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

Office of AIDS Research Advisory Council
Fifty-Fifth Meeting

October 29, 2020
Virtual
https://videocast.nih.gov/watch=38731

Meeting Minutes

Council Members Present: Dr. Jennifer Kates (Chair), CAPT Mary Glenshaw (Executive Secretary), Dr. Maureen M. Goodenow (Director, Office of AIDS Research), Dr. Tabia K. Henry Akintobi, Dr. Ingrid V. Bassett, Dr. Margaret L. Brandeau, Dr. Tricia H. Burdo, Dr. John C. Chin, Dr. Kathleen L. Collins, Dr. Heidi M. Crane, Ms. Lynda M. Dee, Dr. Veronica Miller, Dr. William G. Powderly, Dr. Ricardo Rivero, Dr. Jonah B. Sacha, Dr. Kimberly K. Scarsi, Dr. Bruce R. Schackman, Dr. John W. Sleasman, Dr. Babafemi Taiwo, Dr. Blanton S. Tolbert

***Ex Officio* Members Present:** LTC Julie Ake, Dr. Carl W. Dieffenbach, RADM Jonathan Mermin

Advisory Council Representatives Present: Dr. Richard E. Chaisson, Dr. Alan Greenberg, Dr. Yuan Chang

OAR Leadership, Invited Speakers, and Guests: Dr. Stacy Carrington-Lawrence, Dr. J. Rafael Gorospe, Dr. Geetanjali Bansal

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Welcome and Introductions

CAPT Mary Glenshaw, Ph.D., M.P.H., Office of AIDS Research, National Institutes of Health
Jennifer Kates, Ph.D., MA, MPA, Kaiser Family Foundation

Dr. Jennifer Kates welcomed participants to the 55th 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, and minutes from the 54th OARAC meeting, held on June 25, 2020.

A motion to accept the minutes of the 54th OARAC meeting was approved unanimously.

Dr. Kates reviewed the 55th OARAC meeting agenda, noting the inclusion of time for public comments.

Report from the Office of AIDS Research (OAR) Director

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

Dr. Maureen M. Goodenow welcomed attendees and thanked them for their commitment to OARAC and advice on the NIH HIV research enterprise. She began by welcoming new OARAC members, who include diverse experts in many relevant disciplines from a variety of geographic areas. Dr. Goodenow emphasized that bidirectional collaboration allows the OAR to update OARAC on changes in HIV science as well as solicit advice from OARAC members regarding future directions for NIH initiatives to end the HIV pandemic and improve the health of persons with HIV. Dr. Goodenow introduced the new OARAC members—Drs. Tabia Akintobi, Kathleen Collins, Veronica Miller, Ricardo Rivero, and John Sleasman—and thanked Drs. Ingrid Bassett, John Chin, Jennifer Kates, and William Powderly for extending their terms.

Dr. Goodenow and RADM Jonathan Mermin reflected on the retirements of Steven Wakefield, Dr. Eugene McCray, and RADM Sylvia Trent-Adams, who have been critical partners in HIV research. Dr. Goodenow noted the death of Timothy Ray Brown, known as the "Berlin Patient" and recognized as the first person to be cured of HIV. She asked attendees to observe a moment of silence in remembrance of persons with HIV who have died of COVID-19. Dr. Goodenow recognized the 80th anniversary of the dedication of the NIH campus on October 31, 2020. She reiterated NIH Director Dr. Francis Collins' recent reminder of NIH's commitment to using the power of science to advance the health of all people with no distinctions of race, creed, or color and his emphasis on ameliorating the COVID-19 pandemic with science and humanity.

Dr. Goodenow provided updates on key OAR accomplishments from fiscal year (FY) 2020 and goals for FY 2021. The *FY 2021 NIH HIV/AIDS Professional Judgment Budget* (PJ), centered on the theme "Catalyzing Partnerships for HIV Prevention," was released in August. The PJ is developed annually to highlight the accomplishments and progress in HIV/AIDS research during the previous year and prepare a full-funding budget to accelerate critical research. The PJ requests an overall increase of approximately 25 percent and is spread over the five research priorities according to OAR's analysis of scientific gaps and opportunities. FY 2021 began on October 1, 2020, with a continuing resolution to provide temporary funding for government operations, including the NIH, through December 11. Under the continuing resolution, current operations will be maintained but no new projects will begin.

This year, the OAR developed its first 5-year *NIH Strategic Plan for HIV and HIV-Related Research* (the Plan), outlining a broad view of the NIH HIV strategy for FYs 2021–2025. This plan provides a roadmap for the NIH HIV/AIDS research portfolio, ensures that funds are allocated based on NIH HIV research priorities, and builds on scientific progress and opportunities to advance HIV/AIDS research. The plan was developed with input from a broad array of stakeholders and subject matter experts and is available on OAR's website.

