming process. The burden and the friction of exchanging data forces staff across the public health enterprise to focus a significant amount of time, effort, and resources on data management rather than conducting public health surveillance and response activities. Much of the time of state and local health department staff is spent in just getting the data in so that they can work on it rather than having the data work for them. Changes are needed so that some jurisdictions are not spending 80% of their time just getting the data in shape in order to analyze it. CDC is working with partners to explore the design and implementation of a modern public health information ecosystem that can be leveraged to reduce the cost and complexity of STLT operations. One component of that information ecosystem could include a centrally hosted infrastructure and services that are provided to jurisdictions by CDC. This diagram illustrates a draft framework that is in development known as the North Star Architecture, which is a joint ONC-CDC effort to help articulate a shared vision of a public health data infrastructure for STLTs to share data with each other and CDC.



This structure is now under discussion through the DMI Consortium, which includes multiple public health and other partners in this public health ecosystem space. This North Star Architecture model describes who, what, and how of a future state of a public health ecosystem where data flows and information systems are coordinated, connected, and interoperable across healthcare and public health at all levels of government. This model maximizes the benefits of cloud computing, open architecture, and industry standards for data collection, exchange, management, and analysis and proposes a spectrum of options for STLT participation that preserves their control of their data and their decision-making autonomy.

As noted, this work is being done jointly between CDC, ONC, DMI Consortium to ensure that the needs of the entire ecosystem are captured and decisions and directions are identified that CDC can help support through the building and development of the necessary components as funding becomes available. This is founded on the lessons learned from the COVID-19 pandemic and draws inspirations from the successes of COVID-19 Electronic Laboratory Reporting (CELR), which enabled a dramatic acceleration of online laboratory reporting; the efforts to modernize the National Syndromic Surveillance Program (NSSP), which provides most of the ED encounters in the US; and the increased scalability of the National Notifiable Diseases Surveillance System (NNDSS), which receives 10 times the usual case files due to COVID-19 among others.

CDC wants to offer a range of support through the DMI effort to STLT partners, realizing that the activities in those departments of health are supported with federal dollars. The agency wants to have solutions that address at least 3 kinds of models for how health data can be shared: 1) a local hosting environment in which the state is responsible for their own systems; 2) a hybrid approach in which states maintain their own cloud, but for which CDC will have services available to help them increase the work they can do and decrease the amount of burden related to preparing data for use; and 3) a central hosting approach, which would be the cloud-based platform that would enable STLTs who do not want to do their hosting the capability to use all of the services available, including the case management tools. This will take time and planning over the next 2 years, and CDC looks forward to ACD's input on this.

*Regarding Issue #2: Data Exchange, the questions for the DSW are:*

- What role should centrally hosted infrastructure and service play in a modern public health information ecosystem?
- How can the structure and use of a modern public health information ecosystem support and ensure that partners receive added value through participation, for example through the sharing of harmonized data to jurisdictions from CDC?

Pertaining to Issue 3: Forecasting and Analytics, policymakers and individual citizens often rely on CDC for guidance and information that depends on the use of models, forecasts, and analytics. Clear applications of these tools for situational awareness, early warning, and emergency response continue to be explored. This issue is a particular opportunity for the new CFA. The new CFA has been up since August 2021 and has begun to take these capabilities to the next level. The work of DMI underpins this work and will be necessary for its success. The priorities of the CFA are to predict, inform, and innovate. That includes parameter estimates, scenario models and forecasts, targeted studies, and responsive analytics.

*Regarding Issue #3: Forecasting & Analytics, the question for the DSW is:*

- How should CDC prioritize advancement of forecasting and analytic efforts to integrate public health activities and address health equity?

Moving to Issue #4: Workforce, CDC is supporting modernization of the public health workforce as a major activity to ensure sufficient capacity and capabilities across STLT health departments and at CDC. In line with the agency's DMI priorities, CDC has been taking a variety of innovative approaches to building a state-of-the-art workforce, including: 1) recruiting and building through fellowships; infrastructure grants, which will have \$3 million available over 2 to 5 years for which the focus is not specifically related to data scientists or DMI-related activities, but for the whole of the public health workforce; and the Public Health AmeriCorps that will be providing over \$65 million in awards to 82 grantees across 32 states; 2) training through Data Science Upskilling (DSU); Data Science Team Training (DSTT), and Applied Public Health Informatics Fellowships (APHIFs) programs

to build informatics, data science, and laboratory capacity at state and local health departments; and 3) forecasting future needs through the HRSA Health Workforce Research Center (HWRC), which will inform health workforce educators, planners, policy-makers, and others interested in public health workforce and working closely with HRSA's National Center for Health Workforce Analysis (NCHWA).

*Regarding Issue #4: Workforce, the question for the DSW is:*

- How can CDC work with partners to support the public health enterprise by increasing access to data science and information technology skillsets and staff from academia and the private sector and addressing barriers to hiring and retaining experts in these fields?

In terms of Issue #5: Breaking Down Siloes, the complicated and disconnected web of public health data systems that create data management and reporting burdens on public health staff are in large part a result of siloed programmatic activities that have been propagated over time by categorical approaches to funding. Various DMI projects are led by or funded through a specific center. Because of the way that CDC traditionally has been funded in the past, each of its centers holds longstanding expertise in specific areas with specific systems. It is important to recognize and tap into that knowledge. At the same time, it is necessary to build bridges. For example, in the first priority to build the right foundation, the Office of the Chief Information Officer (OCIO) at CDC is leading the development of the cloud-based enterprise data, analytics, and visualization platform. The Center for Surveillance, Epidemiology, and Laboratory Services (CELS) and the National Center for Health Statistics (NCHS) are leading much of the work pertaining to CDC's core surveillance systems. At the same time, the National Center for Immunization and Respiratory Diseases (NCIRD) is leading the way on the agency's immunization systems modernization.

While recognizing the expertise, it also is important to recognize that the "old way" of working no longer serves the agency at an enterprise level. The DMI approach is applying mechanisms that will bring CDC out of its siloes. They have begun forming across agency teams that will allow the agency to find shared solutions to shared problems. A structure has been set up that is guided by the DMI priorities and objectives and is not dictated or limited by center or even who is funding and who is not. The hope is to ensure that CDC is serving the greater needs of the agency and that its investments are available and reusable across the enterprise. CDC wants to unlock the answers to large public health challenges by using all of the data they can across program areas. This is a major shift from how the agency has done things in the past that will have meaningful implications for what CDC is able to do in the future.

*Regarding Issue #5: Breaking Down Siloes, the questions for the DSW are:*

- For the next phase of DMI, what agency-wide activities would most benefit from a coordinated, all-of-CDC approach?
- What efforts could ensure long-term sustainability and success in achieving modernization and supporting advancement of agency priorities like climate change and health equity?

Pertaining to Issue #6: Assuring Sustainability, implementing and maintaining a modern public health data ecosystem will require all levels of public health to rethink the business policies, practices, and procedures of public health agencies to support more nimble approaches to information technology and sustainability of data infrastructure. Sustainability is critical and jurisdictions repeatedly caution CDC that their hands are often tied when support is limited to annual funding. To address this, CDC included a component in the new Public Health Infrastructure Grants being managed out of CELS that could fund data modernization activities for a 5-year period. If funding were to become available for the DMI portion of the grant program, CDC's STLT partners

would have more time over which to plan and implement modernization activities. They would have more flexibility in how to use those funds compared to the current cooperative agreement mechanisms. The current mechanism being used is the Epidemiology and Laboratory Capacity (ELC) Grant Program cooperative agreement that has delivered \$200 million in direct DMI funding for jurisdictions in FY21. That funding is focused on supporting foundational data modernization activities, accelerating modernization of the National Vital Statistics System (NVSS), and leveraging the incredible progress made over the last 2 years by scaling up electronic case reporting to include all notifiable conditions. This is a major task, but is one for which CDC is prioritizing through the funding provided. Through ELC, CDC also has increased access to technical experts and consultants and provided funding for a variety of mechanisms through national partners such as the Council of State and Territorial Epidemiologists (CSTE), Association of State and Territorial Health Officials (ASTHO), Public Health Informatics Institute (PHII), and others to strengthen learning communities, Communities of Practice (CoP), and targeted workshops. By putting the new infrastructure grant mechanism in place now, CDC has opened the door for more flexibility and sustainability as the agency's state and local partners build upon this progress.

