Secretary's Advisory Committee on Infant Mortality

Meeting Minutes of January 25-26, 2021

Virtual Meeting via Zoom

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DAY ONE: Monday, January 25, 2021

Welcome, Call to Order & Introductions

David de la Cruz, Ph.D., M.P.H., SACIM Designated Federal Official Edward Ehlinger, M.D., M.S.P.H., SACIM Acting Chair

Dr. David de la Cruz called the meeting to order, and Dr. Edward Ehlinger welcomed participants to the virtual meeting. Dr. Ehlinger opened by telling the story of Elizabeth Jane Cochrane, a journalist known as Nellie Bly, who worked undercover at an "institution for women" in 1887. Her investigative journalism exposed the harsh treatment of incarcerated women, which subsequently resulted in criminal justice reform. Dr. Ehlinger highlighted the story as an example of how one person can make a significant difference in the lives of others. In light of the many recent events affecting the nation, including the beginning of a new administration, there are opportunities to make a difference. He acknowledged that SACIM members may not yet have full understanding of the opportunities for moving an agenda forward, as the administration is still in its early days. Each Committee member then introduced themselves and shared one thing they were looking forward to, followed by introductions from the Ex-Officio members.

Review and Approve Minutes, Objectives for the January Meeting

Edward Ehlinger, SACIM Acting Chair

The Committee unanimously passed a motion to approve the Minutes of the September 2020 meeting. Dr. Ehlinger reminded the Committee that they had agreed to keep equity at the center of everything they do and reviewed the objectives for the meeting which were to: 1) ensure that systemic and structural racism are reflected in all discussions, 2) build capacity to respond to the COVID-19 pandemic, particularly with regard to vaccines, and 3) establish a framework of activities to recalibrate to the new administration and facilitate the effective execution of SACIM's charge. Maternal and child health of individuals at the border and environmental impacts were also significant issues to be discussed.

CDC's Hear Her Campaign

Dr. Ehlinger introduced the Centers for Disease Control and Prevention (CDC) <u>Hear Her Campaign</u> with a video highlighting stories from women who experienced pregnancy-related complications. He spoke about the importance of including these personal stories and encouraged members to find people in their communities who could bring a voice to the critical issues that SACIM supports. He suggested that there be a process for compensating people for their important work and efforts to share their stories.

Committee members agreed that voices from the community provide valuable insight and should always be a part of SACIM meetings. Efforts to engage the community could be supported through compensation for their time, travel, and childcare and/or inviting people from the community to become full Committee members. There are scientific models for engaging communities and the use of storytelling that are important to consider for guidance on ethical concerns, such as ownership or exploitation. For instance, it is important to ensure that personal stories come from primary sources. Dr. Ehlinger reiterated that Committee members are

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geographically diverse and should connect with voices in their communities to bring their stories forward. He will reach out to members for input about building ethics guidelines and a process for connecting with communities.

Update from the Maternal & Child Health Bureau

Michael Warren, M.D., M.P.H., F.A.A.P., Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA)

Dr. Michael Warren provided an update on the Maternal & Child Health Bureau (MCHB). He highlighted the recent MCHB appropriations for Fiscal Year 2021 across the 11 different MCHB programs. Each program has a different budget, none of which lost funding, and some of which received budget increases. Notably, MCHB received a \$25 million increase to the Title V MCH Block Grant. The appropriation also included funds for the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program that can be used for emergency supplies and support for virtual visits through staff training and the acquisition of technologies for family participation.

The Title V MCH Block Grants to the states are unique in that they allow some flexibility to spend according to a state's <u>action plan</u>, which outlines specific needs, priorities, and capacity. In the last funding cycle, there was an increase in the priority of reducing maternal and infant morbidity and mortality. Annual reviews of these Block Grants were done virtually this past year because of the pandemic, which has resulted in an increase in family reviewers and, subsequently, better accountability on more difficult review questions. Different states use different performance measures, which in turn drive <u>national outcome measures</u> to create a framework of accountability.

Dr. Warren talked about Healthy People 2030 and the goal to reduce infant mortality to five deaths per 1,000 live births. He discussed infant mortality rates by race and ethnicity, emphasizing that the only racial/ethnic groups that have not met the 2030 goal are non-Hispanic Blacks and American Indian/Alaska Natives. They also have not met the original Healthy People 2000 target of seven deaths per live 1,000 births. In contrast, non-Hispanic White infants are projected to have a rate as low as four deaths per 1,000 live births by 2030. This presents an urgent need to accelerate efforts to achieve equity in infant mortality across racial groups. To do this, an additional 4,186 Black and American Indian/Alaska Native infant deaths need to be prevented annually, or 12 infants a day, in order to reach equity in infant mortality rates across races by 2030. He asked the Committee for input on the existing programs, new approaches, communication strategies, or key partnerships needed to achieve equity (4.0 infant deaths per 1,000 live births for all racial/ethnic groups by 2030).

Discussion

Dr. Warren was asked about the flexibility states have to innovate and advance racial equity using Title V program funds. He answered that states have the flexibility to address their priorities and that innovation is actively encouraged as long as it falls within guidelines. There is an opportunity to address racial equity through Title V Block Grant guidance, which is rewritten every few years to update outcome measures for health disparities. Dr. Warren was also asked for more detail about how race/ethnicity data is collected and reported. He clarified that data on race/ethnicity disparities is reported both by raw numbers, to better understand disparities in small populations, and by rates, to understand the proportions relative to the population.

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Committee members suggested that both types of data are important—prevalence data may help identify areas of greatest potential impact and local data could improve understanding of the social determinants of health that affect disparities. They suggested that more rigorous data collection on racial disparities would position the Title V program to have a greater impact on health equity. Committee members also expressed concern over the small number of states that have made racial equity a priority. They noted that this may be an artifact of the states not being able to report all of their activities. The Committee praised the Bureau's efforts to advance racial equity in infant mortality by 2030.