Dr. Goodenow reviewed FY 2020 accomplishments and plans for FY 2021 in the context of the goals outlined in the Plan. **The first strategic goal is to advance rigorous and innovative research to end the HIV pandemic and improve the health of people with, at risk for, or affected by HIV across the lifespan**. Ensuring funds are invested in the highest areas of scientific priority is central to OAR's mission. OAR's efforts in this area since FY 2015 have resulted in nearly 100 percent of NIH HIV-related projects and dollars aligned to OAR's HIV-related research priorities. Multiple checkpoints have been integrated into the funding cycle to ensure that alignment continues. In addition to planned funding, the new 5-year length of the Plan gives OAR and the NIH the flexibility to respond to any unexpected challenges or opportunities, such as natural disasters, SARS-CoV-2, or adjustments to funding the Ending the HIV Epidemic (EHE) initiative, clinical trials, and treatment and prevention guidelines groups.

Drs. Goodenow and Dieffenbach represent the NIH on the HHS Operational Leadership team for the EHE initiative. In FY 2020, OAR's EHE activities focused on resource monitoring, systems development, and an overarching effort to develop the groundwork for a coordinated, NIH-wide approach to the initiative. Initial steps of NIH's EHE response included 65 awards to NIH Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs) in 43 of the 57 targeted EHE jurisdictions. OAR also developed a process for tracking FY 2020 EHE funding using OAR's budget systems and will refine the tracking process in FY 2021.

The NIH HIV/AIDS Executive Committee (NAEC) EHE Working Group—which consists of HIV/AIDS research coordinators from 12 Institutes, Centers, and Offices (ICOs)—was established to diversify and coordinate NIH EHE research. The working group reviewed almost 200 FY 2019 projects and grants that met EHE objectives to identify opportunities for future resource allocation and expansion of NIH EHE research. FY 2020 and planned FY 2021 projects will be reviewed to continue to improve coordination, disseminate lessons learned, and identify and address gaps in the portfolio. The critical goals and rapid timeline for the initiative make accelerated and iterative implementation and dissemination essential. In FY 2021 and beyond, the NAEC EHE Working Group will classify projects, identify opportunities, develop policies, and plan programs across the NIH. The OAR will continue to facilitate EHE-related activities across the NIH, including the Research Centers in Minority Institutions (RCMIs) and Institutional Development Award (IDeA) program states along with contributions from the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS). The OAR aims to prioritize diversification and inclusion within the EHE initiative across the NIH.

Additional priority activities to reach Strategic Goal #1 include the work of OAR's data analytics team. This group is expanding the Office's analysis of the NIH HIV research portfolio and will finalize a series of reports in FY 2021. Analyses are focused on funding trends and gap analyses and topics include EHE, early-stage investigators (ESIs), rural health, coinfections, and behavioral and social sciences research. The reports map research milestones, burden of disease and locations as a framework for integration with other HIV and related activities, to create synergy and expand research capacity building in the United States and internationally.

The Plan's second strategic goal is to ensure that the NIH HIV research portfolio remains flexible and responsive to emerging scientific opportunities and discoveries. COVID-19 was a focal point under this goal for FY 2020 and will remain so into FY 2021. The OAR and the NIH rapidly responded to telework guidance issued in March and ensured continuous and effective operations. Other activities in FY 2020 included the establishment of the OAR COVID-19 and HIV Taskforce and the publication of *Interim Guidance for COVID-19 and Persons with HIV*, produced by OARAC Clinical Guidelines working groups. In FY 2021, the OAR will assess the impact of COVID-19 on the HIV research agenda and infrastructure, develop guidance for intramural program reporting related to the effects of COVID-19 in FY 2020, and track and report on research recovery.

Dr. Goodenow emphasized that many of the major COVID-19 initiatives were built on existing HIV frameworks, which allowed research to make progress quickly. Recently, the Moderna phase 3 vaccine trial reached its enrollment goal of 30,000 participants—42 percent of whom are from high-risk groups. The NIH played an important role in the efforts to increase representation of minority groups in the trial population. Dr. Goodenow expects that the HIV field will in turn benefit from COVID-19 research progress, such as accelerating widespread telemedicine use, launching and expanding clinical trials, and implementing multiple simultaneous vaccine development efforts.

Recently, the OAR assumed management of the AIDSinfo and InfoSIDA websites, which include the Clinical Treatment Guidelines developed by the OARAC working groups. The new website—HIVinfo.nih.gov—includes resources and information outlined in the 1988 legislation that established the

OAR. The OAR partnered with the Department of Health and Human Services Office of Infectious Disease and HIV Policy to coordinate information dissemination for the Clinical Treatment Guidelines, which are located at the new clinicalinfo.hiv.gov website. These two sites will continue to offer access to the latest federally approved HIV/AIDS clinical treatment and prevention guidelines, as well as other HIV research information for health care providers, researchers, people affected by HIV/AIDS, and the general public. Dr. Goodenow expressed OAR's enthusiasm regarding the opportunity to work more closely with the Guidelines working groups.