*Regarding Issue #6: Assuring Sustainability, the questions for the DSW are:*

- How can CDC work with partners to address barriers related to funding mechanisms, procurement, and program delivery?
- What mechanisms for assuring sustainability of modernized systems need to be developed and implemented?

The DSW has some specific activities, which include the following:

- Participating in sessions to consider and address the guiding questions, and drafting a report of the findings, observations, and outcomes.
- Receiving ad hoc presentations from the CDC DMI Leadership Team to review the aims, content, and underlying assumptions of the DMI Strategy; from CDC programs on evidence-based approaches, tools, and what is driving successful implementation of data modernization activities; and on internal and external initiatives that will impact DMI outcomes.
- Reviewing CDC's DMI implementation outcomes, progress, and metrics to provide feedback to the ACD, CDC.
- Providing updates to the ACD, CDC at each meeting.

## Discussion Summary

Dr. Medows emphasized the importance of including non-traditional public health partners. Much has been learned during the H1N1 influenza and COVID-19 pandemics about how to use non-traditional public health data to identify where hotspots are developing/problems may be emerging. New ways also have been discovered for using information coming from the public health side to the healthcare side. She expressed her hope that the DSW would include many people who have work on the ground from a variety of settings (e.g., hospital, ED, primary care, pharmacy, et cetera). Consideration must be given to how to leverage all of these diverse information sets and data to be faster, better, stronger before the next wave or the next pandemic occurs.

Dr. Jernigan recognized the importance of the focus on non-traditional data. There is much that needs to be done with traditional public health data, but there are other data sources that clearly have been used throughout the pandemic that provide additional information and can be significant sources of SDOH information and health equity data. CDC has been considering those as a part of the data sources, but identifying how to call that out would be helpful.

Dr. Sharfstein emphasized the importance of defining the purpose of data collection. Alongside the technical goals, he wondered whether CDC has a set of goals for what the public health system can do. For instance, people should be able to obtain their immunization records wherever they are, or it should be possible to identify outbreaks of asthma within a week. There must be functionality that inspires people to do all of this work underneath the surface.

Dr. Jernigan indicated that much of that is defined in the objectives, key results, and measurable outcomes that were presented previously. These are being further defined and will be present in the updated implementation strategy.

Dr. Shah recalled mention of the term “all-of-CDC approach,” but wondered what thought had been given to groups beyond CDC such as Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and other government entities outside of HHS.

Dr. Jernigan indicated that in terms of the DMI, most of CDC’s work thus far has been within HHS. He is working closely now with CMS on some of the capabilities they have that might be leveraged to improve data reporting and gathering. CDC also has been working very closely with the ONC and using their capabilities to build EHRs and certification systems. They also have had some discussions with the Department of Defense (DoD) and Veterans Affairs (VA), as well as activities with them throughout the pandemic and have used some of their data sources for some of the pandemic work. The agency has not tried to have a whole-of-government approach, given that they have been focused on advancing those issues that are within the CDC and STLT partner ecosystem because of the near-term need to focus on those. There are numerous possibilities of leveraging other data sources and systems, and CDC would appreciate the ACD’s input on how best to utilize those.

Dr. Martinez emphasized the importance of including members on the DSW who have skillsets and expertise in communication. Effective and evidence-based communication is truly a skill. Everyone thinks they can communicate. While everyone can talk, that does not necessarily mean that they are communicating. It is key in this work to have members who understand the nuances between regular communication, public health communication, and so forth. Communications skills also could help to break down the siloes that must be dealt with, especially in terms of data.

Dr. Fleming reminded everyone that the WGs are constituted of ACD members and are supplemented with non-ACD members as well. CDC has been working hard on this and soon will publish a Federal Register Notice (FRN) to solicit outside applications to join the WG.<sup>2</sup> He encouraged all ACD members to recommend potential members who could provide value to the ACD WGs, and called upon Drs. Shah and Morita to mention some of the criteria of interest for outside applicants.

Drs. Shah and Morita suggested individuals with active experience in state and local data and issues, lawyers who understand data privacy, SMEs with expertise on cybersecurity, individuals in healthcare systems and with EHR expertise who recognize the value of those systems and the data they have in terms of informing public

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<sup>2</sup> <https://www.federalregister.gov/public-inspection/2022-09538/requests-for-nominations-advisory-committee-to-the-director-data-and-surveillance-workgroup>

health, and people with expertise in data and public health data health systems as it relates to equity as well. They have a spreadsheet of names and invited others to provide additional suggestions. They also are seeking additional ACD members interested in joining the group.

Dr. Adimora pointed out that some EHR systems appear to have been developed more as billing systems rather than medical communication tools or surveillance systems, so the systems themselves seem to work against this. Added to that are issues and laws related to privacy. Nevertheless, they are great sources of data and she supported the effort to try to loop those in. One suggestion would be representatives from some of the major EHR companies, such as Epic and Cerner. She requested additional information regarding the idea of a centrally hosted hub in terms of whether that meant that the data could go to state and local health departments and CDC simultaneously, which seemed like a good idea and would be much faster.

Dr. Jernigan indicated that solutions are currently in place for electronic case reporting such that reports from EHRs go to one place and are then made available to state and territorial partners. That model could be leveraged to make some information available through that mechanism. This would be done through Data Use Agreements (DUA) and other approaches such that the technological models already being used for electronic case reporting also are used for syndromic reporting in which 71% of all EDs in the US are currently able to be represented with their information captured in a place where state health departments have access to those data. There are capabilities whereby at a federal level it is possible to see what is occurring within various EDs, certainly in terms of COVID-19. CDC would like input from the ACD on how best to enter into that activity for a broader part of the public health ecosystem—not just those two examples. There is a difference between claims data and data that are captured in the EHR that is used for medical encounters. Case reporting data that CDC receives currently is coming from health records and includes information about the patient, demographics, encounter information, medical therapeutics listed, vaccines, et cetera. The data that are collected as a part of encounters for reportable events are being captured and sent to state health departments. The capability to use the health record is anywhere EHRs are used. Most of the facilities reporting now are doctors' offices and other settings. The DMI is allowing for those capabilities to have increased use. CDC is working with CMS to make sure there are incentives or conditions that will result in EHRs being used more substantively. CDC also is communicating with vendors as part of the agency's public-private partnerships through the CDC Foundation.

Dr. Goldman expressed appreciation for how thoroughly the agency is mapping out this effort. There are a lot of data sources outside of CDC that the agency needs to consider. While EHRs are among those sources, they do not collect a lot of the information about SDOH that they could collect and that would make that system better from the standpoint of addressing public health. Working with the vendors is important as there is a lot of room for improvement. The data will not all be within the health arena, so the group needs to think more broadly. For instance, the data about travel and the amount of time people were spending in their cars every day became important due to COVID-19.

Mr. Dawes asked whether the inequities in digital health and related technology design, application, and digital and technological conditions that influence health inequities will be specifically considered within the 6 priority areas.

Dr. Jernigan clarified that the 6 questions were the ones posed to the DSW for consideration. The issue Mr. Dawes was raising pertained to the problems with inequities that may be introduced through the technologies themselves. As part of the CFA, funding is being provided to academic partners to assess inherent bias in algorithms, predictive analytics, and other tools that are used. There is a means by which these systems can be taught to provide predictions and forecasts, but the information provided in order to do that forecasting may not be equitable in terms of describing the broader populations. The agency is considering ways to improve health equity through collection of information, development of standards to acquire health equity data, and thinking about ways to connect the various data sources to the programs so that they can link data and understand the context around the case in order to infer the SDOH and other factors that may be available in other data sources to that case. While there is not a specific focus within DMI on digital equity at this time, they recognize that it is an important issue to be working on and would appreciate feedback from the ACD.

Given the amount of data within CMS, Dr. Sharfstein asked whether part of this effort would help other agencies package their data and make it more available for state and local public health or CDC. That is not exactly building the pipes of a new system, but CMS has so much information that often it is difficult for state and local health departments to access. He wondered if they saw this as primarily about the data resources CDC is engaged in building or if perhaps this could be a conduit for other data to the public health system.

