U.S. Department of Health and Human Services
National Institutes of Health
Office of AIDS Research

Office of AIDS Research Advisory Council
Fifty-Eighth Meeting
October 28, 2021

Virtual
https://videocast.nih.gov/watch=42661

Meeting Minutes

Council Members Present: Dr. Blanton S. Tolbert (Chair), Dr. Tabia H. Akintobi, Dr. Margaret L. Brandeau, Dr. Tricia H. Burdo, Dr. Heidi M. Crane, Ms. Lynda M. Dee, Dr. Shruti H. Mehta, Dr. Veronica Miller, Dr. Ricardo A. Rivero, Dr. Jonah B. Sacha, Dr. Kimberly K. Scarsi, Dr. Bruce R. Schackman, Dr. John W. Sleasman, Dr. Ivy Turnbull

***Ex Officio* Members Present:** COL Julie A. Ake, Dr. Victoria J. Davey, Dr. Carl W. Dieffenbach, Dr. Rohan Hazra, RADM Jonathan Mermin

Advisory Council Representatives Present: Dr. Francis Ali-Osman, Dr. Monica Gandhi, Dr. J. Rafael Gorospe, Dr. Carlos del Rio, Dr. Dianne Rausch

Office of AIDS Research Leadership Present: Dr. Maureen M. Goodenow, Director; RADM Timothy H. Holtz, Deputy Director; CAPT Mary T. Glenshaw, OARAC Designated Federal Official and Supervisory Senior Science Advisor; Dr. J. Rafael Gorospe, Medical Officer

Invited Speakers Present: Dr. Bill G. Kapogiannis, Dr. Henry Masur, Mr. Harold J. Phillips, Dr. Rochelle P. Walensky

Welcome and Introductions

Blanton S. Tolbert, Ph.D., OAR Advisory Council Chairperson and Professor, Case Western Reserve University
CAPT Mary Glenshaw, Ph.D., M.P.H., OAR, National Institutes of Health

Dr. Blanton S. Tolbert welcomed participants to the fifty-eighth meeting of the National Institutes of Health (NIH) Office of AIDS Research Advisory Council (OARAC). A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, background information relating to OAR activities, and minutes from the fifty-seventh OARAC meeting, held on June 24, 2021.

A motion to accept the minutes of the fifty-seventh OARAC meeting was approved unanimously.

Dr. Tolbert reviewed the fifty-eighth meeting agenda, noting the inclusion of time for public comments.

Report from the NIH Office of AIDS Research Director

Maureen M. Goodenow, Ph.D., OAR, NIH

Dr. Maureen M. Goodenow welcomed attendees. She pointed out that this is the first OARAC meeting of fiscal year (FY) 2022. The NIH OAR ensures that research funds are invested in line with the *NIH Strategic Plan for HIV and HIV-Related Research* and that the investment enhances NIH collaboration, minimizes duplication, and identifies new opportunities. In the process, OAR engages with multiple stakeholders from the scientific, policy, and advocacy communities and maintains close relationships throughout the federal government.

OAR continues to organize formal listening sessions to hear directly from its stakeholders. Since 2018, OAR has held 48 domestic listening sessions and community engagements at 15 locations. In FY 2021, 10 virtual sessions with 250 participants took place. Sites were selected to encompass a broad cross-section of perspectives from diverse stakeholders, as well as overlaps with *Ending the HIV Epidemic in the U.S.* (EHE) jurisdictions, rural epidemic locations, and locations central to key HIV stakeholder organizations. Themes that emerged included the importance of transparency and information-sharing among investigators and community members and the need for stronger community engagement and participation in HIV research. Increasing engagement and research participation is particularly relevant to make an impact on HIV in Black women, migrant health, and substance use disorders beyond opioids. OAR released a report summarizing the first phase of in-person sessions; a report covering the virtual sessions is planned for the first quarter of calendar year 2022. Listening sessions are an intrinsic component of OAR engagements and will continue as virtual events, with some in-person sessions possible later in 2022. Sessions are planned around domestic and international meetings and conferences, site visits to endemic hot spots, and discussions with partners and stakeholders at diverse research centers and service delivery locations. The next listening session is scheduled for December 3 in conjunction with the virtual U.S. Conference on HIV/AIDS (USCHA). Dr. Goodenow asked Council members to provide suggestions for future listening sessions.

OAR recently disseminated the FY 2019 report on the NIH role in the EHE initiative, which was developed with the NIH AIDS Executive Committee (NAEC). NIH Institutes, Centers, and Offices (ICOs) submitted more than 300 projects in response to a data call requesting information about FY 2019 EHE research. After analysis by senior science advisors and OAR leadership, 210 projects were classified as EHE-relevant. Of these, 67 received 1-year supplements funded by the National Institute of Allergy and Infectious Disease (NIAID) and the National Institute of Mental Health (NIMH) through the Centers for AIDS Research (CFARs), OAR, and the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Fund (MHAF). This analysis establishes a framework for OAR to monitor, classify, and track NIH EHE investments across ICOs and provides a clear baseline for metrics. OAR and NIAID are developing a visualization dashboard to allow ICOs to explore the EHE data for a comprehensive inventory of the scope of EHE research underway across the NIH. OAR is preparing a new report for FY 2021–2022, including EHE projects funded at a total of $16 million, which will be available next year. The HHS America's HIV Epidemic Analysis Dashboard (AHEAD) displays national and jurisdictional baselines and targets for each EHE indicator.

During FY 2021, NIH OAR participated in multiple engagements with Congress, the White House, and HHS. These include the Congressional Budget Justification (CJ) for the president's FY 2022 budget, submitted to Congress, and the Professional Judgment Budget (PJ), submitted to the president and Congress. The FY 2023 CJ and PJ documents are both in development.

OAR participated with the HHS Assistant Secretary of Health (ASH), ADM Rachel Levine, and the EHE Operational Leadership Team in a congressional briefing on NIH EHE-related activities to date and plans for FY 2022 and beyond. OAR, the EHE Operational Leadership Team, and HHS budget staff briefed the Office of Management and Budget on NIH HIV prevention research with a focus on pre-exposure prophylaxis (PrEP) and NIH EHE-specific research. Dr. Goodenow represents the NIH as an *ex officio* member of the Presidential Advisory Council on HIV/AIDS (PACHA) and its Stigma and Disparities Subcommittee. PACHA added eight new members this year to expand and diversify its membership, representing a variety of populations and organizations. Additionally, OAR provided NIH representation on the National HIV/AIDS Strategy (NHAS) Steering Committee and collaborated with the reactivated White House Office of National AIDS Policy (ONAP) and the NAEC to draft a series of HIV research objectives for the revision of the national strategy.