HHS Maternal Health Activities

Dorothy Fink, M.D., Office on Women's Health, US Department of Health and Human Services (HHS)

Dr. Dorothy Fink provided an update on the activities from the Office on Women's Health (OWH). OWH provides national leadership and coordination to improve the health of women and girls through policy, education, and innovative programs. Dr. Fink said that disparities in maternal health are significant, with higher rates of pregnancy-related mortality, severe pregnancy complications, and pre-pregnancy hypertension among Black women as compared to White, Hispanic, and Asian/Pacific Islander women.

OWH addresses these disparities by monitoring and targeting their outreach efforts and social media messaging. For instance, an OWH tweet about the relationship between hypertension and breastfeeding provided awareness about two issues that were not commonly thought of as related. These efforts impact both maternal and infant health. Additionally, OWH will soon announce the winners of the HHS-sponsored Hypertension Innovator Award competition. Another HHS competition focused on breastfeeding initiation and continuation and was one of the most popular competitions on challenge.gov. The goal of these competitions was to focus on racial/ethnic and urban/rural disparities and to demonstrate sustainability or expand programs.

Dr. Fink talked about other OWH initiatives, including Move Your Way, which focuses on increasing physical activity, and the Maternal Morbidity and Mortality Data and Analysis Initiative, which will leverage data to inform program planning and policy development at HHS. OWH is also working to recruit a network of at least 200 diverse birthing hospitals to define areas of maternal health focus and to analyze the impact of evidence-based interventions.

Caryn Marks, Office of Intergovernmental and External Affairs, HHS

Ms. Caryn Marks reviewed the role of the Office of Intergovernmental and External Affairs (IEA), which is the Secretary's primary liaison for state, local, and tribal governments and non-governmental organizations. Over the past few years, IEA has focused on improving maternal health outcomes for Black women. There are racial disparities in maternal mortality, with mortality rates for pregnant Black women being three times higher than for pregnant White women, and in quality of care, with pregnant Black women receiving lower quality care associated with delivery than pregnant White women. She described a public-private partnership with March of Dimes that aims to decrease the racial disparity gap by identifying and implementing evidence-based quality improvement interventions in at least 100 hospitals over five years. The public-private structure of this initiative will help identify gaps in care that the public sector could not address alone. The project is designed to ensure that interventions are

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equitable, collaborative, sustainable, scalable, easy-to-implement, and measurable. The project is currently in its nascent stage, finalizing its methodology and obtaining funding to conduct a pilot.

Charlan Kroelinger, Ph.D., Division of Reproductive Health, CDC

Dr. Charlan Kroelinger provided an update on the CDC <u>Division of Reproductive Health</u>. She talked about the <u>Hear Her</u> campaign to raise awareness of early warning signs to reduce maternal mortality. CDC launched the campaign in 2020, and it has since received strong social media engagement and media interest. Messaging is available in <u>Spanish</u>, and CDC is now looking to expand its reach to American Indian/Alaska Native women, as well as healthcare providers, families, and friends who support pregnant individuals.

CDC is also working to strengthen maternal mortality data through existing Maternal Mortality Review Committees (MMRCs). They recently received increased funding to the MMRCs to improve review processes, develop a common data language, and document a range of data. These efforts will help better understand and develop prevention recommendations for pregnant individuals with heart conditions. The data collection will also support the comparison of community, state, and nationwide social determinants of health measures in pregnant or postpartum individuals to target recommendations and develop tools to address discrimination, interpersonal racism, and structural racism. Dr. Kroelinger said the office plans to create a roadmap for MMRCs to collaborate with community organizers and develop a Community Vital Signs web portal to provide access to the social determinants of health data.

Allison Cernich, Ph.D., ABPP-Cn, National Institute of Child Health and Human Development, National Institutes of Health (NIH)

Dr. Allison Cernich presented three NIH efforts to improve maternal mortality. First, Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) is focused on the root causes of maternal morbidity and mortality, as well as engaging with the community to ensure that NIH research is tailored to their needs. NICHD has awarded \$7.2 million in grants through this initiative, in research areas of interest including diabetes, obesity, mental health, substance use disorders, and structural factors that contribute to delays or disruptions in maternal care that lead to maternal mortality.

Second, NICHD coordinated the <u>Task Force on Research Specific to Pregnant Women and Lactating Women</u> (PRGLAC), which was established by the 21st Century Cures Act to target gaps in understanding on therapies for pregnant and lactating individuals. NICHD has submitted an <u>Implementation Plan</u> to the Secretary in September 2020. Specifically, a PRGLAC recommendation to protect women *through* research rather than *from* research is relevant in terms of COVID-19 vaccine clinical trials, and their aim to remove pregnant and postpartum individuals as a vulnerable population going forward.

Third, the Severe Maternal Morbidity and Mortality EHR Data Infrastructure project is an initiative through the Patient Centered Outcomes Research Trust Fund (PCOR-TF) to strengthen and standardize maternal and infant health data that would facilitate research on medical conditions and interventions.

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Dr. Cernich also highlighted NICHD collaborations with other NIH Institutes in research focused on <u>racial disparities and IDeA states</u> and NIH's meeting with the <u>Black Maternal Health Caucus</u> toward making research more inclusive.

Michael Warren, Maternal and Child Health Bureau, HRSA

Dr. Warren spoke about the <u>Life Course Approach</u> as a paradigm that MCHB uses for improving women's health across the life course. This paradigm supports the acceleration of change; consideration of upstream social determinants of health; and partnership with states, communities, and other federal agencies. MCHB has three core investments related to improving maternal health: the <u>Title V MCH Block Grant Program</u>, the <u>MIECHV Program</u>, and the <u>Healthy Start</u>: Eliminating Disparities in Perinatal Health (Healthy Start) Program.

Dr. Warren then reviewed six MCHB targeted investments related to maternal health, including the <u>State Maternal Health Innovation Program</u>, <u>Alliance for Innovation on Maternal Health</u> (AIM), a new Maternal Mental Health Hotline (for 2021), <u>Screening and Treatment for Maternal Depression and Related Behavioral Disorders</u>, <u>Challenge Competitions</u>, and the <u>Women's Preventive Services</u> Initiative.

MCHB has had a significant impact in improving care. Among these programs, there has been a 75% increase in caregivers screened for depression in MIECHV, nearly 78% of Healthy Start participants initiating prenatal care in the first trimester, and increased positive health outcomes among AIM states.

