CDC Advisory Committee to the Director (ACD)

Minutes from the August 9, 2022

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Advisory Committee to the Director: Record of the August 9, 2022 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on August 9, 2022 in-person, via Zoom for Government and teleconference. The agenda included highlights of recent developments from the CDC Director; updates from the Data and Surveillance Workgroup (DSW), Laboratory Workgroup (LW), and Health Equity Workgroups (HEW); an update on COVID-19 and monkeypox; a presentation on climate and health; and public comments.

Welcome and Introductions

David Fleming, MD (ACD Chair) welcomed ACD members and CDC leadership, emphasizing how great it was to finally have a largely in-person meeting. 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 funds from Merck and Gilead and her institution receives funding from these companies for her research.
- Dr. Goldman: Her university receives funding from various companies that may be involved with some of the ACD efforts and has received funding from CDC, though she could not identify any specific conflicts relevant to this meeting.
- Dr. Shah: Serves as Independent Director of STERIS and Kinsa Health.

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, expressing her delight at meeting mostly in-person and recognizing those who made the meeting possible.. She expressed her gratitude for everyone's time and commitment to CDC and public health as a whole. There are now 3 workgroups up and running (e.g., DSW, HEW, and LW), which are critical. The members of each group are already diving into the hard work. Not surprisingly, much of this hard work relies on having data and being able to move forward based on those data. Later in the day, they would hear from Dr. Patrick Breysse about the agency-wide workgroup on climate change. CDC has formed a partnership with the Office of Environment Justice (OEJ) and recently announced the release of the Environmental Justice Index (EJI), which is the first national place-based tool

that will measure the impact of climate and environmental burden on human health and health equity.

In terms of staffing, Dr. Barbara Mahon, who served as the CDC Incident Manager for a long time, has stepped aside and Dr. Ian Williams is now serving in that role. CDC owes an immense amount of gratitude to Dr. Mahon for leading the COVID-19 response from mid-September 2021 to mid-May 2022. This was a tireless task in which Dr. Mahon thrived. She now has returned to the National Center for Immunization and Respiratory Diseases (NCIRD) where she serves as the Centers, Institutes, and Offices Responsible Official (CRO) as the agency works to move activities back to programs. There is now a COVID CRO in all of CDC's national centers. In addition, she announced that Kevin Griffis is the new Communications Director—a role that has been vacant for about 4 years.

The tragic milestone of 1 million COVID-19 deaths was reached in May 2022, which seemed unthinkable in March 2020. Even now, there are about 400 deaths per day. While everyone has become accustomed to seeing this, it cannot become a number that is considered acceptable. The BA.5 Omicron subvariant now accounts for nearly 90% of cases in the United States (US). There has been a doubling in the number of hospitalizations since April 2022, though the hope is that this is starting to plateau if not trend out somewhat. The largest percentage of deaths have occurred among those ≥65 years of age. Some people are thinking that instead of starting their primary series or getting boosted now, they will await the new vaccine that is anticipated for Fall 2022. However, Dr. Walensky discouraged that as staying up-to-date (UTD) is critically important. Many Americans remain under-vaccinated, with only 32% of all ages having received 1 booster dose. Of those ≥65 years of age, only 25% have received their second booster dose.

The CDC has been in close contact with the Food and Drug Administration (FDA) regarding actions that will occur in Fall 2022, but those who have not received their primary series or been boosted should do so now. The bivalent booster that will be available in the Fall will be part prototype and part BA.5. There is a lot of discussion about the timing from last boost to next boost, but especially those ≥65 years of age should get boosted now. There are other types of protection for those who are immunosuppressed, such as EVUSHELD™. Data demonstrate that a second booster results in a 4-fold decrease in deaths compared to a first booster. Dr. Walensky stressed that she is especially concerned about children. Although the CDC authorized use of a vaccine for children 6 months to 5 years of age on June 19, 2022, only 4% of children in this age group have received 1 dose. Only 30% of children 5-11 years of age have received a primary series. This age group is eligible for boosting as well. Moreover, this is in the context of children returning to school. A lot of work needs to be done on the pediatric front in terms of COVID-19 vaccination, in addition to addressing the 1% decrease in incoming kindergarteners being UTD on all of their vaccines. That amounts to approximately 35,000 children who are under-vaccinated, which is fewer than vaccinated in 2001.

The first case of monkeypox was identified in the US on May 17, 2022. CDC has now activated a monkeypox response that is being led by Captain Jennifer McQuiston, DVM, MS.. The agency has been tracking cases closely since mid-May. A total of 8,933 cases had been confirmed as of August 8, 2022 across 49 states, the District of Columbia (DC), and Puerto Rico (PR). Montana is the only state not yet to have reported a case. Data indicate that this infection spreads through close person-to-person skin contact, which is how most transmissions are occurring. This is generally being called a sexually transmissive infection. While it certainly can be transmitted through encounters that occur during sex, it also the

case that science is evolving regarding whether it is transmitted through semen and vaginal fluid. CDC has been engaged in an extraordinary amount of outreach through its jurisdictional partners, community-based organizations (CBO), civil societies, and academic societies to talk about vaccination. The agency welcomes any additional ideas on how orwhere more outreach can be done.

The Department of Health and Human Services (HHS) has been working to allocate monkeypox vaccines to the Strategic National Stockpile (SNS) within the Assistant Secretary for Preparedness and Response (ASPR) office. The initial response was based largely on cases followed by at-risk demographics. The allocation algorithm early on was based primarily on hardest hit jurisdictions, with the allocations based 75% on cases and 25% on at-risk populations. FDA announced a supplemental Biologics License Application (sBLA) on July 27, 2022 of the JYNNEOS® vaccine of Bavarian-Nordic, meaning approximately 780,000 available doses. This represents the Phase III allocation that is based more on at-risk populations than cases. There are pretty good data for at-risk populations, which includes those who are eligible for pre-exposure prophylaxis (PrEP). However, this does not capture those who have human immunodeficiency virus (HIV). The denominator is HIV-infected men who have sex with men (MSM) plus the PrEP-eligible population, which totals about 1.6 million people. It also is the case that it remains unknown whether those are the people who have been vaccinated thus far. CDC is working closely with HHS and the FDA is assessing a new intradermal dosing strategy rather than subcutaneous dosing.

Health equity has been at the forefront of CDC's effort and is clearly driving a number of efforts inside and outside the agency, particularly in terms of COVID-19 boosters and monkeypox vaccine. One of the things that is most frustrating is that while they are starting to get case demographic data on monkeypox, there are not yet any data from the JYNNEOS® vaccine. A few jurisdictional Data Use Agreements (DUAs) need to be signed in order to begin receiving those data. CDC also is working closely with the US Department of Housing and Urban Development (HUD). The agency was awarded over $11 billion for housing and is looking at supporting healthy housing for people who are experiencing homelessness and residents of public and multi-family housing, and is working closely across the government for participation in strategic planning and equity in the Department of Transportation (DOT), advancing ongoing cross-agency work in combatting unhealthy social determinants of health (SDOH), and ensuring that that the voices of the community are heard and included in all of CDC's work. The most exciting news in that regard is the release of a Notice of Funding Opportunity (NOFO) for almost $4 billion in workforce and infrastructure. As Dr. Walensky has been saying far and wide, a public health workforce is

needed that is as diverse as the communities they serve—people who are from those communities, serve those communities, and who are culturally competent within those communities. This does not require a disease-specific focus, which is critically important because it allows the agency to pivot its resources when there is an urgency or emergency to use an infrastructure rather than a line item that was intended for a specific disease. It also allows the agency to consider the creation of new and innovative positions such as those built on multisector partnerships, while also ensuring support for CDC's traditional core work.

Through all of this and with the help of the ACD, it is Dr. Walensky's hope to have a new chapter in public health. While continuing to provide core public health services, she wants to make sure that CDC can address those who are in greatest need—those who have been neglected for years and specifically during COVID-19. She has had the opportunity to start traveling the country and to see public health at its best, as well as some of the challenges in the field. When she visited the Los Angeles Department of Public Health, she saw a Youth Advisory Council (YAC) vaccinating children at a playground where she sat with a 7-year-old who was receiving his first dose right off of the jungle gym bars. She visited Federally Qualified Healthcare Centers (FQHCs) in St. Louis New Jersey. Some of the FQHCs are experiencing very challenges times. Most recently she returned from her first international trip during which she visited Zanzibar, Tanzania, and Uganda. She was inspired and able to reflect on how CDC is so essential and revered for its work across the world.

In a healthcare facility in Zanzibar, she heard from commercial sex workers who said it was the only place they could receive stigma-free care. She visited a DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe Women) site. . She also visited a clinic site with approximately 6000 patients that was giving patients their antiretrovirals. Looking at global health security on the Congo beyond the border, Dr. Walensky met a young man who was working triage at a local hospital near the Congo border who detected a woman and her 4-year-old baby who likely had Ebola, placed them in isolation, and probably saved a good 500 lives because he had CDC training and knew what to look for. It was very inspiring to see the educational work the agency is doing and how it translates into better health security not only in the US, but also across the globe.

Dr. Walensky closed by saying that while these are hard times for CDC, they are also exciting times. There is a moment now in which the agency can pivot to be in a better place. She expressed her gratitude to the ACD in getting CDC to that place.

Discussion Summary

Mr. Dawes noted that Dr. Walensky ended with gratitude and he wanted to open the discussion with gratitude for the excellent work that she and her team have been doing. He was delighted that she included a report on health equity and was curious as to whether there were any bright spots in the data in terms of children from which lessons could be leveraged for replication.

Dr. Walensky indicated that when they began to collect data on vaccination, they looked geographically and at the Social Vulnerability Index (SVI). The data were good in terms of the SVI in equity. While it took a huge amount of work, equity eventually was achieved with the primary series. Boosters continued to lag with children in terms of the rural/urban divide, with a vaccination rate that was twice as high for urban versus rural children. This suggests that it is not just racial and ethnicity equity, but also is frontier equity in terms of whether vaccines are getting to pediatricians and family doctors in rural areas. Some call that the red/blue divide, but she does not think that is necessarily the case. Regardless, there are propensities for different messages in those areas. She said that while she has been on rural television, she is probably not the best messenger for those communities, so they are working hard to identify who the best messengers are. While there is a discrepancy between rural and urban communities, there still is a problem in urban areas as well.

Dr. Goldman thanked Dr. Walensky for her service to the country, recognizing that this has been an amazing time to step up to the responsibilities she has. She is the Dean of a School of Public Health (SPH) that is involved with a considerable amount of research funded primarily by the National Institutes of Health (NIH). While resources flowing to NIH are good, insufficient resources are flowing to CDC. She asked what would be helpful in terms of opportunities to innovate in the area of public health in terms of the implementation, environmental, behavioral, and data science needed to support CDC's efforts and the efforts of the state and local health departments.