In FY 2021, OAR convened five engagements related to early-career HIV investigators, including four listening sessions with more than 65 early investigators and a consultation with an expert panel of senior researchers. Key issues included the challenges for expansion and support of new HIV investigators, including increased diversity; supported mentoring; innovative funding mechanisms; appropriate peer review; enhanced networking opportunities; and centralized information. OAR established an NAEC working group on this topic to prioritize actions that include increasing funds to support HIV early-career investigator research applications to match the overall proportion of funded early-career investigators across the NIH; initiating and supporting opportunities to expand the research workforce, especially among underrepresented minority groups and in under-resourced institutions; developing OAR web-based HIV early-career investigator resources and guidance to enhance communications, which is scheduled to launch during the second quarter of FY 2022; and convening a 2022 symposium to catalyze networking among HIV-focused early-career and senior investigators with NIH OAR and ICO program experts.

Dr. Goodenow pointed out that many HIV research priorities involve and require collaborative approaches to advance multidisciplinary and intersectional science. Collaborations with NIH leaders provide an opportunity to advance cutting-edge science at the intersection of various research fields across multiple populations affected by HIV. OAR initiated new engagements with ICO directors via joint blog posts featured on OAR's website. In these posts, Dr. Goodenow discussed HIV and aging issues—such as HIV-associated cognitive impairment—with the directors of the National Institute on Aging (NIA) and the National Institute of Neurological Disorders and Stroke (NINDS), Drs. Richard J. Hodes and Walter J. Koroshetz. She reviewed unique concerns for women and girls—including biological and social factors that create gendered inequalities and shape HIV risk—with Dr. Janine Austin Clayton, Director of the Office of Research on Women's Health (ORWH) and partnered with the director of the Sexual & Gender Minority Research Office (SGMRO), Dr. Karen Parker, to discuss obstacles to HIV testing faced by transgender individuals, such as finding inclusive, representative, culturally competent health care. With Dr. David R. Wilson, the director of the Tribal Health Research Office (THRO), Dr. Goodenow explored unique challenges facing American Indian and Alaska Native communities, including misclassification, stigma, and the need for improved opportunities for whole-person care. Finally, with Dr. Franziska B. Grieder, the director of the Office of Research Infrastructure Programs (ORIP), she discussed the status of the NIH HIV vaccine research program, including nonhuman primate resources and physical infrastructure needs. Briefings from ICO directors are planned for future OARAC meetings.

OAR continues to deploy as much as $8 million annually for construction and renovation projects. Since FY 2016, OAR has funded a total of $36.5 million in construction projects to

expand infrastructure—including recent investments in rural areas and at minority-serving institutions—through collaborations with the National Institute of Minority Health and Health Disparities (NIMHD). In FY 2021, OAR worked with ORIP to provide $7.5 million to nonhuman primate facilities and $500,000 for facility alterations and renovations at the Meharry Medical College Center for AIDS Health Disparities Research. OAR facilitated a new EHE research opportunity for Research Centers in Minority Institutions (RCMI) announced in June. The opportunity reflects a funding collaboration between NIMHD and the HHS Office of the ASH (OASH) through the MHAF. The OASH approved $2.275 million from the MHAF for administrative supplements to support collaborative HIV/AIDS research at NIMHD RCMI.

OAR coordinates the annual NIH observance of World AIDS Day on December 1. This year, the event will focus on the role of research in the NHAS and feature such partnerships as the Martin Delaney Collaboratories and community-based advocacy groups. These collaborations exemplify relationships necessary to achieve NHAS goals. Congresswoman Barbara Lee (District) and Mr. Harold J. Phillips will provide remarks. Dr. Wafaa El Sadr from Columbia University will moderate and be joined by panelists Dr. Blanton Tolbert (Case Western Reserve University), Dr. Luis Montaner (Wistar Institute), Dr. LaRon Nelson (Yale University School of Nursing), and Ms. Gina Brown (Southern AIDS Coalition). The event will be videocast in real time and archived for later viewing.

OAR is authorized to disseminate information about NIH HIV research priorities through the PJ, which estimates the funding necessary for the NIH to carry out all HIV/AIDS activities determined by the OAR to be appropriate without regard to the probability that such amounts will be appropriated. The FY 2022 PJ estimate for the NIH-wide HIV research program is $3.875 billion, an increase of $775 million or 25 percent over the FY 2021 estimate. The theme of the FY 2022 PJ is "Optimizing the Investment in HIV Research: Pandemics, Pipelines, and Partnerships." The PJ outlines how increased investment would address critical scientific opportunities and accelerate control of the HIV epidemic. Investing in vaccines, long-acting formulations, and new therapeutics and studying neurologic complications across the lifespan, virus–host interactions, implementation science, and health disparities and stigma would be particularly beneficial. To determine the research opportunities with the greatest potential for long-term impact, OAR analyzes the current and past funding distributions by overarching priority in the HIV portfolio—including consideration of funding activities that are ending and new initiatives and funding opportunities from the ICOs—and compares current investments with the goals of the *NIH Strategic Plan for HIV and HIV-Related Research*. New and continuing or reissued HIV research concepts are proposed and approved by NIH ICOs. Dr. Goodenow explained that although NIH HIV funding has increased slowly, HIV research spending power has eroded since 2004. If the $775 million requested in the FY 2022 PJ were allocated, the spending power would be close to that of 2010.

Dr. Goodenow then reviewed FY 2021 achievements and updates in the HIV research field. The NIH supported studies in extramural and intramural research programs that combined imaging and molecular virology to shed light on specific details of the HIV life cycle—in particular, the dynamic virus–host cell interactions that occur between entry and integration. The revised model of pre-integration events in HIV replication expands potential targets for the development of new drugs. A potential combination strategy involving vaccination and anti-PD-1 therapy improves the functional CD8+ T cell response and reduces viral reservoirs in the lymphoid tissues in a chronic simian immunodeficiency virus (SIV) infection model.

In August, the Data and Safety Monitoring Board (DSMB) recommended that HIV Vaccine Trials Network (HVTN) 705/HPX 2008, the Imbokodo vaccine trial, not proceed to the next stage

because the trial failed to meet the prespecified level of efficacy for HIV acquisition prevention among young cisgender women in sub-Saharan Africa. Because of differences in the vaccines used in the Imbokodo and Mosaico trials, the DSMB recommended that Mosaico, conducted in men who have sex with men (MSM) and transgender populations, should continue for now. If the trial goes to completion, the study is scheduled to end in March 2024.

In late October, NIAID sponsored a workshop reviewing the lessons learned from COVID-19 vaccine development and the implications for HIV vaccines. Dr. Goodenow invited Dr. Carl W. Dieffenbach, director of NIAID's Division of AIDS Research, to provide highlights from the workshop. Dr. Dieffenbach explained that the workshop focused on interactions between platforms built for HIV research and the successful development of COVID-19 strategies. Years of HIV research and development allowed researchers to address simultaneously questions of immunogen design and novel strategies for antigen delivery, as well as provide expertise in clinical trial site capacity to drive recruitment in hard-to-reach, traditionally marginalized communities. This foundation was combined with a whole-of-government approach to produce, evaluate, secure approval, and distribute the COVID-19 vaccine, resulting in distribution of more than 400 million doses. Researchers now must consider how the successes of COVID-19 strategies can be built upon to improve HIV vaccine and prevention research. Dr. Dieffenbach pointed out that unlike COVID-19, immune response to HIV by natural infection does not trigger protection, so more complex strategies are needed. He emphasized the significant amount of work required to assess the landscape and revitalize the HIV research agenda.