MCHB also partners with the <u>Federal Office of Rural Health Policy</u> on a pilot program called <u>Rural Maternity and Obstetrics Management Strategies</u> (RMOMS), which aims to develop a network approach to coordinate sustainable maternal and obstetrics care in rural areas.

Discussion

Committee members asked about administration of the COVID-19 vaccine for pregnant women when pregnant women were not included in clinical trials. Dr. Cernich clarified that the vaccine poses no theoretical threat to pregnant individuals, though it has not been licensed for that use. In the context of a public health crisis, the benefit outweighs the potential risk and therefore the vaccine is being provided to pregnant individuals with the recommendation to consult with their doctors. A pending issue is determining how to include pregnant and lactating individuals in clinical trials. Currently, pregnant individuals are considered a vulnerable population, which is the primary reason they are not included in trials. But a vulnerable population, as defined in the context of a clinical trial, is one that cannot provide consent due to power structures. Dr. Wanda Barfield added that the V-safe program is an opportunity to collect more information from pregnant individuals pre- and post-vaccination.

Ms. Marks was asked if counties with the highest rates of infant mortality would be prioritized in their study and how they intend to follow both mother and child through the system. Dr. Cernich answered that there will be a focus on southern states with higher infant morbidity and mortality, and that the study will focus on all stages of care. The Committee members continued with a discussion about the mother-infant dyad and the social determinants of health that affect it. They voiced a need to better understand both the factors that contribute to infant health as well as the factors that affect the pregnant individual, especially in the context of mortality. Implicit bias,

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discrimination, and systemic racism all contribute to mortality and there should be a whole-of-government effort to address it.

COVID-19 Federal Activities

Wanda Barfield, M.D., M.P.H., FAAP, Division of Reproductive Health, CDC

Dr. Wanda Barfield talked about how pregnant individuals are at an increased risk for severe illness from COVID-19, including an increased risk of adverse pregnancy outcomes. Hispanic and non-Hispanic Black pregnant individuals are at a significantly disproportionate risk. She spoke about the CDC effort to better understand the effect of COVID-19 on pregnant individuals and infants through the Pregnancy and Infant Linked Outcomes Team (PILOT). This program coordinates studies with clinical partners and other agencies to inform clinical practice guidelines.

They have released two studies on pregnancy complications and adverse outcomes in pregnant individuals with COVID-19. One study associated SARS-CoV-2 with a prothrombotic state, and a systematic review showed a higher incidence of adverse outcomes, such as preterm births and low birth weight. It is now important to focus on mitigating this risk. Surveillance and testing for asymptomatic pregnant individuals are important because COVID-19 symptoms can be easily missed during pregnancy. There is also little known about disease severity among infants, with limited data suggesting a higher risk of developing severe illness. Health inequities and social determinants of health are also critical research topics, as COVID-19 has exposed disparities among some racial/ethnic populations.

Dr. Barfield indicated that CDC provides weekly updates on COVID-19 related <u>pregnancy</u> and birth data.

Allison Cernich, National Institute of Child Health & Human Development, NIH

Dr. Cernich summarized the <u>ongoing NICHD activities</u> related to COVID-19 and maternal and child health. The <u>Gestational Research Assessments for COVID-19 (GRAVID)</u> evaluates maternal morbidity and mortality during the COVID-19 pandemic using medical records from the <u>Maternal-Fetal Medicine Units</u> (MFMU) Networks. NICHD is also studying the prevalence of COVID-19 infection during pregnancy and its impact on pregnancy outcomes using data from the <u>Global Research Network</u>.

Another NICHD-funded study evaluating the effect of <u>SARS-CoV-2 on breast milk</u> showed that the active virus does not seem to transmit from mother to infant through breastfeeding and may even provide protective antibodies. A study of <u>Multi-System Inflammatory Syndrome (MIS-C) in children</u> is using data from the Pediatric Trials Network to develop therapeutics. NICHD is also involved in studies of RNA sequencing in the placenta to better understand why so few fetuses are infected through maternal transmission. Findings suggest that the placenta lacks the mRNA needed to make the enzyme the virus uses to enter a cell.

Dr. Cernich outlined other intramural research activities at NICHD, such as studies on the effects of the spike protein and preclinical therapeutic targets. Across NIH, there are efforts to develop novel, non-traditional strategies and technologies to understand, predict, diagnose, and tailor management across the spectrum of pediatric COVID-19. There is also a trans-NIH effort to harmonize data and develop common data elements to combine datasets for future analyses.

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NICHD partners with HRSA and the Agency for Healthcare Research and Quality (AHRQ) to host COVID-19 related workshops.

Dana Meaney-Delman, M.D., P.P.H., COVID-19 Maternal Immunization Expert representing Advisory Committee on Immunization Practices (ACIP) Work Group Dr. Dana Meaney-Delman spoke about the CDC response to COVID-19 vaccination during pregnancy and the ACIP Work Group's efforts to integrate published and unpublished data toward the development of recommendations. There are limited data on the safety of COVID-19 vaccines in pregnancy and there are ongoing efforts to increase understanding through animal, reproductive toxicity, and human studies.

The ACIP Work Group recommended that a pregnant individual may choose to receive the COVID-19 vaccine if they are part of a group authorized to receive the vaccine. A discussion with a healthcare provider can help make an informed decision, but is not required. As fever has been associated with adverse pregnancy outcomes, ACIP recommends that pregnant individuals take acetaminophen if they experience fever following vaccination. ACIP does not recommend routine testing for pregnancy prior to receiving the vaccine. There are currently no data on the safety of the vaccine in lactating individuals, although mRNA vaccines are not considered to be a risk to a breastfeeding infant. ACIP therefore recommends that a lactating individual may also receive a vaccine when part of an authorized group.

CDC is using <u>V-safe</u>, a mobile application designed to provide personalized health check-ins and to collect data on individuals who received the vaccine during pregnancy or within 30 days of becoming pregnant. These data will help better understand the effect of the COVID-19 vaccine and its effect and impact on pregnancy.

