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

Office of AIDS Research Advisory Council
Fifty-Fourth Meeting

June 25, 2020
12:00 PM- 4:15 PM ET
Virtual Meeting

Meeting Minutes

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

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

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

OAR Leadership, Invited Speakers, and Guests: RADM Timothy Holtz, Ms. Amber Wilson

Public Comment Participants: Mr. Jules Levin

Welcome and Introductions

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

Dr. Jennifer Kates welcomed participants to the fifty-fourth meeting of the National Institutes of Health (NIH) Office of AIDS Research Advisory Council (OARAC). Meeting materials provided to Council members included the agenda, presentation materials, a conflict-of-interest form, and minutes from the fifty-third OARAC meeting, held on February 27, 2020.

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

Dr. Kates reviewed the fifty-fourth 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 the OARAC and advice on the NIH HIV research enterprise. She thanked the OAR team for their hard work, dedication, and flexibility while teleworking.

Dr. Goodenow began with comments on diversity and inclusion at the NIH, recounting NIH Director Dr. Francis Collins' statement denouncing the ongoing bias and prejudice behind racially motivated violence. Dr. Goodenow underscored Dr. Collins' message that these actions are a crime against humanity and antithetical to NIH's commitment to reducing suffering and promoting health for everyone, and that diversity fuels creativity and draws innovation. Dr. Goodenow expressed her pride in the diversity at the OAR, and among HIV stakeholders both within the NIH and across the network of external partners. The OAR recently engaged expert facilitators to lead a session sharing thoughts and experiences regarding systemic racism. Dr. Goodenow encouraged participants to seize the opportunity of this pivotal moment to journey toward reconciliation and healing.

Dr. Goodenow announced that the HIV Prevention Trials Network (HPTN) 083 study showed that the long-acting injectable cabotegravir was as effective as daily oral Truvada® for HIV prevention in a study population of cisgender men and transgender women who have sex with men. In light of these encouraging results, investigators recommended termination of the blinded phase of the study. A companion study, HPTN 084, is comparing the long-acting injectable cabotegravir with daily oral Truvada in cisgender women in South Africa and the DSMB will review data later this year.

Dr. Goodenow reminded attendees that the fiscal year (FY) 2021 Congressional Justification Budget was released earlier in the year and is available on the OAR website, which recently was updated to improve user-friendliness. OAR is in the final stages of preparing the FY 2021 Professional Judgment Budget (PJ), which is an aspirational budget that explains how requested increases would provide the NIH with the resources needed to address specific critical scientific studies related to the portfolio for HIV. The FY 2021 PJ theme is "Catalyzing Partnerships for HIV Prevention" and the document will be posted to the OAR website when cleared.

In September 2019, the OAR and the National Heart, Lung, and Blood Institute cosponsored a 2-day HIV action workshop focused on comorbidities, coinfections, and complications. The June 17, 2020, issue of *Pathogens and Immunity* features a review article that describes the highlights of the discussion during the workshop, which focused on three priority topics: immunopathogenesis, the microbiome and virome, and aging and senescence. The article summarizes research and key questions on the pathogenesis of aging and age-related comorbidities in persons with HIV. Discovering the drivers and mechanisms underlying HIV pathogenesis will help researchers identify therapeutic targets to improve the health span in older persons with HIV.

Upcoming OAR activities include the International AIDS Society annual meeting (AIDS 2020), which has shifted to a virtual platform. The OAR is leading an NIH satellite session on the intersection of HIV prevention, treatment, and disparities across the lifespan. The live session and panel, moderated by Dr. Kates, will be combined with prerecorded content. Dr. Goodenow is scheduled to present live opening and closing remarks. The OAR is also planning a series of upcoming virtual workshops and listening sessions to maintain engagement with stakeholders. A planned workshop on HIV and intersectional stigma, cohosted with the National Institute of Mental Health, has been restructured into three phases: an opening session, a series of working group meetings, and an open public report-out.