Two of the three U.S.-approved COVID-19 vaccines are mRNA vaccines. Originating from pioneering work by HIV vaccine investigators, the mRNA strategy has proven to be a rapid, economical, and highly immunogenic human vaccine development platform. This year, the Lasker Award for Clinical Medical Research was presented to two mRNA vaccine scientists, Drs. Drew Weissman and Katalin Kariko. Dr. Goodenow noted that Dr. Weissman is an NIH-funded HIV investigator—his first R01 submission was titled "RNA Delivery for Dendritic Cell HIV Antigen Prevention" and was funded by NIAID in 2002.

In addition to vaccines, other recent developments in HIV prevention include those related to PrEP. Long-acting injectable cabotegravir is under U.S. Food and Drug Administration (FDA) review for prevention of HIV infection among MSM, transgender women, and cisgender women. Meanwhile, sub-studies of HIV Prevention Trials Network (HPTN) 083 and 084 are ongoing for safety among adolescents and for adherence among adults. Ongoing prevention studies focused on key populations include HPTN 091, a feasibility and acceptability study of a multicomponent strategy, including peer navigation and gender-affirming medical care, to prevent HIV acquisition among transgender women; HPTN 094, a study in five U.S. cities to determine the efficacy of integrated health services through mobile health units to people with opioid use disorder who inject drugs and are at risk of HIV acquisition or are living with HIV; and HPTN 096, a four-community randomized pilot to assess an HIV status-neutral approach to reduce HIV incidence among Black MSM in the Southern United States.

Dr. Goodenow welcomed two new *ad hoc* OARAC members, Drs. Shruti H. Mehta and Ivy Turnbull, and thanked the five OARAC members from the 2017 slate who extended their membership through March 2022. She noted the announcement that NIH Director Dr. Francis S. Collins will retire from his position as NIH Director at the end of 2021. Additionally, ASH ADM Levine recently was sworn in as an admiral of the U.S. Public Health Service Commissioned Corps, making her the first openly transgender four-star officer in the U.S. uniformed services. Dr. Goodenow noted President Joseph Biden's intent to nominate Dr. John N. Nkengasong as Ambassador-at-Large and U.S. Global AIDS Coordinator at the U.S. Department of State. This

position leads, manages, and oversees the President's Emergency Plan for AIDS Relief (PEPFAR). Dr. Goodenow then recognized the deaths of Dr. Arthur Ammann and Archbishop Carl Bean.

Dr. Goodenow reviewed the meeting agenda and noted that the next OARAC meeting, February 24, 2022, will be virtual and will follow include the annual new member orientation on February 23, 2022.

Discussion Highlights

When asked about the next steps for the mRNA vaccine approach in HIV, Dr. Goodenow commented on the enthusiasm for implementing an increased and rapid approach to an HIV vaccine but pointed out that the monetary investment in HIV vaccine research is significantly less than the investment in COVID-19 vaccine research. She suggested that a significant increase in resources would be needed to achieve an HIV vaccine. However, this is an opportunity to review the general vaccine landscape for new ideas. Dr. Goodenow noted a presentation at the recent NIAID workshop that presented a detailed analysis of the difficulties associated with HIV vaccine development, which will be important to communicate to convince funders to increase resources.

OARAC members suggested that OAR schedule a listening session to coincide with the American Public Health Association's Annual Meeting and Expo, adding that it could be a strategic opportunity to gather a broad group of people with interest in HIV research, community leaders engaging in community-based participatory research, and those with expertise in dissemination and implementation.

When asked if the listening sessions have illustrated regional barriers to research, care, and prevention, Dr. Goodenow stressed that different areas of the country have very different HIV epidemics. For example, the listening session in Nebraska illustrated differences between the rural epidemic in the Midwest and in the Southeast. She added that special methods for approaching health care delivery in different parts of the country are needed.

Dr. Tolbert invited OAR to host a listening session in Cleveland and suggested conducting follow-up engagement with communities in which listening sessions are held to increase transparency and trust. Dr. Goodenow pointed out that the rapid changes in the field make maintaining connections with the community increasingly important. She added that the virtual listening sessions were more successful than expected. OARAC members agreed about the importance of repeated connections in establishing trust with communities.

OARAC members pointed out that COVID-19 and HIV lessons learned can be implemented in both directions, but the acute nature of the COVID-19 research effort is a notable difference. Dr. Goodenow added that COVID-19 successes show what is possible, but researchers have been frank about their inability to sustain that pace indefinitely. She added that the pace of HIV research needs to be increased; many places along the pipeline could be improved with lessons learned from COVID-19.

Attendees pointed out that despite the excitement about mRNA vaccines for HIV, the nature of an effective immune response in HIV remains unknown. More fundamental research is required—the immunology of COVID-19 may not be translatable to HIV. Dr. Goodenow noted that the recent NIAID workshop emphasized basic research, as does the NIH agenda of research toward a cure. Many aspects of HIV remain unknown, and those that are known show

that the unique aspects of lentiviruses, in particular HIV. Dr. Goodenow reiterated the importance of revitalizing and expanding basic science as much as possible.

In response to a question about whether the persistence of COVID-19 would reduce the number of researchers drawn to HIV research, Dr. Dieffenbach confirmed that while much HIV research and clinical trials shifted entirely to COVID-19 in 2020, there are remains strong commit to addressing the HIV global pandemic, with emphasis on basic science. He noted that some researchers are committed to HIV specifically and theorized that such researchers will continue to emerge.

Dr. Monica Gandhi commented on the difficulty of studying long-acting injectable use by poorly adherent patients, who often are not considered for clinical trials but could most benefit from long-acting therapies. Ms. Lynda M. Dee offered to help Dr. Gandhi arrange a meeting with pharmaceutical companies.

HIV Clinical Guidelines Working Groups of OARAC Working Group Updates

Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV

Henry Masur, M.D., Chief, Critical Care Medicine Department, Clinical Center, NIH

Dr. Henry Masur outlined updates in the Adult and Adolescent Opportunistic Infection (OI) Guidelines. Panel leadership has been changing to include younger and more diverse members. Dr. Masur pointed out that new information about OIs often comes from outside the United States, so the panel is considering how to incorporate that information and assess generalizability. A number of sections currently are undergoing revision and will be released shortly. The Adult and Adolescent OI Guidelines are accessed frequently by a substantial number of people both in and outside the United States. Panel members maintain that the Guidelines remain important resources that the NIH should continue to support.