Dr. Jernigan emphasized the importance of pushing against the concept of one-way data flow. CDC is trying to speed up the one-way data flow and decrease the friction of data getting to those who need to do the work at the national, state, and local levels. Through a number of processes learned due to COVID-19, there is a capability of getting data back to the state and local levels that is aggregated and provides meaningful data for jurisdictions. Giving data back is critical. There are numerous data sources that are not captured through any other traditional public health routes, such as CMS data, that could be made available to STLT partners. As a part of the bidirectional flow of data, CDC would like to think through the authorities for sharing CMS information and consider ways to give access to jurisdictions to elements of those data so that they have ready access to helpful information.

Dr. Taylor highlighted an issue of many years regarding the determination of what meta data should be included with laboratory data and inquired as what mechanisms CDC would use to figure that out.

Dr. Jernigan emphasized that historically, laboratory data has been a critical component of what the public health establishment needs in order to become a case. The collection of those data is where CDC has moved forward the most. The collection of those data often comes from Laboratory Information Management Systems (LIMS), reference laboratories, and other places that are performing the tests that are not providing the care to those patients. CDC receives a lot of laboratory data that does not include a lot of meta data. There may be ways that data coming from places that have to report it, like reference laboratories, could be augmented through other means to provide some of the data that would offer more information about the demographics such as race, ethnicity, et cetera. Possibilities are being explored in the standards development space whereby a laboratory that is reporting may be able to do an automatic query of the reporter who ordered the test to collect additional information. This is not an easy issue to address as a "low hanging fruit" but it is important to address. CDC recognizes that laboratory data is probably one of the most critical components of the information needed. As a part of the DMI Consortium, laboratory and test ordering results are one of its primary use cases.

Dr. Fleming asked Drs. Shah and Morita to express their comfort level with the DSW TOR. Both indicated that they had the opportunity to review the DSW TOR, engage in conversations with Dr. Jernigan, and were comfortable with them. With thoughtful selection of additional members, they expect the DSW to be able to accomplish a lot.

## Vote

A motion was made and seconded to adopt the DSW TOR. The ACD voted unanimously to adopt the DSW TOR, with no dissensions or abstentions.

## COVID-19 Response Update

**Barbara Mahon, MD, MPH** (Incident Manager, CDC COVID-19 Response) provided an update on the COVID-19 pandemic response. As of April 25, 2022, there were nearly 507,501,771 confirmed cases and over 6,220,390 cumulative deaths globally. These are rather somber milestones, both of which are underestimates.<sup>3</sup> CDC rolled out a new metric called COVID-19 Community Levels (CCLs) in February 2022, which is a measure of the impact COVID-19 is having on communities and is intended to be the link to mitigation recommendations. CCLs are based on hospitalization rates and the proportion of staffed hospital beds that are filled with COVID-19 patients, as well as on case incidence. At this point in the pandemic, it is clear that SARS-CoV-2 is going to continue to circulate. Therefore, the metrics that link to action need to be focused and reflect the goals of preventing medically significant illness, protecting the most vulnerable, and minimizing stress on the healthcare system.

The CCLs have not changed CDC's surveillance system. The agency continues to collect and report daily cases, hospitalizations, deaths, variants, et cetera. None of that has changed. The CCLs are built on hospitalizations, which were selected as the foundation because hospitalization data are available for every health service area, which includes every county in the nation, and because hospitalizations correlate with the outcomes of public health significance including: deaths, intensive care unit (ICU) admissions, medically-attended outpatient illnesses, loss of work and school time, and post-COVID conditions. The framework in which CDC encourages jurisdictions to think about their CCLs also includes their vaccination coverage and other local information that may be available. For instance, some localities have access to information about wastewater surveillance or ED syndromic surveillance. CCLs can be an addition for localities that have that type of information, but is certainly not intended to replace other data. CDC also continues to closely monitor leading indicators of potential new surges.

Looking at CCLs from April 21, 2022, more than 92% of the US population was in a location with low or medium CCL. By the 28<sup>th</sup>, that number increased to over 98% of the US population.<sup>4</sup> COVID-19 cases have increased steady in recent weeks with some increases in hospitalizations as well. CDC continues to follow these transitions and to work jurisdictions on the data and implementation questions. As of April 24, 2022, the 7-day average of daily case counts increased 22.7% compared with previous week. As of April 23, 2022, the 7-day average of daily new hospitalizations increased 6.6% compared with previous week. Deaths have thankfully been decreasing for several months. As of April 24, 2022, the 7-day average of daily death counts decreased 13.2% compared with the previous week.

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<sup>3</sup> WHO Coronavirus (COVID-19) Dashboard <https://covid19.who.int/>

<sup>4</sup> <https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html>

Wastewater surveillance has been in the news quite a lot recently. This is a promising approach, but it is a new approach and CDC is still learning how to best take advantage of it for COVID-19. At the same time across the agency, consideration is being given to other pathogens or conditions for which wastewater surveillance could be useful. These are very local measures and there is a lot of variation across the country. One thing CDC is learning about this is that the variation can be due to things that have nothing to do with disease rates, such as rainfall or how close a case lives to a sewage treatment facility. Nevertheless, wastewater surveillance is a leading indicator. Increases have been seen consistently about 4 to 6 days before there are increases in cases. Wastewater also has the potential to identify a known variant before case surveillance does. Decreases have been observed in New York State (NYS). This is hoped to be a leading indicator of a decrease of cases in NYS, which has been the state with the greatest increases and highest CCLs over the previous month or so. Other states have very mixed pictures of areas of increase and areas of decrease.<sup>5</sup>

In terms of circulating variants, the US has been seeing all Omicron.<sup>6</sup> The estimated percentage of COVID-19 variants circulating in the U.S. as of April 23, 2022 included the following:<sup>7</sup>

- Omicron BA.2: 68.1% of cases
- Omicron BA.2.12.1: 28.7% of cases
- Omicron BA.1.1: 2.8% of cases
- Omicron B.1.1.529: 0.2% of cases
- Other variants: 0.2% of cases

The subvariant BA.2 has been comprising an increasing percentage of what was a decreasing number of cases across time. In recent weeks, the subvariant BA.2.12.1 has been making up an increasing proportion of the cases. While first observed around NYS, it is now present in all regions of the US. BA.4 and BA.5 have been causing cases in South Africa and India. The US has identified a handful of BA.4 and BA.5 in the US since the end of March. These variants have not been increasing rapidly in the US, but CDC continues to monitor them carefully.

In terms of domestic vaccination uptake, the US passed 500 million doses administered. While this is not the extent of what the US hopes to achieve, it is worth pausing to celebrate. This is a lot of doses of vaccine and represents a huge amount of good work, even though it is not the ultimate goal and there is still a lot of work to be done. There is a lot of geographic variability in vaccine uptake. Most of the doses now being administered are second boosters. Over three-quarters (77.5%) of the US population have now been vaccinated with at least 1 dose of COVID-19 vaccine, 66.1% of the US population are fully vaccinated, and 45.6% of fully vaccinated persons have received an additional dose.<sup>8</sup> In terms of demographics as of April 25<sup>th</sup>, the highest rate of booster receipt among people eligible for a booster was in the Asian Non-Hispanic group at 54% and the lowest was in the Hispanic/Latino group at 40.8%.<sup>9</sup> There has been a remarkable range in booster receipt by age group over time from over 70% among adults 75 years of age and older, 67% among adults 65-74 years of age, and just over 24% in youth 12-17 years of age.<sup>10</sup>

<sup>5</sup> <https://covid.cdc.gov/covid-data-tracker/#wastewater-surveillance>

<sup>6</sup> <https://covid.cdc.gov/covid-data-tracker/#variants-genomic-surveillance>

<sup>7</sup> <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

<sup>8</sup> Source: CDC COVID Data Tracker: Vaccinations as of April 25, 2022

<sup>9</sup> CDC COVID Data Tracker: Vaccination Demographics Trends

<sup>10</sup> CDC COVID Data Tracker: Vaccination Demographics

FDA authorized a second booster dose at the end of March 2022 of either the Pfizer-BioNTech or Moderna COVID-19 vaccine for adults  $\geq 50$  years of age and immunocompromised individuals  $\geq 12$  years of age who received a primary series and booster of Pfizer-BioNTech or Moderna OR who first received a J&J/Janssen COVID-19 vaccine, regardless of what type of booster they received, or for anyone who received a J&J/Janssen COVID-19 vaccine for both their primary dose and booster. Individuals are eligible to receive a second booster at least 4 months after their first booster, and the second booster must be with an mRNA COVID-19 vaccine.<sup>11</sup> The CDC Director and the Advisory Committee on Immunization Practices (ACIP) both endorsed the options for these groups and those who received 2 doses of the J&J/Janssen COVID-19 vaccine at least 4 months previously. CDC recently posted considerations that people who are eligible for a second booster can use to decide whether to get their second booster now or to wait until later in the summer or early in the fall.