Michelle Osterman, M.H.S., National Center for Health Statistics, CDC

Ms. Michelle Osterman reviewed the National Center for Health Statistics' (NCHS) effort to understand the maternal and infant characteristics with presumed or confirmed COVID-19 during pregnancy. In March 2020, NCHS encouraged states to collect maternal COVID-19 status via the vital statistics system. States differed in the timing and methods of collecting and reporting, and the data are therefore not representative of the nation.

A <u>recent data release</u> showed characteristics from 9,195 births to mothers with COVID-19 during pregnancy. Distribution by race/ethnicity showed a disproportionate number of Hispanic pregnant individuals with COVID-19 as compared to other race/ethnicities. Distribution by age showed slightly more COVID-19 cases in the age bracket of 20-29 as compared to other ages. Distribution by education showed higher numbers of COVID-19 cases among those with a high school or less than high school education. The number of births covered by Medicaid were higher among individuals with COVID-19, and NICU admissions were more likely for infants of individuals with COVID-19. Ms. Osterman said that updated data should be published every two months. They hope to continue adding more states as data become available and plan to perform more detailed statistical analyses.

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Leyla Sahin, M.D., FACOG, MBA., Division of Pediatric and Maternal Health, CDER, Food and Drug Administration (FDA)

Dr. Leyla Sahin spoke about the FDA <u>Coronavirus Treatment Acceleration Program</u> (CTAP), which provides an expedited response to pharmaceutical companies and scientists in their discovery for new COVID-19 vaccines, therapeutics, diagnostics, and medical devices. The FDA has published 70 <u>guidance documents</u> related to COVID-19 since March 2020. These documents provide recommendations for drug development and encourage the enrollment of pregnant and lactating individuals in Phase 3 clinical trials.

The FDA funded a study using the <u>Sentinel System</u> that includes various cohorts to address regulatory issues of therapeutics used in pregnancy and pediatrics. They are also holding public workshops on the scientific and ethical considerations for including pregnant individuals in clinical trials, acknowledging the need to change the culture of excluding pregnant individuals and shift toward "thoughtful inclusion."

Michael Warren, Maternal and Child Health Bureau, HRSA

Dr. Warren discussed the MCHB <u>award of \$15 million</u> through the CARES Act to expand telehealth care in support of maternal and child health during the pandemic. Since HRSA is primarily a grant-making agency, HRSA/MCHB has focused on grantee support during the pandemic, providing flexibility in service and program delivery, use of funds, and deadline extensions. Many programs shifted to virtual meetings and training, which created an extended reach to people who had previously been unable to attend due to travel barriers. Some programs have also temporarily reassigned personnel to respond to this emergency situation. The only program unable to repurpose personnel is MIECHV, due to legislative restriction.

MCHB has also promoted innovative programs in response to the pandemic including #WellChildWednesdays to promote preventive care and immunizations and the <u>P4 Challenge</u> to incentivize innovations to increase well-child visits and immunizations. MCHB is providing new funding for rural health clinics, tribes, and hospitals and toward expanded telehealth capabilities and utilization.

Discussion and Recommendations

Dr. Sahin was asked about the Post-Licensure Rapid Immunization Safety Monitoring System (PRISM) that was set up to track the safety of H1N1 vaccinations and if PRISM was or could be used to monitor effects of the COVID-19 vaccine in pregnant individuals. She answered that Moderna has set up their own pregnancy registry, but she did not believe that other pharmaceutical companies had. She will look into the use of PRISM and bring an answer back to the Committee.

Dr. Cernich was asked about accessibility to large data systems, such as Kaiser Permanente's. She answered that NICHD has discussed this possibility. The <u>National COVID Cohort</u> Collaborative (N3C) is another large data hub from which researchers can query for pregnancy.

Immigrant Infant and Maternal Health Issues

Paul Wise, M.D., M.P.H., Stanford University, SACIM Member

Dr. Paul Wise talked about his appointment to the United States (U.S.) Federal Court to provide independent assessment and monitoring of medical care for the children in the immigration

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detention system. His role also includes working with federal agencies' response for this care and advocating for improvement. Dr. Wise provided a broad overview of the issues in immigrant infant and maternal health. The apprehension of unaccompanied children is primarily at Border Patrol for initial processing, and the structure of care that occurs upon the children's transfer to the Office of Refugee Resettlement (ORR), which falls under HHS and is responsible for reengagement with family. Children who arrive with family are turned over to Immigration Control and Enforcement (ICE), which has three family residential centers for detention and legal processing. Pregnant individuals in their third trimester are released, and children with significant health issues are transferred to the U.S. to wait for legal processing.

The challenge for children detained with ICE is the misalignment of the immigration policies (e.g., asylum, release, or apprehension) against the custodial policies related to medical care and humanitarian provision of assistance (e.g., food and shelter). Problems emerge when the consequence of immigration policies result in either reduced or enhanced incentives for care, such as using inadequate custodial care as deterrence. Dr. Wise reviewed the history of immigration policies including the Zero Tolerance Policy that resulted in family separation, Migrant Protection Protocols (MPP) that resulted in families being returned to Mexico to await an asylum hearing, and the Title 42 CDC Control of Communicable Diseases that returned families to their home country in response to the COVID-19 pandemic.

The current challenge for HHS is responding to evolving detention protocols and the COVID-19 pandemic. There has been a dramatic reduction in the capacity of the U.S. Government to process children because of restrictions on separation and isolation. Recent policy changes that realign incentives for care will potentially increase the numbers of children and families attempting to enter the U.S. and further burden the already decreased capacity of the detention system. There is also a need for enhanced coordination among federal agencies during the detention processes and in providing support and infrastructure for those needing medical care. Detention centers were built for adult Mexican men seeking work; they are not adequate for taking care of children. Dr. Wise stated there was an opportunity to step back and coordinate an approach for the care of children coming through these systems.