The most-used sections align with the frequency of infection. Dr. Masur emphasized that maintaining less-used sections remains important because the Guidelines are known as a reliable source of information on rare OIs. The immunizations section has been delayed in its updates not because of debate but because of a series of events and changes, such as the COVID-19 vaccine guidance and changes in recommendations for other vaccinations. Dr. Masur emphasized the importance of providing clear recommendations for COVID-19 vaccination in people with HIV.

Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children

Bill G. Kapogiannis, M.D., FIDSA, Senior Medical Officer, Maternal and Pediatric Infectious Diseases Branch, Eunice Kennedy Shriver *National Institute of Child Health and Human Development, NIH*

Dr. Bill G. Kapogiannis reported on the rescoping effort for the Pediatric OI Guidelines, noting that changes in the landscape of pediatric OIs led the panel to reevaluate the Guidelines to improve the scope and align them with the contemporary landscape and current needs of clinical providers caring for children affected by HIV. The rescoping process included a review of materials and guidelines use, an epidemiological analysis of recent OIs in U.S. children, a review of the Adult and Adolescent OI Guidelines, a survey of panel members, and a pre-retreat webinar. The rescoping retreat included about 50 participants, evenly divided between current

authors and non-panel members. Participants agreed that the Guidelines should serve as the best single source of current information on the management of OIs, with the retreat aiming to optimize the focus of the Guidelines on OIs and determine the most efficient and effective way to update them. Dr. Kapogiannis noted that rescoping the Guidelines can inform the NIH HIV research agenda, given the importance of the NIH's considering this population and incorporating the data gaps into the research agenda.

Retreat participants recommended maintaining the Pediatric OI Guidelines because they provide uniquely helpful clinical information to providers caring for children with HIV. Mobile applications should be optimized to increase accessibility and usability. Section revision frequency should be adapted and implemented based on new advancements in each topic. Dr. Kapogiannis explained that the section on preventing vaccine-preventable diseases in children with HIV is revised annually; the sections on higher-frequency OIs are updated every 2 years, with sections on less common OIs updated every 4 years. Participants recommended consolidating, reducing, or removing sections on OIs that have low incidence in HIV-affected children, no HIV-specific management implications, or robust information in other sources.

The participants recommended aligning the rating scheme with the rating scheme used in other HIV guidelines and discontinuing the use of mGRADE, which is unfeasible and cumbersome, particularly given the small amount of data usually available for pediatric patients. This change will align the Pediatric OI Guidelines with other groups that base their guidance on key recommendations rather than individual studies. Participants recommended more frequent check-ins with authors on revision needs and editing, contracts with clinicians and content experts to support panel leadership, and reconsideration of co-endorsement from external organizations to make external input less formal and more consultative. Dr. Kapogiannis encouraged OARAC members to review the more detailed report available through OAR.

Discussion Highlights

In response to a question about reviewing how often other guidance sources refer to the HIVinfo Guidelines, Dr. Masur agreed that the Guidelines are unique in the number of experts involved, how current they are, and the infrastructure that allows rapid changes. Dr. Kapogiannis added that similar principles apply to the pediatrics guidelines. Drs. Masur and Kapogiannis did not have information on how often other sources reference the Guidelines but agreed that such data would be illustrative.

Participants discussed how to ensure drug interaction tables remain current. Dr. Masur pointed out that Dr. Alice Pau updates the Adult and Adolescent OI Guidelines tables diligently; additionally, subgroup leads meet quarterly to certify that they have reviewed the section and recommend updates if needed. Dr. Kapogiannis explained that Table 5 in the Pediatric OI Guidelines will contain some pediatric-specific information but link to the Adult and Adolescent OI Guidelines for most information.

Updates from the NIH Advisory Council Representatives
Centers for Disease Control and Prevention's Role in Ending the HIV Epidemic

Rochelle P. Walensky, M.D., M.P.H., Director, CDC

CDC Director and former OARAC Chairperson Dr. Rochelle P. Walensky thanked members of the HIV community for their work on the COVID-19 effort, commenting on the way important expertise was diverted. She explained that powerful tools to practically eliminate HIV transmission in the United States are available but need to be improved and made more

accessible. In 2021, the CDC awarded $117 million to health departments to help rebuild and expand HIV prevention and treatment efforts, which is intended to re-energize activities that were paused during the COVID-19 pandemic. Communities will use this funding to customize and implement high-impact strategies that reduce local barriers to HIV prevention and care. The CDC will work with each community to establish on-the-ground teams that include local experts from multiple disciplines. The CDC's approach to ending the HIV epidemic is based on the four EHE pillars: *diagnosing* all people with HIV as early as possible, *treating* people with HIV rapidly and effectively to reach sustained viral suppression, *preventing* new HIV transmissions by using proven interventions, and *responding* quickly to potential HIV outbreaks to deliver prevention and treatment services to people who need them. Dr. Walensky presented examples of how the CDC will address each pillar.

To make HIV testing simple, accessible, and routine in line with the *Diagnose* pillar, the CDC plans to develop new HIV testing technologies, expand HIV self-testing efforts, increase routine HIV screening in traditional and nontraditional care settings, and identify innovative and effective testing interventions. Across all four strategies and all pillars, the CDC will address social and structural factors that serve as barriers to HIV testing and to making testing more equitable. Dr. Walensky focused on strategies for expanding testing, such as a clinical trial of self-testing efficacy and feasibility. A 12-month longitudinal study recruited approximately 2,500 MSM through online advertisements. Participants received home HIV tests after completing a survey and could acquire more tests or share the site with their networks. Enrollment focused on diverse communities. This trial led to more overall diagnoses, more first-time and repeat tests, and improved access to at-risk networks. The study calculated that these efforts averted 3.34 potential transmissions, saved about 15 quality-of-life years, and averted nearly $1.6 million in lifetime HIV treatment costs. The next step was a demonstration project that enrolled participants in 26 EHE jurisdictions and mailed tests between March 2020 and March 2021. This project had an English/Spanish portal and included more than one-third of participants who had never been tested and about one-half of participants who were tested more than 1 year ago. Participants were able to access additional services, such as sexually transmitted infection (STI) testing and PrEP. Another interesting feature of this study was that 30 percent of enrollees were young adults.

Under the *Treat* pillar, the CDC plans to increase rapid linkage to care and treatment, reengage those who are not in care, improve viral suppression and increase ART adherence in people with HIV, and employ status-neutral approaches to care delivery. Across all these processes, the CDC will address social and structural factors that serve as barriers to treatment and care, as well as decrease disparities in viral suppression. Dr. Walensky presented some examples of projects focused on improving viral suppression, noting that patient navigation increasingly is incorporated to address barriers to timely linkage to care. The CDC developed a STEPS to Care Toolkit to help local clinics build the basics of patient navigation services. One part of this toolkit is the Positive Health Check, a brief, highly tailored behavioral intervention to support viral suppression and retention in care that is delivered on tablets in HIV primary care clinics to supplement visits. In a randomized trial simultaneously evaluating health outcomes and implementation in real-world settings, male participants were more likely to achieve viral suppression at 12 months. Both younger and older participants achieved a lower risk of a 6-month gap between visits. Such factors as organizational climate and readiness played important roles in implementation over time. Dr. Walensky highlighted fingerstick testing technologies that provide quick results and remote consultations with providers to discuss results.