Turning to some current priorities and recent achievements of the response, CDC continues to prioritize health equity. In the last couple of months, there has been an increased emphasis on persons with disabilities and CDC established a Disability Officer position within the Response Unit of the Chief Health Equity Officer. Some of the work in health equity has related to strengthening ties and addressing concerns of people with disabilities and people with immunocompromising conditions, and ensuring involvement from these communities in planning and/or responding to new developments such as travel-related mask mandates. CDC also is working with other governmental departments that are in the lead on therapeutics to promote accessibility of therapeutics to marginalized communities regardless of whether they are immunocompromised or have a disability. The agency also is reviewing the impact of and lessons learned from the grants awarded earlier in the pandemic that focus on communities of color, and is planning to ensure that equity remains a priority inside the COVID-19 Response and CDC CIOs as activities are moved to programmatic homes. This is an area for which CDC would appreciate advice from the ACD moving forward into the next phase of COVID-19.

Relatedly, CDC has been working on and recently launched tools and materials to help community COVID-19 risks to the public. These materials are to help people, especially those at high risk, better understand their risk level and actions they can take to protect themselves from getting seriously ill. Planned is a "Know Your Risk" tool and communication of treatment availability.<sup>12</sup> Sustained use of vaccines protects the health of individuals and communities. CDC supports uptake of 4<sup>th</sup> doses (2<sup>nd</sup> boosters), improvement of equitable access to vaccines domestically and globally, efforts for all eligible individuals to be up-to-date on vaccines, and preparation of vaccine for children  $< 5$  years of age.

In terms of the COVID-19 Response activity transition planning, CDC is planning for sustainability and incorporation of COVID-19 into routine public health practice. This will be achieved by transitioning the majority of programmatic and scientific COVID-19 Response activities to long-term "homes" within the agency. A streamlined COVID-19 Incident Management Structure (IMS) will remain activated.

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<sup>11</sup> Stay Up to Date with Your Vaccines | CDC: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

<sup>12</sup> <https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/print-resources/Test-Soon-Treat-Early.pdf>

## Discussion Summary

Dr. Morita expressed concern related to the therapeutics and vaccine work moving forward with regard to how this information will be placed in the hands of the communities that have been so disproportionately impacted throughout the pandemic. People who have access to information know that PAXLOVID™ is a good option, but it has to be started within a certain period of time after diagnosis. Communities of color, low-income communities, and rural communities might not have access to this information. She encouraged CDC to build support to get that information into communities, and to think about leveraging that same kind of community-based effort to support childhood vaccines when they become available. Being on the verge of having vaccines available for children under 5 years of age is very exciting, but she does not want to see the disparities that have occurred in the past with childhood and adult vaccines play out again with this effort. She expressed her hope that CDC would put the effort and resources into the support of community organizations that can distributed information into communities about therapeutics and childhood vaccines. As a pediatrician, she is cognizant of the role that healthcare providers (HCP) play in administration of vaccines in young children. Yet, she also is a firm believer that there is a need to complement that through educational efforts throughout the community to ensure that people are getting the messages from other trusted sources of information. In thinking about COVID-19 vaccine back into the rest of CDC's efforts, the reduction in childhood vaccine coverage levels due to COVID-19 for other childhood vaccines also needs a coordinated effort for improving uptake.

Dr. Mahon responded that CDC is working with the ASPR on options for expanding access to the Test to Treat Program. The ability to go into a pharmacy with a home test or to get tested there and receive a prescription immediately, it also is known that the pharmacies that have prescribers tend to be in wealthier, lower Social Vulnerability Index (SVI) communities. CDC has been actively working with the ASPR to evaluate how equitably the distribution of the antivirals has been so far, and to explore ways of expanding access. In addition to access, CDC agrees that communication is critical as well. While there is a lot more to be done, they are working with the ASPR and the Surgeon General on communications pertaining to oral antivirals and share the sense of urgency to disseminate the information. In terms of vaccines, the ≤5 years of age group is somewhat different from the other groups in terms of where they will be vaccinated. Children under 2 years of age are unlikely to be getting vaccinated in pharmacies very much, if at all. Even more than for older children, it is going to be very important for providers of primary care for children to have all of the information and operational support they need to be able to administer these vaccines. CDC is working with a number of organizations such as the American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), and others on planning. Dr. Levine, the Assistant Secretary for Health (ASH), is very concerned about pediatric issues as well. Therefore, Dr. Mahon is hopeful that there will be an equitable rollout. She also is concerned about a number of potential barriers and is anticipating many questions from parents.

Ms. Gary asked whether the increase in the BA.2.12.1 variant was being seen in hospitalizations or only in the community. She is hearing a lot of confusion about the difference, if any, between "eligible" and "recommended."

Dr. Mahon indicated that there are two components to the answer to the BA.2.12.1 variant question. CDC's variant surveillance is based on strains received at laboratories, which is not necessarily linked to clinical information. There has been somewhat of an increase in hospitalizations, but less than the increase in cases in recent weeks. CDC is following that closely. Separately, CDC and others are working on studies to assess the severity of BA.2.12.1 in populations where there is an ability to gather the data, control for confounders, and robustly assess severity. To date, there is no information suggesting that BA.2.12.1 is more severe than the disease caused by other variants. It may be somewhat more transmissible, but there is no indication at this point of an increase in severity. There has been confusion about the terms "eligible" versus "recommended." Even before COVID-19, it was known that vaccine recommendations that are not clear-cut with the word "should" are always difficult for providers and the public. Those who have had a complete primary series and the relevant

time of 4 months has passed are “eligible” and “should” receive the first booster. The second booster is “eligible” and “may” if 4 months have passed since someone’s first booster, they are  $\geq 50$  years of age or  $\geq 12$  years of age and moderately or severely immunocompromised, or they had 2 J&J vaccinations. The considerations mentioned are an attempt to help people work through this.

Ms. Valdes Lupi reported that she has been hearing from community-based organizations (CBOs), partners, and local health departments about the concerns of parents and families who are heading into summer with masks off and people traveling. She asked Dr. Mahon whether she could share more details about any planning, collaboration, and preparation CDC is doing to address this in terms of tailored outreach to Black, Indigenous, and People of Color (BIPOC) and lower income communities. While the numbers vaccinated across the country are amazing, there are still persistent inequities in specific cities and regions of the country.

Dr. Mahon indicated that CDC has an extensive network of partners, provider organizations, and community-based organizations that they have been working with since the start of the vaccination campaign. The agency has very detailed operational planning to roll out the vaccines, support vaccine availability, and support providers and CBOs with information for parents. CDC’s teams have been working intensively for a number of months on adjusting information for the  $\geq 5$  years of age scenario for which vaccination in pharmacies will be less important.

Dr. Martinez asked whether CDC is making a concerted effort to address the inequities identified among Hispanic/Latino vaccination rates. He asked about the process for reaching out to trusted voices for community engagement in terms of procedures and skillsets, and how many/what types of materials and what languages are being used.

Dr. Mahon responded that quite a lot of work has been undertaken in this area, which she will provide to Mr. Auerbach to be shared with the ACD.

## Laboratory Workgroup Update / TOR

**Jim Pirkle, MD, PhD** (Acting Associate Director for Laboratory Science and Safety) provided an update on the formation of the Laboratory WG. By way of background, 6 CDC Centers and the National Institute for Occupational Safety and Health (NIOSH) have laboratories. There are over 2500 laboratorians and over 200 laboratories, so this is a major group within CDC. Overall, the public health role of CDC laboratories is to provide laboratory science that effectively supports the detection, diagnosis, treatment, and prevention of disease and harmful exposures in populations. As such, the goal of these laboratories is to support the mission of CDC. Most of the CDC laboratories are engaged in the following common daily laboratory activities, which are to:

- Analyze samples to find an unknown pathogen or toxic agent in an outbreak
- Develop better diagnostic methods for diseases and harmful exposures
- Support detection and diagnosis of infectious diseases, including extremely dangerous pathogens requiring high containment laboratories
- Support surveillance of disease incidence and prevalence
- Identify vulnerable population groups at higher risk of disease or harmful exposures
- Identify risk factors that cause people to be at higher risk of disease or harmful exposures
- Serve as reference laboratories that provide quality testing to other labs
- Conduct quality assurance programs to assist state, local, and other laboratories
- Provide technical assistance on performance and interpretation of diagnostic tests
- Help address treatment challenges such as antibiotic resistance

- Support research studies to better understand disease pathogenesis, transmission, and virulence resulting in better public health prevention actions
- Help evaluate effectiveness of treatments or preventive actions

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) largely addresses bacterial and viral pathogens. While there are viral pathogens in several centers, NCEZID is the largest center that deals with bacterial and viral pathogens. In addition to research and control of dangerous bacterial and viral pathogens, NCEZID conducts outbreak response, bioterrorism response, and suspicious material identification. They also have a heavy emphasis on identifying pathogens that other laboratories cannot. In addition, NCEZID develops methods to detect emerging healthcare-associated infection (HAIs) threats, including antimicrobial resistance (AR).