The OAR will hold two events to address the needs of early-stage investigators (ESIs). The first event will convene a virtual expert panel in late 2020 to consult with expert principal investigators, mentors, private-sector representatives, and successful ESIs in the HIV field. The second event will be an ESI workshop in later in 2021, informed by the expert panel, to learn about the experiences of junior investigators and ESIs and provide input and guidance. This workshop will help the OAR develop a roadmap to expand and improve the landscape for ESIs, who Dr. Goodenow noted are a critically important part of the biomedical research workforce. Furthermore, the OAR will move forward with listening sessions to reengage with the community. The strategic framework for future listening sessions will be adjusted based on feedback from priority populations.

Dr. Goodenow commented on the NIH response to COVID-19. The NIH quickly transitioned to maximum telework and established an internal informational website. The NIH has established a plan for returning staff to the office in successive groups and has published guidance for investigators on the protection of research participants and staff. Mitigation efforts instituted by local, state, and federal agencies affected the operations of NIH-funded clinical research and clinical trials, resulting in the halting of research at most academic institutions across the country. The OAR will work with stakeholders to alleviate the impact on research and identify ways to commence recovery efforts. The NIH has provided supplemental funding to several Institutes, Centers, and Offices (ICOs) for research in specific areas related to COVID-19.

A major initiative, Operation Warp Speed, aims to develop substantial quantities of a safe, effective vaccine by January 2021. This public-private partnership, involving multiple agencies, facilitates an unprecedented pace of development, manufacturing, and distribution of COVID-19 countermeasures. The Accelerating COVID-19 Therapeutic Interventions and Vaccines partnership (ACTIV) is another public-private partnership and is aimed at speeding vaccine and treatment research. The NIH Rapid Acceleration of Diagnostics initiative is aimed at accelerating the innovation, development, and commercialization of COVID-19 testing technologies. The NIH is seeking opportunities to move more advanced diagnostic technologies through the development pipeline toward commercialization and broad availability.

Dr. Goodenow outlined COVID-19-related HIV research activities at the NIH, including studies to assess the impact of COVID-19 on HIV comorbidity, coinfection, and complications and examine the risk outcomes for COVID-19 and HIV-affected populations. Research on the intersection of COVID-19 mental health and HIV treatment and prevention is planned. The ICOs' requests for administrative supplements related to COVID-19 to date relate to the impacts on HIV comorbidities, coinfections, and complications; risks and outcomes in substance-using populations with HIV; and the intersection of COVID-19 mental health and HIV treatment and prevention. Some long-running studies have been able to move to remote operations quickly; Dr. Goodenow commented that the harmonization of these changes will be invaluable in measuring the long-term effects of COVID-19.

Prior to the June meeting, OAR obtained a notational vote from the OARAC to publish interim COVID-19 treatment guidance developed by representatives from the five treatment guidelines panels for persons with HIV. The OAR participated in the development of potential NIH-wide initiatives to address the pandemic, including centralizing coordinated clinical trials infrastructure across the NIH and enhancing efficiency, planning, launching, and execution of ongoing and future COVID-19 clinical studies that include key populations and persons at risk. Furthermore, the OAR is working across the NIH to address the anticipated exacerbation of existing socioeconomic and health disparities..

The OAR released an interim policy document to provide guidance to the ICOs on managing supplements and grants related to COVID-19 in the context of HIV and with research using HIV funding. The policy is aimed at ensuring that such research conforms to current priorities and allows researchers the flexibility to adjust to new information about the effects of COVID-19 on persons with HIV. Additional OAR

activities related to COVID-19 include the formation of the OAR Task Force on COVID-19 and HIV (discussed later during this meeting), and CAPT Glenshaw's deployment to a COVID-19 community testing site. As the NIH representative on the Presidential Advisory Council on HIV/AIDS, Dr. Goodenow presented on various agencies' perspectives on the challenges for the *Ending the HIV Epidemic* initiative in relation to COVID-19. Dr. Goodenow displayed data showing the current global distribution of HIV and COVID-19. The United States, overall, has a high prevalence of COVID-19 and a low prevalence of HIV, but several hotspots overlap.