The Plan's third strategic goal is to promote dissemination and implementation of discoveries. The OAR has been disseminating information through a variety of stakeholder engagements, and has been a strong presence at major HIV-related events. Examples include the International AIDS Society meeting (AIDS 2020), CFAR Directors meeting, annual NIH World AIDS Day celebrations, Southern AIDS Coalition meeting, 4th Annual Biomedical HIV Prevention Summit, and the Research Centers in Minority Institutions 2019 Conference. In FY 2020 OAR sponsored in-person events in the beginning of the year, and transitioned to all virtual events by March. Two of the three NIH-wide OAR Directors' Scientific Briefings to enhance dialogue and evaluation of new research were virtual, as was the AIDS 2020 conference satellite OAR organized titled "The Impact of NIH HIV/AIDS Research and Discovery at the Intersection of Prevention, Treatment, and Disparities Across the Lifespan." OAR's virtual stakeholder engagement activities will continue into FY 2021. The OAR-hosted NIH World AIDS Day event for 2020 will occur on December 1, and will focus on building the capacity of current and future generations to address 21st century challenges with 21st century solutions.

Dr. Goodenow noted that OAR's listening sessions have continued during the pandemic and OAR has observed a greater breadth and size of audiences than at the in-person events can. The next session—hosted by the Tennessee CFAR, Meharry Medical College, and Vanderbilt University—will occur on November 18, 2020, and a separate event will be hosted by faith-based and community groups. Planning for the spring sessions is ongoing; Dr. Goodenow invited comments and suggestions from OARAC members.

Key NIH HIV research areas in the 5-year strategic plan include health disparities and stigma. The NIH will support further research to better understand and address key individual, relational, community, and social-structural dynamics—including the role of stigma and discrimination—that fuel or mitigate HIV epidemics in diverse populations and settings. The OAR recently convened a scientific briefing on HIV, COVID-19, and health disparities. At a recent meeting of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund, and Joint United Nations Programme on HIV/AIDS (UNAIDS), Dr. Goodenow provided an overview of NIH HIV stigma research funded by NIH and PEPFAR. The meeting featured discussions on the People Living with Stigma Index, which is the most widely used survey measuring stigma and discrimination experienced by people living with HIV from their perspective. Another recent workshop, hosted by the OAR and the National Institute of Mental Health (NIMH), aimed to inform HIV efforts worldwide through furthering HIV-related intersectional stigma and discrimination research advances and opportunities, particularly as related to HIV prevention and treatment. The OAR commitment to addressing HIV-related stigma is reflected in Dr. Goodenow's representation as a member of the Presidential Advisory Council on HIV/AIDS (PACHA) Stigma and Discrimination Subcommittee.

Dr. Goodenow shared that the number of NIH projects related to stigma research broadly almost doubled from FY 2015 to FY 2019. This increase was driven by the number of stigma research projects in the HIV portfolio, which more than doubled. Funding increases follow a similar trend, with about 40 percent of NIH's $100 million in FY 2019 stigma research funds dedicated to HIV. Dr. Goodenow further noted that funding for HIV stigma research increased during the relatively flat HIV research funding allocation in this period. In summary, the total HIV stigma research investment has more than tripled since FY 2015, emphasizing the importance of HIV leadership in this field and the work by several NIH ICOs on this

topic. The NIH has dozens of active HIV projects around the world related to HIV stigma and discrimination. Dr. Goodenow noted that this important and relevant work continues to grow both internationally and domestically.

The fourth strategic goal outlined in the Plan is to build human resource and infrastructure capacity to enhance the sustainability of HIV research discovery and the implementation of findings by a diverse and multidisciplinary workforce. A dominant theme in the listening sessions was the need to increase support for Early Stage Investigators (ESIs). The OAR is committed to supporting NIH's effort related to ESI and to address the needs of the HIV research community specifically. In FY 2020, the OAR analyzed HIV ESI data from FY 2015 to FY 2019 to compare distribution and investment across the NIH. This analysis includes assessments of transitions between career development K awards and ESI applications for R01 and equivalent awards, and outlines potential frameworks, mechanisms, and programs that increase support to HIV ESI applications and advance careers. Through strategic investments, the OAR increased the number of HIV ESI awardees in FY 2020 and plans to continue doing so in FY 2021. Plans for 2021 include organizing an expert panel consultation, working with ICOs identify barriers to funding of HIV ESI's and l leveraging existing resources to increase the number of HIV ESIs in the pipeline, and, sponsoring a workshop to help identify challenges and opportunities for HIV ESIs, while continuing to track and report HIV ESI funding.