Regarding the *Prevent* pillar, the CDC plans to develop, evaluate, and optimize novel PrEP interventions; integrate new technologies; and prepare for novel biomedical prevention agents. The CDC will partner with other agencies and communities to develop, evaluate, and optimize syringe services programs and employ status-neutral approaches to PrEP delivery. In both of these efforts, the CDC will continue to address social and structural factors that serve as barriers to accessing PrEP and syringe service programs. Dr. Walensky featured the Targeted Highly Effective Interventions to Reverse the HIV Epidemic (THRIVE) 4-year demonstration project to support state health departments in leading community collaboratives to implement comprehensive HIV prevention services in seven communities with high disease burden. In the THRIVE project, PrEP navigation was associated with increased linkage to care among MSM from 2015 to 2020. PrEP prescriptions increased with co-located HIV testing and PrEP services, which Dr. Walensky noted was a promising example of how PrEP navigation can reduce the number of HIV cases.

Under the *Respond* pillar, the CDC will develop new and better approaches to evaluating response outcomes and develop and assess investigation approaches, high-yield HIV testing interventions, and effective interventions to rapidly improve care delivery and HIV prevention services in response scenarios. These response efforts will include descriptions of the contribution of HIV clusters to overall HIV incidence. Social and structural factors will be addressed under this strategy as well. Cluster and outbreak data will be used to direct resources to the communities most in need of HIV prevention and care services. Dr. Walensky explained that genomic fingerprinting can be used to identify tightly linked genetic clusters of HIV cases diagnosed within the past 3 years. Priority clusters are considered as those with at least five people with HIV diagnosed within the past 12 months. None of the first 60 molecular clusters identified through this process would have been identified through traditional epidemiological methods alone. Whereas the general rate of transmissions per 100 person-years is about 4, the rate for molecular clusters was about 44, so rapid intervention in these clusters would decrease transmission. The CDC has identified 240 clusters and is working to intervene. A secure system is available to health departments to trace a molecular cluster of rapid transmission in near-real time. Dr. Walensky added that qualitative interviews conducted with people who inject drugs, providers, and stakeholders identified challenges in the accessibility of HIV treatment and syringe service programs, leading to rapid expansion of services locally and statewide, but more information is needed to understand how to intervene more effectively at the local level.

Dr. Walensky emphasized the unprecedented opportunity to end America's HIV epidemic. The CDC's strengths are its strong track record of innovative research and development, decades of experience developing and evaluating HIV prevention interventions, investments in demonstration projects to ensure effectiveness on the ground, and expertise responding to outbreaks. She emphasized the need to commit to filling existing research gaps and strengthening the research-to-practice cycle together. In particular, Dr. Walensky stressed the need to work together to shorten the time required to transform original research to patient care. To do this, the CDC must be innovative in its research and use its resources wisely to get the most out of limited research dollars. It must commit to connectedness in the research-to-practice cycle, including breaking down siloes and improving transparency across scientific and programmatic entities. The CDC must address barriers to health equity from the beginning of the cycle and work to close these gaps. Additionally, the CDC values collaboration and partnership to achieve EHE goals together.

Discussion Highlights

In response to a question about the 340B Drug Pricing Program set to expire on January 1, 2022, Dr. Walensky noted that although this issue is under the purview of the HHS Health Resources and Services Administration, the CDC is aware of it. She commented that because the funding often is used for ancillary services, those services can be covered by EHE funding in EHE jurisdictions, but the issue is more challenging in other locations. The CDC is working with the U.S. Preventive Services Task Force to determine how to cover these services. RADM Mermin confirmed that the CDC is working to ensure Affordable Care Act (ACA) support for insurers covering Category A medications, which is a major challenge for the HIV community. The larger issue is how to ensure that PrEP is available to all who need it, which the CDC is working to address more comprehensively in collaboration with other agencies.

OARAC members emphasized the need for more studies with younger adults and to determine the mechanisms of success for patient navigation strategies used with young adults.

When asked about what the CDC is doing to help states that do not have Medicaid expansion, Dr. Walensky explained that all chronic diseases, not just HIV, show worse outcomes in those states. The CDC is working with jurisdictions on improvements to public health infrastructure and to ensure that those improvements are disease-agnostic. Dr. Walensky emphasized that the HIV community will be lifted by broad public health improvements that promote a disease-agnostic workforce.

In response to a question about the data used for molecular clustering, Dr. Walensky noted her understanding that full genetic sequences are used. She expressed the importance of building on sequencing advances used in COVID-19. Dr. Walensky suggested that local workforces could be scaled up to intervene in these transmissions. RADM Mermin added that these sequences are identified in data available from routine ARV resistance sequencing, so no additional blood draws are required. He explained that efforts to respond quickly are being refined. Working closely with local communities has been effective, but some circumstances—such as the absence of syringe service programs—complicate the response.

When asked about privacy issues for sequencing, Dr. Walensky acknowledged the potential for a virus sequence to be linked to the person carrying it and noted that the CDC works with local health departments to conduct sensitive contact tracing. Similar issues have arisen in COVID-19 tracing, such as wastewater surveillance. RADM Mermin added that the CDC recently released new privacy guidance and has been working to reduce HIV criminalization laws.

Updates—ONAP: NHAS

Harold J. Phillips, MRP, Director, ONAP, Domestic Policy Council, Executive Office of the President

Mr. Phillips presented the U.S. government's "Four for Forty" themes in line with the 40th year of progress on HIV response. President Biden reopened ONAP in June with the announcement of the four themes—*reflect, recommit, reenergize,* and *reengage*—and announced his continued support for the EHE initiative. Mr. Phillips noted that new HIV diagnoses decreased by 8 percent between 2015 and 2019 after a period of general stability, adding that this decrease prior to the implementation of EHE strategies is a hopeful sign that the EHE goals can be reached, particularly with a renewal of focused attention after the challenges of the COVID-19 pandemic. However, HIV disparities persist among the populations most affected in the United States and must be addressed among these populations—including Black and Latino MSM and Black heterosexual women—to end the epidemic. Mr. Phillips noted that the rates of diagnosis among

people who inject drugs have increased, which is related to the opioid crisis and the injection of stimulants.