Dr. Goodenow recognized the recent passing of notable HIV advocates and researchers, including:

- Larry Kramer, a renowned advocate and writer, who was instrumental in bringing needed attention to the HIV and AIDS crisis to the forefront in the United States. His role with the Gay Men's Health Crisis and the AIDS Coalition to Unleash Power, or ACT UP, were critical to unleash the scientific funds needed to address the epidemic and give voice to the community.

- Dr. Frank Plummer, a world-renowned microbiologist and professor at the University of Manitoba. Dr. Plummer is known for his ground-breaking research in Africa to understand HIV transmission as well as his work to develop HIV vaccine.

- Dr. Gita Ramjee, who was the Chief Scientific Officer at the Aurum Institute, a leading authority in the fight against HIV and TB, and a world-renowned virologist who made a tremendous impact in the science of HIV prevention, with a focus on women.

- Dr. Ron Simmons, who was President and CEO of Us Helping Us. An HIV survivor, he worked tirelessly to support the health of gay and bisexual African Americans, had been a faculty member at Howard University, and was an original member of the DC Center for AIDS Research (CFAR) Community Advisory Board.

- Deloris Dockrey, a champion for women living with HIV and long-term survivor of HIV, who was the Director of Clinical Services at the Hyacinth AIDS Foundation.

In concluding her remarks, Dr. Goodenow welcomed and introduced the following new staff: Michael Apata (Program Analyst/Contracting Officer Representative), Debbie Brathwaite (contract Travel Planner), Kelley Lennon (contract Communications Advisor), Wendy Papier (Communications Specialist), Candace Sibley (Health Science Policy Analyst), Kristen Riesberg (contract Program Support Assistant), and Mick Williams (contract Program Support Analyst).

Discussion Highlights

When asked whether the HIV field can offer any lessons to help assuage disparities highlighted by COVID-19, Dr. Goodenow emphasized that many disparities are exacerbated by structural barriers. Although the HIV field has not surmounted those barriers completely, HIV experts can offer guidance and lessons learnedfor COVID-19. She pointed out that, additionally, COVID-19 diagnosis, treatment, and vaccine trials should be developed without exclusion criteria for people with HIV and actively include them in appropriate locations.

In response to a question about potential mask studies at the NIH, Dr. Goodenow suggested that the National Institute for Nursing Research, which has an interest in community health, could consider such studies.

Participants suggested linking the *Ending the HIV Epidemic* initiative activities to COVID-19-related activities, particularly because the many years of investment in HIV research infrastructure are the reason this infrastructure is available to conduct COVID-19 research. The Centers for AIDS Research (CFARs) were able to apply to the new Rapid Acceleration of Diagnostics (RADx) initiative, allowing them to take advantage of existing partnerships to work on this effort.

Although the maps of HIV and COVID-19 incidence currently do not overlap entirely, projections for global COVID-19 involvement suggest that the maps may align more in the future. Participants encouraged the NIH to consider global context when appropriate.

Dr. Kates commented on the connections to stigma and discrimination, noting that HIV has shown that structural issues and lack of access, rather than behaviors, are the strongest contributors to infection rates. The NIH and Centers for Disease Control and Prevention could work to clearly identify why some people are put in situations that increase their risk of infection, as well as the reasons certain groups are at higher risk of severe disease and death.

Update Discussion: HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups of OARAC

Jennifer Kates, Ph.D., Kaiser Family Foundation

Dr. Kates informed attendees that two sections were added to the Adult and Adolescent Opportunistic Infections Guidelines, which currently are being edited. The guidelines now contain a section on interim guidance for COVID-19 and persons with HIV. This was a joint effort by all five guidelines panels and continues to be updated as more information becomes available. The update stresses that whether persons with HIV may be at higher risk for complications associated with COVID-19, apart from underlying health conditions, remains unknown. The guidelines emphasize that persons with HIV should be treated the same as other patients for clinical management and medical triage.