In FY 2020, the OAR entered a new collaboration with the National Institute of Minority Health and Health Disparities (NIMHD)to provide supplements for minor physical alterations or renovations to support ongoing HIV/AIDS research projects funded by the RCMI program. Two research supplements were funded. In FY 2021, the OAR plans to expand the program to provide additional supplements to RCMI, as well as provide supplements to IDeA states and Native American Research Centers for Health (NARCH).

Dr. Goodenow then acknowledged new OAR staff members:

- Danny Murphy, who joins OAR's Science Team as a Public Health Analyst;
- Danny Hanson, who comes to OAR as a Program Analyst; and
- Jasamine Stephens (contractor), who joined OAR's Front Office as OAR's Intra-Office Coordinator.

Before concluding her remarks, Dr. Goodenow reviewed the meeting agenda and informed attendees that the February 25, 2021, OARAC meeting will be held virtually, as will the annual new OARAC member orientation on February 24, 2021.

Discussion Highlights

Dr. Kates commended the alignment between projects and investments, which has been a focused effort for several years.

When asked how the current continuing resolution compounds the impact of the COVID-19 pandemic on research, Dr. Goodenow speculated that a short-term continuing resolution would likely not cause significant problems. Dr. Dieffenbach added that, because a full year of funding was anticipated, some projects already have been reviewed. Although the continuing resolution does not provide funds to mitigate the impact of the COVID-19 shutdowns—which would have to be part of a new appropriation—standard activities can continue, so forward progress has been maintained.

In response to a question about the current state of resuming research, Dr. Goodenow noted that the NIH Office of Extramural Research has released surveys to individual investigators and institutions to track the effects of the COVID-19 pandemic on the research enterprise. She invited OARAC members to comment

on the state of research at their institutions. Many members commented that their respective institutions have returned to partial or full capacity in basic or clinical research as long as researchers can be appropriately spaced and provided with personal protective equipment. Continuing challenges include field work that cannot be moved online, international collaborations, and logistical complications (e.g., a shortage of dry ice for shipping specimens). Members noted that institutional research boards (IRBs) have been more amenable to approving online components than previously. Much of the HIV clinical trials network enterprise has been diverted to COVID-19 clinical trials, which causes capacity issues. Although enrollments in the AIDS Clinical Trials Group (ACTG) have increased significantly since the spring, many of these enrollments are international. Participants noted that concurrent COVID-19 trials are ensuring that the HIV research infrastructure, which includes components such as ACTG, continues to be utilized, but the HIV research field must consider how to restore potential participants' confidence in the safety of in-person research visits unrelated to COVID-19.

HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups of OARAC Report Out and Discussion

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

Dr. J. Rafael Gorospe presented an overview of the HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups' recent activities. He reminded attendees that the seven sets of HIV clinical guidelines are posted on the Clinical Guidelines page of the Clinicalinfo.hiv.gov website. These guidelines are maintained by five separate panels, which are official working groups of the OARAC. Two other documents produced by the panels provide guidance on caring for persons with HIV in disaster areas and interim guidance on COVID-19 and HIV.

Dr. Gorospe briefly outlined the history of the guidelines. In the late 1980s, infectious disease clinical management began to address opportunistic infections; the OAR was established in 1988. In 1996, a public–private partnership convened a panel to provide evidence-based guidance on the use of three approved protease inhibitors, known as highly active antiretroviral therapy (HAART). The first antiretroviral treatment guidelines were published in the *Morbidity and Mortality Weekly Report.* Dr. Gorospe added that the perinatal guidelines was first published in 1996. In 2005, the Guidelines Panels became official working groups of OARAC.

Dr. Gorospe commented on the recent transition of AIDSInfo website and logistical support to the OAR. This transition has involved an uptick in OAR and panel engagement, which has increased OAR's understanding of how the panels function. Although each panel has evolved separately, Dr. Gorospe noted that some areas of the panels' operations could be harmonized and streamlined for consistency and uniformity. One idea is to create a steering committee with representatives of the five panels. Leaders of the five panels and the OAR met in October to share updates on the transition and OAR's plans and expectations moving forward. To date, the transition has been a success.

Dr. Gorospe asked OARAC members to provide further feedback on both the transition and reporting of guidelines updates at future OARAC meetings, noting that, as of the previous meeting, the process was changed to provide detailed updates in the briefing book instead of formal presentations.

Discussion Highlights

When asked who currently uses the guidelines, Dr. Gorospe explained that Google Analytics methodology has been implemented on the new website to study traffic; the OAR will monitor comments and inquiries as well. Many questions have been received from non-HIV providers both in the United

States and worldwide, and Dr. Gorospe plans to share more information when it is available. Participants commented that the guidelines can help non-HIV clinicians become more comfortable with HIV treatment standards.