Tools are available for both prevention and treatment, but as testing efforts are scaled up, the entire toolbox must be used. Prevention efforts should be tailored to meet individuals' needs based on their life circumstances, which may require a combination of tools. Mr. Phillips noted the promise of long-acting injectables and implantables but emphasized the importance of ensuring that the individuals who could benefit most from long-acting treatments have access to them to avoid creating new disparities. He added that the HIV community is focusing increasingly on status-neutral approaches to HIV prevention and care services by reducing stigma and using different modalities—such as self-testing—to make prevention more convenient and accessible.

Mr. Phillips outlined the Biden-Harris Administration HIV priorities. One priority in the updated NHAS is accelerating efforts to end the epidemic, recognizing that some activities were delayed by the COVID-19 pandemic in 2020. Mr. Phillips noted the amazing innovations created during the COVID-19 pandemic to continue prevention and treatment services and emphasized the importance of ensuring no populations or geographic regions are left behind as work to end the epidemic continues. The administration prioritizes eliminating HIV-related stigma and discrimination and HIV criminalization; Mr. Phillips noted that ONAP is reviewing actions it can take to help states address criminalization. The administration aims to expand and improve access to health coverage for people with or at risk for HIV, including by leveraging ACA provisions to help more efficiently individuals at risk for and living with HIV. Social determinants of health that affect HIV risk and outcomes will be addressed by expanding a whole-of-government approach. Mr. Phillips noted that these factors cannot be addressed by HHS alone.

The administration prioritizes creating social, physical, and economic environments that promote attainment of good health and well-being for those at risk for or living with HIV. Efforts to better integrate the national responses to the syndemic of HIV, STIs, viral hepatitis, substance use, and mental health disorders will be enhanced. ONAP plans to improve behavioral health screening, as well as linkage and access to substance use and mental health services for individuals at risk for or living with HIV, including expanding the availability of harm-reduction services, such as syringe service programs, which often are misunderstood but can be a gateway to care and treatment. The administration aims to sustain program innovations and administrative changes implemented in response to the COVID-19 public health emergency that can continue to support and improve access to and engagement in HIV testing, prevention, care, treatment, and other related services.

Finally, the administration hopes to expand and diversify the engagement of the private sector in the HIV response. Mr. Phillips noted that some new partnerships are with federal departments, agencies, and programs, especially those outside HHS. Faith- and community-based organizations serving disproportionately affected populations will be partnering with ONAP. Mr. Phillips noted that these organizations often are the most diligent addressers of social determinants of health. Additional partnerships will be developed with academic institutions, both K–12 and higher education, that can provide comprehensive sexual education. Other partnerships could include programs serving older adults, people experiencing housing instability or homelessness, individuals who are justice-involved, and immigrants. Within the health care field, partners could include pharmacists, oral health providers, nurses, and STI specialty clinics; Mr. Phillips explained that ONAP can identify barriers that prevent such health care partners from increasing their efforts to end the epidemic.

Continuing the EHE initiative is an administration priority. President Biden has requested $670 million from Congress in FY 2022 for continued implementation of the EHE initiative. The administration is committed to helping accelerate and strengthen efforts to end the HIV/AIDS epidemic in the United States. Several non–HIV specific administration initiatives can help end the HIV epidemic, including the expansion of health care coverage and access through the ACA, increases in public health infrastructure and harm-reduction strategies through the American Rescue Plan, the social determinants of health addressed in the American Jobs Plan, and several executive orders on relevant topics. The infrastructure plan and new National Drug Control Strategy would provide additional support. These efforts provide opportunities to strengthen public health and work in disease-agnostic ways to consider the communities most in need and the diseases that affect their overall quality of life. Mr. Phillips pointed out that the administration is taking a holistic approach, while his job is to ensure an HIV-related lens is present and connect parties working on HIV.

The 2022–2025 NHAS is in progress, building on previous strategies and setting the framework for other projects. The time frame aligns with EHE and the previous NHAS. Mr. Phillips' team currently is incorporating the most recent data and feedback from engagements with additional federal partners and many community stakeholders. A release is planned for December 1, 2021, coinciding with World AIDS Day. Implementation will begin rapidly in January, with an increased focus on substance abuse, behavioral health, harm reduction, and a strengthened syndemic response. The NHAS will include greater emphasis on strategies for people aging with HIV and improved quality of life. Mr. Phillips noted that the ability to focus on these topics indicates how far the HIV field has progressed. The new NHAS will include a strengthened focus on moving research into practice more quickly. Mr. Phillips pointed out that this plan is not only for federal agencies—it will include state and local agencies, private-sector groups, community-based groups, and academic institutions, all of which can help reach the EHE goal.

The NHAS does not include implementation activities because such activities require budgets, so federal partners will submit those budgets in the first quarter of 2022. Priority populations include gay and bisexual men, as well as other MSM, in particular Black, Latino, and American Indian and Alaska Native populations; Black women; transgender women; youths ages 13 to 24; and people who inject drugs. Mr. Phillips noted that although some progress has been seen regarding a decrease in infections among youth, the effort and focus should continue. The new NHAS points out the difference between youths and those 25 and older. Mr. Phillips commented that some discussion had occurred about whether to include sex workers as a priority population, but data on incidence, diagnosis, and viral suppression among this population are lacking; some studies supported in the new strategy will provide insights into the needs of this population.

ONAP continues to work with federal agencies, such as the U.S. Department of Veterans Affairs, which has scaled up availability of PrEP and HIV testing under its own plan. The U.S. Department of Housing and Urban Development has been a productive partner, particularly regarding the needs of those unstably housed and at risk of HIV infection. Increased federal engagement includes the HHS Administration for Community Living's Administration on Aging, which identified older adults as a population of significant need, particularly LGBTQ populations. This group plans to implement measures to demonstrate progress toward serving older adults with HIV/AIDS. Mr. Phillips noted that multiple federal partners are working on focused projects to identify policy, programmatic, clinical, and research opportunities to expand and improve care for aging people with HIV.

Mr. Phillips reviewed a number of challenges and opportunities. COVID-19 remains a significant issue, but he hopes the recent advances in vaccinations will help improve the situation. Funding priorities and a lack of adequate funding could be challenging, particularly if the focus on EHE diverts funds from base programs for prevention, care, and treatment. Sufficient focus is lacking on geographic disparity areas and populations that are affected disproportionately. Importantly, political will may be lacking at some local levels. The opioid epidemic and increasing methamphetamine use remain a challenge, which ONAP is working with the substance misuse disorder community to address. Additionally, general mistrust and misinformation regarding public health and government persist. Clinical issues that could slow progress include missed opportunities for HIV diagnosis, suboptimal PrEP uptake and support to continue medication, and availability of health care providers with HIV knowledge and skills where they are most needed, including knowledge and skills in serving the populations that are most affected. The uptake of evidence-based practices in clinical care and public health remains slow. Finally, unrecognized and unaddressed biases in systems and individual health care providers remain a challenge. Mr. Phillips suggested several opportunities for focus, including geographic areas where disparities exist, ways to ensure that responses address populations most at risk, improvements in communication about and ways to address mistrust and misinformation, and methods to ensure rapid, efficient uptake of models and continued support for uptake of evidence-based practices.