Dr. Walensky noted that she was thinking about vaccine rollout and how what probably would matter more than effectiveness would be vaccine uptake and the behavior science around that. She thinks that behavioral and implementation science are underestimated and undervalued in public health. In 2020, if there was recognition that there would be a problem with uptake, some of the Operation Warp Speed (OWS) resources would have been spent on making sure that people were primed and ready to get the vaccine when it became available. One of the challenges in public health is that public health works when it is quiet and no one knows it is around.

For instance, there were 54 foodborne outbreaks in 2021 that most people did not hear about beyond perhaps a recall in a local community. Programmatic work on the ground also is important. One anecdote involves Operation Allies Welcome (OAW), which was an extraordinary CDC effort. There were 47 imported active measles, the results of which would have been different in the absence of massive public health work during that time. While Dr. Walensky trained in a SPH where she learned research methods, there were not a lot of placements in state public health department settings—the "bread and butter" of public health. It is not clear that this is sufficiently appreciated in the SPH. She spent some time in the academic world trying to mesh an academic center with public health. While they had a sexually transmitted infection (STI) clinic in their hospital, it did not talk to public health as much as she thought they should. Other challengesCDC has relate to regulatory, human resource, operational, contracting, deployment response, and data authorities. This takes more than money. In terms of comparing the monkeypox response to the COVID-19 response, it is still the case that CDC does not have the data needed to provide the status of vaccine distribution and equity with monkeypox. While the agency is called upon to deliver that information, she does not have it. Although over half a million vaccine doses have been distributed, she cannot report the number administered. These are just some of the areas that would be very helpful to address.

Dr. Sharfstein echoed the appreciation of others and emphasized that he could not think of another time when there have been so many major public health challenges and extra degrees of difficulty to navigate. Another major public health challenge in the last few weeks was the Supreme Court decision overturning Roe v. Wade and the threat that poses to the health of pregnant women and other health implications for people in the US. He wondered whether CDC has been thinking about its role in surveillance related to this development in terms of routine complications in pregnancy being unattended, the risk to maternal mortality, et cetera.

Dr. Walensky emphasized that much of equity has to do with access to care, and this is a massive access to care issue. She and Dr. Deb Houry, the Acting Principal Deputy Director of CDC and Director of the agency's National Center for Injury Prevention and Control (NCIPC), have engaged in numerous conversations about the available surveillance data CDC has currently that can be used to assess maternal mortality, women's suicide, women's suicide ideation, mental health, fetal outcomes, and so forth.

Dr. Houry added that it is important to assess data and outcomes, with a focus on health outcomes. CDC has several data systems in place that collect data on births. One planned activity is to assess births among persons 10-14 years of age to determine whether there is a change by age groups. Another database collects information on fetal demise at ≥20 weeks, which can be assessed for changes in the rates of fetal demise. There have been delays in how maternal mortality is reported. They have been working with the National Center for Health Statistics (NCHS), which hopes within the next couple of months to be able to report provisional estimates as NCHS has done with drug overdoses. Syndromic surveillance and electronic health record (EHR) datasets are being considered in terms of filling gaps. In terms of mortality, CDC has excellent data that is becoming timelier. The Pregnancy Risk Assessment Monitoring System (PRAMS) allows the agency to assess state-level data pertaining to pregnancy and reproductive access and other health outcomes, such as adverse childhood experiences (ACEs), to understand the impact on young children.

Ms. Valdes Lupi expressed her gratitude for the remarkable issues CDC is confronting daily. She appreciated that Dr. Walensky lifted up COVID-19 vaccine rates among the pediatric population, as well as the challenges in terms of general pediatric vaccines. Dr. Morita, Dr. Monroe, Ms. Valdes, and colleagues from several foundations such as Kellogg and Packard are part of biweekly meetings on pediatric vaccines that is led by Health Leads. The American Academy of Pediatrics (AAP), NACCHO, and other partners are involved as well. They have been attempting to be creative and "sound the bell" about vaccines among the

pediatric population, especially with children returning to school. This group stands ready to work and partner with CDC.

Dr. Walensky responded that while there will be more rollout campaigns, there are limited resources left and many people seem to be finished with talking about this. A challenge in pediatric vaccines has been that pediatric outcomes have been compared to outcomes for adults 80 years of age. While it is good news that children fair better that people who are chronically unwell, it also is the case that COVID-19 is one of the top 5 leading causes of death (COD) and the top infectious COD in every pediatric age demographic ≤18 years of age. There remains work to do and she will convey the opportunity for outreach Ms. Valdes Lupi identified.

Dr. Morita wondered whether additional resources would become available to CDC with the Public Health Emergency (PHE) declaration for monkeypox. She had the opportunity to engage with a cohort of State Health Officers a few weeks previously during which one of the issues they raised up was a question about disparities funding drying up and how they had used that funding to build up infrastructure to support community efforts to reach deeply into the communities that are most in need to drive vaccine efforts. There is a need and opportunity with monkeypox for community-level engagement in participation in planning and response as it relates to vaccination efforts.

Dr. Walensky responded that when she came into CDC in January 2021, resources were devoted to COVID-19 already and more were allocated. Clearly fewer resources have been devoted to the new challenge of monkeypox. She called upon Sherri Berger, CDC's Chief of Staff, to further elaborate.

Ms. Berger added that the declaration of a PHE does not necessarily unlock access to any additional funding. It does increase visibility about the public health concern, and there are a number of groups are actively engaging with Congress on the need for community outreach related to monkeypox.

Dr. Hardiman emphasized the impact of the Dobbs decision on public and population health. Current nationwide estimates show that there would be an estimated 33% increase in maternal mortality and deaths among Black/ African American people. In thinking about the declaration of racism as a public health crisis and all of the ripple effects that are going to impact racialized communities, she wondered how someone like herself who is a reproductive health researcher and is running a research center focused

on this issue should look at the evidence base that is needed to support CDC's work and effort in moving forward.

Dr. Walensky indicated that the HHS Secretary also is very interested in maternal mortality, so CDC has been able to raise that issue up. Prior to Dobbs, there was agreement that maternal mortality could be tackled. Dobbs has placed some blockades in the way of that effort that will make it somewhat harder.

Dr. Houry added that disparities are worsening and deaths have increased. Dr. Wanda Barfield is the Director of the Division of Reproductive Health (DRH) within CDC's the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and has done fantastic work to elevate efforts such as the Hear Her campaign to ensure that women get access to healthcare and the providers understand systemic racism and the barriers that are present. There also are the Perinatal Quality Collaboratives (PQCs) and the Maternal Mortality Review Committees (MMRCs). A lot of this effort will involve expanding what is known to work, breaking down barriers, and having timely data coming from NCHS to be able to show improvements and drill down by state. CDC has been fortunate that in the recent President's Budget, increases have been proposed for maternal mortality work.

Dr. Albert congratulated Dr. Walensky for her leadership during this really challenging time. Given the concerns regarding communication strategies with regard to COVID-19, she requested additional information about CDC's strategic plans for communication to the public related to the current PHEs and how the agency is coordinating with other entities on this effort.

Dr. Walensky emphasized the importance of this question. When she began at CDC in January 2021, there had been a position posted for Director of Communications for several years. CDC's communications budget has remained the same since about 2014, yet the agency is in a different time about what needs to be done about communications and how it needs to communicate. Some communications challenges predate her tenure while have occurred since she arrived. Previously, CDC's consumers were state and local health departments and hospital facilities. During this pandemic, the agency's consumers became every American. There have been incredible challenges with social media and misinformation. CDC as an agency is not funded from a communications standpoint to tackle those kinds of challenges. When she has known that inaccurate information was about to be posted on Twitter and Instagram, she has considered whether CDC and other major agencies were prepared to combat it from a communications standpoint. Everyone

has to work collaboratively to tackle misinformation. CDC has done some introspective work on where the agency has challenges with communication and what needs to be done moving forward. Hopefully, people are starting to recognize that CDC's current communications are more plain language, timelier, simpler to understand and do not try to tackle every question..

Ms. Berger added that under Chief Operation Officer (COO), Robin Bailey, CDC has an Enterprise Risk Management Team (ERM Team) that is diving into health risk communication as a vulnerability so that they can think through mitigation strategies and begin to implement changes. Perhaps it would be beneficial to have communication as a topic during a future ACD meeting so that Kevin Griffis could present on CDC's capabilities and gaps and perhaps obtain some recommendations from ACD.

Data & Surveillance Workgroup Update

Julie Morita and Neriv Shah (DSW Co-Chairs) presented an update on the activities of the DSW. Since its last update to the ACD, the DSW has identified its members and convened 2 meetings. In addition to orientation, the first meeting included presentations and discussions on the Data Modernization Initiative (DMI) and the DSW's Terms of Reference (TOR), which focus on authorities, data exchange, forecasting and analytics, workforce, breaking down siloes, and assuring sustainability. The DSW identified the concerns about data sharing and the first 2 terms of reference (e.g., authorities and data exchange) as its priorities, which aligned with the CDC's identification of priorities. The second DSW meeting focused on certification, with a presentation from Ms. Alisha Beckett on the United States Digital Service's (USDS's) assessment and findings related to system variability, challenges, and impact of standards and certification. One of the major benefits of certification highlighted was efficient data exchange and data sharing. In addition, Dr. Micky Tripathi from the Office of the National Coordinator (ONC) delivered a presentation that focused on public health system certification in terms of the process, value proposition, and potential impact. The theme of data sharing was top of mind. Everyone agreed that greater focus is needed on standardization. This can begin with a floor of minimum standards, followed by phase-in of additional standards, and should include state and local public health from the outset. Standardization must apply not only to state, tribal, local, and territorial (STLT) public health, but also may start with CDC focusing on how they ask for reporting and what systems they use. There must be attention to data quality, use, and impact; not creating new burden or unstainable costs; and recognition of the workforce challenges that everyone in public health is facing. Other areas the DSW discussed as raising up include public health law in terms of issues with privacy, sharing, disclosure, and governance; data authorities; the ultimate goal of all of this data work as being customer-focused and remembering that the American public is the ultimate customer; interoperability; transparency; interdependence with STLT public health; private-sector friendly; and response-oriented. Monthly DSW meetings are planned through the end of 2022.

Discussion Summary

Dr. Taylor emphasized that while these are difficult times, but they also present opportunities. The new Center for Forecasting and Outbreak Analytics (CFA) group at CDC and its partners presents an opportunity for CDC and the laboratory infrastructure to be ready for the development of new assays for emerging pathogens and older pathogens that are re-emerging such as polio. She would like to hear more about and be involved in this incredible opportunity.

Dr. Shah indicated that the DSW has spoken extensively with Dylan George, CFA's Director of Operations. CDC has taken some steps in this direction with data from wastewater and other novel sources. The challenge regards how to work with messy, incomplete data that is not available from all 50 states in a way that is actionable and drives decision-making in real-time as opposed to waiting for the perfect dataset and building it. Dr. George and his team are well-suited to help get there.

Dr. Sharfstein asked how the DSW is thinking about challenges faced at CDC in that a lot of data related to public health is not necessarily the core data responsibility of CDC. For instance, the Centers for Medicare and Medicaid Services (CMS) and Veterans Affairs (VA) have tremendous amounts of data relevant to public health. On one hand, CDC has absolute responsibility to ensure that its surveillance systems are working. Conversely, devoting too much attention to those may miss the bigger picture of what can be used for public health. He asked how the DSW is thinking about the incredible data resources that exist outside of CDC but within the federal government and their relevance to CDC and the WG.