One participant commented that Guidelines panels often provided information on the geographic location of site users and the most frequently visited pages. Although the guidelines' primary goal is to provide information to U.S. users, the guidelines are used extensively worldwide.

Participants commented that the National HIV Curriculum is used worldwide and references the guidelines repeatedly.

Listening Session Report-Out and Discussion

Stacy Carrington-Lawrence, Ph.D., Senior Science Advisor, OAR, NIH

Dr. Stacy Carrington-Lawrence reported on recent OAR outreach and engagement activities. OAR listening sessions aim to reach a more diverse set of stakeholders across the United States, provide a forum for constituents to communicate with the OAR and the NIH from local perspectives, and help the OAR make informed decisions regarding the NIH HIV research agenda. Many outreach activities were initiated in 2017 and 2018; the primary focus is on hearing perspectives from stakeholders where they work and live. On-site sessions primarily occurred in 2019 and have currently transitioned to virtual formats. Discussions during these listening sessions were framed around stakeholders' most important unanswered questions related to the HIV research priority areas; how attention to these topics will contribute to ending the HIV epidemic in the United States and globally; and what types of training, infrastructure, capacity-building, community engagement, and educational outreach efforts will be required.

Overarching themes from stakeholder feedback centered around the need for federal agency coordination and collaboration to facilitate HIV prevention, treatment, and care across the spectrum of social and structural issues affecting individuals and communities and the need to increase communication within and outside the NIH to highlight NIH-supported research. Some of the specific feedback received was used to inform the development of the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research*. Dr. Carrington-Lawrence reported that stakeholders:

- Emphasized the importance of maintaining a robust portfolio of HIV research at the NIH across scientific disciplines while focusing investment in top-level priority areas.
- Emphasized that the OAR should continue to conduct portfolio reviews and analyses, as well as outreach activities, to ensure that the most current HIV research priorities are being addressed.
- Indicated a desire to see more and stronger partnerships among federal agencies and improved coordination between public health officials and clinicians to ensure more rapid research dissemination and implementation across settings.
- Noted the importance of enhancing the pipeline of HIV researchers across disciplines and settings and ensuring institutional capacity to conduct cutting-edge science with community relevance.

Based on this feedback, the OAR has started to implement several action plans. An interim outreach and engagement report is in development and will be made available soon. The OAR has developed a communication strategy to disseminate information to stakeholders and within the NIH. Networks and strategies are expanding to reach populations most affected by the HIV epidemic and specific sectors engaged in HIV research efforts. The OAR will facilitate workshops that address the opportunities identified, as well as gather information from ICOs on activities currently underway that address the focus areas identified by stakeholders.

Three listening sessions have been held to date in 2020. The first 2020 listening session was held in person in Washington, DC, on February 20, 2020, and was hosted by the Washington, DC CFAR at Howard University. The other two sessions were held virtually in September. One was hosted by the Harvard University CFAR in Boston, MA; the other was hosted by West Virginia University and the Community Education Group in Morgantown, WV. Dr. Carrington-Lawrence noted the upcoming session in Tennessee. The recent listening sessions included additional questions, given the current research climate, to gain more insights into issues related to COVID-19 and social justice. Stakeholders were asked about: (1) the implication of current research strategies on the efforts related to EHE and developing a cure for HIV, as well as other research efforts, and how the NIH can maximize investments to meet goals; (2) the effects of COVID-19 and the racial justice movements on HIV research and how to continue conducting high-priority HIV science in these contexts; and (3) concrete steps that can be taken to meaningfully diversify the HIV research workforce.

Dr. Carrington-Lawrence emphasized that the OAR has listened and will continue to listen during future outreach events. She invited OARAC members to contribute thoughts, ideas, and questions.

Discussion Highlights

Ms. Lynda Dee pointed out that during the listening session held in Baltimore, community members outlined many ways in which their basic needs are not being met; without these basic needs, participants cannot begin to consider participating in research. Dr. Carrington-Lawrence concurred, emphasizing that the listening sessions have illuminated the unique issues that affect residents' lives at each location and connect research to the community. She noted that the high level of trauma-related issues, as well as the variety of trauma, were particularly noted in the Baltimore listening session. Trauma affects many ways in which participants could engage with HIV research; Dr. Carrington-Lawrence noted the childcare issues raised by Baltimore participants that affect their participation in trials as well. Dr. Goodenow added that the Baltimore listening session underscored the importance of engaging with the community outside of academic institutions and determining how to integrate these important issues into the projects sponsored by the NIH.