Other guidance provided is aimed at clinicians and persons with HIV obtaining adequate medications and monitoring frequency during the pandemic, noting that telehealth may be helpful in lieu of in-person visits. The guidelines emphasize the importance of continuing antiretroviral treatment and monitoring drug-drug interactions, overlapping toxicities, and areas that need more research. New information is provided on special COVID-related considerations for children and for people with HIV who are pregnant. The updates made most recently addressed the risks of gender-based violence against women and girls, as well as recommendations for pregnancy planning in the context of the COVID pandemic.

Discussion Highlights

When asked whether the COVID-specific guidelines panel includes community representation, Dr. Alice Pau responded that because the group was formed within 48 hours, the initial membership comprised people who were known to respond quickly. As the panels move into the maintenance phase after the initial release of the first set of guidance, the group is working to identify potential community representatives.

Dr. Henry Masur noted the important consideration of whom community members should represent on the COVID panel; although many concerns overlap with HIV, many others are different. Community representation in the execution of studies is another important consideration. Participants suggested that community members involved in other panels could mentor new representatives to the COVID panel, noting the importance of engaging with populations strongly affected by COVID, including the difficult-to-reach populations of people who have poorer access to both housing and resources to stay home and

stay safe. Community participants could be gathered by working with a network of community engagement programs across the country.

OARAC *Ending the HIV Epidemic* Opportunities Analysis

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, OAR, NIH
Ms. Amber Wilson, M.P.H., The Scientific Consulting Group, Inc.

Ms. Amber Wilson provided an orientation to the *Ending the HIV Epidemic* (EHE) initiative , noting that it is a once-in-a-generation opportunity for agencies to work together to implement, monitor, and study expansions and innovations in HIV prevention, treatment, and response activities over the next 10 years. The overarching goals of the initiative are to reduce new HIV infections in the United States by 75 percent by 2025 and by at least 90 percent by 2030. Phase 1 of the initiative focuses on the 57 jurisdictions that account for more than half of new HIV infections in America. The initiative is operationalized through four pillars focused on diagnosing, testing, preventing, and responding to HIV domestically. The NIH strategic goals for HIV-related research align with these pillars and are to: (1) advance rigorous and innovative research, (2) ensure that NIH's HIV research program remains flexible and responsive to emerging scientific opportunities and discoveries, (3) promote dissemination and implementation of research discoveries, and (4) build human resource and infrastructure capacity.

The initial NIH research focus for this initiative prioritizes implementation science to demonstrate the most effective strategies to adopt and integrate evidence-based HIV services, interventions, and policies that support the most affected populations and jurisdictions. NIH's HIV research includes biomedical, behavioral, and social science approaches to address EHE pillars. The OAR monitors, tracks, and reports on *EHE* research across the ICOs. Furthermore, the NIH collaborates with stakeholders, implementation partners, agencies, and communities.

The EHE discussion panel of representatives from key agencies held during the February 2020 OARAC meeting was the primary data source for Ms. Wilson's analysis, which focused on reviewing research opportunities suggested during this panel, determining the responsiveness of the current research portfolio, and continuing feedback with the OARAC about the initiative. A list of FY 2019 EHE-related research projects submitted by nine ICOs was incorporated into the analysis; further analysis of this project list is ongoing.

The analysis of the panel discussion identified 50 EHE research opportunities in nine primary categories. The list of EHE-related research projects submitted by the ICOs includes 321 projects, 185 of which currently are deemed relevant to the initiative. Ms. Wilson analyzed these and grouped them into five broad themes.

- The first theme captures opportunities related to research on social determinants of health, implementation science, and health disparities to address the needs of those disproportionately affected by HIV.

- The second theme centers on the HIV care continuum, including primary prevention and linkage to care.

- The third theme—supportive activities—includes fostering collaboration and strengthening the HIV workforce.

- The fourth theme—health outcomes—includes research opportunities related to substance use disorder and sexually transmitted infections.

- The last theme captures the use of social media and applications (apps) for HIV efforts.

During the panel discussion, the mentions of research areas within the first theme represented half of the discussion. Aspects of the second and third themes were mentioned six or seven times each; the remainder of the topics were mentioned less frequently. Ms. Wilson provided a snapshot of the research activities from the 185 FY 2019 projects aligned with the common foci of social determinants of health, implementation science, health disparities, primary prevention, linkage to care, collaboration, strengthening the workforce, substance use disorder, sexually transmitted infections, social media, and apps. She noted several example studies within each focus area.