Dr. Morita agreed that this is such an important aspect of the work in terms of thinking about SDOH and other sources of data that are not primarily CDC's responsibility. While CDC plays a major role in helping to bring these sources together, this is not listed as a top priority in the DSW's TOR. Therefore, the DSW has not embarked on deep discussions on this topic yet. That does not mean they will not address the topic and she will add this to the DSW's list of considerations. However, they have focused on the top 2 TORs because they were listed in order of priority from a CDC perspective, and the group itself is focused on data sharing and standardization. This is why they have discussed the public health certification process extensively.

Dr. Goldman, a member of the DSW, added that this issue has been raised in terms of data sharing not being a 1-way street. Many other agencies are trying to move into addressing SDOH and/or environmental determinants of health and do not necessarily know how to

do this. An example is that the data standardization processes in which CDC engages also could help others have better data in EHRs. Clinicians would like to know how to use those data. She highlighted the pragmatic reality of the limited amount of money in the public health system for creating or adopting new data systems compared to the private healthcare sector. Those who bridge across the spaces know how much money healthcare paid to adopt EHRs. Public health has nothing like that in the way of resources. In addition to wanting standardization, it is important to understand why, that there may be a need to prioritize some areas over others, and that perhaps there will need to be a phased approach. Given the resource constraints, pragmatism must be factored into this—especially among STLTs.

Dr. Adimora emphasized that EHRs represent an incredibly rich source of data and requested further information about how much the DSW has dealt with this and if it is in the TOR, recognizing that accessing such data in any meaningful way can be extraordinarily difficult. In theory, that was the purpose and these systems were not built for research purposes. She wondered whether the DSW has any suggestions thus far about how these data might be accessed. The owners of EHR data are not STLTs. These data are owned by healthcare systems that may not be used to sharing data, which is presumably another challenge.

Dr. Morita indicated that this issue has been central to the DSW's conversations. The ONC discussion about certification for public health agencies is to standardize the information technology (IT) infrastructure to allow for exchange of information in a more interoperable way than in the past. It is about determining how those data become available from a public health perspective so that public health agencies can receive that kind of information, and the establishment of the standards that would be necessary to allow that to happen. The most recent DSW meeting focused on this topic with the presentations from the USDS that conducted an assessment of CDC systems and provided recommendations regarding the need for standardization and certification. The presentation from ONC detailed the proposed plans for public health certification. The DSW will have the opportunity to assess this effort and think about what CDC's role can be as it relates to implementation of the certification. CDC would have a major role to play in terms of engagement with STLTs and other parties as this is being developed. A representative of the Healthcare Information and Management Systems Society (HIMSS), which represents the pool of EHRs, is a member of the DSW. In addition, the DSW anticipates having EHR systems coming in to talk to the group as well.

Dr. Shah added that an example shared during the last DSW meeting was of a large national hospital chain that has to create 190 different variations to report across the states to the various jurisdictions. As Dr. Tripathi put it, it is about the "pitchers and the catchers" being standardized. Those who want to send the data are happy to do so, but there is a great expense to creating many variations versus the "catchers" needing to standardize at least a minimum dataset. This relates to the conversation about having a floor on both sides in order to have vital information early on, which can be built upon in later phases.
Dr. Fleming said that in reflecting back on his days of working in a communicable disease unit in a health department, one of the issues there was that the information they needed from the healthcare system was only part of the information that was needed to do the public health job. An enhancement was needed as each case was reported with medical information. Then there was a set of activities that health departments needed to implement to conduct a proper investigation, assure that contacts were identified, et cetera that ultimately needed to be part of the case record within the health department. A challenge at the time was that not all of that information was necessarily information in which CDC was interested or that should be reported centrally, so there was a split into 2 types of information—the generic information that was useful to CDC and the additional information that the health department collected that was critical to health department investigations. He asked how this should be approached in terms of certification, the potential expenses associated with that, and whether additional critical case information collected locally should be included as part of the certification process.

Dr. Morita added that many former and current state and local health officials talked during the last DSW meeting about how much data they collected that is not necessarily required to be reported to CDC. This raised the conversation about the floor and establishing a phasing in of the certification expectation.

Dr. Medows agreed that the data traditionally provided to CDC may not be what is needed going forward. A more robust set of integrated datasets may be needed to inform the improvements that include healthcare, pharmacy, et cetera.

Laboratory Workgroup Update

Joshua Sharfstein, MD and Jill Taylor, PhD (LW Co-Chairs) provided a LW update. Since the last ACD meeting, the LW TOR were finalized and the LW was able to convene its first meeting on June 17, 2022. The topics during that meeting included introduction of members, Federal Advisory Committee Act (FACA) ground rules, the purpose of the ACD LW, a detailed review of CDC's Laboratory Quality Plan (LQP) and description of how the

LQP will address previous issues and deficiencies, a review of the TOR, and a discussion about accomplishing the work ahead. Given that it had been a few months since the LW TOR were presented and there would be a vote, the TOR were reviewed for the ACD:

The purpose of the LW is to provide advice and work products for the ACD,CDC regarding the effective implementation of CDC agency-wide laboratory quality improvements across the agency to meet CDC's
ultimate goal of ensuring the agency's laboratories maintain a gold-standard level of quality using advanced laboratory science. The finalized TOR include the following:

Issue #1: CDC is sometimes the laboratory of last resort for testing specimens that may have been stored in less-than-acceptable conditions, be an unusual specimen type, or contain less-than-acceptable volume. These specimens would not meet requirements for acceptable specimens and, adhering to Clinical Laboratory Improvement Amendments (CLIA) regulations, CDC would have to reject them. In so doing, rare or difficult-toobtain specimens, whose results could have a meaningful impact on public health, could be rejected.

Questions:

- Considering CLIA requirements, should CDC support investigation of unknown infectious agents or diseases using less-than-acceptable specimens, when acceptable specimens are not available?
- If so, how should an appropriate disclaimer be worded regarding result interpretation that acknowledges the specimens are outside validated parameters?

Issue #2: CDC is writing a Quality Manual for Microbiological Laboratories (QMML) to be its primary resource for quality standards for infectious disease laboratory operation. LW high-level review of the CDC quality framework described in the QMML could result in insights for the ACD, CDC that may strengthen the overall quality approach and help to ensure that the work done in CDC infectious disease laboratories meets and maintains excellent standards of laboratory quality.

Question:

- Is the CDC quality framework described in the QMML an appropriate quality framework to ensure high quality laboratory standards for infectious disease laboratory operation?

Issue #3: Clinical testing in the U.S. in emergency and non-emergency situations is conducted by government-run public health laboratories, private hospital and commercial laboratories. In addition, new laboratory technologies and laboratory diagnostic tests often spring from academia or small companies. CDC needs excellent collaboration with both public and private-sector laboratories to ensure appropriate laboratory response to emergencies and ensure that CDC is using the best laboratory science advances to protect public health.

Task:

- The LW will provide feedback to the ACD, CDC on how CDC can better collaborate with laboratory partners in state and local public health laboratories and the private sector to: 1) respond to test development and analytic capacity needs of large emergencies (e.g., the COVID pandemic); and 2) ensure CDC stays at the forefront of laboratory technology and laboratory science advances that benefit public health.

Issue #4: Excellent laboratory scientists are essential for high-quality, advanced laboratory testing, laboratory research and clinical laboratory testing. The market for such scientists is highly competitive with the private sector offering compensation that is extremely difficult for CDC to match.

Question:

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

Issue #5: In the 2022 budget agreement, Congress requested that the Office of the Secretary, HHS 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 that should be established to mitigate future issues.

Question:

- Will the new LQP that CDC has developed and begun implementing address previous deficiencies and mitigate future issues in diagnostic test development for public health outbreaks?

The LW opted to address as its first priority, TOR Issue 5, pending approval of the TOR by the ACD. The Congressional report language reads as follows:

- *The agreement includes direction in the Office of the Secretary to establish a Task Force, including participation from outside stakeholders and subject matter experts, to evaluate what contributed to the shortcomings of the first COVID-19 tests, including laboratory irregularities, and what policies, practices and systems should be established to address these issues in the future:*

- *The Task Force shall also examine CDC's processes for the development and deployment of diagnostics and its ongoing operations, including communications and electronic lab reporting with clinical, commercial, and State and local public health laboratories.*
- *Based on the conclusions of this effort, CDC shall develop an agency-wide coordination plan for developing and deploying assays during a public health emergency that engages a nationwide system, as appropriate, and leverages the expertise offered by the public and private sectors.*

To address TOR Issue 5, the LW will:

- Review reports on the challenges with the SARS-CoV-2 diagnostic assay in the Spring of 2020
- Review the framework established in the LQP
- Meet on August 24, 2022 to:
  - Discuss key issues raised by reviews to date
  - Assess LQP in addressing these issues
  - Identify outstanding questions to develop report that meets Congressional request
  - Plan for 1-2 additional meetings on this task

  Receive guidance on format of the report, which also may address other issues in the TOR

In terms of expectations for the ACD Meeting in November 2022, pending approval of the TORs by the ACD, the LW will report on progress regarding Issue 5 and the requirements in the Congressional language.

Discussion Summary

Dr. Shah asked whether the purview of the Task Force extends beyond public laboratories and into the space of private laboratories and the broader response and approach. A huge new laboratory workforce was created with private laboratories springing up to provide testing, which is part of the overall response.

Dr. Sharfstein said he thought the LW was not trying to address all of the laboratory response to a public health emergency. The focus is really on the development and deployment initially of the diagnostics that are critical. However, that task does involve every laboratory, including commercial laboratories and how they relate to the

development and deployment of diagnostics initially. In addition, there are many FDA issues in terms of laboratory test regulation. How to get to the tests at a reasonable scale that will make a difference for controlling an emerging infectious disease is relevant and does pertain to commercial laboratories.

Dr. Taylor added that multiple initiatives are underway in parallel in healthcare laboratory systems that she is aware of, and she hopes to bring that knowledge to the LW's discussions so that it is concordant rather than in opposition. There has been talk of a pandemic for many years that now has happened, which certainly has taught some lessons. One of these lessons is that one system is not enough—everybody is needed.

Dr. Martinez observed that there is a tremendous opportunity to examine TOR Issues #4 and #5 through the equity lens in terms of who now comprises the laboratory workforce, whether it is diverse, and if it represents the community. COVID-19 highlighted the public's response to how and who is engaged in development and deployment, has elevated interest in that, and relates to the trust factor now with the CDC.

Dr. Sharfstein indicated that there is no restriction on the types of policies and systems the LW can discuss, so they can raise this very important observation to the larger LW for further discussion.

Dr. Taylor added that a great deal of funding has been allocated to workforce development, part of which is being handled with the CDC and the Association of Public Health Laboratories (APHL) for internships and fellowships in public health laboratories, including local health laboratories. Every effort is being made to have diversity, inclusion, and equity in the workforce and this is being tracked.