The National Center for Immunization and Respiratory Diseases (NCIRD) conducts outbreak investigations and has reference laboratories for respiratory and vaccine-preventable diseases. They monitor and control influenza through global surveillance and advancing vaccine development and testing. In addition, NCIRD develops and support the use of vaccines; medical countermeasures; and diagnostics for anthrax, respiratory disease, and other priority pathogens. This group also detects gastroenteric and respiratory viruses, including coronaviruses. NCIRD also supports the Global Polio Eradication Initiative (GPEI) including polio outbreak investigations. The COVID-19 outbreak has had major support from NCIRD.

The National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) develops biomedical interventions and testing for HIV infections, and serves as the national HIV reference laboratory, including drug-resistance testing. This center develops diagnostic testing, including point-of-care testing, for sexually transmitted diseases. They also serve as the national tuberculosis laboratory, strengthening vaccination strategies, testing, and understanding of drug resistance in addition to serving as the national reference laboratory for viral hepatitis.

The Center for Global Health (CGH) provides reference laboratory support for more than 50 countries, including outbreak response, laboratory systems, and pathogen discovery. They also serve as a reference laboratory for diagnosing parasitic diseases and conducting surveillance for malaria drug resistance, monitor quality of anti-malarial drugs, and evaluate insecticide resistance among mosquitos that can carry malaria. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) has a small laboratory that monitors for select infectious agents and other abnormal factors among persons with bleeding disorders.

The National Center for Environmental Health (NCEH) measures population and individual exposures to environmental chemicals and assesses human exposure to chemical threat agents, toxins, and radiologic threats. This center also provides quality-assurance, proficiency testing, and technical assistance for state newborn screening testing for early detection of treatable diseases. In addition, they assess the nation's nutritional status using laboratory testing in the National Health and Nutrition Examination Survey (NHANES). NCEH also measures addictive and toxic substances in tobacco products, vaping products, and in the urine and blood of people who are exposed to these products. This center also improves the quality of laboratory measurements of state, clinical, and research partners addressing chronic diseases, nutrition status, and environmental exposures.

The National Institute for Occupational Safety and Health (NIOSH) tests and certifies respirators to ensure they meet filter efficiency standards; develops methods for sampling and analyzing contaminants in workplace air and in blood and urine of workers exposed to hazards in the workplace; conducts applied research on health hazards, safety hazards, and disaster prevention in mining; and develops engineering controls and safe work practices for preventing work-related fatalities and work-related traumatic injuries across all industry sectors.

While that completes a brief overview of the types of efforts underway at CDC, this presentation is intended to focus largely on the CDC Laboratory Quality Plan. Dr. Pirkle noted that Dr. Walensky asked him to take this position because CDC experienced some problems in February 2020 with the initial COVID-19 test. The review inside of CDC that resulted from that identified other problems that the agency needs to address. She asked Dr. Pirkle to work on this and make sure that CDC laboratories operate at a gold-standard quality level and are at the forefront of advances in laboratory science that benefit public health. He began this position in November 2021 with that vision in mind, which is the vision for the strategic plan. The strategic plan has 6 specific goals, which are to ensure that CDC has: 1) excellent quality Infectious Disease (ID) laboratory methods with review documenting that excellent quality; 2) excellent quality ID laboratory results that pass appropriate quality control criteria; 3) passing external reviews of the ID clinical laboratory with only occasional minor deficiencies; 4) demonstrated effective capability to rapidly develop high-quality diagnostic tests for new high-risk pathogens under emergency conditions in collaboration with private and public health partners; 5) a single, excellent Quality Manual for Microbiological Laboratories (QMML); and 6) needed scientists and sustained funding are available so labs can ensure high quality and be at the forefront of advances in laboratory science that benefit public health.

There are several major constraints that make those goals difficult. Clinical, surveillance, and research laboratories at CDC are commonly together. This is a very tough constraint. It is very common that someone will work in a diagnostic laboratory in the morning that is a clinical laboratory, and in the afternoon they will spend 3 to 4 hours working in a research laboratory perhaps working on the development of a new diagnostic assay. It also is possible that people could be working in a research laboratory developing something or conducting studies, and then running samples in the afternoon that are used for surveillance that are not used for strict clinical testing. It is very important for CDC to have an integrated quality plan so that the individual working in one laboratory in the afternoon is not unclear about what they are responsible for, and that there are common quality standards going across clinical surveillance and research laboratories. The agency has spent a lot of time addressing this major challenge. Quality must be ensured for emergency rapid test development for tests that have high consequences for quality failure. There are 3 conditions that fight each other and must be balanced, including quality, time, and resources. Everyone in management wants everything at high quality, in a very fast time, and that use very little resources. CDC is locking quality at high. That means the only two things they really have to adjust are resources and time. An emergency locks time at fast, which means CDC has to adjust resources and make sure that the resources are trained ahead of time, the systems are in place, and everything can work as smoothly as possible. There are more than 1,700 CDC laboratory scientists who are spread out in over 200 infectious disease laboratories in multiple states and territories.

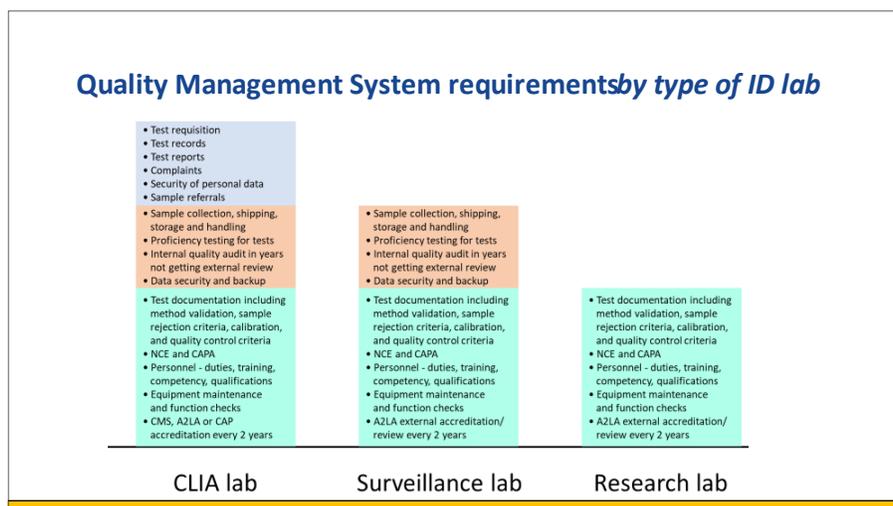
With all of this in mind, a Laboratory Quality Plan was developed that has these 5 elements:

1. Infectious Disease (ID) Test Review Board
2. Three (3) separate Quality Management Systems for infectious, non-infectious, and NIOSH laboratories
3. Quality Manual for Microbiological Laboratories (QMML)
4. Flexible and user-friendly quality management software
5. Biennial external review of every laboratory – clinical, surveillance and research

The function of the ID Test Review Board is to review test methods developed at CDC before they are shared with external laboratories to ensure the quality of the test and the transferability of the test is suitable for its intended use. A panel of at least 3 scientists with expertise in the method science, but not involved with the test development, must recommend approval of the method to the Test Review Board who must vote and provide final approval. The Test Review Board reviews diagnostic sensitivity, diagnostic specificity, limit of detection, sample collection and stability, quality control criteria, and successful transfer of the test to another laboratory. The ultimate goal is finding the positive and negative predictive value of the test. It is always beneficial to get the false positive and false negative rates as low as possible as it helps considerably in predictive value. It also must be taken into consideration that predictive value is a function of prevalence of disease, so it does have to do with the population being sampled. The ID Test Review Board began meeting in early March 2022. If this board had been in place in February 2020, that test would not have been shared and the problems with the test would have been identified. Now any ID test to be shared with an outside laboratory must now go through this board for review. This is a major quality check at the end to make sure the product to be sent out is an excellent quality product suitable for the intended purposes.