Annie Leone, M.S.N., APRN, CNM, Holy Family Birth Center, Weslaco, TX

Ms. Annie Leone is a nurse midwife who works at the <u>Humanitarian Respite Center</u> in Rio Grande Valley in Texas. The center serves migrant families coming from ICE or Customs and Border Protection (CBP), and the families often not intact when they arrive. Some common reasons the families are seeking asylum are to escape gang or intimate partner violence, kidnappings, death threats, poverty, or to reunite with family members. Ms. Leone is part of the Babies at Borders program, which saw 413 pregnant or newly postpartum individuals in 2020. She presented personal stories from some of the mothers seeking asylum. Many of the pregnant individuals come to the shelter having had little to no healthcare and are experiencing health issues such as infections, high blood pressure, and mental health conditions. They are also at a high risk of exposure to COVID-19. Many who are newly postpartum arrive at the shelter without their infants. They also feel trepidation receiving care, fearing they will jeopardize their immigration status.

Ms. Leone recommended a number of policy actions that would help this population. She recommended an end to separating babies from their fathers. All pregnant individuals should be

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accepted at the border, regardless of their stage of pregnancy. The CBP should stop confiscating medications and medical records. Clinicians and therapists should participate in all shelters, providing evaluation and connection to care. She recommends an overall expansion of CHIP and Medicaid, investment in clinical networking systems, and elimination of penalties for federal centers for accepting pregnant individuals past a certain gestation. She referenced a number of successful program models such as the Migrant Clinicians Network, the Specialty Care Access Network, the Nurse-Family Partnership, and expanded care models from Washington State.

Discussion and Recommendations

Committee members expressed gratitude for the two presentations on immigrant health issues and the importance of putting the issues within an "ethical perspective." The presenters were asked about the shifts in migration patterns anticipated from the change in administration. Dr. Wise suggested that many of the previous administration's policies will be rescinded or revised. This will incentivize people to cross the border. He suggested that the biggest challenge at the border, in its detention systems, is hope—the greater the hope, the more pressure there is on systems of care. The safety policies for COVID-19 require additional resources to provide masks and sanitation—a surge in numbers will result in the system of care being saturated very quickly. Changes in policies will have to be met with comprehensive planning and increased resources to adapt to the number of people coming across and to provide care ethically and humanely. Ms. Leone agreed and added that there is currently a lull before the anticipated surge, which could be used to build up the system. She recommended preparing all facilities with capacity to manage the surge during the pandemic.

Committee members asked how SACIM could shine a spotlight on this sentinel population and prioritize policy recommendations for the prevention of maternal and infant mortality. Dr. Wise said that the recommendations are opportunities for SACIM to provide expert guidance to other agencies on the care of children with special healthcare needs.

Workgroup Breakout Sessions

Day One of the meeting concluded with breakout sessions for each of the Committee Workgroups: Data, Research, and Action; Quality and Access; and Health Equity. Dr. Ehlinger asked members of the Workgroups to think about recommendations in each of the topic areas covered on Day One and to review the draft letter to the President that he emailed the Committee for discussion on Day Two.

Day 1 Adjourn

Dr. Ehlinger adjourned Day One of the meeting at 4:40 P.M.

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Day Two: Tuesday, January 26, 2021

Overview of Day One

Edward Ehlinger, SACIM Acting Chair

Dr. Ehlinger summarized the Day One proceedings. The Committee received updates from MCHB and HRSA, as well as activities and initiatives related to maternal health throughout the federal government. Notably, the Committee heard how the COVID-19 pandemic has resulted in new data, including information about vaccines. They also learned about the issues affecting immigrant maternal and child health. He spoke about how virtual meetings provide access to people who might not otherwise have the opportunity to join, which is one way to reduce inequity.

The Workgroups met in separate breakout groups on Day One, and Dr. Ehlinger invited the Workgroup Chairs to report on their Workgroup's deliberations.

Workgroup Breakout Session Reports

Report from the Health Equity Workgroup Belinda Pettiford, M.P.H., B.S., B.A., Co-Chair

The Health Equity Workgroup reviewed the draft letter to the President. The intention of the letter was to make a first step in communicating SACIM's purpose and priorities in health equity. Workgroup members discussed the content of the letter, suggesting that the letter did not explicitly address social determinants of health, which encompass the predominant factors related to structural racism. They suggested that the letter to the President also be copied to the new Secretary as the appropriate chain of command.

The Workgroup also discussed recommendations specific to COVID-19. In terms of equity, it is challenging to make a recommendation without understanding people's behavior. For instance, the reluctance in Black individuals to accept the COVID-19 vaccine has roots in the history of racism. The terms being used are "vaccine hesitancy" or "vaccine reluctance," but neither accurately describe the barrier. It is important to understand connections of trust, especially with older adults, and the transmission of culture and messaging to children. Members recommended collecting data to better understand people's attitudes and behaviors about the vaccine.

The Workgroup then discussed recommendations for immigrant health, specifically looking at the recommendations from Ms. Leone's presentation. They reiterated the need to be prepared for a surge in numbers. They recommended addressing policies that result in negative consequences, such as the presumptive release of pregnant individuals from detention and the public charge regulation that disincentivizes seeking care. The new Executive Order specifies that agencies address access to services for underserved populations.

The Workgroup addressed recommendations for structural racism by reviewing the implications of the new administration's rescinding of the Executive Order to prohibit diversity training. They recommended an active reestablishment of trainings that are in-depth, that support equity in all workplace operations and grant-making procedures, and that document outcome measures. Members discussed asking states to include equity data in their reports, and Dr. Warren said that MCHB has latitude to ask for these data. They recommended asking the Secretary to support

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equity assessments in federal agencies and block grants. Members recommended asking for a data collection infrastructure that includes social determinants of health.

Lastly, the Workgroup discussed recommendations for environmental health, recommending that the Secretary develop an active partnership with the Secretary of the Environmental Protection Agency (EPA) based on the effect that exposure to environmental agents has on maternal and infant health. A Workgroup member recommended engaging with Gina McCarthy, former EPA Administrator and current Domestic Climate Coordinator for the White House. Members also discussed environmental justice and the impact of environmental disasters on childhood trauma.

Workgroup members also discussed Healthy Start as a program that has the potential to be organized specifically to target the goal of infant mortality equity by 2030. Ms. Pettiford talked about how the Healthy Start program evolved from a systems-level focus to an individual-level focus and suggested that a systems-level perspective is important to maintain. Workgroup members requested that Dr. Warren provide an update on Healthy Start at a future meeting.