Regarding TOR #5, Dr. Goldman cautioned against honing down on the minutia of the laboratory procedures that were developed and ensuring that the LW includes members who understand management science and systems engineering who can evaluate the bigger picture of how laboratorians fit within the decision-making process in CDC, at what point flaws were identified, why that was not communicated at a higher level earlier, and other issues that lead to a technical error becoming a disaster. For instance, the o-ring problem was just a little technical issue on one level. However, the embedded communications and management issues that was embedded in turned the o-ring into a disaster. In her experience, that is usually the case.

Dr. Adimora expanded and underscored Dr. Shah's concern and question, which goes along with the idea that the TOR are not too restrictive. From her vantage point as a clinician, part of the problem with the COVID-19 laboratory debacle actually was not just CDC. It was a big structural problem with the FDA and how that affected individual laboratories, such as hospital laboratories, that actually knew how to do the test but seemed to have been prevented from actually implementing and using it by FDA requirements. Yes, the ACD and workgroup members are all responding to CDC, but this was not just a CDC siloed problem. She expressed her hope that this would be addressed as well.

Dr. Morita noted that the Co-Chairs of the various workgroups met earlier in the day and were discussing common themes that have been emerging in the workgroups, one of which is siloed work in terms of how that relates to data, laboratory, equity, et cetera. She asked whether the LW's current TOR allows them to explore the concept of siloed work, such that they potential could develop recommendations to address the challenges of siloed work within the organization.

Dr. Sharfstein said he thought the LW is very happy with the TOR in that they address policies, practices, and systems that need to be put into place to address a variety of issues. Understanding the role of CDC in the deployment and development of the test is necessary to understand the environment CDC is in. While this is not going to be primarily a report about FDA standards, it will have to relate to how laboratory tests are developed

and made available more broadly. It is quite likely that the LW will bump into some of those issues as they get to the point of considering what type of system should be pursued to develop and deploy tests effectively.

Dr. Fleming observed that there is still some uncertainty as to whether the LW's work on TOR #5 would be brought back to the ACD for affirmation or would be submitted directly to Congress. Notably, this does not affect the TOR.

Teresa Durden, Deputy Director of the CDC Office of Appropriations, responded that CDC is still working through this with the Department in terms of how the LW's recommendations will be transmitted.

Vote

Dr. Goldman made a motion to adopt the LW TOR, which was seconded by Ms. Gary. The ACD voted unanimously to approve the LW TOR, with no dissentions or abstentions.

Health Equity Workgroup Update

Daniel Dawes, JD and Monica Valdes Lupi, JD, MPH (HEW Co-Chairs) provided the HEW update. As a reminder the HEW is striving to change the conditions in the nation through the work of the CDC. The HEW is comprised of 19 diverse members who represent various geographies (rural, frontier, urban, suburban), the LGBTQ+ (lesbian, gay, bisexual, transgender, queer/questioning) community, racial and ethnic minority communities, people with disabilities, homeless populations, et cetera. Recognizing that this is a diverse group representing diverse interests, the following set of guiding principles was established:

Presume Good Intent	Provide each person the benefit of the doubt. Assume everyone has positive intentions. Act honestly and in good faith to serve the best interests of the committee and communities we serve.
Foster a Culture of Respect and Appreciation	Ensure that every voice is heard and valued. Provide everyone space to share thoughts, ideas, and recommendations. Listen with empathy and appreciation for the lived experiences of others. Address differences of opinion as opportunities for collaboration, learning, and growth. Remember, the collective voice of this group builds upon community.
Uphold Justice, Equity, and Ethical Standards	Commit to maintaining accountability, declaring any conflicts of interest, and recusal self from discussion or votes which may present a conflict.
Generate Solutions	To truly achieve health equity, employ a collaborative and solutions-based approach by engaging in cross-collaborative efforts with key strategic partners.
Commit to a Community-Centric Approach	Community is at the core of advancing health equity. Advance inclusive programs, policies, and strategies to reduce inequities for all population groups, and do no harm to those most at risk. Exhibit integrity and good stewardship of resources and ideas generated by this group.

During its initial meetings, the HEW members reviewed the TOR, identified the following 3 priority issues/task areas, and now have assigned an ACD Lead, Subject Matter Experts (SMEs), and HEW members to each and reflected in the following table (not in prioritized order):

TASK AREA #1	TASK AREA #2	TASK AREA #3
Enable and assure the meaningful involvement of communities in agency decision-making, the development of health equity policies, program implementation, and evaluation	Align, and restructure as necessary, CDC policies, resource allocation, and program practices so as maximize the ability for staff and partners to address health inequities in their day-to-day work	Elevate and expand focused activities to measure and address the upstream factors and their consequences, including social and structural determinants of health that contribute to and drive health inequities
ACD Lead: Daniel Dawes	**ACD Lead**: Monica Valdes-Lupi	**ACD Lead:** David Fleming
CDC SME: Euna August and Leandris Liburd	**CDC SME**: Jennifer Meunier and John Auerbach (DFO)	**CDC SME:** Becky Bunnell and NaTasha Hollis
MEMBERS	**MEMBERS**	**MEMBERS**
Bonnie Swenor	Paula Tran	Philip Alberti
David Brown	Nafissa Cisse Egbuonye	Rachel Hardeman
Bobby Watts	Julie Morita	Cary Fremin
Maria Lemus	Octavio Martinez	Ada Adimora
Delmonte Jefferson	Rhonda Medows*	Michelle Albert*
	Mysheika Roberts*	

Themes that are beginning to emerge, which have emerged across other workgroups as well, include the following:

- There is a need to be customer-focused and look beyond the standard STLT customers to community members, community non-profits, industry, the private sector, and other partners.
- There is a need to break down silos internally within CDC and in the ways in which CDC works with external partners.
- Workforce development is needed internally and externally, with a focus on diversity, equity, and inclusion (DEI) in terms of pipeline programs and workforce development opportunities within CDC and in the field within STLT health agencies.

During the last HEW meeting the previous day, the members of the 3 Task Areas divided into breakout groups during which they heard presentations and discussed facilitators and barriers to strengthening CDC's work in their respective task areas.

During the breakout session for Task Area #1 (Community Engagement), Nicole Alexander-Scott, MD, MPH (Former Director, Rhode Island Department of Health) presented on facilitators and barriers to strengthening CDC's work in community engagement. Alice Chen, MD (Former Senior Advisor, Made to Save) described community engagement strategies based on the experiences of a National COVID-19 Vaccine Outreach Campaign. During the subsequent discussion, the Task Area #1 group made the following observations:

1) It is important to assess who is invited to the table and which groups are missing, such as persons with disabilities. The right questions must be asked to ensure that the community is engaged. There should be a systemic, equitable, and authentic process to identify/involve communities and community-based organizations (CBOs), particularly given that there are over 3000 local health departments. Intermediaries should come from communities. Many CBOs have grown in stature that can serve as intermediaries and help build the capacity of small and medium sized CBOs.
2) Leadership is critical in the work of health equity and community engagement, so there must be authentic and sincere leadership. Community-led program designed with staff support are key. CDC could help facilitate community-led program discussions.
3) There are a number of issues with regard to funding, including the need to: a) Ensure that people are made aware of what funding is available and how to access it; b) Rethink how communities are funded. Funding typically is allocated to states, universities, and other organizations. Perhaps there are ways to fund communities

directly to let them solve their own issues; c) Examine the overall infrastructure of funding and sustaining funding (e.g., COVID-19 funding is a good example of direct support to communities that cannot sustain it or seek future funding without the structure/capacity to receive/manage funds). Funding often falls short of the amount it actually costs to implement programs and sustain programs; and d) Examine/address the disconnects that occur in how the pipeline of funding flows from the federal, to the state, to the local, to the community levels.

4) A key question to address regards what constitutes health and who is healthy.
5) Policies/structure around policies, particularly in terms of Congress and Governors, need to be assessed in terms of barriers and how to remove them.
6) Consider the re-establishment of the Health Disparities Subcommittee (HDS) to aid the Office of Minority Health and Health Equity (OMHHE) as they engage with their NOFO Sprint Teams to ensure that the community voice is included in development of the NOFOs.
7) Analyze what is traditional versus what is required by law.

During the breakout session for Task Area #2 (Policies and Practices), Grace Connolly, JD (Former Director, Administration Finance, Boston Public Health Commission) and Fritz J. Gustave, MBA (Former Policy and Strategy Specialist, Administration Finance, Boston Public Health Commission) discussed considerations for integrating equity into administrative processes. Brandy Emily, DNP, RN, PCNS-BC (Health Equity Branch Chief, Colorado Department of Public Health and Environment) presented on strengthening health equity through grant making. The Task Area #2 group made the following 4 key points:

1) There is a need for a CDC culture shift and inclusion of diverse groups in setting policies and science agendas. In this moment, CDC has a unique and important opportunity to build institutional capacity and change the systemic environment. The questions raised included: How does CDC see itself in the health equity work? How does the agency work toward identifying solutions? What is the level of accountability? How does the agency make sure that partners know about these?

2) Regarding procurement, NOFOs, and reporting requirements, what should be included in standards, policies, and guidance. There is a desire to provide some flexibility at all levels without being too prescriptive:

   - An example was shared from Colorado, which appreciated the ability to make advance payments to CBOs in terms of reaching smaller non-profits that might not have been the usual partners the health department engaged with prior to COVID-19. The challenge that they shared is that their department and many state agencies are not allowed to provide advance payments because the contracts are cost reimbursement.
   - A city health department example focused on benchmarking in terms of their equitable procurement process and not setting benchmarks in terms of X percent of grants or procurements to CBOs or minority woman-owned business because setting a minimum floor might have an unintended consequence of having departments and programs stop once the minimum is met.

3) Project Officer engagement and training seem very siloed in terms of technical assistance (TA), guidance, and support that agencies receive from their Project Officers. Perhaps a shift in culture is needed in terms of being the administrator of grant funds and shifting from that mindset to collaborators and partners in achieving community health and health equity.

4) Communities of practice and action are important internally at CDC so that there is a continuous growth mindset and learning among the centers, branches, divisions, and programs. It also is important to try to understand better ways for creating these opportunities for learning in timely ways in the field, such that peer-to-peer sharing occurs amongst communities similar to how this traditionally occurs among national organizations and associations. CDC can play an important role in these learning communities and action-oriented work in the field.