One of the early issues that Dr. Pirkle had to address was that there have been many quality meetings at CDC over the years, there are a lot of quality systems throughout CDC, and there have been concerted efforts to try to bring things together. One of the difficulties has been that CDC has such a diverse set of laboratories, a quality management system to fit everyone cannot get down to the details needed. One of the first items of business was to establish 3 separate Quality Management Systems for infectious, non-infectious, and NIOSH laboratories. This allows for the specific quality requirements at depth that are needed to assure excellent quality. This is similar to separation of microbiology from clinical chemistry laboratories. NIOSH has specialized laboratory functions.

The QMML is a major anchor of all that CDC is doing. The concept for this manual is that it will be a one-stop resource for excellent microbiology laboratory quality practices like the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual is for safety. The BMBL is the “go to” manual for safety. Just like the BMBL, CDC wants to have a “go to” manual for quality. The mantra at CDC would be “Safety First and Quality Second.” The QMML standards will exceed Clinical Laboratory Improvement Amendments (CLIA) and FDA requirements. It will include separate sections for CLIA laboratories, surveillance labs, and research laboratories. This graphic illustrates the Quality Management System requirements by type of ID laboratory. The items in teal are commonly found in all 3 types of laboratories, the items in salmon are found in both CLIA and surveillance laboratories, and the items in blue are found only in CLIA laboratories:



Also major in the QMML is that CDC is convening Method Expert Groups comprised of 3 CDC laboratory scientists per group, each of which will develop excellent test method quality standards for each method type (RT-PCR, enzyme immunoassay, serology, et cetera). Every CDC method in that method type must meet those standards. The standards include diagnostic sensitivity, diagnostic specificity (include samples likely to cross react), limit of detection, number and types of quality control samples, quality control criteria including result rejection criteria, sample collection and stability, thorough method documentation so another laboratory can readily bring up the test, and transparent listing of all data used to evaluate method quality.

When the test documents are worked up for these methods, there will be 2 special sections put into these methods: Safety Pointers and Quality Pointers. This will include 5 to 10 pointers to pay attention to when running an assay in the laboratory.

The first comments under Safety Pointers will be on every assay:

- If you are not certain about the safety of every step in this procedure, then **STOP** and consult your supervisor.
- Do not hurry – work at a steady, controlled pace.
- All steps require double gloving.
- There are additional pointers as well.

The first comment under Quality Pointers will be on every assay:

- If you are not certain you can perform every step in this procedure at the quality level needed, then **STOP** and consult your supervisor.
- There are additional pointers as well.

In terms of flexible and user-friendly quality management software, to be clear a LIMS is a management system that tracks a sample from cradle-to-grave. This is very valuable, but totally separate from a LIMS is another type of software called an Electronic Quality Management System (eQMS). eQMS software facilitates document management, identifies, and tracks non-conforming events (NCE), tracks corrective and preventive actions (CAPAs), manages training records and competency testing, tracks equipment maintenance, and more. CDC already has identified and beta-tested a promising software package.

All laboratories have to have an external review every 2 years. All CLIA laboratories (clinical) must be accredited according to CLIA standards. This review must be performed by CMS inspectors, the American Association for Laboratory Accreditation (A2LA), or the College of American Pathology (CAP). CDC has worked out arrangements to have special reviews for its surveillance and research laboratories, which will participate in an external review by A2LA every 2 years based on quality standards in QMML. They are very interested in making sure this research effort can get off the ground because general quality management systems for research laboratories are not available. If this works out well the A2LA is very interested in promulgating it out to the larger research community in the federal and state governments and the private sector.

Turning to the LW TOR, the LW has been established to provide work products to assist the ACD in developing recommendations to CDC on agency-wide activities related to the scope and implementation of improvements to strengthen the quality of work within CDC laboratories. The LW's charge is to help to identify innovative processes and systems to: 1) assist CDC laboratories to operate at a gold-standard quality level and remain at the forefront of advances in laboratory science that benefit public health; 2) ensure that CDC has demonstrated capability to rapidly develop high-quality diagnostic tests for new high-risk pathogens under emergency conditions; and 3) recruit and retain highly qualified laboratory scientists. With that in mind, the LW can provide input on the following:

- CDC is sometimes the laboratory of last resort for testing specimens with less-than-acceptable or unusual specimen types:
  - Considering regulatory requirements, when should CDC support investigation of these less-than-acceptable specimens?
  - How can results be reported with appropriate limitations in interpretation?
- The QMML will be the primary resource for quality standards for infectious disease laboratory operation:
  - The LW review could result in insights that strengthen the manual and help to ensure that the work done in CDC infectious disease laboratories meet and maintain the highest standard of laboratory quality.
- Excellent laboratory scientists are essential for high-quality, advanced laboratory testing:
  - How can CDC recruit and retain outstanding laboratory scientists to ensure high-quality, advanced laboratory testing at CDC?
- HHS was directed in the 2022 federal budget agreement to establish a Task Force to evaluate factors contributing to the shortcomings of CDC's first COVID-19 test, as well as policies, practices, and systems to mitigate future issues:
  - Will the Laboratory Quality Plan that CDC has developed address previous deficiencies and mitigate future challenges in diagnostic test development for public health outbreaks?

## Discussion Summary

Dr. Sharfstein requested additional information about what CDC was trying to accomplish with this laboratory plan beyond correcting for the COVID-19 test problem that occurred in early 2020 and the goal to have excellent laboratories.

Dr. Pirkle responded that this is largely reflected in the goals in that every goal is addressing a problem that CDC has had. There have been some problems with some test results not going through as thorough a quality review as they need before they are shared outside of CDC. Some deficiencies have been found during external reviews. Another major issue was the lack of overall quality standards that were uniformly accepted. There were many pockets of people who had worked on quality, but there was no consistency. They also must be able to give Dr. Walensky assurance that when something comes out of CDC, she can stand on it and it will be absolutely right because she must make decisions that have a lot of implications and must be highly confident that the laboratory got it right.

Dr. Taylor inquired about partnerships, especially with public health partners, in relation to the development of a test for a high-risk pathogen. Because failures can occur in any laboratory for reasons that do not relate to quality issues, redundancies must be built into the system. Given that it is not possible to know when the next pandemic will occur, she urged CDC to keep this high on the list.

Dr. Pirkle reported that the current plan is that if there is a situation for which CDC needs to develop a rapid test and there are significant consequences for failure, CDC does not want to be the only laboratory that is working on it. They want to have at least 2 other laboratories that are working independently and parallel on the same task, and wants to fund them in advance to be prepared and able to work rapidly.

Dr. Sharfstein noted that a good quality plan is one component of quality. Among others, another element is performance management and whether the plan is being followed at different levels. He wondered whether it would be useful for the LW to assist with this.

Dr. Pirkle noted that in the past, there was the CLIA Compliance Program in the infectious disease centers. That has been changed, made much larger, and moved up toward the Office of the Deputy Director for Infectious Disease (DDID) and it is a laboratory quality office. They are assigned to the infectious disease laboratories for the very purpose of having oversight to make sure that when people are engaging in these efforts, everything gets checked. An internal review is done at least once a year and an external review is done every two years to monitor how well these performance requirements are being met. If the performance requirements are not met, there is a straightforward path of citing a deficiency, a plan has to be implemented to correct the deficiency, and then there are checks after a certain period of time to ensure that the correction has been sustained. In addition to that, the Office of Laboratory Science and Safety (OLSS) that Dr. Pirkle heads adds another layer above that to ensure that checks to ensure that the review being done by the body in DDID is done well. If the eQMS software is in every laboratory, a center director could sit in their office, do a direct query, and review all of the non-conforming events in the last year without talking to anyone.

Dr. Martinez said he really liked the major quality check of the ID Test Review Board and asked whether CDC is sharing and exporting that concept with other laboratories nationally and internationally.

Dr. Pirkle indicated that this would be in the quality manual. While everyone may not have the same structure as CDC, but the concept of having a Test Review Board independent of the people who develop the test will be well-written up in that manual. The intent is for this to be a living document that will be continuously improved and made available to many laboratories.