When asked how locations are selected and what further locations are being considered, Dr. Carrington-Lawrence explained that early selections were based on timing and the location of major HIV-related conferences as well as an effort to reach EHE jurisdictions. Initial recruitment for the listening sessions occurred via the OAR contacting CFARs, NIH networks, and community-based organizations in cities and states the OAR planned to visit. For present and future engagements, the OAR is trying to reach more diverse locations, which will be easier with virtual sessions. Locations considered include New Orleans and Baton Rouge in Louisiana; sites in Florida and Texas; and areas with large Native American populations, such as Oklahoma. Dr. Carrington-Lawrence emphasized the intent to choose strategic locations that also reach stakeholders across the country and internationally. After Dr. Carrington-Lawrence suggested that OARAC members could host sessions, Dr. Tabia Akintobi offered to facilitate a session hosted by Morehouse College. Dr. Goodenow emphasized the importance of utilizing OARAC members' contact networks to expand OAR's reach and determine locations at which listening sessions would be useful. Dr. Carlos del Rio commented on the necessity of the community seeing the NIH and the NIH seeing the community.

Dr. Carrington-Lawrence was asked to provide examples of improved coordination among federal agencies. She elaborated on the listening session feedback, which often centered on the interconnection between the dissemination of research and the overall care and treatment of people living with HIV. This link has not been as strong as it could be, suggesting that there is more to be done to ensure that connections among agencies are strong enough to rapidly disseminate the work of the NIH and the OAR. Listening session participants suggested additional partnership opportunities, such as those with agencies

related to housing or justice. OARAC members suggested that, even if the OAR is communicating with federal agencies at high levels, communication may be lacking at the local levels—where people's lives are most directly affected.

In response to a question about the *National HIV/AIDS Strategy (NHAS)*, Dr. Carrington-Lawrence agreed that the NHAS could be a mechanism to help bridge gaps between agencies. Dr. Kates noted that the NHAS is in the process of being updated; Dr. Goodenow added that updates are being performed in conjunction with the *National Viral Hepatitis Action Plan*, which has provided an opportunity for interagency collaboration. LTC Julie Ake clarified that these strategies are produced by different organizations within the Department of Defense (DoD), but collaboration is possible. RADM Jonathan Mermin added that a large amount of discussion about research gaps had occurred related to the EHE initiative, much of which was incorporated into the NHAS draft and will be applicable moving forward. Overarching strategies have been established to enable the right environment and framework, and important details are provided by NIH-led engagement activities. The NHAS includes a strong focus on continuing downward trends and reducing disparities. Ms. Dee pointed out that the Health Resources and Services Administration (HRSA) specializes in meeting basic needs, yet collaborations with HRSA are lacking. She added that the EHE initiative does not address mental health.

Dr. Carrington-Lawrence reiterated that strategies developed to address HIV have been used to address COVID-19 and that COVID-19 strategies likely will inform future HIV efforts. She reminded OARAC members that one of the questions for the new listening sessions is related to disparities in HIV and COVID-19.

LTC Ake noted that DoD systems include a diverse population of people living with HIV who have similar access to health care; treatment cascade data published within the DoD health system show good results, demonstrating the importance of access and understanding gaps. She commented that trials are improving at assessing usability, access, and how procedures fit into trial participants' lives, but the inherent limitation is that many people cannot surmount challenges in their daily lives to become trial participants. OARAC members added that federally funded researchers may be viewed with skepticism by people who do not believe that the government is addressing their needs.

Updates from the NIH Advisory Council Representatives

AIDS Research Advisory Committee (ARAC)

Richard E. Chaisson, M.D., Professor of Medicine, Epidemiology, and International Health, Johns Hopkins University School of Medicine, Baltimore, MD

Dr. Richard Chaisson provided updates on the September 14, 2020, ARAC meeting. He highlighted discussions and data related to the success of K grant awardees. About 90 percent of former recipients of NIAID K awards applied for a subsequent research project grant (RPG); approximately 60 percent of those applicants were funded. The percentages of former K award applicants who applied for and received R01 grants were slightly lower. When applicants were assessed according to their degrees, data showed that Ph.D. researchers apply for and receive more RPGs and R01s than researchers with clinical degrees; Dr. Chaisson suggested that these researchers likely apply for more grants because they cannot apply for clinical positions as backup. These analyses showed that overall, a large proportion of K awardees subsequently compete successfully for RPGs and R01s. Dr. Chaisson noted the small but important number of K awardees who never apply for subsequent grants. He pointed out that K awardees within DAIDS have slightly higher success rates than those in NIAID overall. Dr. Chaisson commented that these data are encouraging regarding the success of the K award pipeline and the success of the K

award program as a whole, both within DAIDS particularly and throughout NIAID generally. He directed attendees to the ARAC website for more information about programs reviewed and approved during the meeting.