Ms. Wilson concluded that most of the research opportunities noted in the February 2020 OARAC meeting are well represented in the list of FY 2019 projects, but some may be underrepresented. Less represented opportunities include research to assess the utilization of social media microinfluencers; behavioral, social science, basic, and epidemiological research on COVID-19 among EHE populations and jurisdictions; novel implementation research on ways to replicate integrative care approaches; and continued and expanded collaboration with research institutes and minority institutions. The review of the alignment between the portfolio and available opportunities is ongoing, but the NIH remains responsive to additional ideas for FY 2021 and beyond. The OAR is reviewing, tracking, and monitoring the NIH HIV portfolio for its timeliness and alignment with *Ending the HIV Epidemic* research needs.

Discussion Highlights

Ms. Wilson clarified that the list of research projects was gathered in response to a call made in early 2020 from the OAR to ICOs requesting information on their *Ending the HIV Epidemic* activities and funded projects.

CAPT Glenshaw clarified that many of the examples were supplements to CFARs and AIDS Research Centers (ARCs) that were provided to launch the *Ending the HIV Epidemic* initiative before EHE funding officially was allocated. Most of those were 1-year pilots; additional supplements and 2-year projects currently are being reviewed. Participants suggested tracking whether those projects will lead to future larger-scale projects.

When asked how to align the identified gaps with OAR priorities, Dr. Goodenow explained that collection of data on grant distribution is a first step to determining how to align the priorities further. She emphasized that 2020 is the first official year of funding for the initiative; although ARCs and CFARs were used to start the initiative, the research footprint will need to be expanded.

OAR Task Force on COVID-19 and HIV: Report Out and Discussion

Jennifer Kates, Ph.D., Kaiser Family Foundation

Dr. Kates explained that a new task force was charged with assisting the OAR in defining its focus areas and action plans in HIV and COVID-19. The task force aims to identify focus areas, priorities, and a timeline. The main activities to date include solicitation of scientific and operational considerations from the NIH AIDS Executive Committee and review of feedback on these responses. The task force then identified priorities, timing, and feasibility for each area discussed.

Recent COVID-19 and HIV-related milestones at the NIH include the publication of guidance related to NIH-funded clinical trials and studies affected by COVID-19 released on March 16 and interim clinical guidance for COVID-19 and people with HIV released on March 20. Since that time, 29 NIH Notices of Special Interest on COVID-19 and two Notices of Special Interest on HIV and COVID-19 have been

released. Dr. Kates noted the number of publications between January and June that focused on COVID-19, specifically, or both COVID-19 and HIV.

The first priority focus area identified by the task force was to describe the impact of COVID-19 on the entire HIV research enterprise. The task force assessed discovery and innovation, suspension and recovery of operations, and research and professional advancement. In the second focus area—COVID-19 Clinical Research for Persons with HIV—the task force assessed the intersection of the two viruses and the implications for research. The third focus area revolved around research on the fundamental knowledge of HIV and SARS-CoV-2 coinfection. In terms of disparities, the task force sought to explore how complex interaction further affects disparities. The task force also discussed the basic epidemiology of both viruses, as well as the pathophysiology, disease course, and basic science.

The task force identified several critical areas important to monitor, including comparative health disparities in the United States and globally, health outcomes across the lifespan, access for persons with HIV and other vulnerable populations affected by the pandemic, economic and environmental factors, and novel approaches. Among those approaches are telehealth, the role of community, and diagnostics and therapeutics. The task force discussed behavioral and social factors and basic science, as well as competition for resources.