Dr. Morita recalled that early on and mid-pandemic, there was a lot of concern about the ability of the US to detect COVID-19 variants. She wondered whether the focus of the genomics surveillance initiative that Dr. Mahon described was on building capacity, while Dr. Pirkle's focus was more on the quality elements.

Dr. Pirkle confirmed that his focus is on quality and there is a major emphasis at CDC to make sure that the agency has the capacity to be able to do a reasonable sampling to spot variants. They were not set up for that at the beginning, but many things have changed over the past 2.5 years at CDC. The changes in surveillance are like night and day. Genetic sequencing keeps getting faster, but 10 or more laboratories will still be needed that CDC is working with that are processing through this data. There is no way CDC can handle this alone. The question pertains to what all of this will look like after the response when the emergency ends and funding streams are different. At a minimum, CDC must have the capability and relationships in place with a number of laboratories such that they can rapidly build up the stream of genetic sequencing and engage at this high level very fast.

An inquiry was posed in the chat regarding approximately when the eQMS software would be available for laboratories to use and who would be responsible for paying for the software (e.g., CIOs or CDC).

Dr. Fleming noted that with regard to the draft TOR, there was a “speedbump” pertaining to the last item. CDC is still waiting for official word from HHS about whether the WG construct is appropriate to address this task that was mentioned in Congressional budget language. The language directed HHS to establish a Task Force to evaluate factors contributing to the shortcomings of CDC’s first COVID-19 test, as well as policies, practices, and systems to mitigate future issues. Until it is resolved whether this should be a part of the LW TOR, voting on the TOR would need to be delayed. That notwithstanding, CDC welcomed comments on the TOR.

Dr. Shah noted that there was a lot of text pertaining to the QMML and he wondered whether the focus on the manual would not provide enough space to all of the other things CDC wants to do. Perhaps it does not belong in the TOR maybe it does, but then how will they improve, put the systems in place, leverage performance management opportunities, et cetera? Without standards, CDC will not get anywhere. He feels like more is needed in this TOR to get to the full scope of quality.

Dr. Pirkle stressed that the QMML certainly includes the standards, whereas the LW would read the manual as a laboratory operation manual. It includes all of the quality standards, as well as everything Dr. Shah mentioned. CDC is going to perform a review of every laboratory every year and that is in the quality manual. CDC is at overkill on performance management, given that there are so many checks. There will be required safety and quality training for all new laboratory staff to ensure that they do not harm themselves and that they understand quality. It is probably best to think of this well beyond just having the standards to the operation of how laboratories work and how all of these elements are checked. This will not just be sitting on paper in the QMML. The major difference is that these will not be guidelines or recommendations—they will be requirements. Hence, they can be considered CDC policy that this must be done. Nothing like this has come out of CDC in the laboratory operations arena in all of the 40 years that Dr. Pirkle has been there.

Dr. Fleming made the ACD aware that as with the DSW, they are moving ahead to fill out the membership of the LW with outside members beyond the ACD. That includes the same FRN that will be published. He called upon the Co-Chairs of the LW to discuss the nature of the expertise in their discussions with CDC that would be important for this group.

Dr. Taylor indicated that the LW is seeking members with clinical and public health experience and State Health Officers with oversight. She did not perceive anything to be wrong with the TOR in any way. However, her gut feeling was that they should be broader given something that Dr. Pirkle said about how laboratories have changed since the pandemic. That is not particular to CDC. Every laboratory in the country suffered the impact of genetic sequencing. There has been change in every area. Given that there is time for a vote before the August meeting, if it is appropriate to have more discussion with CDC about how they may define a somewhat broader scope in the TOR to address other issues that are known to be critical at CDC but are affecting diagnostic laboratories generally across the country would be helpful. She stressed that this is an opportunity in time that should not be let go.

Dr. Pirkle explained that when they were developing the TOR, they were trying to prioritize so that the LW was not tasked with too much. There is a balance and more items can be added to the list. For instance, there could be discussion about the difficulty of developing something in very short order and how that could be done better. The TOR was the result of thinking about some areas where CDC needs some good ideas on some difficult issues on which they are having difficulty moving forward. The work being done on the manual is a complete culture change at CDC. Just reviewing the quality manual could take the LW a year because there are so many issues. He emphasized that while he is open to going wider, he does not want to overload the LW. Certainly, more items can be added in the future and CDC is very willing to do that. The 4 items they listed are a lot of work. He is open to all ideas.

Dr. Sharfstein suggested for a future conversation a very small change about the quality manual and its implementation. He expressed concern about sending it to FDA. He would bet that when FDA looks at it, they will see a written document that is just one piece of the quality puzzle that is hard to interpret outside the context of its implementation. Understanding the CDC's focus on the quality manual, it can be hard to say how useful it is entirely without understanding how it will be put into practice, what the oversight will be, et cetera. There may be a way to limit some of the scope while being focused on the quality manual without having just a textual analysis.

Dr. Pirkle expressed concern that the name had thrown things too far. The first chapter of the quality manual lays out the responsibility of the CDC Directory, DDID, each CIO Director, and all of their responsibilities on implementing what is written in the manual. It is very much an operational instruction rather than just setting up some quality standards.

### Vote

Due to a delay in the clearance process of the LW TOR, the vote was deferred to the August 2022 ACD meeting. However, this was not anticipated to hamper the formation or work of the LW.

## Health Equity Workgroup (HEW) Update / TOR

**Monica Valdes Lupi, JD, MPH** (HEW Co-Chair; Managing Director, Health Program, The Kresge Foundation) and **Daniel Dawes, JD** (HEW Co-Chair; Executive Director; Satcher Health Leadership Institute, Morehouse School of Medicine) provided an HEW update. Mr. Dawes stressed that he and Ms. Valdes Lupi are delighted to Co-Chair the HEW and are happy to be joined by 7 of their fellow ACD members who will be sharing their time and talents, including Drs. Adimora, Albert, Fleming, Hardeman, Medows, Morita, and Martinez. The HEW was spawned owing to the "CDC Strategic Plan on Advancing Science and Health Equity." The official health equity discussions began during the ACD orientation session in October 2021 to think about how to proceed with the HEW, who to invite, and what gaps and challenges exist. In March 2022, an FRN was published soliciting nominations from individuals with health equity; public health science and practice; and public health policy development, analysis, and implementation expertise. Over 100 nominations were received from people with front line and field experience at the local, state, tribal, and territorial levels. After receipt of those nominations, 3 rounds of reviews were conducted in March and early April 2022 before the HEW's first official meeting on April 14, 2022. The CDC team provided a technical review of all the HEW nominations to ensure they were eligible for further review and ranking. The CDC panel of health equity experts reviewed and ranked all nominations and made recommendations to the HEW Co-Chairs and ACD leadership. HEW Co-Chairs, DFO, ACD Chair, and CDC's leading health equity experts met and reviewed the highest ranked recommendations. Of the many talented nominees, 10 outside experts were selected in addition to the 9 ACD members to serve one-year terms. Those selected had expertise in the promotion of equity among many populations including those with disabilities, Alaskan Natives, those experiencing homelessness, LGBTQ+ people, those in correctional facilities, among others.

## Health Equity Workgroup Membership

### Outside Experts

Name	Organization	Title
Philip Alberti, PhD	Association of American Medical Colleges	Founding Director
David Brown, MBA	YMCA	President and CEO
Nafissa Cisse Egbuonye, PhD, MPH	Black Hawk County Public Health (Iowa)	Public Health Director
Cary Fremin, BS	Dot Lake Village Council, Dot Lake Village	Director of Health and Social Services
Delmonte Jefferson, BS	Center for Black Health & Equity	Executive Director
Maria Lemus, BA	Visión y Compromiso and Network of Promotoras & Community Health Workers	Founding Executive Director
Mysheika Roberts, MD, MPH	Department of Public Health - Columbus, Ohio	Public Health Commissioner
Bonnielin K. Swenor, PhD, MPH	Johns Hopkins University Disability Health Research Center	Founder and Director
Paula Tran, MPH	Wisconsin Department of Health Services	State Public Health Officer
Mr. G. Robert Watts, MPH, MS	National Health Care for the Homeless Council	Chief Executive Officer

Ms. Valdes Lupi reported that the first HEW meeting was productive. The next steps agreed upon were that the HEW will meet monthly through the end of the year; CDC support staff were identified; consideration was given to the process, including the use of sub-groups and guest panels to help advance and work on action steps between the monthly meetings; and a goal was set to present a draft report during the November 2022 ACD meeting. The HEW discussed ways to invite some of the other 100 applicants who could bring a lot of expertise and experience to the work of health equity. The convening of the HEW was approved in February 2022, but the TOR must be approved as well. The only change from the original TOR was that 15 seats were designated that included current ACD members, and the request was made to increase that to 19 seats. The purpose of the HEW is to: 1) provide input to ACD on the scope and implementation of CDC’s CORE strategy; 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/practices in public health programs. Because many steps were included in the original TOR, the HEW agreed to emphasize and focus on the first 3 topics in the TOR:

1. What will CDC need to do to be successful in CORE implementation? What are the best 3 agency-wide CORE goals and most important changes to advance CORE?
2. What are potential unanticipated barriers to CORE implementation and how can they be minimized?
3. How can CDC accelerate work on health equity at the state, territorial, local, and tribal levels?