National Advisory Council on Drug Abuse (NACDA)

Carlos del Rio, M.D., Department of Global Health, Rollins School of Public Health, Emory University School of Medicine, Atlanta, GA

Dr. del Rio emphasized that the beginning of the COVID-19 epidemic in the United States coincided with a period during which the national response to the opioid crisis was coalescing into stronger action, creating a "collision of epidemics." COVID-19 has left many people locked down, laid off, and in uncertainty. Alcohol and drug purchase levels have increased; drug use has become riskier. Overdoses have increased dramatically during the COVID-19 pandemic. After a period of stabilization, drug-involved deaths have resumed rising. For those with substance use disorder (SUD) or opioid use disorder (OUD) who already were in care, the disruption in care—particularly access to medications for addiction treatment—is a problem. The Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance that increases the ability of opioid treatment programs to transfer treatment to take-home methadone maintenance protocols. Additionally, the U.S. Drug Enforcement Administration has allowed remote prescription of buprenorphine if two-way audiovisual communication between the prescriber and the patient is in place; however, patients may not have adequate data access plans to support this system. Dr. del Rio emphasized that COVID-19 threatens to halt much of the essential SUD and OUD clinical research.

Dr. del Rio noted a recent study showing that those with a recent diagnosis of SUD are at significant risk for COVID-19. The effect is strongest for individuals with OUD. African Americans with SUD have a significantly higher risk of COVID-19 compared to white individuals. Additionally, patients with both COVID-19 and SUD have significantly worse outcomes than COVID-19 patients who do not have SUD. Dr. del Rio emphasized that SUD appears to increase both susceptibility to and complications from COVID-19. He noted two other studies, one showing that crystal methamphetamine is the biggest risk factor for HIV seroconversion among gay men in the United States today and another indicating that both acute and chronic opioid exposure may suppress antiviral immunity. Further studies are needed to fully understand the implications of chronic opioid usage on susceptibility to HIV and other opportunistic infections in people with OUD. Dr. del Rio displayed a list of NIDA HIV initiatives.

National Advisory Mental Health Council (NAMHC)

Alan Greenberg, M.D., Chair, Department of Epidemiology and Biostatistics, Milken Institute School of Public Health, The George Washington University, Washington, DC

Dr. Alan Greenberg reminded attendees that NAMHC largely addresses issues not related to HIV. At its most recent meeting, two concept clearances were approved. The first is a P30 mechanism to support infrastructure to develop high-impact science in behavioral science and neuro-HIV that is complementary to the CFAR program. Updated research directions and priority areas associated with this mechanism are addressing systematic factors that influence health disparities, optimizing the impact of new prevention and treatment strategies, collaborating with local health departments and community-based organizations, and studying biologic mechanisms of HIV-associated central nervous system dysfunction and mental health outcomes. The second concept aims to strengthen HIV prevention efforts among women in the southern United States. Use of pre-exposure prophylaxis (PrEP) is low among women in the South because of a lack of awareness and access, low perceptions of risk, gender-based violence, economic concerns, stigma, and syndemics. The initiative will support implementation science to understand how EHE efforts are reaching women, mass media research to improve awareness of and interest in HIV prevention, and services research to expand the number of options available to women.

Discussion Highlights

RADM Mermin commented on the intersection between injection drug use and HIV, noting that the recent increases in stress have increased drug use, likely for some time. He added that syringe service programs and treatment sites are stressed and asked Dr. del Rio whether any discussions have addressed what strategies could be implemented to reverse the negative effects and prevent increases in HIV infection. Dr. del Rio responded that he was not aware of any discussions related to needle exchange, access to PrEP, or improving access to HIV testing. He explained that HIV testing rates have dropped significantly, causing worry about micro-epidemics, so innovative strategies are needed.

OAR Taskforce on COVID and HIV Update

Jennifer Kates, Ph.D., Kaiser Family Foundation

Dr. Kates reported on the OAR Taskforce on COVID-19 and HIV, which has met several times since the previous (June 2020) OARAC meeting. She reminded attendees of the taskforce's charge—to provide input to the OAR on focus areas and action plans in the HIV and COVID-19 space and to foster bilateral discussions between the OAR and HIV stakeholders on shared scientific, programmatic, and operational interests relevant to HIV and COVID-19. The taskforce consists of eight OARAC members, eight NAEC representatives, two invited stakeholders, and four OAR science staff members.

The most recent meeting focused on COVID-19 and HIV global health issues, updates on NIH COVID-19 initiatives and programs, OAR COVID-19 and HIV activities, and related funding and research activities from NIH ICO representatives. Discussions centered on research recovery and vaccine implications. Dr. Kates commented that the COVID-19 pandemic has highlighted global public health vulnerabilities, particularly for populations affected by HIV and in resource-limited health and research infrastructures that focus on HIV. Some low- and middle-income countries (LMICs) are leading large-scale, coordinated, and comprehensive responses amid challenges posed by COVID-19. Features of COVID-19 responses in LMICs include commitment to response at every level of government, implementation of diagnostics or testing, contact tracing with community engagement, utilization of coordinated surveillance, dissemination of COVID-19 risk communications, and leveraging existing health care infrastructures, including those for HIV.