During the breakout session for Task Area #3 (Measuring and Addressing Upstream Data), Claude Jacobs, DrPH(c), MPH (Health Director, San Antonio Metropolitan Health District) discussed San Antonio social and economic factors affecting health. Alonzo L. Plough, PhD, MPH, MA (Chief Science Officer & Vice President, Research-Evaluation-Learning, Robert Wood Johnson Foundation) explained how the path to health equity requires transformed public health data and community engagement approaches. The Task Area #3 group spent a fair amount of time discussing a straw proposal for what the top possible action steps coming out of this task area might be. Consideration was given to subdividing the Task Area #3 work into 2 large action steps, each illustrated by a specific set of examples:

1) Suggest that CDC take leadership in identifying/assessing measures of underlying determinants of equity and health equity in ways that make them as accessible/useful as possible to localities and public health programs. Examples: a) Synthetize state-of-the-art measurement of determinants of health occurring in communities, nationally, and academically (these measures need to be quantitative and qualitative and developed taking the community narratives into account); b) Synthesize frameworks. It was noted that "Frameworks are like toothbrushes. Everyone has one and no one wants to use someone else's." Examples: a) Initiate a process with key partners/stakeholders to assess the capabilities of common methods/measures across programs/jurisdictions, recognizing that measures take time and early successes may be partial successes so measures should not be only long-term; b) Focus on developing asset-based measures instead of deficit-based; and c) Focus on current and locally available/actionable measures and perhaps some elements of big data and other non-traditional sources of public health information, with CDC programs and funding encouraging the use of these measures.

2) Suggest that CDC take an agency-wide approach to developing/integrating methods and strategies to influence/mitigate the effects of health equity determinants across the range of public health programs. Examples: a) Include CDC funding and encouragement for all public health programs to routinely assess and map the effects of determinants of health in their work, considering all relevant power dynamics and ensuring there is an understanding of other interventions in communities that might intersect with an individual public health program; b) Encourage and fund identification/incorporation of interventions to begin to tackle/mitigate the underlying determinants instead of just measuring them; and c) Consider incorporating an asset-based approach rather than a deficit-based approach and interventions into all phases of program implementation and evaluation.

In terms of the timeline, each of the Task Area leads will begin to draft their respective sections with the members. During the November 2, 2022 ACD meeting, the hope is to present high-level preliminary findings across the Task Areas and some suggestions in terms of possible action steps for the CDC. Having heard the other workgroup reports, the HEW also will work with intentionality in terms of across workgroup recommendations where the issues are cross-cutting.

Discussion Summary

Dr. Martinez commended the Co-Chairs for bringing in Gail Christopher, Executive Director of the National Collaborative for Health Equity and former Chairperson of the Board for Trust for America's Health, to deliver the opening remarks during the last HEW meeting. Dr. Christopher was able to contextualize the environments in which they all work, which is highly relevant to the work CDC is doing. She began with the "Jeffersonian Contradiction" that says the country espouses equality, while in fact the environment is structured based on a hierarchy of human value. This resonated with Dr. Martinez in terms of why this work is so difficult. Within that construct, she laid out 3 principles that: 1) the country has a system of separation; 2) the US legal system is designed to maintain this hierarchy of human value; and 3) the US economy thrives on a hierarchy of human value. This combination is why it is so formidable and difficult to change the culture, though espousing egalitarian values. To paraphrase a quote Dr. Christopher made at the end of her remarks, "What we should be is not what we are against, because that doesn't get us to the future. In fact, it is what we are for that is going to get us there."

Dr. Shah said he heard a lot about structure and processes and wondered if the HEW would be able to get to very specific outcomes to which everyone aspires as the focus of their work. For example, they heard earlier that maternal mortality is known to be a challenge among Black women that is getting worse. He asked whether the HEW has thought about specific areas of prioritization or focus for outcomes, or if this was part of their charge.

Ms. Valdes Lupi indicated that this came up in Task Area #2 in terms of how to weave this into the DSW activities, but without any specificity at this point. At the state and local levels, outcomes are explicit in terms of improvements and accountability.

Mr. Dawes added that Task Area #1 did not explicitly address the area of outcomes. They basically focused on high-level processes and structure. The 3 meetings they have had thus far have been about educating them on what those are. Perhaps moving forward, that would be a good consideration for the task areas.

Dr. Fleming said that growing up as an epidemiologist, outcomes are always critical. One of the problems that has occurred in this area is that some of the measurements of outcome have been more advanced than the processes that need to be followed for public health and communities to achieve those outcomes. Something that has been missing regards identifying ways that communities can work to achieve improved outcomes. Therefore, he does not want to lower the importance of process by any means. In

addition, one of the principles is that as communities are empowered, they will have strong opinions about what outcomes are most important to them. Information probably can be provided about measurement, processes, and strategies to get there, but probably not about prioritizing outcomes.

Dr. Morita said she thought part of how they are approaching this is looking upstream at the systems and process changes that need to occur, believing that when those process and systems changes occur, the downstream health outcomes across the board will be impacted more positively and health equity will be addressed in all health outcomes. She agreed that health outcomes are critical to consider, but also feels like the focus must be on upstream factors, process, and systems that are in place in order to impact all health outcomes in an equitable manner.

Dr. Sharfstein said he particularly appreciated the point about focusing on what they are working toward and not so much what they are trying to avoid. Although there is a situation now in which there is a lobby against health equity. Generally speaking that is outside the field of public health, but not entirely. He wondered whether the HEW was thinking about advising CDC on how to pursue equity in a world where there really are people with expressed opposition to accomplishing that.

Ms. Valdes Lupi pointed out that Dr. Christopher tried to describe the importance of external forces perhaps pitting partners on equity into infighting and recognizing the humanity that exists in the work ahead. She appreciated Dr. Sharftein's comments about how to counteract external forces and barriers, or build that into ways in which the HEW is thinking about the proposed suggestions they will put forward. Communities need to be part of defining success measures/outcomes.

Dr. Goldman supported the notion of considering outcomes as well as processes, because she does not think that all of the upstream causes of health inequity and disparity are understood. Despite all of the work that has been done on this in her lifetime, these disparities have persisted. While they should do everything possible to address the upstream factors to which evidence to date points to as being causal, but that they also rigorously focus on outcomes. Engaging communities in defining success measures/outcomes is an incredible challenge and she is glad the HEW is taking that on, but what constitutes community and how communities organize themselves is a constantly shifting landscape.

Dr. Albert observed that the concept of outcomes leaves out the concept of well-being. The concept of looking at structure leading up to so-called outcomes is extremely important because one of the things that relates to structural discrimination and structural racisms, the underbelly of many health inequities related to vulnerable populations, leaves out the concept of population well-being. In addition to focusing on structures, there needs to be a focus on dismantling structural discrimination as part of the health equity work. Even though at a population-level people have been talking about organizing communities and helping communities have a voice in processes, a large part of the reason why progress has not been made relates to structural discrimination. Focusing on having the workforce be representative of the population as a whole and the population who have the lived experiences to make structural change is key. In thinking about different groups, especially groups that have been largely discriminated against, it will be very important for the groups to be able to harmonize with each other. One of the tactics put forward to impede progress is to have the different groups fight with each other for their stake. Having works aligned and working collectively will be very important to dismantle the outside forces that are not in support of health equity.

Dr. Hardeman said she thinks a lot is known about the drivers of racial inequity and their contribution to population health. Certainly, the past 2.5 to 3 years have uncovered even more of that. She encouraged the workgroups, especially the DSW, to think about the reliance on causality as a gold standard as not necessarily the right direction. The reliance on causality has stopped short the focus on uncovering and discussing racism as a fundamental cause of health inequities. This makes it challenging to tell that story and create that causal pathway. One thing that Dr. Alberti has lifted up is the importance of qualitative data and the fact that in the measurement space, consideration should be given to both quantitative and qualitative datasets that need to be used nationally and at a state level to tell the story. The qualitative data are necessary to move past the causality piece that is blocking progress in a lot of ways.

Dr. Adimora agreed that a lot is known about the causes of structural racism. In addition to some of the concerns Dr. Goldman mentioned, the Task Area #3 group talked about some of Nancy Krieger's work and her explication of ecosocial theory and looking at the pathways and who benefits. CDC may not be able to actively do this because it is inherently political. However, having that sort of thinking behind building variables and developing further models would be helpful. She thinks that the idea of approaching equity and building variables from an asset standpoint is really good idea, largely because of decreasing stigma and also in search of solutions. However, she also things it is important to exercise some caution because much of what CDC is doing and should be

doing is garnering more resources. The agency is challenged in every way from a resource standpoint, money, personnel, et cetera. It is important to be wise about this presentation of assets because public health is not necessarily perceived as a right in this country and there will be those who, upon hearing about all of these assets, will presume CDC to being doing fine. While that is an important approach, it should be used carefully and with the understanding of what could happen next and how that information will be used.

Ms. Gary agreed that a lot is known about the drivers of health inequities and with what Dr. Goldman said, which is that there is a tendency to try to address and tweak them, but there does not appear to be a will to get to the root causes of the drivers. In the past, there has been a lot of deflection rather than putting the effort into changing the structures that have perpetuated this. Now there is a lot of misinformation and deflection. In addition to hearing more about communication strategies in the next ACD meeting, she would like to hear more about what can be done to address the misinformation that is being put out around heath inequities and health disparities.

Mr. Dawes applauded the CDC for taking on this very old agenda. As they heard from Dr. Sharfstein, whenever advances have been made in equity or egalitarian-focused policies, there has been retrenchment. This is occurring now, so he is glad to see the level of engagement from the committee members on this and the excellent feedback they have received.

COVID-19 and Monkeypox Update

Ian Williams, PhD, MS (Incident Manager, CDC COVID-19 Response) provided an update on the state of the COVID-19 pandemic, as well as an overview of the agency's activities in terms of transitioning the efforts back to programs to address COVID-19 sustainably. The current story of COVID-19 in the US and around the world is one driven by the BA.5 variant. The BA.5 variant is currently the predominant lineage in the US. It began accelerating in the US in early June and now accounts for 86% of cases and more than 75% of all cases in all parts of the country. Most recently, CDC began tracking BA.4.6 separately from BA.4 to determine whether it exhibits positive growth rates relative to the other variants. The interest in this is because BA.4.6 has an additional spike substation in position 346, which might impact the performance of monoclonal antibodies. The agency continues to watch for the next variant and collaborates very closely with partners around the globe to see what is happening elsewhere.

It appears that in certain parts of Europe, BA.5 is beginning to peak. There may be stabilizing or a possible peak in the US, but it is really too early to say. Cases in the uses are beginning to stabilize at around 110,000. This is far below the peak of last January when more than 800,000 cases were being reported daily. Hospitalizations climbed over the spring, but have begun to stabilize over the last couple of weeks. There are currently about 5,500 hospitalizations on the 7-day average, which is far below the peak of more than 21,000 last January. The good news overall with hospitalizations is that even though hospitalizations of adults started to climb over the Spring, the proportion of adult cases in the intensive care unit (ICU) has remained essentially unchanged since the end of April at about 10% to 15%. Deaths have remained relatively constant for the past several months at around 350 to 400, which is far below the peak of about 2,700 a day in February 2022.