Report from Data, Research, & Action Workgroup *Magda Peck, Sc.D.*, Chair

The Data, Research, & Action Workgroup first discussed a letter drafted by Dr. Ehlinger on the Workgroup's behalf that was sent to the former Secretary recommending that the COVID-19 response expand investment toward a robust, standardized data collection system to include data on race/ethnicity. This data collection system would help identify the social and environmental factors driving the racial disparities amidst the pandemic. The Workgroup discussed data specific to COVID-19, including data collection for healthcare providers who are pregnant and receiving the vaccine. Members mentioned that data collection is not always representative and recommended exploring options for accessing more comprehensive sources (e.g., in California, Kaiser Permanente or Los Angeles hospital databases).

Dr. Wise was asked to contribute to recommendations for COVID-19 data and research for border and migrant health. He recommended a coordination of ICE, HHS, and CDC policies and data collection, and a coordination of care from the border to the migrant clinician network to provide vaccinations to pregnant individuals. These coordination efforts are important for migrant groups to have appropriate access to vaccines and other preventative measures. The efforts are also important to SACIM in terms of rapid coordination from the Department of Homeland Security (DHS) and CDC guidelines. Members advised this effort as an ideal opportunity to provide guidance to other organizations on best practices for healthcare at the border and within the U.S. and to strengthen a whole-of-government collaboration.

The Workgroup discussed the vaccination rollout for healthcare workers and the relatively good data collection for that well-defined group. In the next few months, CDC will be recommending vaccinations for individuals over the age of 65 and then the general public. Members suggested that the Workgroup should anticipate the data requirements and tracking mechanisms needed to identify social inequities related to vaccination. As more individuals become eligible for the vaccine, the population will become increasingly diverse.

Workgroup members talked about data and research for disparities in race/ethnicity, recommending that equity metrics should be built into Title V Block Grant guidance. They

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discussed the need for improved electronic health records (EHR) and the lack of a single electronic birth registration system, recommending funding for EHR or an update to current records systems. Members noted ongoing collaborations between agencies, such as Office on Women's Health and Office of Minority Health, that link maternal and infant health in terms of inequities.

Finally, the Workgroup discussed the draft letter to the President. Members suggested organizing the letter in a more standardized format to summarize the overall SACIM vision and outline specific recommendations on advancing racial equity. The Workgroup also discussed drafting a letter to the new Secretary to introduce SACIM and outline recommendations for advancing racial equity particularly in maternal and infant mortality and morbidity.

Report from Quality and Access Workgroup *Steve Calvin, M.D.*, Chair

The Quality and Access Workgroup discussed the need for an increased number of providers of care to ensure sufficient access to care. The American College of Obstetricians and Gynecologists (ACOG) and the American College of Nurse-Midwives (ACNM) do well with workforce issues, but the challenge of limited access to care will only become more acute without funding. A good measure of access to care and healthcare quality is following where money is spent. For instance, Medicaid pays for four out of ten births, bur the majority of Medicaid funds are being administered without data collection on outcomes. There is an effort to expand and update Medicaid through the Medicaid and CHIP Payment and Access Commission (MACPAC), which includes guidance for improved outcome data collection and will support the development of specific recommendations for equity and health. Another potential direction towards data collection and analysis is to link data from HRSA and MCHB to data from entities administrating care across each state to determine who is administering the care, what is or is not working, and how the money is being used.

The Workgroup discussed legislation to improve access to care. The Helping Moms Act provides states with the option to expand postpartum care to a "fourth trimester" of 12 months after birth. The Midwives for Maximizing Optimal Maternity (MOMS) Act increases the number of midwives by funding midwifery programs and support. Members discussed the need for midwife training, as well as the potential barriers to expansion of training. Increased funding and tax breaks in rural areas might expand access to care. The MOMS Act also encourages doula services, and Members recommended that individuals from underrepresented communities be encouraged to become doulas. They also suggested that doula services be elevated to a Level A preventive service under the U.S., Preventive Service Task Force.

The Workgroup discussed telehealth for maternity and newborn care, which has value, but mothers also want in-person visits. Some members suggested that telehealth is not a complete solution, but a tool for certain situations. Other members spoke about the "iron triangle" of access, cost, and quality and suggested that telehealth is important for infant care and parental support.

The Workgroup also discussed the need to collect and convey accurate information about vaccination in pregnant individuals. Members mentioned that ACOG recommends that pregnant individuals receive the vaccine, especially in Black and minority communities.

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Finally, the Workgroup discussed the draft letter to the President and the need for SACIM to maintain nonpartisanship.

Discussion

Committee members discussed the overlap in Workgroup efforts and the need for synergy in developing recommendations. They suggested not limiting discussion among the three Workgroup leads, but to include all Workgroup members. Some of the recommendations span across Workgroups—border health, the anticipated surge at the border, data collection, doula service expansion, barriers to care access related to COVID-19, and the need for federal- and state-level equity assessments.

Voices from Communities - Flint, MI

Amanda Brousseau and Kinea (Kandi) Wright

SACIM invited two members from the Flint, Michigan community to speak about their experience with pregnancy and the health of their children during the Flint Water Crisis, which began in 2014.

Amanda Brousseau spoke about becoming pregnant in 2014 before the news about lead contamination in the water was made public. She had experienced post-partum depression, which was exacerbated with the news about the tainted water. She felt devastated that she might have unintentionally harmed her baby during pregnancy and struggled with daily activities. She also worried about future developmental issues and the possibility that the effects of the tainted water could even affect her daughter's future children. She learned a lot through professional development and gained support, which was afforded through a HRSA grant. She continues to advocate for other Flint parents, share her knowledge with others, and pass on much needed resources in her community.

Kandi Wright had experienced severe, complex health issues starting in 2014, which were difficult to diagnose and required multiple hospital visits. While in the hospital, she experienced bias and disrespect. In 2015, she discovered that she was pregnant and also learned about the high lead levels in the Flint water supply. She experienced significant anxiety about lead exposure. Both she and her baby were admitted to the hospital after getting sick. She also experienced post-partum depression, compounded by the unknown effects of the tainted water, the challenges of raising a Black male child, and the cost of obtaining clean water. She currently receives services through programs such as the Healthy Start Lead Exposure Assistance Project (LEAP), which has helped support her growth and provides resources to the family.