Discussion Highlights

Participants expressed concern that researchers early in their careers who have been called to support COVID-19 patient care would be affected by the lower research productivity during this critical time in their careers. Participants noted that all investigators, regardless of career stage, will be affected by this situation. Established infectious disease researchers, unable to conduct research on HIV, have shifted their research focus, thus reducing the size of the HIV workforce. These changes should be tracked and addressed whenever possible. If skilled researchers can be encouraged to enter the field of virology and infectious disease research, some of those researchers may move into HIV research. Furthermore, participants suggested that the ability of the HIV research system to recover will depend on how long the pandemic lasts. Attendees suggested including community members in the discussions of trial designs, reviews, and protocols. Dr. Kates noted that the task force is planning additional discussion on research recovery efforts and community participation..

Participants expressed concern that the *Ending the HIV Epidemic* efforts would lose focus or funding as a result of the pandemic. Dr. Kates added that this is a fundamental concern of the task force. Attendees commented that collateral damage of COVID-19 on the HIV infrastructure must be explored, including how well people are maintaining their treatment and how they are adapting to the new environment. The effects of age on both the course of COVID-19 and the HIV population in America, as well as the interactions of multiple medications, must be explored. Participants noted that the impact of this epidemic on other major health issues, especially in resource-constrained settings, must be quantified and will be important for policy.

An attendee encouraged the HIV community to celebrate that their expertise and skills have been able to contribute to COVID-19 research and treatment. Much of the COVID-19 research can be synergistic with HIV research; attendees suggested expanding collaborations and removing silos whenever possible. A participant noted that messaging about research closures has been inconsistent and not coordinated, which requires institutions and researchers to make additional decisions about patient safety. Participants noted that NIH decisions will drive research in academia, so ensuring that NIH-supported HIV research remains possible is critical. Other smaller groups will be challenged to recover after the pandemic. A participant suggested that research should focus on developing not only a vaccine but also antivirals.

Dr. Goodenow encouraged attendees to think in the long term when planning for the use of COVID-19 allocations, noting that its current 4-year timespan will pass quickly. Sustainability is an important issue. Participants suggested that many questions related to COVID-19, including the effects on research and the economy, are imponderable because they depend on the development of a vaccine. Implementation plans will be critical to ensure that the vaccine is deployed to the communities that need it the most and that those communities trust the vaccine—ensuring that the vaccine does not increase disparities is critical. Dr. Kates noted that COVID-19 could provide the opportunity to perform a broader survey gauging attitudes, knowledge, and receptivity in real time and explore hesitancies and fears.

Research Recovery Planning and Efforts: A Discussion with OARAC Members

Blanton Tolbert, Ph.D., Case Western Reserve University

Dr. Blanton Tolbert moderated a discussion of research recovery among OARAC members, beginning by asking participants to comment on the challenges experienced at their own institutions and how the pandemic has affected personnel. Dr. Tricia Burdo's institution has been closed since March, with only research related to COVID-19 considered essential. Her institution is beginning to bring people back safely but has not begun to recover research. Dr. Burdo noted that she is working to arrange additional time for her T32 researchers.

After a lockdown of everything, with the exception of COVID-19 research in March, Dr. William Powderly's institution resumed basic research in May. Research recovery is proceeding in phases, but some laboratories are challenged to develop plans that include the necessary social distancing. Patient-facing clinical research has resumed at a low level and only when regarded as beneficial to the patient. Clinical trials continued through the lockdown if the trials benefitted the patient, including significant percentages of oncology and HIV treatment trials and some virtual visits approved by the institutional review board (IRB). Ms. Lynda Dee questioned whether patients would be willing to enroll in clinical trials; many people remain reluctant to visit hospitals or clinics.

Dr. Bruce Schackman noted that dry laboratory research could continue through telehealth, but IRB approval may be delayed by the number of proposals related to COVID-19. Telehealth has improved participation rates in some cases because transportation is no longer a barrier. He added that his institution has extended the tenure clock for faculty whose research has slowed because of COVID-19.

Dr. Alan Greenberg commented on the existential threat to higher education if students are unable to return to campus and universities lose significant funding.