Dr. Kates encouraged attendees to review UNAIDS' recent report, *COVID-19 and HIV: 1 moment, 2 epidemics, 3 opportunities—how to seize the moment to learn, leverage and build a new way forward for everyone's health and rights*. The report discusses how countries are using the experience and infrastructure of HIV to ensure a robust response to COVID-19 and HIV pandemics. The report focuses on human rights, stigma, and discrimination, as well as the importance of community engagement. Dr. Kates noted PEPFAR's rapid and early pivot to responding to COVID-19 and providing guidance on how to continue essential HIV services safely. PEPFAR guidance is updated regularly and has provided significant flexibility for programs' service delivery, allowing providers to continue caring for persons with HIV with reduced staff and procedures to reduce COVID-19 exposure in health care settings. Dr. Kates noted that implementation of multi-month drug dispensing and telehealth have been desired for a long time, but the COVID-19 pandemic has provided the incentive for rapid implementation.

Dr. Kates displayed an overview of current COVID-19 clinical trials and studies and noted the updates to the treatment guidelines, including the *Interim Guidance for COVID-19 and Persons with HIV*, published originally in March 2020 and maintained by the OARAC clinical HIV guidelines working groups, and the more recently published *COVID-19 Treatment Guidelines*, which are maintained by NIAID and include a

section on special considerations in persons with HIV. Another initiative in progress is NIH's Rapid Acceleration of Diagnostics (RADx) initiative; RADx aims to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing.

Dr. Kates outlined relevant topics the Taskforce has been discussing. For HIV research recovery, most research institutions are engaged in phased reopening of laboratories, many of which are currently at 75 percent capacity. Patient-centered research has pivoted to remote and digital platforms. More clarity is needed regarding factoring in COVID-19 issues into recruitment plans for new studies in applications. Additionally, the prioritization of COVID-19 activities has caused logistical challenges for EHE-related work and increased researchers' clinical responsibilities. As referenced earlier by Dr. Goodenow, Dr. Kates noted that the NIH has deployed a survey to understand the effects of the COVID-19 pandemic on extramural research; results likely will be shared by the NIH soon.

Discussions of the multifold economic impact noted budget cuts to state, local, and community partners and challenges in how to support and adapt non-laboratory research. The continuing resolution and limited institutional support have made awards uncertain. Hiring freezes impact ESIs' ability to obtain faculty positions. Additional discussions centered around the implications of a vaccine and the opportunity to leverage HIV research experience relevant to the inclusion of health disparity populations in vaccine trials, delivery planning, and uptake hesitancy.

Discussion Highlights

Dr. del Rio commented that the reason HIV research has been overtaken by COVID-19 research is because the researchers are the same—these researchers do not have the capacity both to continue their former HIV research and to conduct new COVID-19 research, and hiring freezes prevent institutions from adding researchers. Dr. del Rio reiterated that the research networks built for HIV enabled the rapid studies and trials for COVID-19. OARAC members commented on this issue at their own institutions and underscored the shortage of researchers and staff.

LTC Ake noted the decrease in prevention services and stressed the need to understand the importance of risk behavior related to transmission rates.

Dr. Goodenow asked OARAC members for ideas on how to prioritize research recovery when the budget to resume research is limited. Members suggested that the NIH could make accommodations for some types of awards, reflecting the difference in impact between laboratory and non-laboratory research, or allowing personnel funds to purchase equipment so that researchers can maximize productivity while maintaining appropriate physical distancing. A budget report could help quantify the impact.

Dr. William Powderly emphasized that the NIH can show leadership by ensuring that the disproportionate effect of the COVID-19 pandemic on women investigators is addressed and that any response includes not only racial and ethnic equity but gender equity.

Public Comment

Jennifer Kates, Ph.D., Kaiser Family Foundation

CAPT Glenshaw summarized an anonymous public comment criticizing the use of public funds for vaccine development and the use of NIH funding for research conducted internationally, as well as animal model research generally. The comment additionally attributed NIH funding decisions to downturns in the U.S. economy.

Closing Remarks and Adjournment

Maureen M. Goodenow, Ph.D., OAR, NIH
Jennifer Kates, Ph.D., Kaiser Family Foundation

Dr. Goodenow thanked the Council members and speakers and commended the productivity of this meeting.

Dr. Kates added her thanks and adjourned the meeting at 4:29 p.m. EDT.

Certification

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

– S –	3/18/2021
Jennifer Kates, Ph.D. Chair, OARAC	Date

– S –	3/10/2021
CAPT Mary Glenshaw, Ph.D., M.P.H. Executive Secretary, OARAC	Date