Discussion

The Flint community members were asked about their trust in the healthcare system after their experiences. They both suggested that trust was extremely difficult and rebuilding trust has not yet been addressed. No one has been prosecuted. The long-term effects of the water on their children are still not known, and they fear that there are not enough resources to meet the special needs of their children through their development. Even the cost of bottled water remains a challenge.

Dr. Ehlinger thanked them for sharing their stories.

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Environmental Contributions to Infant and Maternal Mortality

Jeanne Conry, M.D., Ph.D., Moderator

Tracey Woodruff, M.D., Ph.D., Program on Reproductive Health and the Environment, University of California, San Francisco (UCSF)

Dr. Tracy Woodruff presented on the UCSF Program on Reproductive Health and the Environment research program, which is part of the program's mission to create a healthier environment for human reproduction and development through efforts to prevent exposure to harmful chemicals. Dr. Woodruff provided an overview of pharmaceuticals and chemicals, such as diethylstilbestrol and other manufactured products (e.g., flame retardant). These products contain chemicals that have been shown to act like hormones and influence neurodevelopmental, reproductive, and other health outcomes. In addition, vulnerable populations tend to have higher exposure to these chemicals.

Dr. Woodruff reviewed another chemical group, phthalates, which is used in common plastic and consumer products and is known to disrupt the endocrine system. Phthalates exposure is higher in certain personal care products that are marketed to Black and other communities of color, contributing to health inequity and racial disparities.

People are exposed to environmental chemicals every day and everywhere. This ubiquitous exposure includes pregnant individuals, and the chemicals can also pass through the umbilical cord into the fetus. Babies can be born "pre-polluted," leading to chronic health conditions, behavioral issues, and learning difficulties. There are differences between manufactured and pharmaceutical chemicals, in that manufactured chemicals do not have to show safety data before being put on market. The UCSF program worked with ACOG and the American Society for Reproductive Medicine (ASRM) to develop a Committee Opinion on the social inequalities in environmental exposure.

Darryl Hood, Ph.D., College of Public Health, Ohio State University

Dr. Darryl Hood spoke about the <u>Public Health Exposome</u> framework, which uses big data to identify and analyze important associations along the life course between place- and population-level disparities. This framework can be applied to examine the association between chemical and non-chemical exposures and chronic health outcomes in vulnerable populations.

He explained how an individual lives in a network that includes a community involving interactions with the built, social, and physical environments. In this socio-ecological model, the individual is exposed to moderating factors in the environment. By using parametric and nonparametric analyses on large, disparate datasets, it is possible to investigate hypotheses about socio-demographic health indicators in high risk communities.

Dr. Hood reviewed the different domains in the Public Health Exposome framework, which are physical, built, social, and policy environments. Additionally, there are both temporal and spatial components to the framework, which are used to identify the environmental variables that contribute to health disparities. Dr. Hood presented an example of how the framework provides an overlay of multiple datasets to illustrate how certain sociodemographic and environmental factors contribute to low birth rates and preterm births. The framework can be used to contextualize associations between social determinants of health and the different types of environments, which can help understand and improve public policy outcomes.

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Maureen Swanson, M.P.A., Project TENDR

Ms. Maureen Swanson gave an overview of <u>Project TENDR</u> (Targeting Environmental Neuro-Developmental Risks), and its mission to reduce children's exposure to toxic chemicals and pollutants. There is scientific consensus that toxic chemicals play a role in neurodevelopmental disorders such as autism spectrum disorder; attention-deficit hyperactivity disorder; and intellectual, developmental, and learning disabilities.

Project TENDR is a collaboration of 25 universities, 17 health professionals, and 15 advocates from national organizations. They work on a consensus basis to translate evidence into policy recommendations, which are then published in professional journals. They also promote media coverage, develop comment letters, brief Congress, provide expert testimony, and meet with decision-makers to advance policy change. Examples of their accomplishments include influencing state bans on neurotoxic pesticides, contributing to federal rulings on flame retardants and lead, and developing recommendations to eliminate child lead poisoning that were taken up by the American Medical Association. They also have champions in the new administration. They hope to use their expertise and actions to foster a world in which children are no longer exposed to harmful chemicals.

Nate DeNicola, M.D., M.S.H.P., ACOG

Dr. Nate DeNicola presented on air pollution, climate change, and pregnancy outcomes. He spoke about various faces of climate change—the polar bear on a shrinking iceberg and a weatherman drenched in a superstorm. He suggested that a most urgent face of climate change might be that of a mother and baby. Climate change significantly affects maternal and child health outcomes. Pediatricians, obstetrician/gynecologists (OB-GYNs), and policy makers should be rallying to communicate the urgency of addressing the climate crisis.

Wildfires in California highlight how air pollution and heat create unavoidable environmental exposure. Dr. DeNicola and his research team conducted a research review indicating that this exposure is related to preterm birth, low birth weight, and stillbirth. There is also the concept of a "heat island," which is a phenomenon related to different parts of communities being affected by a high concentration of heat due to city planning, with minority communities tending to be disproportionately affected. Heat islands have been related to adverse outcomes in pregnancy, especially in Black mothers.

Dr. DeNicola presented some past government approaches to systemically address environmental issues and suggested that this approach must be taken again to demand a different future for children.

Linda McCauley RN, Ph.D., FAAN, FAAOHN, Nell Hodgson Woodruff School of Nursing, Emory University

Dr. Linda McCauley talked about building trust and community around maternal and infant environmental health. Environmental justice has roots in the history of racism and the legacy of slavery and distrust. Dr. McCauley spoke about Atlanta, Georgia as an example of a highly segregated community, providing context for this distrust and its barriers to the COVID-19 vaccine.

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It is important to cultivate environmental health literacy and empower communities to take the lead. Community-academic partnerships are key to environmental health literacy, which is challenging, multidirectional work that needs to be nurtured over time. There needs to be careful monitoring of tone and messaging, and respect for the community to guide this communication.