Dr. Tolbert asked about the plans institutions are implementing to prepare for a potential second wave. Dr. Babafemi Taiwo commented on the need to consider the mental health toll on workers, particularly clinicians and clinical researchers, and prevent burnout. Dr. Powderly noted the effects of anxiety and depression on trainees, adding that the highest rates of mental health issues have been recorded in researchers unable to return to work, such as trainees. Anxieties focus on both their training and their job prospects, contributing to a generation's worry that decreased science funding will eliminate their ability to have careers in science. Dr. Powderly emphasized the need to address both immediate and long-term mental health needs. Dr. Tolbert observed that international students, particularly those from China, are experiencing increased levels of anxiety related to COVID-19.

Dr. Tolbert asked how many HIV researchers at participants' institutions have pivoted to COVID-19 science, noting that at his institution, rapidly established a COVID-19 task force involving a number of HIV researchers. Dr. Powderly added that similar activities had taken place at his institution, which began developing COVID-19 research in January, resulting in 33 laboratories with a significant part of their work converted to COVID-19 research at this time. However, the laboratories now are constrained in

their ability to conduct research not related to COVID-19. For example, biosafety level 3 laboratories, formerly studying tuberculosis, have been converted to accommodate COVID-19 studies, affecting the basic research on tuberculosis. Viral disease researchers have had to slow their work to comply with distancing guidelines, which may reduce their productivity levels in a way that affects their grant funding. Clinical research similarly is affected by the need to balance research that advances the understanding of COVID-19 with research in the funded area.

Dr. Tolbert asked about the implications for personnel. Some faculty recruitment has resumed at Dr. Powderly's institution, whereas other institutions have instituted hiring freezes or have hired only scientists completely funded by research. Dr. Burdo's institution has reduced operational and departmental budgets and reduced pay for some of the faculty. Dr. Kimberly Scarsi pointed out that although she was unable to collect the data needed to write the renewal for her R01 because of the pandemic, the renewal is needed to pay her staff. Dr. Ingrid Bassett commented that much of her research in South Africa has been affected by the lockdown there, including work by her postdoctoral researchers who are dependent on smaller projects supported by the infrastructure of larger projects. She commented on her struggle with the existential question of whether HIV researchers should switch to COVID-19 research but emphasized that the practical considerations surrounding research must be prioritized.

Dr. Powderly suggested that the OARAC convey to the NIH that, because many institutions have relaxed the tenure clock, extending the length of grants should be considered similarly. He emphasized that this change would be an investment in the future and act as a stimulus for the economy.

Public Comment

Jennifer Kates, Ph.D., Kaiser Family Foundation

CAPT Glenshaw read excerpts from a public comment received from Jules Levin, the executive director of the National AIDS Treatment Advocacy Project, regarding elderly persons living with HIV who are in declining health or are at risk for poor health and, potentially, premature death. Mr. Levin expressed concern regarding the attention paid to aging and HIV. Although the OAR has named aging and HIV a priority, Mr. Levin commented that many in the community have not perceived progress toward improving care and services for older persons with HIV or progress in research that is meaningful in implementation to the clinic. COVID-19 has increased the challenges experienced by older persons with HIV. The infrastructure does not adequately address the needs of older persons with HIV who are suffering the consequences of premature aging, so Mr. Levin emphasized the need for a mechanism that funds multi-morbidity endpoint clinical trials in HIV from multiple ICOs. Furthermore, he pointed out that no U.S.-based community member is involved in OAR's aging-related discussions and that researchers are not incentivized adequately to be interested in aging and HIV research.

Closing Remarks and Adjournment

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

Dr. Goodenow thanked the Council members, the guidelines working groups, and speakers and noted that the October OARAC meeting will be virtual. She encouraged participants to submit comments regarding their experiences using the virtual platform for this meeting.

Dr. Kates added her thanks and adjourned the meeting at 4:11 p.m. EDT.

Certification

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

Jennifer Kates Digitally signed by Jennifer Kates DN: cn=Jennifer Kates, o, ou, email=jkates@kff.org, c=US Date: 2020.11.10 12:18:52 -05'00'

Jennifer Kates, Ph.D.
Chair, OARAC

11-10-20

Date

Mary Glenshaw -S Digitally signed by Mary Glenshaw -S Date: 2020.11.09 13:43:39 -05'00'

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

11-09-20

Date