Discussion Highlights

When asked about the need for more robust community engagement to achieve the EHE 2030 goal, Mr. Phillips reported that federal partners have conducted many listening tours to gather information on which strategies used in the initial implementation of EHE were successful. This feedback will help determine future strategies to engage communities and tailor the interventions to the specific needs of each community.

In response to a question about communicating the value of harm-reduction strategies to local communities, Mr. Phillips explained that his team has had casual conversations with colleagues at the Office of National Drug Control Policy (ONDCP) about how the White House can support localities around such issues. The CDC has funded technical assistance centers. Engaging local law enforcement around syringe service programs is an underutilized tool. After the new ONDCP director is confirmed, ONAP will organize a summit to determine how to communicate with localities on these issues.

Ms. Dee suggested reaching out to communities, rather than industry, regarding strategies for increasing the enrollment of women and people of color in clinical trials and offered to discuss these issues further on a call.

When asked about the changes to the 340B program, Mr. Phillips responded that this issue is a complex one; ONAP is reviewing the landscape to determine how to apply tiered financing strategies to support PrEP access.

OARAC members noted the need to add young men of color to the national strategy, particularly because the regional challenges to reaching this population may vary less than other populations.

Updates from the NIH Advisory Council Representatives

AIDS Research Advisory Committee (ARAC)

Monica Gandhi, M.D., M.P.H., Professor of Medicine and Associate Chief, Division of HIV, Infectious Diseases, School of Medicine, University of California, San Francisco (UCSF); Global Medicine Director, UCSF-Gladstone Center for AIDS Research; Medical Director, "Ward 86" HIV Clinic, San Francisco General Hospital

Dr. Monica Gandhi provided updates on the most September 13, 2021 ARAC meeting, noting the increase in budget allocated across Institutes and Centers (ICs). She commented on the Imbokodo trial, which was launched in November 2017 but recently stopped because the vaccine candidate did not show sufficient protection. The Mosaico trial, launched in September 2019, is ongoing for MSMs and transgender women. The ARAC discussed the successes of Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), particularly the diverse SARS-CoV-2 antibody landscape and the investigation of combination monoclonal antibodies. Dr. Gandhi commented that a specific investment in HIV research in this sphere is unlikely, but additional investments in antivirals to combat pandemics are under consideration. She added that a broad antiviral strategy—the Antiviral Program for Pandemics, which was funded for 5 years to discover and accelerate antivirals.

Dr. Gandhi reviewed upcoming requests for proposals (RFPs) presented to the ARAC for feedback. An RFP titled "Multi-omics Approach to Immune Responses in HIV Vaccination and Intervention" is designed to integrate bioinformatics and experimental approaches to define signatures of outcomes of HIV and SIV vaccination or intervention. This research will target gaps in the effects of immune heterogeneity on outcomes, provide validation of computationally generated hypotheses, improve the predictive value of models, and apply multiple unbiased approaches. An RFP titled "Molecular Dynamics of HIV" will support structural, computational, and functional studies of key dynamic processes that occur during the HIV life cycle and capture the movement of molecules using molecular dynamics. The RFP titled "Limited Interaction Targeted Epidemiology: Viral Suppression" will find individual and contextual risk factors associated with inadequate viral suppression, using methods that maximize the outreach to unsuppressed people with HIV. During the COVID-19 pandemic, virologic suppression outcomes have decreased, but current data must be gathered and assessed to determine geographic and population differences. This RFP would enroll large cohorts digitally and identify ways to measure antiretroviral therapy (ART) adherence remotely, with the intent to develop low-cost, scalable programs to improve rates of virologic suppression across the United States.

National Advisory Mental Health Council (NAMHC)

Dianne Rausch, Ph.D., Director, Division of AIDS Research, NIMH, NIH

Dr. Dianne Rausch explained that the NIMH AIDS program supports research to reduce incidence worldwide and decrease burden through both behavioral and social sciences and neuroscience. These disciplines are both considered mental health, which is critical across the lifespan. She provided an update on NIMH's EHE activities. The University of California, San Francisco's NIMH AIDS Research Center has partnered with the CFARs' Diversity, Equity, and Inclusion initiative to create mentoring programs across CFARs and minority-serving institutions. The program aims to increase participants' capacity to conduct high-impact research to address HIV-related health inequities in African American and Black communities, provide research funding and mentoring for scholars' proposed projects, and support the development of scholars' research careers through training, mentoring, and networking opportunities. The pilot program was developed as part of the NIH UNITE Initiative to address structural racism in the

biomedical research enterprise. The goal is to increase the number of trainees from underrepresented minorities who are engaged in HIV science at the high school, undergraduate, graduate, and postdoctoral levels. This effort will involve developing new programs and enhancing existing programs across CFARs and collaborating with historically Black colleges and universities and minority-serving institutions.

Dr. Rausch outlined recent requests for application (RFA) updates. The first RFA, in collaboration with many ICOs, funded studies targeting the goal of strengthening HIV prevention strategies among women in the Southern United States, which would contribute to EHE goals. Grants funded had broad geographic and venue diversity. Another RFA aims to identify mechanisms and pathways contributing to mood disorders in people with HIV, which received a robust response with creative approaches. Two RFAs currently are active. The first will support studies to identify mechanisms contributing to central nervous system (CNS) comorbidities in people with HIV through immune-CNS interactions; this RFA closes in December. The second open RFA will evaluate differentiated care models to maintain or improve health outcomes for adolescents and young adults with HIV around the world; this RFA closes in January, so Dr. Rausch invited submissions to both open RFAs.

Dr. Rausch highlighted three recent meetings sponsored by NIMH. First, a meeting on human mobility and HIV assessed methodological approaches to understanding mobility patterns, lessons learned from humanitarian settings, and implications for the development of HIV interventions. Second, a meeting on HIV infection of macrophages and the implications for pathogenesis and cure efforts examined emerging data related to macrophage interactions with the immune system during HIV infection, macrophage reservoirs and approaches to their elimination, and the involvement of CNS myeloid reservoirs and associated comorbidities. Finally, a meeting on biotypes of CNS complications in people with HIV focused on identifying and analyzing common data elements from multiple HIV-associated CNS disease studies by integrating elements of underlying psychopathology using self-report, neuropsychological testing, neuroimaging, and plasma/cerebrospinal fluid biomarker analyses.