With the increase of at-home testing over the past year or so, CDC has started to lose fidelity of its case counts. To start to provide some tools to the community, the COVID-19 Community Levels (CCLs) was developed. This tool was developed to measure the impact of illness on health and healthcare systems. It is a combination of 3 metrics that includes new COVID-19 admissions per 100,000 in the past 7 days, the percent of inpatient beds occupied by COVID-19 patients, and the total new COVID-19 cases per 100,000 in the past 7 days. New admissions and percent of inpatient beds occupied by COVID-19 patients represent the current potential for strain on the healthcare system, while data on new cases acts as an early warning indicator of potential increases in health system strain in

the event of a COVID-19 surge. CCLs can be low, medium, or high. As of late the previous week, more than half of the population remained at a high level.[1]

Turning to vaccination, current COVID-19 vaccines are doing a very good job at protecting against serious outcomes and deaths. However, they have not been doing such a great job at protecting against infection. Most of the US has now had an immunizing event through vaccination and/or infection. This is a much different place than 6 months to a year ago. As of July 26, 2022, 78.7% of the US population had received at least 1 dose of COVID-19 vaccination, 67.2% of the US population had been fully vaccinated, 48.2% of fully vaccinated persons had received 1 additional dose, and 29.7% of fully vaccinated persons > 50 years of age had received a second booster dose. On June 28, 2022, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to recommend the inclusion of an Omicron component in COVID-19 booster doses. FDA advised manufacturers seeking to update their COVID-19 vaccines to create a bivalent vaccine with an Omicron BA.4/5 spike protein component added to the current vaccine composition.[2] New bivalent vaccines are expected in the Fall. Vaccination remains a key component of the public health strategy.

[1] https://covid.cdc.gov/covid-data-tracker/#county-view?list_select_state=all_states
[2] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

CDC is in the process of working on guidance update refresh, given that the landscape has changed in the US. The agency recognizes that SARS-CoV-2 will continue to circulate in the US and globally. As mentioned, there are high levels of vaccine- and infection-induced immunity in the country. Highly effective treatment and prevention tools are available. The risk of medically significant illness, hospitalization, and death from SARS-CoV-2 has been greatly reduced for most people. This is now about pivoting public health focus on sustainable efforts to minimize the impact of COVID-19 on health and society. As part of this effort, the CDC guidance is being refreshed to focus on 4 main core areas to make it easier for people to know their risk, understand how to protect themselves and others, what action needs to be taken if exposed to the virus that causes COVID-19, and what action to take if someone has symptoms or tests positive. These prevention strategies will be tied to the CCL. As part of the streamlined guidance refresh, CDC will be updating and consolidating its COVID-19 website, amplifying messages through partner outreach, and conducting proactive media and social outreach.

In terms of transition of COVID-19 response activities to program, CDC has been working for the past several months to make this happen. This shift will allow CDC to optimize its work on COVID and non-COVID activities and to continue to leverage the incredible expertise of the agency. In terms of the Incident Management Structure (IMS) structure, there were 10 separate task forces comprised of about 60 teams before the transition. These teams had a series of supporting structures for science, communications, policy, health equity, staff, management, and operations. Overall, about 2500 people were deployed to the response efforts at the peak of the pandemic who were operating under this structure. The formal transition back to program began around the beginning of July. The IMS is about a quarter of the size it was a year ago, with a focus on retaining cross-cutting functions and activities needed to help with response work between centers and programs throughout the agency.

Part of the transition is that each CIO now has a designated CRO who is not officially deployed to the response, but essentially represents their CIO to the response. The CROs' responsibilities are to maintain awareness of COVID-19 activity status within the CIO, ensure bi-directional communication is occurring between the CIO and IMS, and respond to IMS data calls and other requests. In terms of transition progress, over 800 activities were identified as needing to be transitioned as part of this. Approximately half of these activities have been successfully transitioned thus far. A number of activities are slated to be transitioned as the response continues to wind down even further. A number of functions will have to be maintained after the response unwinds. The transition is meant to be a more sustainable way to maintain the momentum that CDC has gained as the

agency continues to work on numerous other COVID activities and a number of different responses. The scaled back IMS structure will remain in place to be a common connector across the agency for the foreseeable future.

Jennifer McQuiston, DVM, MS (Incident Manager, CDC Multi-National Monkeypox Response 2022) indicated that CDC's response to monkeypox began on May 17, 2022, which was the date of the first reported case in the US that occurred in Boston, Massachusetts. Kudos to the astute clinical who recognized what they were seeing as an unusual rash not responsive to other therapies and made the connection to what they were seeing in the media with recent cases reported out of the United Kingdom (UK). CDC stood up a program-led response immediately and began to work with Boston to develop a Health Alert Notice (HAN) and other information to get the word out that people should be looking for monkeypox. The early cases identified in the US were travel-associated. After a few weeks of that, cases were identified among known contacts of monkeypox cases and among people who were infected through community spread. Currently, there is primarily community spread in the US and globally among the gay, bisexual, and other MSM communities. CDC's messaging focus is that anybody can get monkeypox through direct close contact. Getting the word out to the most impacted community while also trying to message in a way that eliminates the stigma is challenge that must be addressed with this response.

CDC has been at agency-level activation with its Emergency Operations Center (EOC) since 28, 2022. The agency is still operating under a containment goal, although many states are starting to wonder if CDC is shifting toward a mitigation phase given that the case counts are still rising rapidly. CDC's efforts are focused on harm reduction messaging, clinical awareness, diagnosis/testing, isolation and treatment of cases, tracing contacts and offering post-exposure prophylaxis (PEP) to people who have had an exposure, and moving to a broader national vaccination strategy.

At the time of this meeting, the currently case counts were 30,189 globally in non-endemic locations. There have been 5 or 6 deaths in non-endemic locations, but the overall case fatality rate remains quite low for this outbreak and is lower than expected for monkeypox in endemic countries. There are 2 clades of monkeypox, a Congo Basin Clade and a West Africa Clade. The Congo Basin Clade has a higher case fatality. The US is dealing with a derivative of the West African Clade with this outbreak. As of August 9, 2022, the US has identified 8,294 cases in 48 states, DC, and PR. The outbreak is rapidly expanding in some places, though some parts of the country still have only a few cases. The doubling time for monkeypox outbreak is estimated to be 9.3 days, but is 8.6 days in areas where there are more than 25 cases that can be tracked.

In terms of the demographics of monkeypox cases in the US, the median age is 35 years with a range of 0-89 years. The majority of cases are occurring in the 25-50 year age range. Like the cases being reported globally, the majority of US cases (99%) are occurring among men who were assigned male sex at birth. There are 50 cases among individuals who were assigned female sex at birth, some of whom are transgender men and some of whom identify as heterosexual women as well. While it is spreading somewhat outside the MSM community, a lot of those are individuals who have contact with MSM. The outbreak continues to be focused in a very specific vulnerable population. For those who are reporting data, 41% are HIV-positive. CDC is aware of 4 pediatric cases in the US: 1 confirmed, 1 probable, and 2 prior that were classified as probable that Dr. McQuiston is labeling as under investigation because further attempts to characterize the virus have shown that those might be false positives or inconclusive results. This highlights an issue that when expanded testing begins outside of the population that has a high incidence, the positive predictive value (PPV) of the test drops.

An interesting shift has been observed in this outbreak over time in terms of race and ethnicity data. In the early days of the outbreak beginning at *MMWR* Week 20, the majority of cases being reported to CDC were occurring in persons who have a white race. As the outbreak has progressed, other races have been rising in terms of the percentage

who are impacted. Some of this might be that the early cases were travel-associated. There are some socioeconomic differences in people who can afford to travel to Europe, so this might be reflective of that. What this really illustrates is that there are some significant health equity concerns that need to be considered with this monkeypox outbreak to ensure that those individuals have access to treatment and vaccines.

The 14-day moving average has been climbing. There was concern that some of the activities occurring during Pride Month in June might facilitate additional spread, but it is difficult to tell whether the upward case count is due only to that since there also was an increase in testing capacity during this time. CDC is continuing to watch this to see what it might mean. Vaccine has been available for known contacts of monkeypox cases since the beginning. Since Day 1 of this outbreak, the FDA-approved JYNNEOS® vaccine has been available to give to known contacts. There was a shift to a national vaccine strategy in which JYNNEOS® vaccine also could be offered to people who reported recent high-risk behaviors that might mean they were at increased risk for monkeypox, which is known as PEP++. There is likely to be a shift to a pre-exposure vaccination strategy if more vaccine becomes available to accommodate that. Laboratory testing also has been available from Day 1, which is a very different situation from the start of COVID-19. Thanks to the smallpox agenda in the US, over 60 laboratories in the country were performing an orthopoxvirus assay and were the backbone of how testing was being done for early cases. CDC heard early and loudly that clinicians wanted commercial laboratory testing, which they expected to have quickly because of COVID. As a result, CDC brought 5 commercial laboratories online that started to offer testing around the beginning of July. That has dramatically increased testing capacity and testing demand in the US compared to the start of the outbreak. There has been a variable positivity rate, but it is settling out to between 30% to 40% of specimens that come in testing positive. It is important to note that a lot of patients have multiple specimens tested, so that is not necessarily reflective only of the percent positivity among persons being tested. The issue in the US is not lack of access to testing, unless there is a barrier that has yet to be identified. CDC has posted its PCR assay online and it is available for anyone who wants to develop a laboratory developed test (LDT) knowing that this is the desire of some laboratories.

In terms of the national vaccine strategy, there are 2 vaccines that could be used. The first is JYNNEOS®, which is a third-generation smallpox vaccine that is non-replicative, meaning that it does not replicate in the body after it is administered. It is a safer vaccine for people who might be immunosuppressed in some way or might have certain skin conditions that predispose them to disseminated vaccinia infection with the older vaccine. It has been available in a more limited supply from the beginning of the outbreak, although the US

Government (USG) has ramped up efforts to bring in more of the vaccine that it owns from Bavarian-Nordic, the manufacturer. To date, the USG has allocated over a million doses to states to some degree based on the at-risk populations living in those states and what the outbreak is doing in those states. JYNNEOS® is licensed as a 2-dose vaccination series and the data suggest that best immunity is achieved with 2 doses. A lot of states are trying to administer the first dose and then pause to see what occurs. CDC's perspective is that even if there is a long interval in between first and second doses, it is ideal for states to try to administer a second dose at some point in the future. A press briefing later in the day would announce moving to an intradermal dose-sparing strategy in order to use a single subcutaneous dose in up to 5 patients, which would increase the availability of vaccine and the coverage that could be achieved.

The second available vaccine, ACAM2000®, is a much-maligned and misunderstood vaccine. It is an excellent orthopoxvirus vaccine that provides strong protection with 1 dose. It is a replicating virus, which means that it has an adverse event (AE) profile that can be challenging for someone who is immunosuppressed, has eczema, or has an underlying skin condition that predisposes them to vaccinia infection. It potentially could be spread to others if someone is not careful with site of inoculation. The other challenge is that it is available under an Expanded Access Investigational New Drug (EA-IND). However, there are millions of doses in the system. Some of the modeling at CDC suggests that it could play an important role in bringing this outbreak to a close if it was used carefully.

Community engagement is absolutely critical and it has been a cornerstone of the CDC response. The agency has been partnered with its colleagues in the National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at CDC who have a lot of expertise in the HIV space and working with persons at risk who seem to be particularly impacted by this outbreak. NCHHSTP has worked hard to develop great graphics and information to share. CDC has channeled targets to disseminate messages to the gay, bisexual, and other MSM community in a way that gets them the information they need. CDC has a fantastic reference online called "Safer Sex" that explains risky activities and lets individuals think about what their responses and behavioral changes would be. The agency also has been participating in many listening sessions to promote dialogue with the affected population, public health departments, and healthcare providers.