It is important to understand the community's specific needs and provide those resources, research results, and continuity of funding to sustain the trust. Focus groups of Black women have found that they are most concerned about chemicals in personal care and cleaning products, lead exposure, and air pollution. She suggested that the key takeaways in building community trust are to listen, stay in for the long haul, and keep the communication channels active and open.

Gwen Collman, Ph.D., National Institute of Environmental Health Sciences, NIH

Dr. Gwen Collman is the Acting Deputy Director for the <u>National Institute of Environmental Health Sciences</u> (NIEHS). NIEHS is home to the <u>National Toxicology Program</u> (NTP) and one of their focus areas is environmental toxicology and the study of environmental exposure through the lifespan. In collaboration with the EPA, NIEHS also works to combine research and community engagement through the <u>Children's Environmental Health and Disease Prevention Research Centers</u> (Children's Centers). The Children's Centers follow more than 16 cohorts and track the health of both mother and child. These data support research on developmental toxicology and environmental exposure over time. The Children's Centers has also helped explore issues of workforce training and research translation.

NIEHS is the primary funder of children's environmental health research and plays an influential role in developing the field. It recently released a new <u>funding announcement</u> for research translation. NIEHS has a translational science hub for work across the spectrum of environmental exposure, including in maternal and child health.

Discussion

Dr. Collman was asked about the genetic susceptibility to environmental exposure and how that might be built into pharmacogenetic studies. Dr. Collman responded that NIEHS is employing the full range of mechanistic approaches, including epigenetic markers, to study the population. They asked Dr. Collman how NIEHS defines community engagement and if it is built into all funding activities. Dr. Collman answered that the agency uses a community-based participatory approach, which is aspirational and takes time to cultivate. They used to refer to it as *community outreach*, but that term implies that one side knows more than the other. The correct term is *community engagement*, which acknowledges that both sides work together.

Dr. Hood was asked how community engagement is defined in the exposome and he answered that their framework is multifaceted and interdisciplinary, allowing them to interface with several different organizations across time as a functional collaborative.

Committee members commented that the consistent message across these presentations was that environmental health is a complex problem. They asked how SACIM could be a partner to the presenters and how to help raise up a workforce that understands social determinants of health and its lens on various topics. Dr. Woodruff answered that they aim to bring environmental

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health to the community through systemic change in health professionals. Their Committee Opinion outlines the specific rules for improving training for researchers and medical students.

In closing, Dr. Jeanne Conry shared a video of Amanda Gorman reciting her poem, "Earthrise."

Dr. Ehlinger said that as SACIM looks forward, it is important that they look to the arts and humanities. In these presentations, science was bracketed with personal stories and poetry, which provides contextual grounding for their work.

Public Comment

David de la Cruz, Maternal and Child Health Bureau, HRSA

Dr. de la Cruz introduced Ms. Brenda Bandy, Executive Director of the <u>Kansas Breastfeeding</u> <u>Coalition</u>. She stated that she shared a mutual passion with SACIM for the importance of breastfeeding with the goal of reducing infant mortality rates. She said her organization supports the work of SACIM and is available for collaboration in breastfeeding support at the state level.

Two other oral public comments were submitted, but they were not available to present.

Discussion and Planning for Next Meeting

Edward P. Ehlinger, SACIM Acting Chair

Dr. Ehlinger talked about the organization of SACIM, the terms of the Committee members, the letter to the President, and the potential synergies among the three Workgroups. Dr. Warren said there was a call for member nominations last year that received a robust response. MCHB took the Committee's recommendations for broadening and expanding perspectives and expertise, and applied it to the list of nominees to ensure diversity and representation. Dr. Ehlinger added that community voices were important to represent in the Committee. Dr. de la Cruz agreed and added that a younger cohort, such as early career professionals, was also important to include.

Dr. de la Cruz talked about the terms of existing members. Currently there are ten members with end dates ranging from June 2022 to December 2024. The new members will have staggered terms in order to have consistent membership and to preserve institutional knowledge. In deciding length of terms, they considered factors such as professional backgrounds, overlapping expertise, region, race, and gender.

Dr. Ehlinger said that the Charter will also need to be renewed and that he is interested in enhancing it. He would like to see a call for more resources to provide permanent staff for the Committee. Dr. Warren said the current charter ends in September 2021, and the Committee will work with HRSA and the Department to gain approval.

Committee members asked for support in strengthening the Workgroups by sharing the lists of members for collaboration.

Dr. Ehlinger proposed some potential dates for the next meeting, including April 6-7 and June 29-30. Dr. de la Cruz said that the logistics contract, which ends in July, covers these proposed meeting dates and that the meetings will need to be completed with enough time to turnaround the meeting reports.

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Dr. Ehlinger asked about the next action with the draft letter to the President, which he explained had been inspired by the new Executive Order on racial equity that was signed the week before the Committee's meeting. He stated that the role of the Acting Chair is to channel the goals and priorities of the Committee and that his one-on-one interviews with each member highlighted their interest in equity as a priority and the willingness of some to take some measured risks. He saw the letter to the President as an opportunity to raise the visibility of, and potentially enhance the influence of, SACIM. He asked Committee members to discuss whether submitting a letter was the most strategic and appropriate approach.

Some Committee members expressed concerns. The Secretary is not currently in place. The Committee may not be fully in agreement or ready to act on some of the issues raised in the letter. Some members expressed concern over the tone of the letter since the Committee is intended to be an apolitical entity. They suggested that writing to one administration, but not another, may express a political stance. Others agreed that SACIM is apolitical and believed that the letter was appropriate for its statement on racism. They suggested that science supports the letter's statement on structural racism and its impact on maternal and infant health outcomes. Dr. Ehlinger asked if the letter is an appropriate strategy *at this time*. Dr. de la Cruz suggested that the letter could be written in such a way as to convey some disagreement. Members suggested that a strategic approach might be to draft a letter to the President and a follow-up letter to the Secretary.

It was decided to delay a decision on the letter to the President and instead to work on a letter to the Secretary. This could be done in April to align with the new Secretary's confirmation.

Day Two Adjourn

Dr. Ehlinger asked that the Workgroup Chairs meet with him in the next few weeks to discuss how to package the recommendations for the discussion at the April 2021 meeting. Dr. de la Cruz adjourned the meeting at 3:49 p.m.

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