Dr. Rausch explained that the NIMH, Fogarty International Center, National Institute on Drug Abuse, and an NIH-wide Scientific Interest Group focused on stigma have partnered to develop a stigma and discrimination research toolkit. This toolkit collects evidence and resources related to stigma and discrimination research and contains information about theories, models, frameworks, methods, and interventions that can be applied across conditions and populations to help reduce the impact of stigma. Additional resources are available for those looking to address stigma and discrimination related to the COVID-19 pandemic. Dr. Rausch noted a study of vaccine hesitancy she presented at the previous OARAC meeting. She clarified that although vaccine hesitancy is an important component of that initiative, the overall goal is to expand communication science around vaccines, as well as HIV prevention and treatment options. She added that given the complexities that have occurred around appropriate messaging about COVID-19 and vaccine hesitancy, the initiative proposes to increase the understanding of how to use communication science better to tailor facts to reach the necessary populations.

National Cancer Advisory Board

Francis Ali-Osman, D.Sc., Professor Emeritus in Neurosurgery;
Member, Duke Cancer Institute, Duke University School of Medicine

Dr. Francis Ali-Osman reminded attendees that the National Cancer Institute (NCI) has been deeply involved in HIV/AIDS research since the beginning of the epidemic; HIV/AIDS research

now is conducted across many divisions of the NCI and coordinated by the Office of HIV and AIDS Malignancy. NCI maintains the AIDS and Cancer Specimen Resource, a biorepository of biospecimens from individuals with HIV with a wide spectrum of HIV-related and associated cancers, as well as HIV-negative controls.

Dr. Ali-Osman highlighted some recent initiatives at the NCI. The Implementation Science for Cancer Control in People Living with HIV in Low- and Middle-Income Countries (LMICs) program addresses the burden of cancer and other comorbidities associated with an aging population of people with HIV, which is much more severe in LMICs. This funding opportunity announcement (FOA) supports integration of evidence-based cancer control interventions for people with HIV in LMICs by leveraging existing HIV treatment and prevention infrastructure. Between six and eight consortia of multidisciplinary teams with expertise in HIV, cancer, and implementation science will investigate barriers to the adoption, integration, and sustainability of evidence-based cancer control interventions among people with HIV in LMICs.

Another FOA will address the role of Epstein-Barr virus (EBV) infection in non-Hodgkin lymphoma and Hodgkin lymphoma development with and without an underlying HIV infection. Dr. Ali-Osman explained that in most healthy individuals, EBV infection remains latent, but reactivation can be devastating to HIV-positive and other immunosuppressed individuals and contribute substantially to mortality and a progressively poor quality of life. In the United States, approximately 40 percent of EBV non-Hodgkin lymphoma diagnoses are in HIV-positive individuals; classical Hodgkin lymphoma is present in nearly all people with both EBV and HIV.

The third FOA is the CASCADE HIV/Cervical Cancer Clinical Trials Network, which is a global, multicenter cooperative agreement clinical trials network for cervical cancer prevention in women with HIV living in LMICs and regions of the United States where the risk of cervical cancer remains high. More women with HIV in LMICs now have access to ART and are living longer, but their risk of acquisition and progression of cervical human papillomavirus is five times higher than that of HIV-negative women. The risk of cervical cancer is higher in LMICs because of a lack of screening and precancer treatment services. The CASCADE Network supports the conduct of clinical trials in both LMICs and U.S. regions with health disparities to evaluate the effectiveness of interventions to optimize cervical cancer screening, management, and access, as well as precancer treatment for women with HIV. The network builds on existing service delivery infrastructures and uses hybrid effectiveness–implementation study designs to evaluate the effectiveness of clinical interventions. The FOA will support a coordinating center and multiple research bases and clinical sites to conduct six to eight multicenter clinical trials over a 5-year period.

Finally, Dr. Ali-Osman updated attendees on the Anal Cancer High-Grade Squamous Intraepithelial Lesions (HSIL) Outcomes Research (ANCHOR) study, a randomized controlled trial initiated in 2015 to determine whether treatment of anal HSILs will reduce anal cancer development in HIV-infected men and women. About 11,000 patients with HIV were screened to identify patients with previously untreated HSILs, who were randomized to a treatment arm or an active monitoring arm. In September 2021, the DSMB recommended halting the study based on the demonstrated efficacy of the treatment arm compared to active monitoring. The ANCHOR study showed conclusively that treating anal HSIL in people with HIV significantly reduced progression of HSILs to anal cancer. Dr. Ali-Osman noted that these study results are likely to change practice guidelines.

NIH HIV/AIDS Executive Committee (NAEC)

J. Rafael Gorospe, M.D., Ph.D., Health Scientist Administrator, Senior Science Advisor, OAR, NIH

Dr. J. Rafael Gorospe presented on behalf of NAEC, an internal NIH committee of all ICO HIV/AIDS coordinators that assists OAR in governance and coordination of research plans relating to HIV/AIDS. Dr. Gorospe reminded attendees that concepts represent the early planning stages of initiatives; the concept clearance process allows ICOs to receive feedback from their respective councils. Following concurrence by advisory councils, concepts are posted for transparency and to alert the research community that an FOA might be forthcoming. Dr. Gorospe noted that concurrence does not guarantee that a concept will become a funded initiative—the final decision is made by ICOs based on priorities and funds.

Between June and October 2021, 22 HIV-related concepts were cleared by advisory councils from the National Heart, Lung, and Blood Institute; the National Institute of Dental and Craniofacial Research; NIDA; NCI; and both the Division of AIDS and the Division of Microbiology and Infectious Diseases at NIAID. Dr. Gorospe noted that the details of many concepts are available on ICOs' websites for those who desire more information.

Discussion Highlights

When asked when data from the ANCHOR study will be published, Dr. Robert Yarchoan reported that the principal investigator and his team have promised to work as quickly as possible to submit data and already have contacted a journal and asked for expedited review. The results have been released and the patients notified.

OARAC members commended the development of the stigma toolkit, the examination of communications effectiveness, and the focus on LMICs.

Dr. Tolbert reported that Dr. Carlos del Rio was unable to present the report from the National Advisory Council on Drug Abuse meeting on September 15, 2021 and encouraged attendees to review the report included in the meeting materials.

Public Comment

CAPT Mary Glenshaw, Ph.D., M.P.H., OAR, NIH

CAPT Glenshaw confirmed that no public comments had been received.

Closing Remarks and Adjournment

Maureen M. Goodenow, Ph.D., OAR, NIH
Blanton Tolbert, Ph.D., OARAC Chairperson, Professor, Case Western Reserve University

Dr. Goodenow thanked the Council members and speakers and reminded attendees that the February meeting will be virtual.

Dr. Tolbert added his thanks and adjourned the meeting at 4:24 p.m. EDT.

Certification

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Blanton Tolbert Digitally signed by Blanton Tolbert Date: 2022.03.04 06:19:05 -05'00'

Blanton Tolbert, Ph.D.
Chair, OARAC

Date

Mary Glenshaw -S Digitally signed by Mary Glenshaw -S Date: 2022.03.08 12:31:12 -05'00'

CAPT Mary Glenshaw, Ph.D., M.P.H.
Executive Secretary, OARAC

Date