In terms of challenges and solutions, a lot of concern was raised over missing early cases. This is a real concern, but CDC did so much looking, cases were found that were not part of the European outbreak. The discomfort with the clinicians not being familiar with the Laboratory Response Network (LRN) was a challenge, but when CDC heard about, they

stood up the 5 commercial laboratories. CDC heard from its state partners that there were challenges with contract tracing, which is one of the most important activities early on in an infectious disease outbreak, was not working because there were too many anonymous partners or this particular social network was hesitant to identify contacts, CDC worked to shift to the expanded PEP strategy. Recognizing that contact tracing was too porous and not effective was one of the reasons for the shift to a national vaccine strategy. CDC has heard that clinicians are having issues accessing TPOXX® to treat patients. Some of this pertained to the cumbersome protocol and reporting burden required by the EA-IND, given that TPOXX® is not licensed for use in monkeypox. CDC has worked to significantly reduce the reporting burden. The shift to the dose-sparing intradermal strategy will address help to address the JYNNEOS® supply issues. In terms of challenges with messaging and behavior, the "Safer Sex" guidance has been revised to address multiple partners, anonymous partners, et cetera. In terms of data sharing, states rightfully have privacy concerns and legal requirements for sharing data. To help ease this, CDC is creating DUAs for vaccine administration data and is working with states to ensure that they have a comfort level with that.

In closing, Dr. McQuiston posed the following questions for ACD's consideration:

- The media is increasingly portraying the US response to monkeypox as a public health failure. Yet, based on a shared global experience, there is no clear solution. What could/should we be doing differently?
- What would "endemnicity" look like for the US? What are the risk factors that might elevate the risk of monkeypox becoming endemic?
- In terms containment versus mitigation, when should CDC shift messaging and response efforts?
- Stigma and equity are significant concerns. What is CDC getting right or wrong and what can the agency do to improve in that area?

Discussion Summary

Regarding risk factors and decreasing health and equity issues, Dr. Albert suggested that one opportunity would be to ensure that when data and/or images are distributed for clinicians and the public about skin findings, all skin tones should be represented. In moving toward a more diverse set of populations being diagnosed with this virus, it is important not to move backwards to the types of images that could be affiliated with the name "monkeypox."

Dr. Adimora noted that as the disease moves like most diseases to more vulnerable populations, thought should be given to the implications for that in terms of the need to isolate for prolonged periods of time and how that will impact people's ability to work and whether they actually will isolate. In addition, distribution of treatment must be truly equitable since it seems that people who are treated clear faster.

Dr. Medows requested a list of the partners and community groups CDC already is working with and who they need help connecting with. People in residential living situations especially colleges, skilled nursing facilities (SNFs), jails, foster care group homes, shelters, et cetera. In addition, she asked whether there are community groups with connections who may be able to help.

Dr. Hardeman called attention to an open letter on monkeypox that was submitted to the Biden Administration the previous day from a group of health scholars that lays out 11 policy solutions.[3] This is a beautifully written and comprehensive piece around steps to consider.

Dr. Sharfstein observed that one of the challenges CDC has had with COVID-19 pandemic and now with monkeypox is that the agency thinks really hard about what it wants to do, announces it, and then receives blowback. The agency has very difficult decisions to make and there is no perfect way to resolve them. No matter what is put forward, CDC is just bracing itself for impact. An alternative approach is to put things out initially as draft, get the comments, see where people are coming from, listen to experts, and then come forward with a more nuanced message that will allow people to focus on the content.

Climate and Health

Patrick Breysse, PhD, CIH (Director, NCEH/ATSDR) began by sharing some talking points he has been using to discuss this program in various venues to discuss how to combat what he refers to as the "headwinds" to getting more support for this program. Among those headwinds, is that it is very clear that there is no appreciation among the public that climate change is a health issue. According to surveys, the vast majority of Americans think that climate change is real but if asked whether it affects them, the vast majority say that it does not. There also is no capacity at the state and local levels to address climate and health. When interviewed, almost 90% of state and local health departments state that they do not have the staff, resources, or capabilities to deal with current climate-related threats. In addition, there is not a lot of appreciation for why CDC is in this space at all.

[3] https://harvardpublichealth.org/an-open-letter-to-the-biden-administration-on-monkeypox/

When people think about climate change and the government, they think about things that the Environmental Protection Agency (EPA) and the Federal Emergency Management Agency (FEMA) deal with in terms of regulating carbon emissions, greenhouse gas reduction, electric vehicles, et cetera. Dr. Breysse has spent a lot of time over the last year or so reaching out to various groups to try to address all of the headwinds, recognizing that there are some nice tailwinds right now with the Biden Administration, CDC leadership, and HHS leadership supporting this work. In his tenure at the CDC, there has never been a constellation of support such as this for this program.

One of the first points he tries to make is that climate change affects everybody. For instance, there were 20 separate billion-dollar weather disasters across the US in 2021. Many of the costs are health-associated. Not only are these events affecting people today, it is known that they are going to get worse in the future—not 20 years down the road, but in the next year or so. When CDC does briefings, they talk a lot about issues that are in the news in terms of heat, flooding, and/or wildfires. New this year is CDC's Heat and Health Tracker, which is a publicly-available, online tool that provides heat and health data and information at the local level to help communities better prepare for and respond to extreme heat events.[4] This is used as an example of a surveillance system that the agency would like to develop more comprehensively for a wider variety of issues, not just extreme heat.

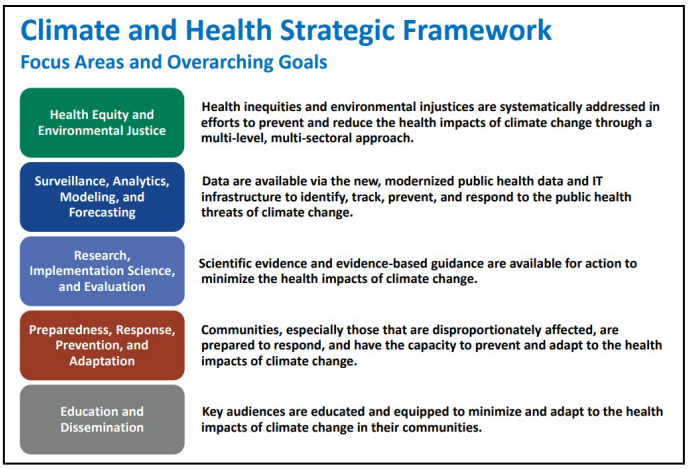
CDC's Climate and Health Program is 13 years old and the agency is now free now to talk about global issues. CDC leadership supports the recognition that climate change is a global health security issue as well. The agency is reaching out to a number of countries who are turning to CDC for advice on how to build a health-related programs across the world where similar climate events are occurring. A lot of time is spent talking about vulnerable populations in a variety of settings. The agency collaborates on climate and health with businesses and across the USG. CDC works with the HHS Office of Climate Change and Health Equity (OCCHE) along
with the National Aeronautics and Space Administration (NASA), National Oceanic and Atmospheric Administration (NOAA), US Department of Agriculture (USDA), and many others. CDC plays a leadership role in multiple cross-USG workgroups, including the Climate Change and Human Health Group (CCHHG), National Integrated Heat Health Information System (NIHHIS), Global Heat Health Information Network (GHHIN), National Drought Resilience Partnership (NDRP), and Wildland Fire Leadership Council (WFLC).

[4] https://ephtracking.cdc.gov/Applications/heatTracker/

Climate and Health Program staff write 2 chapters in the “National Climate Assessment” each year.

As part of CDC, the Climate and Health Program talks about what it is doing in the context of CDC priorities in terms of the public health workforce, data modernization, health equity and climate justice, and SDOH. The Climate and Health Program currently funds state and local health departments through its Climate-Ready States and Cities Initiative to provide resources to 11 state and local health departments to build the Building Resilience Against Climate Effects (BRACE) Framework. The BRACE Framework provides resources for local communities to identify their biggest risks, quantify that risk in terms of the health burden, develop adaptation plans to minimize risk, and evaluate that the plans have mitigated that risk going forward. In the 10 years of experience with this plan, there are a number of great success stories. Ultimately, the goal is to grow this program in order to fund more of the country moving forward.

In the last year, the Climate and Health Program developed the first ever CDC-wide Climate and Health Strategic Framework. Approximately 30 to 40 activities were identified across CDC that staff consider to be climate-related. A Task Force was established that involves every CDC CIO involved to develop the strategic framework. A mission statement and visions were developed. The mission statement is to detect, investigate, forecast, track,
prevent and respond to the public health threats of climate change, addressing health inequities and strengthening community resilience. The vision is to have a nation prepared to respond to the public health threats of climate change, at home and abroad. This was done in anticipation of a request in 2021 in the President’s Budget for a $100 million increase for the Climate and Health Program, which was not received. This year’s request is for $100 million, which they hope comes through so that they can implement this program. The components of the strategic framework are shown here:



The Climate and Health Program also is partnering with CDC Foundation to amplify and advance climate and health impact and is developing a number of initiatives in terms of supporting local communities that have experienced marginalization, creating a workforce that is climate-savvy and climate-capable, partnering with healthcare, and social marketing around climate and health. Dr. Breysse opened the floor for discussion, emphasizing that he would like to hear input on how they can do a better job of addressing the headwinds, given that they have a nice tailwind within which to work.

Discussion Summary

Dr. Martinez noted that one thing that stood out to him that needs to be considered diligently is the fact that there is no health without mental health. While health also includes mental health, it does not mean that people are thinking about mental health. With the Heat and Health Tracker and any other communication that includes the word "health," he strongly encouraged the CDC to consider also including the term "mental health." This will send the message to the population that climate affects both physical and mental health. Many of the examples provided (heat, flooding, wildfires) cause stress and anxiety increase risk factors for depression and post-traumatic stress disorder (PTSD). For instance, people from Hurricane Katrina are still dealing with the aftermath effects on their mental health. While CDC may be considering this, it did not come across in the presentation or sample communications.

Dr. Breysse indicated that they absolutely are considering mental health and agreed that it did not come across in the communications, but they will work on making this clearer moving forward. When they talk about building community resilience, it is not just about the resilience of the physical changes occurring—it also is about the mental health impacts and is part of their discussion.

Dr. Goldman has been working on this in the context of programs in SPH for which a policy has recently been established that across the board, SPH will consistently educate, partner, and conduct research—not only in the environmental disciplines, but across all of the disciplines in public health. They built in concepts around justice because of how unequally climate is impacting health across all communities. Another element is partnerships. On the advocacy side, they are supporting the appropriation for CDC. She was thrilled to hear that the CDC Foundation is working with the Climate and Health Program. There are many people in the foundation community who want to partner with the program as well. She would like to hear more about what the CDC Foundation is doing.