### Discussion Summary

Dr. Martinez inquired as to whether the other WGs also could access the pool of applicants who applied for the HEW, given that health equity is integral to the entire enterprise, or if they would have to reapply.

Mr. Auerbach indicated that while they could notify the applicants of the opportunity to apply to the other new WGs, the language in the *Federal Registry* clearly specifies the procedures that must be followed in order to apply to either of the other groups. It may be possible to contact them to at least encourage them to apply. For some of the members, there are other internal CDC groups seeking external members and the CVs of the remaining applicants for the HEW have been shared with those groups. Some of the people who applied also may be considered to serve as an expert guest speaker to present to the HEW.

Ms. Valdes Lupi and Mr. Dawes indicated that they and the HEW members were pleased with what was laid out in the HEW TOR and the decision to focus on the first 3 topics.

## Vote

A motion was made and seconded to adopt the HEW TOR. The ACD voted unanimously to adopt the HEW TOR, with no dissensions or abstentions.

## Public Comments

The floor was opened for public comment on May 3, 2022 at 3:15 PM ET. Public engagement and input are vital to ACD's work. Prior to each meeting, members of the public are invited through a notice in the *Federal Register* to submit written and/or oral comments. No public comments were made during this meeting. Members of the public also were invited to submit written public comments to the ACD through the Federal eRulemaking Portal at <http://www.regulations.gov> for access to the docket in order to submit written comments or to read background documents and comments received.

## Meeting Wrap-Up / Adjourn

**David Fleming, MD** (ACD Chair) emphasized the amount of work the ACD accomplished throughout the day. He expressed gratitude to Dr. Walensky for her clarity and specificity in discussing the important policies and progress that CDC is making, Dr. Mahon for her presentation and her past and future work for the agency with regard to COVID-19, Mr. Auerbach for his expert and tireless touting of the work of the ACD, the WGs for their progress and future work, everyone behind the scenes who made this meeting possible, and everyone across CDC for their work to keep families and communities safe and healthy.

**John Auerbach, MBA** (Director, Intergovernmental and Strategic Affairs, ACD DFO) emphasized how much has been accomplished already. This is only the second meeting of the ACD and already, 3 WGs have been established who will be diving into critically important issues for which CDC needs to be advised and informed. He extended special gratitude to those who agreed to Co-Chair the WGs, particularly given the significant amount of work that goes into overseeing a WG. It is anticipated that the August 9, 2022 ACD meeting will be convened in person.

*With no further business posed or questions/comments raised, the meeting was officially adjourned at 4:00 PM ET.*

## Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the May 3, 2022 meeting of the Advisory Committee to the Director, CDC are accurate and complete.

\_\_\_\_\_  
Date

\_\_\_\_\_  
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

**John Auerbach, MBA**

Director, Intergovernmental and Strategic Affairs  
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

**Michelle A. Albert, MD, MPH, FACC, FAHA**

Walter A. Haas-Lucie Stern Endowed Chair in Cardiology Professor of Medicine  
Director, CeNter for the StUdy of AdveRsiTy and CardiovascUlaR DiseasE (NURTURE Center)  
Associate Dean of Admissions  
Division of Cardiology, Department of Medicine  
University of California, San Francisco School of Medicine  
San Francisco, California  
Term: 09-27-2021 – 06-30-2024

**Daniel E. Dawes, JD**

Executive Director  
Satcher Health Leadership Institute  
Morehouse School of Medicine  
Atlanta, Georgia  
Term: 09-28-2021 – 06-30-2024

**Cristal A. Gary, MPH**

Chief Advocacy Officer  
Amita Health  
Chicago, Illinois  
Term: 09-30-2021 – 06-30-2023

**Lynn R. Goldman, MD, MS, MPH**

Dean and Professor of Environmental and Occupational Health  
Milken Institute School of Public Health  
George Washington University  
Washington, District of Columbia  
Term: 09-28-2021 – 06-30-2023

**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

**Jeffrey D. Sachs, PhD**

University Professor and Director  
Center for Sustainable Development  
Columbia University  
New York, New York  
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## Attachment #2: Acronyms Used in this Document

Acronym	Expansion
A2LA	American Association for Laboratory Accreditation
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACD	Advisory Committee to the Director
ACIP	Advisory Committee on Immunization Practices
APHIF	Applied Public Health Informatics Fellowship
ARP	American Rescue Plan
ASH	Assistant Secretary for Health
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BIPOC	Black, Indigenous, and People of Color
CAP	College of American Pathology
CAPA	Corrective and Preventive Actions
CBO	Community-Based Organization
CCLs	COVID-19 Community Levels
CELR	COVID-19 Electronic Laboratory Reporting
CLIA	Clinical Laboratory Improvement Amendments
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CFA	Center for Forecasting and Outbreak Analytics
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health
COI	Conflict of Interest
CIOs	Centers, Institutes, and Offices
COO	Chief Operating Officer
CoP	Community of Practice
CMS	Centers for Medicare and Medicaid Services
CSTE	Council of State and Territorial Epidemiologists
DDID	Deputy Director for Infectious Diseases
DFO	Designated Federal Officer
DMI	Data Modernization Initiative
DoD	Department of Defense
DSTT	Data Science Team Training
DSU	Data Science Upskilling
DSW	Data & Surveillance Workgroup
DUA	Data Use Agreements
eCR	Electronic Case Reporting
ED	Emergency Department
EHR	Electronic Health Record
ELC	Epidemiology and Laboratory Capacity Program
ELR	Electronic Laboratory Reporting
eQMS	Electronic Quality Management System
ET	Eastern Time
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration

<b>Acronym</b>	<b>Expansion</b>
FRN	Federal Register Notice
GPEI	Global Polio Eradication Initiative
HAIs	Healthcare-Associated Infection
HEW	Health Equity Workgroup
HHS	(United States Department of) Health and Human Services
HRSA	Health Resources and Services Administration
HWRC	Health Workforce Research Center
ICU	Intensive Care Unit
ID	Infectious Disease
IDSA	Infectious Disease Society of America
IM	Incident Management
IMS	Incident Management Structure
IT	Information Technology
LIMS	Laboratory Information Management Systems
LW	Laboratory Workgroup
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NHANES	National Health and Nutrition Examination Survey
NCE	Non-Conforming Events
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHHSTP	National Center for HIV, Viral Hepatitis, STD, and TB Prevention
NCIRD	National Center for Immunization and Respiratory Diseases
NCHS	National Center for Health Statistics
NCHWA	National Center for Health Workforce Analysis
NCIRD	National Center for Immunization and Respiratory Diseases
NIOSH	National Institute for Occupational Safety and Health
NNDSS	National Notifiable Diseases Surveillance System
NSSP	National Syndromic Surveillance Program
NVSS	National Vital Statistics System
OCIO	Office of the Chief Information Officer
OLSS	Office of Laboratory Science and Safety
ONC	Office of the National Coordinator for Health Information Technology
PHII	Public Health Informatics Institute
QMML	Quality Manual for Microbiological Labs
SDOH	Social Determinants of Health
SME	Subject Matter Expert
SPG	Sachs Policy Group
STDs	Sexually Transmitted Diseases
STLT	State, Tribal, Local, and Territorial
SVI	Social Vulnerability Index
TA	Technical Assistance
TOR	Terms of Reference
US	United States
WG	Workgroup