Dr. Breysse indicated that the Climate and Health Program and CDC have created presentations for those interested in partnering with them. He gave a presentation to the CDC Foundation Board of Directors about this and there is a lot of enthusiasm for this across the foundation. The CDC Foundation is particularly interested in developing Climate Ambassadors among young people to serve as the spokespeople for the future going forward.

Dr. Monroe, President and CEO of the CDC Foundation, added that the CDC Foundation is prioritizing this issue front and center. She announced that on October 18, 2022, they will build on its *Lights, Camera, Action: The Future of Public Health Summit Series* to have a very large summit on climate and health to bring in philanthropy, business, and youth-serving organizations (YSOs) to focus particularly on climate and health. Mental health is incredibly important. They are hearing from youth about their lack of hope, despair, anxiety, and disparity and how much of that is related to what they are hearing about the climate in addition to so many other issues.

Dr. Medows There are many corporations, companies, and non-profits that are very interested in doing something in the realm of environmental health and climate change, but sometimes they do not have a direction for how to do it. They have the dollars, will, and commitment. The information Dr. Breysse presented would be very helpful to them. It would be beneficial to provide information about environmental impacts on health for each state down to the county level areas of increased (and increasing) health disparities. This could help direct where people are putting their money.

Dr. Breysse indicated that they are working with the CDC Foundation to reach out to any and all groups that they can, a lot which they have done already. However, they can do more.

Dr. Shah pointed out that there is a huge opportunity with every publicly listed company that is thinking about environmental, social, and governance (ESG) issues. This is on their agendas, they have money to spend, and they are very early in their thinking. Everyone is thinking about carbon footprint, but CDC can give them something else to focus on that is meaningful. CDC should think of them as clients and customers in terms of what data they need, what they should be measuring, and how they should be reporting out in their communities.

Ms. Valdes Lupi shared that the team she leads at the Kresge Foundation has a multi-year multi-million dollar effort, in which the environment team is involved as well. They are working with America's Essential Hospitals (AEH), CBOs, and initially worked with Dr. Monroe and the CDC Foundation. They created a messaging guide in partnership with the Metropolitan Group that includes messages that help clarify the nexus of climate change and health and messages that live up to the values of their grantee partners by integrating health equity, prosperity, safety, and the impact of racism on health and climate change. She would be delighted to share this information with everyone and will follow-up offline.

Dr. Breysse closed by noting that he spent the first 5 years of his tenure in the Climate and Health Program trying to keep the program funded. He is proud of the fact that it survived and is looking forward to what the future might hold, especially given that they have the support of CDC to create a CDC-wide first-ever program on climate and health.

Public Comments

The floor was opened for public comment on August 9, 2022 1:25 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. 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. While no oral public comments were made during this meeting, a number of written comments were received.

Plans for Future Meetings / Wrap-Up / Adjourn

David Fleming, MD (ACD Chair) reminded everyone that the ACD meets 4 times a year, with the next meeting scheduled for November 2, 2022. It is not clear whether that meeting will be virtual or in-person, but it may be hybrid again. As they heard throughout the day, there are now 3 workgroups up and running. They are now shifting into high gear, with most meeting monthly. Reports from those workgroups will be an important part of the November ACD meeting. There will be substantive presentations, though the extent to

which there will be specific recommendations or reports on progress is not yet clear. Regardless, there is likely to be an opportunity for committee input into the process. The TOR for the working groups are broad, so he encouraged everyone to think about the initial reports as interim with an opportunity of a subsequent series of proposed action or potential action steps from the working groups during subsequent meetings. The workgroups should prepare content for the February and May 2023 ACD meetings.

In addition to the working group updates, presentations from CDC on current topics will continue to be part of the agenda. It would be beneficial to hear future presentations on special issues of cross-cutting interest. The ACD heard about climate change during this meeting and would like that to be, which they would like to be the first in a series of activities at CDC. Because these are cross-cutting issues, they fall into the domain of the ACD. As they hear cross-cutting issues or issues of special interest to CDC, the ACD should explore way to more rapidly provide high-level input on these topics as they arise. Working groups are a great way to do deep dives, but there is time associated with them. The ACD's goal is to be helpful to CDC, but sometimes that requires emerging issues/suggestions between the planned quarterly meetings. Comments and advice are welcomed from all ACD members and from CDC leadership on how to continue to make the ACD meetings as productive and useful as possible as possible.

John Auerbach, MBA (ACD DFO) added that if people have additional thoughts about ways CDC can tap the ACD, they are open to that. During this meeting, the following proposed presentation topics were identified for future ACD meetings:

- CDC's communication capabilities and gaps, as well as narrative building for public health moving beyond crisis communications to build trust
- Addressing misinformation being perpetuated about heath inequities and health disparities
- SDOH
- Tackling the mental health issue, which has been elevated by the pandemic and the social justice movement impacting the country
- Workforce
- Community safety
- Insight into how to strengthen the idea of policy causing many downstream effects
- In perhaps a year's time, a presentation on the data coming in on the impact of the Supreme Court decision

Because planning is still underway, the progress of the workgroups is not yet clear. They want to ensure that when a workgroup is ready for a full presentation during an ACD meeting, sufficient time is allocated for that.

Discussion Summary

In response to Dr. Martinez's request for a presentation on how CDC is addressing mental health, Mr. Auberbach noted that for the past 6 months, there has been an internal effort across CDC to reflect upon its role in terms of addressing mental health and wellbeing and a recognition that this is an important part of public health. Dr. Walensky has requested that Dr. Celeste Philip, Deputy Director for Non-Infectious Diseases (DDNID), oversee an internal process to identify what appropriate action steps the agency should take to address the issue.

In terms of how to use the ACD meetings well, Dr. Sharfstein said he appreciated when they heard presentations about the response and the presenters posed questions for the ACD. Having protected time on the agenda for that kind of interaction with a specific set of questions could be a directly valuable way for the ACD to engage with the agency.

Dr. Morita suggested that to save time, perhaps the workgroups could provide written updates in advance so that ACD committee members could read those instead of just hearing them in order to spend more time dialoging.

With no further business posed or questions/comments raised, the meeting was officially adjourned at 2:20 PM ET.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the August 9, 2022 meeting of the Advisory Committee to the Director, CDC are accurate and complete.

10/13/2022

Date

David Fleming

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

Attachment #1: ACD Membership

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

DESIGNATED FEDERAL OFFICER
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
Term: 09-29-2021 – 06-30-2025

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

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

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

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

Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ACD	Advisory Committee to the Director
ACEs	Adverse Childhood Experiences
AE	Adverse Event
AEH	America's Essential Hospitals
APHL	Association of Public Health Laboratories
ASPR	Assistant Secretary for Preparedness and Response
BLA	Biologics License Application
BRACE Framework	Building Resilience Against Climate Effects Framework
CBO	Community-Based Organization
CCHHG	Climate Change and Human Health Group
CCLs	COVID-19 Community Levels
CDC	Centers for Disease Control and Prevention
CFA	Center for Forecasting and Outbreak Analytics
CIOs	Centers, Institutes, and Offices
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
COD	Causes of Death
COI	Conflict of Interest
COO	Chief Operating Officer
CoP	Community of Practice
DDNID	Deputy Director for Non-Infectious Diseases
DFO	Designated Federal Officer
DMI	Data Modernization Initiative
DOT	Department of Transportation
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe Women
DRH	Division of Reproductive Health
DSW	Data & Surveillance Workgroup
DUA	Data Use Agreements
EA-IND	Expanded Access Investigational New Drug
EHR	Electronic Health Record
EJI	Environmental Justice Index

Acronym	Expansion
ELR	Electronic Laboratory Reporting
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
ERM Team	Enterprise Risk Management Team
ESG	Environmental, Social, and Governance
ET	Eastern Time
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FQHC	Federally Qualified Healthcare Center
GHHIN	Global Heat Health Information Network
HAN	Health Alert Notice
HDS	Health Disparities Subcommittee
HEW	Health Equity Workgroup
HHS	(United States Department of) Health and Human Services
HIV	Human Immunodeficiency Virus
HUD	US Department of Housing and Urban Development
ICU	Intensive Care Unit
IDSA	Infectious Disease Society of America
IM	Incident Management
IMS	Incident Management Structure
IT	Information Technology
LDT	Laboratory Developed Test
LDT	Laboratory Developed Test
LQP	Laboratory Quality Plan
LW	Laboratory Workgroup
MMRCs	Maternal Mortality Review Committees
MSM	Men Who Have Sex with Men
NACCHO	National Association of County and City Health Officials
NASA	National Aeronautics and Space Administration
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCHHSTP	National Center for HIV, Viral Hepatitis, STD, and TB Prevention
NCHS	National Center for Health Statistics
NCIRD	National Center for Immunization and Respiratory Diseases

Acronym	Expansion
NDRP	National Drought Resilience Partnership
NIH	National Institutes of Health
NIHHIS	National Integrated Heat Health Information System
NOAA	National Oceanic and Atmospheric Administration
NOFO	Notice of Funding Opportunity
OAW	Operation Allies Welcome
OCCHE	Office of Climate Change and Health Equity
OEJ	Office of Environment Justice
OMHHE	Office of Minority Health and Health Equity
ONC	Office of the National Coordinator for Health Information Technology
OWS	Operation Warp Speed
PEP	Post-Exposure Prophylaxis
PHE	Public Health Emergency
PPV	Positive Predictive Value
PQCs	Perinatal Quality Collaboratives
PRAMS	Pregnancy Risk Assessment Monitoring System
PrEP	Pre-Exposure Prophylaxis
PTSD	Post-Traumatic Stress Disorder
QMML	Quality Manual for Microbiological Laboratories
sBLA	Supplemental Biologics License Application
SDOH	Social Determinants of Health
SME	Subject Matter Expert
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SPH	School of Public Health
STI	Sexually Transmitted Infection
STLT	State, Tribal, Local, and Territorial
SVI	Social Vulnerability Index
TA	Technical Assistance
TOR	Terms of Reference
UK	United Kingdom
US	United States
USDA	US Department of Agriculture
USDS	United States Digital Service
USG	United States Government

Acronym	Expansion
UTD	Up-To-Date
VA	Veterans Affairs
VRBPAC	Vaccines and Related Biological Products Advisory Committee
WFLC	Wildland Fire Leadership Council
WG	Workgroup
YAC	Youth Advisory Council
YSO	Youth-Serving Organizations

Attachment #3: ACD Workgroup Minutes

Workgroup	Meeting Date	Minutes
Health Equity	June 3, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/HEWMinutes_06032022_Final_Signed.pdf
	July 15, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/July-15-2022-HEW-Minutes_FinalSigned.pdf
	August 8, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/August-8-2022-HEW-Minutes-Final-Signed.pdf
Data and Surveillance	July 11, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/July-11-2022-DSW-Minutes-Final-_Signed.pdf
	August 5, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/August-5-2022-DSW-WG-Minutes-Final-Signed.pdf
Lab Workgroup	June 17, 2022	https://www.cdc.gov/about/advisory-committee-director/pdf/June-17-2022-LW-Minutes.pdf